Pursuant to the Article 14, paragraph 17, Article 17, paragraph 16, Article 21, paragraph 10, Article 22, paragraph 13, Article 28, paragraph 5 of the Law on Interoperability of the Railwa System (”Official Gazette of the Republic of Serbia” No. 41/18 and 16/22 – authentic interpretation) and Article 113, paragraph 1 of the Law on Railway Safety (”Official Gazette of the Republic of Serbia” No. 41/18),

Acting Director of the Directorate for Railways adopts the following:

RULEBOOK ON CONFORMITY ASSESSMENT OF INTEROPERABILITY CONSTITUENTS AND ELEMENTS OF STRUCTURAL SUBSYSTEMS, VERIFICATION OF STRUCTURAL SUBSYSTEMS AND GRANTING AUTHORISATIONS FOR PLACING IN SERVICE OF STRUCTURAL SUBSYSTEMS

**1. Basic Provisions**

Subject Matter

Article 1.

The Rulebook hereof prescribes the procedures and modules for conformity and suitability for use assessment of interoperability constituents and elements of structural subsystems to which national railway technical rules are applied, which are subject to assessment of conformity and suitability for use, technical file accompanying the declaration of conformity and declaration of suitability for use, contents of the declaration of conformity and declaration of suitability for use, procedures and modules for verification of subsystems, technical file accompanying the declaration of verification of subsystems, contents of the declaration of verification of subsystems, procedure of granting authorisations for placing in service of structural subsystems, documentation accompanying the application for granting the authorisation for placing in sevice of structural subsystems, contents and form of the authorisation for placing in service for structural subsystems, procedure of granting authorisations for vehicle type, documentation accompanying supporting the application for granting authorisation for vehicle type, contents and form of the declaration of verification to the vehicle type, contents and form of authorisation of the vehicle type, numeration of authorisations in line with the European identification number and parameters subject to check in conjunction with granting authorisation for placing in service and additional authorisation for vehicles which are not in conformity with the technical specifications of interoperability (hereinafter: TSIs).

Definitions of Terms

Article 2.

Terms used in this Rulebook have the following meaning:

1) *Safe integration* means a set of measures with the aim of ensuring that implementation of an element (e.g. new vehicle type, subsystem, part, component, constituent, software, procedure, organization etc.) into a larger system, does not cause unacceptable risk to the system;

2) *Verification of subsystem* means the procedure carried out by the conformity assessment body in order to check and confirm that the subsystem is in conformity with the relevant technical rules;

3) *Authorisation for placing in service* means a document authorizing placing in service of a subsystem;

4) *Authorisation for vehicle type* means a document confirming that a rail vehicle type is in conformity with the technical specifications of interoperability or national railway technical rules;

5) *Structural subsystem elements* means components, groups of components, subassembly or complete assembly of equipment, as well as software, incorporated or intended to be incorporated into a subsystem, subject to national railway technical rules;

6) *Substitution in the framework of maintenance* means any replacement of components with parts having the same function and performance within preventive or corrective maintenance;

7) *Designated body* means the body responsible for assessing the conformity or suitability for use of the structural subsystem elements, to which national railway technical rules are applied, and for verification procedure of subsystems, in line with the national railway technical rules;

8) *Document**on conformity* means the declaration of conformity, declaration of verification, testing report, , certificate of conformity, certificate of verification or any other document confirming the product is in conformity with the prescribed requirements;

9) *OTIF* means an inter-governmental organization for international carriage by rail;

10) *Assessment of* *suitability for use* is an assessment procedure if the suitability for use requirements stated in the relevant technical rule relating to the interoperability constituent, or the structural subsystem element, are met;<0}

11) *Assessment* *of conformity* means the method of assessing if the requirements stated in the relevant technical rule relating to the interoperability constituent, or the element of a structural subsystem, are met; <0}

12) *Notified body* means the body designated for assessing conformity and suitability for use of interoperability constituents and for the procedure of subsystem verification subject to technical specifications of interoperability, which is notified to the General Secretary of OTIF or the European Commission;

13) *Structural subsystems* means theparts of railway system: infrastructure, energy, control, command and signalling – track-side, control, command and signalling – on board and rolling stock (locomotives, electric and diesel multiple units, special purpose towing vehicles, passenger coaches and freight wagons);

14) *Conformity assessment* *body* is a common term used for the notified body and designated body;

15) *Technical compatibility* means the ability of two or more structural subsystems or their parts, having at least one mutual interface, to interact while simultaneously retaining a design operating state and expected level of performance;

16) *Technical* *specifications of interoperability* means technical specifications with which subsystem or part of a subsystem of a conventional railway system must comply with the aim of fulfilling essential requirements and enabling interoperability of the railway system;

17) *Vehicle type* comprises basic design features of a railway vehicle covered by type examination or project examination certificate;

18) *Interoperability constituents* means any component, group of components, subassembly or complete assembly of equipment, as well as software, incorporated or intended to be incorporated into a subsystem, on which the interoperability of the railway system depends directly or indirectly.

**2. Conformity and Suitability for Use Assessment of**

**Interoperability Constituents and Elements of Structural Subsystems Which Are Subject to National Railway Technical Rules**

Procedures and Modules for Assessment of Conformity and Assessment of Suitability for Use

Article 3.

Notified body, in line with the Law on Safety and Interoperability of Railway, performs assessment of conformity and assessment of suitability for use of interoperability constituents, whereas the designated body, in line with the Law on Safety and Interoperability of Railway, performs assessment of conformity and assessment of suitability for use of structural subsystems’ elements, subject to the national railway technical rules (hereinafter: elements of structural subsystems) by applying modules for assessment of conformity and suitability for use.

Interoperability constituents and elements of structural subsystems subject to assessment of conformity and assessment of suitability for use, and the modules applicable to assessment of conformity and assessment of suitability for use are provided in the Appendix 1, which is printed to support this Rulebook and is an integral part thereof.

Modules for assessment of conformity or suitability for use and the procedures applied in each of the modules, are provided in the Appendix 2, which is printed to support this Rulebook and is an integral part thereof.

Manufacturer chooses which module/combination of modules will be applied for assessment of conformity and assessment of suitability for use of interoperability constituents, or elements of structural subsystems.

Application for Assessment of Conformity and Assessment of Suitability for Use

Article 4.

Application for assessment of conformity and assessment of suitability for use shall in particular comprise the following:

1) Trade name and address of the applicant’s head office;

2) Identification and name of the person authorized to represent the applicant;

3) Name and description of the interoperability constituent or the element of a structural subsystem, subject to assessment of conformity or suitability for use, as well as required module/combination of modules for assessment of conformity or suitability for use;

4) Title of the technical rule based on which assessment of conformity or suitability for use is requested, including the number of the Official Gazette where the rule is published, and

5) Initial technical documentation needed for assessment of conformity for assessment of suitability for use, which is attached to the application.

Initial Technical Documentation

Article 5.

Initial technical documentation enabling assessment of conformity and assessment of suitability for use of interoperability constituents or elements of structural subsystems, is made by the manufacturer.

Elements of the initial technical documentation are prescribed within each module for assessment of conformity, or module for assessment of suitability for use.

Certificate of Conformity and Certificate of Suitability for Use of

Interoperability Constituent or Element of Structural Subsystem

Article 6.

Conformity assessment body issues the certificate of conformity and certificate of suitability for use of interoperability constituent or element of structural subsystem in line with the Law on Safety and Interoperability of Railway.

Certificate of {0>The certificate and its annexes shall contain all relevant information to allow the conformity of interoperability constituents with the examined type to be evaluated.<}0{>conformity and certificate of suitability for use of interoperability constituent or element of structural subsystem comprises the following:

1. Name of the Conformity assessment body, having issued the certificate;
2. Title „Certificate of Conformity” or „Certificate of Suitability for Use” and the number of the certificate;
3. Name of the interoperability constituent or the element of structural subsystem (brand, type, code etc.);
4. Trade name of the manufacturer and its address;
5. List of technical rules and standards to which an interoperability constituent or an element of structural subsystem comply with;
6. Conditions, if any, for its validity;
7. Date of issuance;
8. Validity period;
9. Stamp and signature of the responsible officer.

Validity period of the certificate referred to in paragraph 1 of this Article is five years.

Certificates referred to in paragraph 1 of this Article can have one or more annexes with the list of parts of {0>The certificate and its annexes shall contain all relevant information to allow the conformity of interoperability constituents with the examined type to be evaluated.<}0{>technical file, examinations results, results of labaratory testing, in-service testing (only for the certificate of suitability for use) and similar.

Certificate of conformity and certificate of suitability for use are issued in two original specimens, one of which is kept by the conformity assessment body whereas the second one is delivered to the applicant.

Declaration of Conformity and Declaration of Suitability for Use of

Interoperability Constituent or Element of Structural Subsystem

Article 7.

колико чинилац интероперабилности/елемент подсистема испуњава захтеве наведене у техничким прописима који се на њега односе.

Based on the certificate referred to in Article 6 of this Rulebook, applicant prepares a declaration of conformity and declaration of suitability for use of the interoperability constituent or the element of structural subsystem.

Declaration of conformity and declaration of suitability for use of interoperability constituent or element of structural subsystem, including the accompanying documents must be signed and dated.

Declarations referred to in paragraph 1 of this Article shall contain the following:

1) Trade name and address of the manufacturer or its authorized representative, with head office in the Republic of Serbia (in case of authorized representative, trade name and address of the manufacturer should also be stated);

2) name of the interoperability constituent or the element of structural subsystem (brand, type, code etc.);

3) reference to the technical rules with which the interoperability constituent or the element of structural subsystem is in conformity;

4) name and address of the conformity assessment body having participated in the assessment of conformity or suitability for use;

5) date of issuance of the certificate of conformity, conditions and validity period of the certificate of conformity;

6) methods (modules) applied for the assessment of conformity or assessment of suitability for use;

7) possible restrictions and conditions for use;

8) reference to standards, if needed;

9) list of appendices, and

10) signatory party data (name, signature and stamp).

Contents of the declaration referred to in paragraph 2 of this Article are described in the Appendix 3, which is printed to support this Rulebook and represents its integral part.

Technical File Accompanying the Declaration of Conformity

and Declaration of Suitability for Use

Article 8.

Technical File accompanying the declaration of conformity and declaration of suitability for use shall comprise the following:

1) initial technical documentation, as set out in the Article 5 of this Rulebook, and

2) specimens of the certificate of conformity, or certificate of suitability for use, including their appendices.

**3. Verification of Structural Subsystems**

General Provisions of verification of Structural Subsystems

Article 9.

Verification of structural subsystem is the procedure carried out by the applicant (contracting entity or the manufacturer of the subsystem) to demonstrate that the requirements of the applicable rules, including the national railway technical rules, referring to the subsystem have been met and the structural subsystem may to be granted the authorisation for placing in service.

Structural subsystems which are subject to verification procedure and modules applicable thereto are provided in the Appendix 4, which is printed to support this Rulebook and represents its integral part.

Subsystem or parts thereof are being checked in each of the following phases:

1) overall project;

2) production – construction of the subsystem, including civil engineering activities in particular, manufacturing, assembling of interoperability constituents, or elements of structural subsystem, adjusting of the entire subsystem, and

3) final testing of the subsystem.

Procedures and Modules for Verification of Structural Subsystems

Article 10.

Conformity assessment body performs verification of structural subsystems by applying the module for verification.

Modules for structural subsystem verification and procedures applied in each of the modules are provided in the Appendix 5, which is printed to support this Rulebook and represents its integral part.

Applicant chooses the modules/combination of modules to be applied to structural subsystem verification.

Application for Verification of Structural Subsystems

Article 11.

Applicationt for verification of structural subsystems shall comprise the following:

1) trade name, i.e. name or title, and address of the applicant’s head office;

2) identification and name of the person authorized to represent the applicant;

3) name and description of the structural subsystem subject to verification, as well as required modules/combination of modules for verification of structural subsystem;

4) title of the technical rule in line with which the verification is requested, including the number of the Official Gazette in which the rule is published, and

5) initial technical file needed for verification of structural subsystem, which supports the application.

Initial Technical File

Article 12.

Initial technical file enabling verification of structural subsystem, is prepared by the manufacturer.

Elements of the initial technical file are prescribed within each module for verification of structural subsystems.

Certificate of Verification of Structural Subsystem

Article 13.

Conformity assessment body executing the verification procedure makes assessment of the design and production of the structural subsystem and, if the structural subsystem meets the requirements of TSIs and/or national railway technical rules, issues the certificate of verification of structural subsystem to the applicant.

If stated in the TSIs, or the national railway technical rules, or upon the applicant’s request, subsystem can be divided into parts or be checked during specific phases of the verification procedure.

Applicant may require an intermediate statement for the design stage (including type examination), and the production stage for the whole subsystem, or any part of the subsystem.

In the case referred to in paragraph 3 of this Article conformity assessment body shall check and verify certain parts of the subsystem, or certain stages of the verification procedure and issues an intermediate statement of verification.

Conformity assessment body issues one or more intermediate statements of verification.

Applicant issues an intermediate declaration of verification for a certain stage.

Based on the certificate referred to in paragraph 1 of this Article, applicant draws up a declaration of verification.

Should there be intermediate statements of verification, conformity assessment body shall take them into consideration, and prior to issuing the certificate referred to in paragraph 1 of this Article shall act as follows:

1) confirm that the intermediate statements of verification cover the relevant requirements of the TSIs or national railway technical rules;

2) check all the elements of structural subsystem not covered by the intermediate statements of verification, and

3) check the results of the final testing of the structural subsystem as a whole.

Cer{0>The certificate and its annexes shall contain all relevant information to allow the conformity of interoperability constituents with the examined type to be evaluated.<}0{>tificate referred to in paragraph 1of this Article shall comprise the following:

1. name of the body responsible for assessing conformity and issuing the certificate;
2. title „Certificate of Verification” and number of the certificate;
3. name/ short description of the structural subsystem;
4. trade name and address of the contracting entity or manufacturer of the structural subsystem;
5. list of technical rules (TSIs and/or national railway technical rules) and standards, to which the structural subsystem complies;
6. reference to TSIs or parts thereof with which conformity has not been assessed (in cases of derogation from application of TSIs, partial application in the course of renewal or upgrading of the subsystem, in specific cases etc.);
7. issuance date;
8. validity period, and
9. stamp and signature of the responsible officer.

Validity period of the certificate referred to in paragraph 1 of this Article is 5 years.

Certificate {0>The certificate and its annexes shall contain all relevant information to allow the conformity of interoperability constituents with the examined type to be evaluated.<}0{>referred to in paragraph 1 of this Article may have one or more annexes containing list of parts of technical file, examination and testing reports, etc.

Certificate referred to in paragraph 1 of this Article shall be issued in two original specimens, one of which is kept by the conformity assessment body, while the other is given to the applicant.

In case of modification of a structural subsystem, for which the certificate of verification has been issued, conformity assessment body shall perform examinations and testing exclusively of those subsystem parts which have been modified, and the interfaces thereof with the unmodified parts of the subsystem.

Declaration of Verification of Structural Subsystem

Article 14.

Declaration of verification of structural subsystem and the accompanying documents shall be signed and dated.

Declaration referred to in 1 of this Article is based on the information resulting from the procedure of the structural subsystem verification, and is prepared in the same language as that of the technical file referred to in Article 17 of this Rulebook, containing in particular the following:

1) reference to the law regulating the safety and interoperability of railway, TSIs and national railway technical rule applied;

2) reference to TSIs or their parts to which conformity was not assessed in the verification procedure, and to the national rules applied, in cases of derogation from TSIs, partial application of TSIs in the course of renewal or upgrading, transition period in the TSIs or in specific cases;

3) trade name and address of the contracting entity or manufacturer or its authorized representative with head office in the Republic of Serbia (in case of the authorized representative trade name of the contracting entity or the manufacturer shall be stated as well);

4) name/short description of the structural subsystem;

5) names, addresses and identification numbers of the notified bodies in charge of the verification procedure according to TSIs;

6) names, addresses and identification numbers of the notified bodies in charge of the verification procedure according to other laws, if applicable;

7) names and addresses of the designated bodies in charge of the verification procedure according to the national railway technical rules;

8) name and address of the risk assessment body that prepares the risk assessment analysis according to the applied common safety method for risk evaluation and assessment (hereinafter: CSM);

9) number and date of issuance of the certificate of structural subsystem verification;

10) all the applicable provisions which the structural subsystem needs to be in conformity with, and in particular, all restrictions or conditions of use, if needed;

11) name of the module the applicant chooses for verification of the structural subsystem;

12) list of documents in the technical file, given in the appendix;

13) validity period of the declaration, if temporary, and

14) signatory party data (name, signature, stamp).

Provisions of para. 1 and 2 of this Article shall be applied accordingly to the intermediate declaration of verification as well.

Contents of the declaration of verification of the structural subsystem and contents of the intermediate declaration of verification shall be provided in the Appendix 6, which is printed to support this Rulebook and represents its integral part.

Declaration of Verification of of Structural Subsystem in the Case of Additional Verification

Article 15.

Declaration of verification of the structural subsystem can be complemented in the case of additional verifications performed, especially if the additional verifications are necessary with the aim of issuing additional authorisation for placing in service for a vehicle.

In the case referred to in paragraph 1 of this Article, scope of application of the additional declaration of verification is limited within the scope of application of additional verifications.

Declaration of Verification of the Modified Structural Subsystem

Article 16.

If an entity introducing modification of the structural subsystem covered by the declaration of verification referred to in Article 14 of this Rulebook, apart from substitution in the framework of maintenance, proves that the modification does not affect the essential characteristics of the subsystem design that are vital for compliance with the requirements related to the essential parameters, than this entity shall update the existing declaration of verification in the part referencing to the documents comprised in the technical file, therefore it shall not be necessary to prepare a new declaration of verification.

If the entity introducing the modification of the structural subsystem covered by declaration of verification referred to in Article 14 of this Rulebook proves that modification affects the essential characteristics of the subsystem design that are vital for compliance with the requirements related to the essential parameters, the following actions shall be taken:

1) entity introducing modification prepares complementary declaration of verification with reference to the relevant essential parameters subject to the modification;

2) complementary declaration of verification shall be accompanied with the list of documents of the technical documentation accompanying the original declaration of verification, which are no longer valid;

3) technical file accompanying the original declaration of verification shall include a demonstration that the effects of modification are limited to the essential parameters referred to in point 1) of this paragraph;

4) provisions of the Article 14 of this Rulebook shall be applied to the additional declaration of verification accordingly;

5) original declaration of verification shall be applied to all the parameters not subject to modification.

Technical File Accompanying

Declaration of Verification of a Structural Subsystem

Article 17.

Technical file accompanying a declaration of verification of structural subsystem shall be compiled by the conformity assessment bodies.

Technical file referred to in paragraph 1 of this Article shall contain the following:

1) initial technical file prescribed by the Article 12 of this Rulebook;

2) list of interoperability constituents, or elements of the structural subsystem incorporated into the subsystem;

3) copies of the declaration of conformity, or declaration fn suitability for use issued for the interoperability constituents, or the elements of the structural subsystem referred to in point 2) of this paragraph, accompanied with corresponding calculation documents and test and examination reports performed by the conformity assessment bodies, where appropriate;

4) where available, intermediate statements of verification and declarations of intermediate statements of verification, if any, including the verification of their validity done by the conformity assessment bodies;

5) certificate(s) of verification of structural subsystem and the relevant calculations attached thereto, signed by the conformity assessment bodies confirming that the structural subsystem is in conformity with TSIs/national railway technical rules, while also containing the list of all the reservations recorded in the course of performing the activity, which have not been withdrawn; the certificate is accompanied with the inspection reports created by the conformity assessment bodies relative to their task;

6) Certificates of verification issued in accordance with other legislation applied to the subject subsystem, if any, and

7) report of the assessment bodies on the application of CSM for risk evaluation and assessment, if safe integration of the structural subsystem into the existing system needs to be confirmed.

Manufacturer or the contracting entity shall keep a copy of the technical file referred to in paragraph 1 of this Article throughout the service life of the structural subsystem.

Technical Compatibility and Safe Integration of the Structural Subsystem

Article 18.

The correct application of the CSM on risk assessment and evaluation is assessed by an independent assessment body.

The assessment body's report is an integral part of the technical documentation that is submitted with the application for the issuance of an authorization for placing in service.

**4. Granting Authorisations for Placing in Service of Structural Subsystems**

Conditions for issuing an authorization for placing in service of structural subsystems

Article 19.

The conditions for issuing an authorization for placing in service of the structural subsystem are:

1) an application for issuing an authorization for placing in sevice for the use of a structural subsystem has been submitted to the Directorate for Railways;

2) the structural subsystem meets the basic requirements prescribed by the laws governing railway safety and interoperability;

3) the structural subsystem complies with the TSI, that is, the national railway technical regulations;

4) the structural subsystem meets the requirements related to technical conformity and safe integration that are not covered by TSIs and/or national railway technical regulations.

During phased implementation, the structural subsystem can be put into operation based on an authorization for placing in service with a validity period of up to four months, under the following conditions:

1) that a request has been submitted for the issuance of an authorization for placing in service of the structural subsystem during the phase implementation;

2) that the structural subsystem complies with the national railway technical regulations, which is confirmed by the corresponding part of the certificate of verification from Article 13, paragraph 6 and paragraph 7 of this rulebook, the declaration of verification from Article 14 of this rulebook, and for the implementation phase, the appropriate part of the technical documentation from Article 17, paragraph 2, items 1), 2), 3), 4) and 7) of this rulebook;

3) that all works on the construction, installation and adjustment of the structural subsystem have been completed, including the necessary tests and examinations, which is confirmed by the exploitation permit issued by the relevant ministry or by the positive report of the Commission for Technical Inspection, in accordance with the provisions of the law regulating planning and construction;

4) that the structural subsystem meets the requirements related to technical compliance and safe integration of the structural subsystem, in accordance with Article 18 of this rulebook.

For the extension of the authorization for placing in service referred to in paragraph 2 of this article, a declaration of verification of the structural subsystem must be submitted with the accompanying documentation prescribed by Article 17 of this rulebook.

Application for Granting of an Authorisation for placing in service for Structural Subsystems

Article 20.

Application for granting the authorisations for placing in service of structural subsystems shall comprise the following:

1) name of the body the application is submitted to;

2) trade name, address, head office, Tax ID and company registration number of the applicant;

3) excerpt from the Business register of the applicant;

4) subject matter of the applicationt (name/brief description of the subsystem, class, type, code etc.);

5) trade name and address of the contracting entity or manufacturer of the subsystem, and

6) as an of appendix - declaration of verification of the subsystem with the accompanying technical file as prescribed by the Article 17 of this Rulebook.

Technical file prescribed by the paragraph 1, point 6) of this Article shall be submitted in two copies at least. .. примеркааејничком документацијоме дсистема и других подсистемабуде покривена одредбама ЈТП и теристика фиксних структурних

Contents and Form of the Authorisation for Placing in Service for Structural Subsystems

Article 21.

Contents and form of the authorisation for placing in service for structural subsystems are set out in the Appendix 7, which is printed to accompany this Rulebook and is an integral part thereof.

Authorisation for placing in service for structural subsystems shall be accompanied with at least one copy of the technical file verified by the Directorate for Railways.

Examples of structural subsystem approval phases are outlined in the Appendix 8, which is printed to accompany this Rulebook and is an integral part thereof.

**5. Authorisation for Placing in Service of a Vehicle**

Procedure for Granting the Authorisation for a Type of Vehicle

Article 22.

Type of vehicle shall meet the following requirements:

1. conformity of the vehicle design with TSIs and/or national railway technical rules, and

2) requirements related to the technical compatibilityand safe integration not covered by the TSIs and /or national railway technical rules.

Fulfilment of requirements referred to in paragraph 1 of this Article shall be demonstrated as follows:

1) certificate of type examination (if module SB is applied) or the certificate of project examination (if module SH1 is applied), with the supporting technical file, which shall be issued by:

(1) notified body, for conformity with TSIs and

(2) designated body, for conformity with the national railway technical rules, and

2) report of a risk assessment body.

Verification of conformity with TSIs, as well as with the national railway technical rules is carried out for each subsystem integrated into the vehicle (e.g. traction unit is made of the rolling stock subsystem , on board control, command and signallling – subsystem and energy sub-system).

Authorisation for a vehicle type is granted upon application comprising of the following:

1) name of the body the application is submitted to;

2) trade name, address, head office, Tax ID and CRN of the applicant;

3) excerpt from the Business Registers of the applicant;

4) subject matter of the application (description of the vehicle type, series and subseries);

5) trade name and address of the vehicle manufacturer, and

6) four copies of technical file.

Example of vehicle type authorisation stages is provided in the Appendix 9, which is printed to accompany this Rulebook and is an integral part thereof.

Technical File Accompanying the Application for Granting the Vehicle Type Authorisation

Article 23.

Technical file accompanying the application for granting the vehicle type authorisation shall comprise of:

1. Certificate of type examination (if module SB is applied) or certificate of project examination (if module SH1 is applied), issued by the notified and/or designated body, with the supporting technical file, which shall enable assessment of conformity with the TSI requirements, or national railway technical rules, and which is prescribed in the module SB, or module SH1, and
2. report of an assessment body on CSM for risk evaluation and assessment used .

Contents and Form of The Vehicle Type Authorisation

Article 24.

Contents and form of the vehicle type authorisation are set out in the Appendix 7.

Form of the authorisation for a type of the vehicle intended for use in the international traffic and to which TSIs are applied, shall be issued in Serbian and English language.

Vehicle type authorisation shall be accompanied with three copies of the technical file verified by the authorisation issuing body.

Granting of Vehicle Authorisation for placing in service

Article 25.

Vehicle authorisation for placing in service shall be granted if:

1) a vehicle type authorisation has been issued, as prescribed in the Article 22 of this Rulebook;

2) the vehicle has been manufactured in line with the technical file accompanying the type examination certificate (module SB), or the project examination certificate(module SH1);

3) the newly manufactured vehicle has passed final testing prescribed by the applied module for verification of the subsystem;

4) every subsystem constituting the vehicle has been verified in line with the applied modules SD, SF or SH1, which the conformity assessment body shall confirm by issuing the certificate of verification, and

5) following the issuance of the certificate referred to in point 4) of this paragraph, the applicant has drawn up the declaration of verification of all the subsystems constituting the vehicle and the declaration of conformity with the approved type of vehicle.

In order to obtain the vehicle authorisation for placing in service, based on the conformity with the approved vehicle type, the applicant shall submit the request containing the following:

1) Name of the body the request is submitted to;

2) Trade name, address, head office, Tax ID and company register number of the applicant;

3) Excerpt from the Business registers for the applicant;

4) Subject matter of the request (vehicle type, series and subseries);

5) Trade name and address of the vehicle manufacturer;

6) Technical file made in four copies.

Technical file accompanying the request for issuance of the vehicle authorisation for placing in service shall contain the following:

1) Vehicle type authorisation ;

2) TSI certificate of verification of the subsystem and/or national certificate of verification;

3) TSI declaration of verification and/or national declaration of verification, and

4) Declaration on conformity with the approved vehicle type, coupled with the supporting technical file.

Contents and form of vehicle authorisation for placing in service are set out in the Appendix 7.

Form of the authorisation for use of the vehicle intended to be used in the international traffic and to which TSIs are applied, shall be issued in the Serbian and English language.

Vehicle authorisation for placing in service shall be accompanied with three copies of the technical file verified by the authorisation issuing body.

Example of a vehicle use authorization procedurel, in stages, is provided in the Appendix 9.

Contents and Form of the Declaration of Conformity with the Vehicle Type

Article 26.

Contents and form of the declaration of conformity with the vehicle type are set out in the Appendix 6.

Parameters Subject to Check Prior to Granting the Authorisation and Additional Authorisation for Placing in Service of non-TSI Conform Vehicles

Article 27.

Prior to granting the authorisation and additional authorisation for placing in service of the non-TSI conform vehicle, following parameters shall be checked:

1) general documentation – including description of the new, renewed or upgraded vehicle and its intended use, information on design, repairs, operation and maintenance, technical file, etc.;

2) structure and mechanical parts – mechanical integrity and interfaces between the vehicles (including draw and buffer gear, gangways), strength of the vehicle structure and its equipment (e.g. seats), loading capacity, passive safety (including internal and external resilience to crashworthiness);

3) Vehicle/rail interaction and gauging –mechanical interfaces to the infrastructure (including static and dynamic behavior, clearances and tolerances, gauge, running gear, etc.);

4) Braking equipment - braking-related components (including wheel-slide protection, braking control, performance in service, emergency and parking);

5) passengers facilities and passenger area (including windows and doors of the passenger coach, special requirements for the people with reduced mobility, etc.);

6) environmental conditions and aerodynamic effects – impact of the environment to the vehicle and vice versa (including the aerodynamic conditions, interfaces between the vehicle and the track-side part of the railway system, and between the vehicle and the external environment);

7) external warnings, markings, requirements for software functions and its integrity, including the information flow through the train;

8) on-board power supply and control systems propulsion, power and control systems, interfaces between the vehicle and the power supply system and all aspects of electromagnetic compatibility;

9) staff facilities, interfaces, working conditions, and working environment for staff (including driver’s cab, driver – machine interface);

10) fire protection and evacuation;

11) servicing – on-board facilities and interfaces;

12) on—board control command and signalilling– all the on-board equipment for ensuring safety, command and control of a train movement, and its impact on the track-side part of the railway system;

13) Specific operational requirements related to the vehicle operations (including degraded mode, vehicles recovery, etc.);

14) Components related to the freight - requirements and environment specific for freight (including facilities specially required for dangerous goods).

**6. Numeration of Authorisations**

Article 28.

Authorisations prescribed by this Rulebook shall be numerated in line with the harmonized system - European Identification Number – EIN, set out in the Appendix 10, which is printed to accompany this Rulebook and is an integral part thereof.

**7. Conformity Documents**

Article 29.

Conformity documents for interoperability constituents, elements of structural subsystems and structural subsystems issued by the conformity assessment bodies and manufacturers, depending on the applied modules, are set out in the Appendix 11, which is printed to accompany this Rulebook and is an integral part thereof.

**8. Final Provisions**

Initiated Procedures

Article 30.

Procedures for granting of authorisation for placing in service initiated prior to this Rulebook entry into force shall be finalized in line with the rules that had been applicable prior to the present Rulebook coming into force.

Cessation of Other Rules

Article 31.

The validity of the Rulebook on Conformity Assessment of Interoperability Constituents and Elements of Structural Subsystems, Verification of Structural Subsystems and Granting Authorisations for Placing in Service of Structural Subsystems („Official Gazette of the Republic of Serbia“, No. 5/19) shall cease as of the date of the present Rulebook coming into force.

Entry Into Force

Article 32.

The Rulebook hereof shall enter into force on the eighth day upon its publication in the Official Gazette of the Republic of Serbia.

No. 340-282/2022

Belgrade, 11 March 2022

Acting Director

Lazar Mosurović

**Annex 1**

**INTEROPERABILITY CONSTITUENTS AND ELEMENTS OF STRUCTURAL SUBSYSTEM SUPPORTING THE ASSESSMENT OF COMPATIBILITY OF USE AND APPLICABLE MODULES**

**SUBSYSTEM INFRASTRUCTURE**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules** |
| tracks | CA\* or СН\*  or  CB+ CD or CB+CF or CH1  and CV\*\* |
| sleepers  .  . | CA or CH  and CV\*\* |
| rail fastening systems | CA or CH  and CV\*\* |

\*) CA and CN modules may be used only in the case of products placed on the market before the entry into force of this Rule, provided that the manufacturer proves that the earlier tests and verification of the products have been carried out successfully under similar conditions and that the product complies with the requirements of the national railway technical rules are in effect. Otherwise, the conformity assessment procedure provided for in this Rulebook shall apply.

\*\*) Assessment of the suitability for using the CV module, if not prescribed by the TSI, is not mandatory, but is carried out at the request of the manufacturer.

**SUBSYSTEM ENERGY**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Моdules** |
| Overhead line | CA\* or CH\* or  CB+CC or CH1  and CV\*\* |

\*) CA and CN modules may be used only in the case of products placed on the market before the entry into force of this Rule, provided that the manufacturer proves that the earlier tests and verification of the products have been carried out successfully under similar conditions and that the product complies with the requirements of the national railway technical rules are in effect. Otherwise, the conformity assessment procedure provided for in this Rulebook shall apply.

\*\*) Assessment of the suitability for using the CV module, if not prescribed by the TSI, is not mandatory, but is carried out at the request of the manufacturer.

**SUBSYSTEM SUPERVISION, MANAGEMENT AND SIGNALIZATION**

**А. Interoperability subsystem**

**1) Rail track part**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules** |

|  |  |
| --- | --- |
| Radio block center | CB +CD or CB+CF or CH1 |
| Еurobaliza | CB +CD or CB+CF or CH1 |
| Еuroloop | CB +CD or CB+CF or CH1 |
| LEU eurobaliza | CB +CD or CB+CF orCH1 |
| LEU euroloop | CB +CD or CB+CF or CH1 |
| Radio in – fill unit | CB +CD or CB+CF or CH1 |

**2) Train part**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules** |
| ERTMS/ETCS on car | CB+CD or CB+CF or CH1 |
| Оdometry equipment | CB+CD or CB+CF or CH1 |
| Specific Transmission Module – STM | CB+CD or CB+CF or CH1 |
| GSM-R for speech transmission | CB+CD or CB+CF or CH1 |
| GSM-R for data transmission | CB+CD or CB+CF or CH1 |
| GSM-R SIM card | CA |

For all interoperability constituents listed in the tables above, the following applies:

1) type examination using the SV module must be carried out with a combination of the type of production and the type of project (see Annex 2, module SV, item 2, second indent), and

2) the application of the CF module does not allow statistical verification of compliance, but each factor must be individually examined (see Appendix 2, module CF, point 4.).

**B. Subsystem to which national railway technical rules apply**

**1) Signaling and security devices**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules** |
| Relay and electronic cell signaling and security devices | CA\* or CB+CC  and CV\*\* |
| Train track slab devices | CA\* or CB+CC  and CV\*\* |
| Signaling lamps | CA\* or CB+CC |
| Railway circuits | CA\* or CB+CC  and CV\*\* |
| Axle counters | CA\* or CB+CC  and CV\*\* |
| Wheels detectors | CA\* or CB+CC  and CV\*\* |
| Automatic block line devices | CA\* or CB+CC  and CV\*\* |
| Inter-station dependency devices | CA\* or CB+CC  and CV\*\* |
| Traffic telecommunication devices | CA\* or CB+CC  and CV\*\* |
| Axle overheat measuring equipment | CA\* or CB+CC |
| Rail track аutostop devices | CA\* or CB+CC  and CV\*\* |
| Power supply parts for signaling and safety devices | CA\* or CB+CC |
| Road crossing command-control part | CA\* or CB+CC  and CV\*\* |
| Half Barrier / bumper level crossing device | CA\* or CB+CC  and CV\*\* |

\*) CA and CN modules may be used only in the case of products placed on the market before the entry into force of this Rule, provided that the manufacturer proves that the earlier tests and verification of the products have been carried out successfully under similar conditions and that the product complies with the requirements of the national railway technical rules are in effect. Otherwise, the conformity assessment procedure provided for in this Rulebook shall apply.

\*\*) Assessment of the suitability for using the CV module is not mandatory, but is carried out at the request of the manufacturer.

**2) Telecommunication devices**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules** |
| Radio Dispatching Devices | CA\* or CB+CС  and CV\*\* |
| Track phone devices | CA\* or CB+CС  and CV\*\* |
| Track cables | CA\* or CB+CС  and CV\*\* |

\*) CA and CN modules may be used only in the case of products placed on the market before the entry into force of this Rule, provided that the manufacturer proves that the earlier tests and verification of the products have been carried out successfully under similar conditions and that the product complies with the requirements of the national railway technical rules are in effect. Otherwise, the conformity assessment procedure provided for in this Rulebook shall apply.

\*\*) Assessment of the suitability for using the CV module is not mandatory, but is carried out at the request of the manufacturer.

**RAILWAY VEHICLES SUBSYSTEM**

**1) Carriage**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules** |
| Automatic central clutch | CA1\* or CA2\* or CH\* or CB+CD or CB+CF or CH1 |
| Hook, folding clutch and traction device | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Trail rescue device | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Wheels | CA1\* or CA2\* or CH\* or CB+CD or CB+CF or CH1 and CV\*\* |
| Anti-slip wheel protection | CA1\* or CA2\* or CH\* or CB+CD or CB+CF or CH1 and CV\*\* |
| Signals on the rear vehicle end | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Connection for discharging toilet cisterns (faecal reservoir) | CA or CB+CC or CH |
| Connection for water reservoir refill | CA or CB+CC or CH |

\*) CA1, CA2 or CH modules may be used only in the case of products that have been developed and marketed before the entry into force of this Rule, provided that the manufacturer demonstrates to the conformity assessment body that the project testing and type testing were carried out under similar conditions, and that the type is compliant with the TSI, or the national railway technical rules in force. This proof must be documented and considered to provide the same evidence as a type test by CB module or project testing by module CH1.

\*\*) Assessment of the suitability for using the CV module, if not prescribed by the TSI, is not mandatory, but is carried out at the request of the manufacturer.

**2) Freight wagon**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules** |
| Running engine | CA1\*or СА2\* or СН\*  or CB+CD or CB+CF or CH1 |
| Shaft assembly | CA1\*or СА2\* or СН\*  or CB+CD or CB+CF or CH1 |
| Wheels | CA1\*or СА2\* or СН\*  or CB+CD or CB+CF or CH1  and CV\*\* |
| Shafts | CA1\*or СА2\* or СН\*  or CB+CD or CB+CF or CH1 |
| Friction element of the brake pedal | CA1\*or СА2\* or СН\*  or CB+CD or CB+CF or CH1  and CV\*\*\* |
| End/final signal | CA1 or CA2 or CH |

\*) CA1, CA2 or CH modules may be used only in the case of products that have been developed and marketed before the entry into force of this Rule, provided that the manufacturer demonstrates to the conformity assessment body that the project testing and type testing were carried out under similar conditions, and that the type is compliant with the TSI, or the national railway technical rules in force. This proof must be documented and considered to provide the same evidence as a type test by CB module or project testing by module CH1.

\*\*) Assessment of the suitability for using the CV module, if not prescribed by the TSI, is not mandatory, but is carried out at the request of the manufacturer.

\*\*\*) Module CV is used in case when the manufacturer of the friction element of the brake pedal does not have sufficient feedback experience (in his opinion) for the project suggestted.

**3) Еlectric locomotive and electric engines**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules for conformity evaluation** |
| Automatic central clutch | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Hook, folding clutch and traction device | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Trail rescue device | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Wheels | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1  and CV\*\* |
| Anti-slip wheel protection | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1  and CV\*\* |
| Front lights | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Parking lights | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Rear lights | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Sirens | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Pantograph | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Pantograph strips | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1  and CV\*\* |
| Main circuit breaker | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Railway driver seat | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Connection for discharging toilet cisterns (faecal reservoir) | CA or CB+CC or CH |
| Connection for water reservoir refill | CA or CB+CC or CH |

**\*)** CA1, CA2 or CH modules may be used only in the case of products that have been developed and marketed before the entry into force of this Rule, provided that the manufacturer demonstrates to the conformity assessment body that the project testing and type testing were carried out under similar conditions, and that the type is compliant with the TSI, or the national railway technical rules in force. This proof must be documented and considered to provide the same evidence as a type test by CB module or project testing by module CH1.

\*\*) Assessment of the suitability for using the CV module, if not prescribed by the TSI, is not mandatory, but is carried out at the request of the manufacturer.

**4) Diesel locomotive, diesel-engine trains and special purpose towing vehicles**

|  |  |
| --- | --- |
| **Subject to evaluation** | **Modules за оцену усаглашености** |
| Automatic central clutch | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Hook, folding clutch and traction device | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Trail rescue device | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Wheels | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1  and CV\*\* |
| Anti-slip wheel protection | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1  and CV\*\* |
| Предња светла | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Parking lights | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Rear lights | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Siren | CA1\* or CA2\* or CH\*  or CB+CC or CB+CD or CH1 |
| Railway driver seat | CA1\* or CA2\* or CH\*  or CB+CD or CB+CF or CH1 |
| Connection for discharging toilet cisterns (faecal reservoir) | CA or CB+CC or CH |
| Connection for water reservoir refill | CA or CB+CC or CH |

\*) CA1, CA2 or CH modules may be used only in the case of products that have been developed and marketed before the entry into force of this Rule, provided that the manufacturer demonstrates to the conformity assessment body that the project testing and type testing were carried out under similar conditions, and that the type is compliant with the TSI, or the national railway technical rules in force. This proof must be documented and considered to provide the same evidence as a type test by CB module or project testing by module CH1.

\*\*) Assessment of the suitability for using the CV module, if not prescribed by the TSI, is not mandatory, but is carried out at the request of the manufacturer.

**Annex 2**

{0>**MODULES FOR CONFORMITY ASSESSMENT OF INTEROPERABILITY CONSTITUENTS**<}0{> **MODULES FOR THE ASSESSMENT OF THE CONFORMITY OF THE INTEROPERABILITY MEASURE, I.E., RELATED ELEMENTS OF STRUCTURAL SUBSYSTEMS**

<0}

**{0>Module CA.<}96{>Module CA. Internal production control**

**<0}**

1. {0>Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.<}0{>Internal production control is a conformity assessment procedure where the manufacturer meets the obligations under points 2, 3 and 4 and ensures and declares to his sole responsibility that the constituent of interoperability / element of the structural subsystem meet the TSI requirements or applicable national technical rules.
2. {0>Technical documentation<}0{>Technical file<0}

{0>The manufacturer shall establish the technical documentation.<}0{> The manufacturer prepares technical file. The documentation enables assessment of the conformity of the interoperability constituent / element of the structural subsystem with the TSI requirements, or the national railway technical rules. The technical file defines the applicable requirements and, to the extent necessary for evaluation, includes the design, manufacture, maintenance and operation of the interoperability constituent / structural subsystem element. <0}

{0>Wherever applicable, the technical documentation shall give evidence that the design of the interoperability constituent, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the interoperability constituent has been used in service in the same area of use.<}0{>Where possible, the technical file shall prove that the interoperability constituent project has already been accepted before the application of the applicable TSI in accordance with the TSI and that the constituent of interoperability is used in the same area.

The technical file shall include, as far as possible, at least the following elements:

- general description of the interoperability constituent / element of the structural subsystem;

- conceptual design and production plans and plans of components, sub-assemblies, circuits, etc.;

- descriptions and explanations necessary for understanding the drawings and plans, as well as the functioning (including the terms of use) and the maintenance of the interoperability constituent / element of the structural subsystem;

- the conditions for integrating the interoperability constituent / element of the structural subsystem into its system environment (sub-assembly, circuit, subsystem) and the necessary interface conditions;

- a list of national railway technical rules applied;

- a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the requirements of the TSI / national railway technical rules, if the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that have been applied;

- results of project budgets, performed reviews, etc., and

- test reports.

<0}

3. {0>Manufacturing<}0{>Production

<0}

{0>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the TSI that apply to them.<}0{>The manufacturer shall take all necessary measures to ensure the conformity of the interoperability constituent / element of the structural subsystem with the technical file referred to in point 2 and the TSI requirements or the national railway technical rules applicable.

4. Declaration of Conformity

<0}

{0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}0{>The manufacturer shall draw up a written declaration of conformity for the interoperability constituent / element of the structural subsystem and shall keep it with the technical file at the disposal of the national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem.

The Declaration of Conformity identifies the interoperability constituent for which it is compiled.

A copy of the Declaration of Conformity is provided at the request of the competent authorities.

<0}

5. {0>Authorised representative<}0{>Authorized representative<0}

{0>The manufacturer’s obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}0{> The manufacturer's obligations under point 4 may be met by his authorized representative, on his behalf and under his responsibility, provided that they are listed in the authorization letter.

<0}

**{0>Module CA1.<}96{><0}{0>Internal production control plus product verification by individual examination<}96{>Module CA1. Internal control of production and product verification by individual testing**

**<0}**

1. {0>Internal production control plus product verification by individual examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.<}83{>The internal control of production and product verification by a single test is the conformity assessment procedure where the manufacturer fulfils the obligations in points 2, 3, 4 and 6 and ensures and declares to his sole responsibility that the interoperability constituent / element of the structural subsystem meets the TSI requirements or applicable national railway technical rules.
2. <0}{0>Technical documentation<}96{>Technical file

The manufacturer prepares technical file. The documentation enables assessment of the conformity of the interoperability constituent / element of the structural subsystem with the TSI requirements or the national railway technical rules.

The technical file defines the applicable requirements and, to the extent necessary for evaluation, includes the design, manufacture, maintenance and operation of the interoperability constituent / element of the structural subsystem.

Where possible, the technical file shall also prove that the interoperability project has already been accepted prior to the application of the applicable TSI in accordance with the TSI and that the interoperability constituent is used in the same area.<0}

Technical file shall include, if possible, at least the following elements:

- general description of the interoperability constituent / element of the structural subsystem;

- conceptual design, production plans and components plans, sub-assemblies, circuits, etc.;

- descriptions and explanations necessary for understanding drawings and plans, and functioning (including usage conditions) and maintenance of the interoperability constituent / element of the structural subsystem;

- the conditions for integrating the interoperability constituent / element of the structural subsystem into its system environment (sub-assembly, circuit, subsystem) and the necessary interface conditions;

- a list of national railway technical rules applied;

- a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the requirements of the TSI / national railway technical rules, if the recognized standards are not applied. In case of partially applied recognized standards, the technical file lists the parts that were applied;

{0>- results of design calculations made, examinations carried out, etc., and<}96{>- results of project budgets, reviews executed, etc., and

- test reports.

<0}

1. {0>Manufacturing<}96{>Production

<0}

{0>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the TSI that apply to them.<}96{>The manufacturer shall take all necessary measures to ensure the conformity of the interoperability constituent / element of the structural subsystem with the technical file referred to in point 2 and the TSI requirements or the national railway technical rules applicable.

4. Product testing{0>Product checks<}0{>Prover

<0}{0>For each individual product manufactured, one or more tests on one or more specific aspects of the interoperability constituent shall be carried out in order to verify conformity with the type described in the technical documentation and the requirements of the TSI.<}0{>For each individual product one or more tests of one or more specific aspects of the interoperability constituent / element of the structural subsystem are performed in order to verify conformity with the type described in the technical file and requirements of the TSI, or the national railway technical rules. As chosen by the manufacturer, the tests are carried out by an accredited internal authority or carried out under the responsibility of the conformity assessment body chosen by the manufacturer.

5. {0>EC certificate of conformity<}71{>Certificate of Conformity<0}

The conformity assessment body issues a certificate of conformity, based on the performed inspections and verification.

The manufacturer shall keep the certificates of conformity available for the inspection of national authorities for a period of ten years after the production of the last interoperability constituent.

6. {0>EC declaration of conformity<}96{> Declaration of Conformity <0}

{0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}96{>The manufacturer shall draw up a written declaration of conformity for the constituent of interoperability / element of the structural subsystem and shall keep it with the technical file at the disposal of the national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem. The Declaration of Conformity identifies the interoperability constituent for which it is compiled.

A copy of the Declaration of Conformity is provided at the request of the competent authorities.

<0}

7. {0>Authorised representative<}96{>Authorized representative

<0}

{0>The manufacturer’s obligations set out in point 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}96{> The manufacturer's obligations under point 6 may be met by his authorized representative, on his behalf and under his responsibility, provided that they are listed in the authorization letter.

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**{0>Module CA2.<}96{><0} {0>Internal production control plus product verification at random intervals<}96{>** **Module CA2. Internal production control including product verification at random intervals**

**<0}**

1. {0>Internal production control plus product verification at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.<}92{>Internal production control including product verification at random intervals is a conformity assessment procedure where the manufacturer meets the obligations as per points 2, 3, 4 and 6 and ensures and declares to his sole responsibility that these interoperability constituents / elements of the structural subsystem meet the TSI requirements or applicable national railway technical rules.

<0}2. {0>Technical documentation<}96{>Technical file

<0}{0>The manufacturer shall establish the technical documentation.<}96{>The manufacturer prepares technical file. The documentation enables assessment of the conformity of the interoperability constituent / element of the structural subsystem with the requirements of the TSI, or the national railway technical rules. The technical file defines the applicable requirements and, to the extent necessary for evaluation, includes the design, manufacture, maintenance and operation of the interoperability constituent / structural subsystem element.

Whenever possible, the technical file also proves that the design of the interoperability constituent / structural component of the structural subsystem already accepted prior to the application of the applicable TSI in accordance with the TSI and that the interoperability constituent / element of the structural subsystem is used in the same area of application.<0}

The technical file shall include, whenever possible, at least the following elements:

- general description of the interoperability constituent / element of the structural subsystem;

- conceptual design and production plans and plans of components, sub-assemblies, circuits, etc.;

- descriptions and explanations necessary for understanding drawings and plans, as well as functions (including usage conditions) and maintenance of the interoperability constituent / element of the structural subsystem;

- the conditions for integrating the interoperability constituent / element of the structural subsystem into its system environment (sub-assembly, circuit, subsystem) and the necessary interface conditions;

- a list of national railway technical rules applied;

- a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements or national railway technical rules, if the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that have been applied;

- results of project budgets, reviews executed, etc. and

- test reports.

3. {0>Manufacturing<}96{>Production

<0}

{0>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the interoperability constituents with the technical documentation referred to in point 2 and with the requirements of the TSI that apply to them.<}96{>The manufacturer shall take all necessary measures to ensure the conformity of the interoperability constituent / element of the structural subsystem with the technical file referred to in point 2 and the TSI requirements or the applicable national railway technical rules.

<0}

4. Product testing{0>Product checks<}96{> <0}

4.1. {0>At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals.<}0{> As chosen by the manufacturer, the accredited internal body or conformity assessment body selected by the manufacturer performs or warrants product testing at random intervals.<0}

4.2. {0>The manufacturer shall present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.<}0{> The manufacturer presents its products in the form of homogeneous batches and takes all necessary measures to ensure the homogeneity of each manufactured batch in the production process.<0}

4.3. {0>All interoperability constituents shall be available for verification in the form of homogeneous lots.<}0{>All interoperability constituents / structural subsystem elements are available for verification in the form of homogeneous batches. From each batch a random sample is taken. All interoperability constituents / elements of the structural subsystem in the sample are individually examined and appropriate tests are carried out to ensure conformity of the product with the type described in the technical file and TSI requirements, or the national railway technical rules that apply, and to determine whether the batch is accepted or rejected.

5. {0>EC certificate of conformity<}96{> Certificate of Conformity

Relevant body shall issue a certificate of conformity based on the examinations and tests carried out.

The manufacturer shall keep the certificates of conformity available for the inspection of national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem.

6. {0>EC declaration of conformity<}96{> Declaration of Conformity *<0}*

{0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}96{>The manufacturer shall draw up a written declaration of conformity for the interoperability constituent / element of the structural subsystem and shall keep it with the technical file at the disposal for the national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem.

The Declaration of Conformity identifies the interoperability constituent / element of the structural subsystem for which it is compiled.

  The Declaration of Conformity is provided at the request of the competent authorities.

<0}

7. {0>Authorised representative<}96{>Authorized representative

<0}

{0>The manufacturer’s obligations set out in point 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}96{> The manufacturer's obligations under point 6 may be met by his authorized representative, on his behalf and under his responsibility, provided that they are listed in the authorization letter.

<0}

**{0>Module CB.<}96{>Module CB.<0} The type examination{0>EC-type examination<}96{>ИИИИ**

**<0}**

1. {0>EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an interoperability constituent and verifies and attests that the technical design of the interoperability constituent meets the requirements of the technical specification for interoperability (TSI) that apply to it.<}0{> The type examination is part of the conformity assessment process where the conformity assessment body reviews the technical design of the interoperability constituent / structural component element and verifies and asserts that the technical design of the interoperability constituent / element of the structural subsystem meets the TSI requirements or the applicable national railway technical rules.

<0}

2. Type examination may be performed in one of the following ways:

- examination of the sample of the interoperability constituent / element of the structural subsystem, representative sample intended for the production (production type);

- assessment of the technical design of the interoperability constituent / element of the structural subsystem through the technical file review and the supporting evidence referred to in point 3 and the examination of samples of one or more critical parts of the interoperability constituent / element of the structural subsystem representative sample intended for production (combination of the production type and project type)

- assessment of the adequacy of the technical project of the interoperability constituent / element of the structural subsystem through the technical file review and supporting evidence from point 3, without sample examination (project type).

3. {0>The manufacturer shall lodge an application for EC-type examination with a notified body of his choice.<}0{>The manufacturer submits at free choice a type-examination request to the body for the conformity assessment.

The request includes:

- the name and address of the manufacturer, and if the request was made by an authorized representative, his name and address;<0}

{0>- a written declaration that the same application has not been lodged with any other notified body,<}0{>- a written statement that the same request was not submitted to another conformity assessment body;

- technical file that enables the assessment of the conformity of the interoperability constituent / element of the structural subsystem with the applicable TSI requirements, or the national railway technical rules and standards. The technical file defines the applicable requirements and, to the extent necessary for evaluation, includes the design, manufacture, maintenance and operation of the interoperability constituent / element of the structural subsystem. The technical file shall include, if possible, at least the following elements:<0}

* + - {0>- a general description of the interoperability constituent,<}96{>a general description of the interoperability constituent / element of the structural subsystem;
    - conceptual design and production plans and plans of components, sub-assemblies, circuits, etc.;
    - descriptions and explanations necessary for understanding the drawings and plans, as well as the functioning (including the terms of use) and the maintenance of the interoperability constituent / element of the structural subsystem;
    - the conditions for integrating the interoperability constituent / element of the structural subsystem into its system environment (sub-assembly, circuit, subsystem) and the necessary interface conditions;
    - a list of national railway technical rules applied;
    - a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements / national railway technical rules, in case that the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that have been applied;
    - results of project budgets, performed tests, etc., and
    - Test reports;<0}

{0>- the specimens representative of the production envisaged.<}0{>- representative samples for the intended production. The conformity assessment body may request additional samples for the performance of the testing program if necessary and

- supporting evidence for the adequacy of the technical project solution. All supporting documents shall be mentioned as supporting evidence, especially when the relevant technical rules and standards are not applied in full. The supporting evidence shall include, where appropriate, the results of testing carried out by the appropriate laboratory of the manufacturer or other laboratory on its behalf and under his full responsibility.

4. Body for Compliance Assessment:<0}

{0>For the interoperability constituent:<}0{> for the interoperability constituent:

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4.1. {0>examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the interoperability constituent with the requirements of the relevant TSI.<}0{>Reviews the technical file and supporting evidence to assess the adequacy of the technical design of the interoperability constituent / element of the structural subsystem with the requirements of the relevant TSI or national railway technical rules.

<0}{0>For the specimen(s):<}0{>for the sample:

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4.2. {0>verify that the specimen(s) have been manufactured in conformity with the requirements of the TSI and the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;<}0{>Confirms that the sample is manufactured in conformity with the TSI requirements or the national railway technical rules and technical file and identifies the elements that have been designed in accordance with the applicable provisions of the relevant recognized standards and / or technical specifications, as well as the elements designed without the application of the relevant provisions of these standards;

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4.3. {0>carry out appropriate examination and test, or have them carried out, to check whether requirements of the TSI have been applied correctly;<}0{>обављљобављизводи Performs or orders the execution of appropriate tests and examinations to check that the TSI requirements or national railway technical rules are correctly applied;<0}

4.4. {0>carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;<}0{>изводи Performs or orders the execution of appropriate tests and examinations to check if the manufacturer has decided to apply the solutions from relevant recognized standards and / or technical specifications, and their proper application;<0}

4.5. {0>carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the TSI;<}0{>изводиизводиPerforms or orders the execution of appropriate tests and examinations to verify, whether the manufacturer has decided not to apply the solutions from the relevant recognized standards and / or technical specifications, and whether the solutions applied by the manufacturer meet the relevant TSI requirements or national railway technical rules;

4.6. {0>agree with the manufacturer on a location where the examinations and tests will be carried out.<}0{> Agrees with the manufacturer on the location of the tests execution.

<0}5. The body for conformity assessment shall draw up an assessment report indicating the activities undertaken in accordance with point 4 and their results. The content of such report shall be published, in whole or in part, only with the consent of the manufacturer.<0}

6. {0>Where the type meets the requirements of the TSI that apply to the interoperability constituent concerned, the notified body shall issue an EC-type examination certificate to the manufacturer.<}0{>When the type meets the TSI requirements or the national railway technical rules applicable to the relevant interoperability constituent, the conformity assessment body issues a type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved type. The certificate may have one or more annexes.

The certificate and its annexes contain all relevant information for assessing the conformity of the interoperability constituent / element of the structural subsystem with the examined type.

When the type does not meet the TSI requirements or the national railway technical rules, the conformity assessment body refuses to issue a type-examination certificate and informs the applicant accordingly, with a detailed explanation for the refusal.

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7. {0>The manufacturer shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the interoperability constituent with the requirements of the TSI or the conditions for validity of the certificate.<}0{>The manufacturer shall notify the conformity assessment body with the technical file for the type-examination certificate of any type-approved changes that may affect the conformity of the interoperability constituent / element of the structural subsystem with the TSI requirements or the national railway technical rules or the conditions of the certificate validity. Such changes require additional approval in a form of an addendum to the original type-examination certificate. Only relevant and necessary tests and examinations are performed for changes made. <0}

8. {0>Each notified body shall inform its notifying authorities concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.<}0{>Each registered body shall notify its registration bodies about the type examination certificates and / or their addenda issued or withdrawn periodically or at the request of their registration authorities, providing a list of certificates and / or their addenda rejected, suspended or limited in any other way.

Each registered body shall notify other registered bodies about the type examination certificates and / or any addenda that have been declined, withdrawn, suspended or restricted in any way and, upon request, inform about the issued certificates and / or their addenda.<0}

OTIF and OTIF Member States and other registered bodies may, upon request, obtain a copy of the type examination certificate and / or relevant addenda. OTIF and OTIF Member States may, upon request, obtain a copy of the technical file and the results of the examination carried out by the registered body.

The body for conformity assessment shall keep a copy of the type-examination certificate, its annexes and addenda, including documentation submitted by the manufacturer, until the certificate’s validity date.<0}

9. {0>The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}76{>The manufacturer shall keep a copy of the type examination certificate, its annexes and addenda together with the technical file available to the national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem. <0}

10. {0>The manufacturer’s authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.<}0{> The authorized representative of the manufacturer may submit the request referred to in point 3 and perform the duties referred to in points 7 and 9, provided that they are defined in the authorization.

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**{0>Module CC.<}96{>Module CC.<0} {0>Conformity to type based on internal production control.<}83{>** **Compliance with type based on internal production control**

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1. {0>Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares on his sole responsibility that the interoperability constituents concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.<}0{>Compliance with the type based on internal production control is part of the conformity assessment procedure where the manufacturer meets the obligations set out in points 2 and 3 and confirms and declares at his own responsibility that the relevant interoperability constituent / element of the structural subsystem is in conformity with the type described in the type-examination certificate and that it meets the TSI requirements or the applicable national railway technical rules. <0}

2. {0>Manufacturing<}96{>Production

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{0>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the interoperability constituents with the approved type described in the EC-type examination certificate and with the requirements of the TSI that apply to them.<}75{>The manufacturer shall take all necessary measures to ensure the conformity of the interoperability constituent / element of the structural subsystem with the approved type described in the type-examination certificate with the TSI requirements and the national railway technical rules applicable. <0}

3. {0>EC declaration of conformity<}96{>Declaration of Conformity<0}

3.1. {0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}87{>The manufacturer shall draw up a written declaration of conformity for the interoperability constituent / element of the structural subsystem and keep it and it made available to the national authorities for a period of ten years after the last interoperability constituent has been manufactured. The Declaration of Conformity identifies the interoperability constituent / element of the structural subsystem for which it is compiled.

A copy of the Declaration of Conformity is provided at the request of the appropriate authorities.

The certificate refers to a type-examination certificate and its addenda.<0}

{0>- the EC type-examination certificate and its additions.<}0{>

4. {0>Authorised representative<}96{>Authorized Representative<0}

{0>The manufacturer’s obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}96{> The manufacturer's obligations set out in 3 may be met by his authorized representative on his behalf and under his full responsibility, provided that they are listed in the authorization.

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**{0>Module CD.<}96{>Module CD.<0} {0>Conformity to type based on quality management system of the production process<}96{>** **Type compliance based on the quality management system of the production process**

**<0}**

1. Type c{0>Conformity to type based on quality management system of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the interoperability constituent concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the technical specification for interoperability (TSI) that apply to it.<}85{>ompliance based on the quality management system of the production process is part of the conformity assessment procedure where the manufacturer meets the obligations set out in points 2 and 5, confirms and declares on his own responsibility that the interoperability constituent / element of the structural subsystem is in conformity with the type described in the type testing certificate and that it meets the TSI requirements or the applicable national railway technical rules.

1. <0}

2. {0>Manufacturing<}96{>Production<0}

{0>The manufacturer shall operate an approved quality management system for production, final product inspection and testing of the interoperability constituents concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.<}0{> The manufacturer implements approved quality management system for the production, final control and testing of the relevant interoperability constituents / elements of the structural subsystem as defined in point 3 and is subject to the examinations defined in point 4.

3. {0>Quality management system<}0{>Quality Management System

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3.1. {0>The manufacturer shall lodge an application for assessment of his quality management system with the notified body of his choice, for the interoperability constituents concerned.<}0{>The manufacturer submits a request for the assessment of its quality management system for relevant interoperability constituents / elements of the structural subsystem to the conformity assessment body chosen by the manufacturer.

Request includes:

- the name and address of the manufacturer and, if the request has been submitted by an authorized representative, his name and address;

- a written statement that the same request was not submitted to another body for the conformity assessment;

- all relevant information for the envisaged category of the interoperability constituent / element of the structural subsystem;

- documentation about the quality management system and

- technical file of the approved type and a copy of the type-examination certificate.

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3.2. {0>The quality management system shall ensure that the interoperability constituents are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the TSI that apply to them.<}0{>The quality management system ensures the conformity of interoperability constituents / elements of the structural subsystem with the type described in the type-examination certificate and the TSI requirements or the applicable national railway technical rules.

All the elements, requirements and provisions adopted by the manufacturer are documented systematically and organized in the form of policies, procedures and instructions. The documentation for the quality management system enables a consistent interpretation of programs, plans, manuals and quality records, and in particular contains the following descriptions:<0}<0}

{0>- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,<}0{>- quality objectives and organizational structure, responsibilities and authority of the management in terms of product quality;

- appropriate techniques, processes and systematic actions used in production, quality control and quality management;

- examinations and tests carried out before, during and after manufacture and their frequency;

- records on quality, such as inspection reports and test data, calibration data, reports on professional staff training, etc. and

- supervision of process of achieving the desired project quality and products and the effectiveness of the quality management system.

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3.3. {0>The notified body shall assess the quality management system to determine whether it satisfies the requirements referred to in point 3.2.<}0{>Body for conformity assessment assesses the quality management system to determine whether it meets the requirements stipulated in item 3.2.

It assumes the compliance with these requirements regarding the elements of a quality management system that comply with the relevant national standard specifications implementing the applicable quality management standard, recognized standards and / or technical specifications.<0}

{0>When the manufacturer operates a certified quality management system certified by an accredited certification body, for the manufacturing of the relevant interoperability constituent, the notified body shall take this into account in the assessment.<}0{>When a manufacturer uses a quality management system that has been certified by an accredited certification body in the production of the appropriate interoperability constituent / element of the structural subsystem, the conformity assessment body shall take this into account.<0} {0>In this case, the notified body will make a detailed assessment of quality management system specific documents and records of the interoperability constituent only.<}0{>In this case, the body for conformity assessment carries out a detailed assessment of the specific documentation and records of the quality management system for that interoperability constituent / structural subsystem element. The body for conformity assessment body does not re-evaluate the entire quality manual and all procedures already assessed by the quality management system certification body.<0}

{0>In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the TSI.<}0{>In addition to experience in the quality management system, the team performing the test has at least one other member with an assessment experience in the area of ​​the interoperability constituent / element of the structural subsystem and technology of the specific product and TSI requirements or the national railway technical rules and standards. Assessment includes a visit to the manufacturer's business premises for evaluation. The inspection team shall review the technical file referred to in item 3.1., paragraph two, item five, in order to verify the manufacturer's ability to recognize the TSI requirements or national railway technical rules and perform necessary tests in order to ensure the conformity of the interoperability constituent / element of the structural subsystem with these requirements. <0}

{0>The decision shall be notified to the manufacturer.<}0{>The manufacturer is provided with the information on the decision. The notice contains the conclusions of the verification and a substantiated assessment decision. Once the assessment of the quality management system provides sufficient evidence that the requirements of point 3.2. are met, the conformity assessment body issues the approval of the quality management system to the applicant.

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3.4. {0>The manufacturer shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.<}0{> The manufacturer undertakes to fulfill the obligations arising out of the approved quality management system, also to maintain it to remain adequate and efficient. <0}

3.5. {0>The manufacturer shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the interoperability constituent, including changes of quality management system certificate.<}0{>The manufacturer shall notify the conformity assessment body that has approved the quality management system about the planned changes in the quality management system affecting the interoperability constituent / element of the structural subsystem, including changes in the quality management system certificate.

The conformity assessment body assesses the proposed changes and decides whether the changed quality management system will continue to meet the requirements as per item 3.2. or re-evaluation is needed. The manufacturer is notified of the decision. The notice contains the conclusions of the review and substantiated assessment decision.

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4. {0>Surveillance under the responsibility of the notified body<}0{> Supervision jurisdiction of the body for conformity assessment <0}

4.1. {0>The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.<}0{> The purpose of the supervision is to verify that the manufacturer duly fulfills the obligations arising from the approved quality management system.<0}

4.2. {0>The manufacturer shall, for periodic audits purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:<}0{>For the purpose of periodic audits, the manufacturer shall provide the body for conformity assessment access to production sites, final examinations, testing and storage and shall provide all necessary information, in particular:

- documentation for the quality management system and

- quality records, such as inspection reports and test data, calibration data, reports on professional staff training, etc..<0}

4.3. The conformity assessment body performs periodic audits to ensure that the manufacturer maintains and applies the quality management system and delivers the audit report to the manufacturer.

Periodic audits are carried out at least once every two years. If manufacturer applies a certified quality management system, the conformity assessment body takes this into account during periodic audits.

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4.4. {0>In addition, the notified body may pay unexpected visits to the manufacturer.<}0{>In addition, the conformity assessment body may pay visit to the manufacturer without any announcement. During such visits, the conformity assessment body may, if necessary, test the interoperability constituent / structural subsystem element or impose its testing to ensure that the quality management system functions properly. The conformity assessment body shall provide the manufacturer with a visit report and, if case of tests carried out, a test report.

5. {0>EC declaration of conformity<}96{>Declaration of conformity*<0}*

5.1. {0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}96{>The manufacturer shall draw up a written declaration of conformity for the interoperability constituent / element of the structural subsystem and keep it at the disposal of the national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem. Declaration of Conformity identifies the interoperability constituent / element of the structural subsystem for which it is compiled.

A copy of the Declaration of Conformity is provided at the request of competent authorities.

5.2. <0}

The certificates referred to in the Declaration of Conformity are:

- approval of the quality management system referred to in point 3.3. and assessment reports from point 4.3, if applicable, and

- type examination certificate and its addenda.

6. {0>The manufacturer shall, for the period defined in the relevant TSI and, where the TSI does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the national authorities:<}0{> The manufacturer shall, for a period of ten years following the production of the last interoperability constituent / element of the structural subsystem, keep the following at the disposal of the national authorities:

- the documentation referred to in point 3.1.,

- the change from point 3.5, as approved,

- the decisions and reports of the conformity assessing body for points 3.5., 4.3. and 4.4.

7. {0>Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.<}0{>Each notified body shall notify its authorities on the notification of issued or withdrawn quality management system approvals, and periodically or upon request, shall make available a list of refused, suspended or otherwise approved quality management system approvals to their notified bodies.

Each notified body shall notify other notified bodies on the quality management system approvals which were declined, suspended, withdrawn or otherwise restricted, and, upon request, provide information on issued approvals of the quality management system.

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8. {0>Authorised representative<}96{>Authorized representative<0}

{0>The manufacturer’s obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}85{> The manufacturer's obligations under points 3.1, 3.5, 5 and 6 may be fulfilled by the authorized representative on his behalf and under his responsibility, provided that they are listed in the authorization.

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**{0>Module CF. Conformity to type based on product verification<}96{>Module CF. Compliance with the type based on product verification**

**<0}**

1. {0>Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.<}80{>Compliance with the type based on product verification is part of the conformity assessment procedure where the manufacturer fulfills the obligations laid down in items 2, 5.1. and 6. and confirms and declares under full responsibility that the relevant interoperability constituents / elements of the structural subsystem, subject to the provisions of point 3, are in conformity with the type described in the type-examination certificate and meet the TSI requirements or applicable national railway technical rules.

2. {0>Manufacturing<}96{>Production<0}

{0>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the interoperability constituents with the approved type described in the EC-type examination certificate and with the requirements of the TSI that apply to them.<}96{>The manufacturer shall take all necessary measures to ensure the conformity of the interoperability constituent / element of the structural subsystem with the approved type described in the type-examination certificate with the TSI requirements and the applicable national railway technical rules.

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3. {0>Verification<}0{>Verification

{0>Verification<}0{><0}

The conformity assessment body selected by the manufacturer shall carry out appropriate assessments and tests to verify the conformity of the interoperability / structural component of the structural subsystem with the approved type as described in the type-examination certificate and with the TSI requirements or national railway technical rules.

Assessments and tests for checking the conformity of the interoperability constituent / element of the structural subsystem with the TSI requirements or the national railway technical rules shall be carried out, at chosen by the manufacturer, by examining and testing each interoperability constituent / element of the structural subsystem, as specified in point 4 or by examining and testing the interoperability constituent / element of the structural subsystem on a statistical basis, as indicated in point 5.

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4.{0>Verification of conformity by examination and testing of every interoperability constituent.<}0{> Verification of compliance by examining and testing of each interoperability constituent / element of the structural subsystem<0}

4.1. {0>All interoperability constituents shall be individually examined and appropriate tests set out in the relevant TSI, harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the requirements of the TSI.<}0{>All interoperability constituents / elements of the structural subsystem shall be individually examined and appropriate tests set out in the TSI, i.e. national railway technical rules and recognized standards and / or technical specifications, or equivalent tests, shall be carried out in order to verify compliance with the approved type described in the test certificate type and with TSI requirements or national railway technical rules. When the test is not established in the TSI, or the national railway technical rules, recognized standards and / or technical specifications, the tests to be carried out shall be decided by the manufacturer and the body for conformity assessment. <0}

4.2. {0>The notified body shall issue an EC certificate of conformity in respect of the examinations and tests carried out.<}96{>Тело The conformity assessment body issues a certificate of conformity based on the examinations and tests carried out.

The manufacturer shall keep the certificate of conformity available for inspection by the national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem.

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5. {0>Statistical verification of conformity<}0{> Statistical compliance verification <0}

5.1. {0>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his interoperability constituents for verification in the form of homogeneous lots.<}0{>The manufacturer shall take all necessary measures to ensure that the production process and its monitoring ensure the homogeneity of each manufactured batch and submit its interoperability constituents / elements of the structural subsystem for verification in the form of homogeneous batches.

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5.2. From e{0>A random sample shall be taken from each lot according to the requirements of the TSI.<}0{>ach batch a random sample is taken in accordance with the TSI requirements or national railway technical rules. All interoperability constituents / elements of the structural subsystem in the sample are individually examined and the appropriate tests set out in the TSI, i.e. national railway technical rules, recognized standards and / or technical specifications, or equivalent tests, are performed in order to verify compliance with the TSI requirements or national railway technical rules and determine whether the batch is accepted or declined. When a test is not specified in the TSI, or the national railway technical rules, recognized standards and / or technical specifications, the tests to be carried out shall be decided by the manufacturer and the body for the conformity assessment. <0}

5.3. {0>If a lot is accepted, all interoperability constituents of the lot shall be considered approved, except for those interoperability constituents from the sample that have been found not to satisfy the tests.<}0{>If the batch is accepted, it is considered that all interoperability constituents / elements of the structural sub-system in the batch are approved, except those interoperability constituents / elements of the structural sub-system from the sample that have been found not to satisfy the tests.

The conformity assessment body issues a certificate of conformity based on the examinations and tests carried out. The manufacturer shall keep the certificate of conformity available to the national authorities for a period of ten years after the production of the last interoperability constituent / element of the structural subsystem.

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5.4. {0>If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot is being placed on the market.<}0{>If the batch is rejected, the conformity assessment body or the competent authority shall take appropriate measures to prevent the placing of such batch on the market. In case of frequent rejection of batches, the conformity assessment body may suspend the statistical check and take appropriate measures. <0}

6. Declaration of Conformity{0>EC declaration of conformity<}96{>ДД<0}

6.1. {0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities, for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}95{>The manufacturer shall draw up a written declaration of conformity for interoperability constituent / element of the structural subsystem and shall keep it at the disposal of the national authorities for a period of ten years after the last interoperability constituent / element of the structural subsystem has been manufactured. The Declaration of Conformity identifies the interoperability constituent / element of the structural subsystem for which it is compiled.

  A copy of the Declaration of Conformity is provided at the request of the competent authorities.

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6.2. {0>The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.<}96{> {0>The certificates to be referred to are:<}96{> The certificates referred to in the Declaration of Conformity are:

- the type-examination certificate and its addenda,

- certificate of conformity referred to in point 4.2. or point 5.3.<0}

7. {0>Authorised representative<}96{>Authorized representative<0}

{0>The manufacturer’s obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}79{> The manufacturer's obligations may be fulfilled by his authorized representative on his behalf and under his responsibility, provided that they are listed in the authorization. The authorized representative may not execute the obligations on behalf of the manufacturer from items 2, 5.1. and 5.2.

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**{0>Module CH. Conformity based on full quality management system<}96{>Моdule CH. Compliance based on a complete quality management system**

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1. {0>Conformity based on full quality management system is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.<}81{>Compliance on the basis of a complete quality management system is a conformity assessment procedure where the manufacturer meets the obligations under points 2 and 5, ensures and declares to his sole responsibility that the interoperability constituents / elements of the structural subsystem meet the TSI requirements or the applicable national railway technical rules.

2. {0>Manufacturing<}96{>Production<0}

{0>The manufacturer shall operate an approved quality management system for design, manufacture and final product inspection and testing of the interoperability constituents concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.<}89{> The manufacturer applies an approved quality management system for the design, manufacture, final control of products and testing of the relevant interoperability constituents / elements of the structural subsystem, as defined in point 3 and subject to the controls defined in point 4.

3. {0>Quality management system<}96{> Quality management system

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3.1. {0>The manufacturer shall lodge an application for assessment of his quality management system with the notified body of his choice, for the interoperability constituents concerned.<}96{> The manufacturer submits a request to the conformity assessment body of its choice for the assessment of its quality management system for relevant interoperability constituents / elements of the structural subsystem. <0}

{0>The application shall include:<}96{>Request includes:

- the name and address of the manufacturer, and if the request has been submitted by an authorized representative, his name and address;

- Technical file for one model from each category of interoperability constituents / elements of the structural subsystem whose production is planned. The technical file shall contain, if possible, at least the following elements:

* + - <0}{0>- a general description of the interoperability constituent,<}96{>a general description of the interoperability constituents / element of the structural subsystem;
    - conceptual design and production plans and schemes of components, sub-assemblies, circuits, etc.;
    - descriptions and explanations necessary for understanding drawings and schemes, and operation (including conditions of use) and maintenance of the interoperability constituent / element of the structural subsystem;
    - the conditions for integrating the interoperability constituent / element of the structural subsystem into its system environment (sub-assembly, circuit, subsystem) and the necessary interface conditions;
    - a list of national railway technical rules applied;
    - a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements or national railway technical rules, if the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that have been applied;
    - results of project budgets, performed tests, etc. and
    - Test reports;

- documentation on the quality management system and

- a written statement that the same request has not been submitted to another conformity assessment body.

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3.2. {0>The quality management system shall ensure compliance of the interoperability constituents with the requirements of the TSI that apply to them.<}0{>The quality management system provides the compliance of the interoperability constituents / elements of the structural subsystem with the TSI requirements or the applicable national railway technical rules.<0}

{0>All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.<}96{>All elements, requirements and provisions adopted by the manufacturer are documented systematically and organized in the form of written policies, procedures and instructions. The documentation for the quality management system enables consistent interpretation of programs, plans, manuals and quality records, and in particular contains detailed descriptions:<0}<0}

{0>- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,<}89{>- quality goals and organizational structure, responsibilities and authority of the management in terms of project quality and product quality;

- the technical specifications of the project, including the standards to be applied;

- techniques, procedures and systematic actions to be used to control and verify the project when designing the interoperability constituents / elements of the structural subsystem belonging to the covered product category;

- appropriate techniques, processes and systematic actions that will be used in production, quality control and quality management;

- examinations and tests carried out before, during and after manufacture and their frequency of performance;

- quality records, such as inspection reports and test data, calibration data, reports on the professional training of staff, etc., and

- the way of monitoring the achievement of the desired product quality and the effectiveness of the quality management system.<0}

3.3. The conformity assessment body assesses the quality management system to determine whether it meets the requirements from section 3.2.

It assumes the compliance with these requirements with regard to the elements of a quality management system that comply with the relevant national standard specifications implementing the applicable quality management standard, recognized standards and / or technical specifications.<0}

{0>When the manufacturer operates a certified quality management system certified by an accredited certification body, for the design and manufacturing of the relevant interoperability constituent, the notified body shall take this into account in the assessment.<}92{>When the manufacturer during the design phase and production of the appropriate interoperability constituent / structural component of the structural subsystem uses a quality management system certified by an accredited certification body, the conformity assessment body takes this into account when assessing it. In this case, the conformity assessment body carries out a detailed assessment of the specific documentation and records of the quality management system only for this interoperability constituent. The conformity assessment body does not re-evaluate the entire quality manual and all procedures already assessed by the certification body for the quality management system.<0}

{0>In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant interoperability constituent field and product technology concerned, and knowledge of the requirements of the TSI.<}88{>In addition to experience gained in the quality management system, the evaluation team has at least one other member with the experience of the evaluator in the area of ​​the appropriate interoperability constituent / element of the structural subsystem and the technology of a particular product and knowledge of the TSI requirements and / or national railway technical rules. Checking includes a visit to the manufacturer's business premises for evaluation. The evaluation team shall review the technical file referred to in point 3.1., item 2, in order to verify the manufacturer's ability to recognize the TSI requirements or national railway technical rules and perform necessary tests in order to ensure the conformity of the interoperability constituent / element of the structural subsystem with these requirements. The manufacturer or his authorized representative shall be informed of the decision.<0}

{0>The notification shall contain the conclusions of the audit and the reasoned assessment decision.<}96{>The notice contains the conclusions of the evaluation and a substantiated assessment decision. If the assessment of the quality management system provided satisfactory evidence that the requirements of point 3.2 are met, the conformity assessment body issues the approval of the quality management system to the Applicant.

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3.4. {0>The manufacturer shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.<}96{> The manufacturer undertakes to fulfill the obligations arising out of the approved quality management system, as well as to keep the system adequate and efficient. <0}

3.5. {0>The manufacturer shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the interoperability constituent, including changes of quality management system certificate.<}96{>The manufacturer shall notify the conformity assessment body that has approved the quality management system about the planned changes in the quality management system affecting the interoperability constituent / subsystem element, including changes in the quality management system certificate.

The conformity assessment body assesses the proposed changes and decides whether the changed quality management system will continue to meet the requirements from item 3.2 or the re-evaluation is needed.

The manufacturer is notified of the decision. The notice contains the conclusions of the review and a substantiated assessment decision.

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4. {0>Surveillance under the responsibility of the notified body<}96{> Supervision in jurisdiction of the conformity assessment body <0}

4.1. {0>The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.<}96{> The purpose of the supervision is to verify that the manufacturer duly fulfills the obligations arising from the approved quality management system.<0}

4.2. {0>The manufacturer shall, for periodic audits purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:<}92{>For the purpose of periodic verification, the manufacturer shall enable the body assessing the conformity access to production, inspection, and testing and storage sites and provide all necessary information, in particular:

- documentation for the quality management system,

- the quality records provided for in the part of the quality management system related to the project, such as the results of analyzes, calculations, tests, etc. and

- the quality records provided for in the part of the quality management system related to production, such as inspection reports and test data, calibration data, reports on staff training, etc..

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4.3. The conformity assessment body performs periodic audits to ensure that the manufacturer maintains and applies the quality management system, and provides the manufacturer with a verification report.

Periodic audits are carried out at least once every two years.

  If a manufacturer applies a certified quality management system, the conformity assessment body shall take this into account during periodic audits.

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4.4. {0>In addition, the notified body may pay unexpected visits to the manufacturer.<}96{>In addition, the conformity assessment body may pay a visit to the manufacturer without a prior announcement. During such visits, the conformity assessment body may, if necessary, carry out tests of the interoperability constituents / elements of the structural subsystem or impose their performance in order to verify the proper functioning of the quality management system. The conformity assessment body shall provide the manufacturer with a visit report and, in case of tests carried out, a test report.

5. Declaration of Conformity{0>EC declaration of conformity<}96{>ДДДД

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5.1. {0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}96{>The manufacturer shall draw up a written declaration of conformity for the interoperability constituent / element of the structural subsystem and shall keep it available to the national authorities for a period of ten years from the date of manufacture of the last interoperability constituent / element of the structural subsystem. The Declaration of Conformity identifies the interoperability constituent / element of the structural subsystem for which it was compiled.<0}

{0>A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.<}96{>Примерак A copy of the Declaration of Conformity is provided at the request of the competent authorities.

<0}

5.2. {0>The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.<}96{> {0>The certificate to be referred to is:<}96{>The certificate referred to in the declaration of conformity is:

- approval of the quality management system referred to in point 3.3 and check reports from point 4.3, if any.

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6. {0>The manufacturer shall, for the period defined in the relevant TSI and, where the TSI does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the national authorities:<}96{> The manufacturer shall, for a period of at least ten years from the date of manufacture of the last interoperability constituent, keep at the disposal of the national authorities:

- the technical file referred to in point 3.1.,

- documentation relating to the quality management system referred to in point 3.1 .;

- the change from point 3.5, as approved, and

- the decisions and reports of the conformity assessment body referred to in points 3.5, 4.3. and 4.4.

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7. {0>Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.<}96{>Each notified body shall notify its reporting authorities on the quality management system approvals issued or withdrawn, and periodically or upon request, shall make available to its authorities a list of rejected, suspended or otherwise limited quality management systems.

Each notified body shall notify other notified bodies on the quality management system approvals which were refused, suspended or withdrawn, and, upon request, on the issued quality management system approvals.

8. {0>Authorised representative<}96{>Authorized Representative<0}

{0>The manufacturer’s obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}96{> The manufacturer's obligations under points 3.1, 3.5, 5 and 6 may be fulfilled by his authorized representative on his behalf and under his responsibility, provided that they are listed in the authorization.<0}

{0>**Module CH1.**<}96{>**Module CH1.**<0}{0>**Conformity based on full quality management system plus design examination**<}87{> **Compliance on the basis of a complete quality management system and project testing**

1. {0>Conformity based on full quality management system plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements of the technical specification for interoperability (TSI) that apply to them.<}90{>Compliance on the basis of a complete quality management system and project testing is a conformity assessment procedure where the manufacturer meets the obligations under points 2 and 6 and confirms and declares to his sole responsibility that the interoperability constituents / elements of the structural subsystem meet the TSI requirements or applicable national railway technical rules.

2. {0>Manufacturing<}96{>Production<0}

{0>The manufacturer shall operate an approved quality management system for design, manufacture and final product inspection and testing of the interoperability constituents concerned as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the interoperability constituents shall have been examined in accordance with point 4.<}0{> The manufacturer applies an approved quality management system for the design, manufacture, final control of products and testing of the interoperability constituents / elements of the structural subsystem, as defined in item 3 and subject to the control referred to in item 5. The adequacy of the technical project of the interoperability constituents / elements of the structural subsystem is reviewed in in accordance with item 4.

{0>Quality management system<}96{>3. Quality Management System

1. <0}

3.1. {0>The manufacturer shall lodge an application for assessment of his quality management system with the notified body of his choice, for the interoperability constituents concerned.<}96{>The manufacturer chooses the conformity assessment body and submits a request for the assessment of its quality management system for relevant interoperability constituents / elements of the structural subsystem.

Request shall include:

- the name and address of the manufacturer, and if the request was made by an authorized representative, his name and address;

- all relevant information for the envisaged category of the interoperability constituent / elements of the structural subsystem;

- documentation on the quality management system and

- A written statement that the same request has not been submitted to the other conformity assessment body.

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3.2. {0>The quality management system shall ensure compliance of the interoperability constituents with the requirements of the TSI that apply to them.<}96{>The quality management system ensures the compliance of the interoperability constituents / elements of the structural subsystem with the TSI requirements or the applicable national railway technical rules.<0}

{0>All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.<}96{>All elements, requirements and provisions adopted by the manufacturer are documented systematically and organized in the form of written policies, procedures and instructions. The documentation for the quality management system shall enable a consistent interpretation of programs, plans, manuals and quality records, and in particular contains descriptions:

{0>- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,<}96{>- quality and organizational goals, responsibilities and authority of the management in terms of project quality and product quality;

- the technical specification of the project, including the standards to be applied, and, if the relevant standards and / or technical specifications are not fully applicable, a description of the solution to be used to ensure compliance with the TSI requirements or applicable national railway technical rules to the interoperability constituent / element of the structural subsystem;

- techniques, procedures and actions to be used for the control and verification of the project when designing interoperability constituents belong to the covered product category;

- appropriate techniques, processes and systematic actions that will be used in production, quality control and quality management;

- examinations and tests carried out before, during and after manufacture, and their frequency;

- quality records, such as inspection reports and test data, calibration data, reports on the professional training of staff, etc. and

- the way of monitoring the achievement of the desired product quality and the effectiveness of the quality management system.

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3.3. The conformity assessment body assesses the quality management system to determine whether it meets the requirements from item 3.2.

It assumes compliance with these requirements with regard to the elements of a quality management system that comply with the relevant national standard specifications implementing the applicable quality management standard, recognized standards and / or technical specifications.<0}

{0>When the manufacturer operates a certified quality management system certified by an accredited certification body, for the design and manufacturing of the relevant interoperability constituent, the notified body shall take this into account in the assessment.<}96{>When the manufacturer during the design phase and production of the appropriate interoperability / structural component of the structural subsystem uses the quality management system that has been certified by an accredited certification body, the conformity assessment body evaluating, shall take this into account. In this case, the conformity assessment body carries out a detailed assessment of the specific documentation and records of the quality management system only for the interoperability constituent / the element of the structural subsystem. The body does not re-evaluate the entire quality manual and all procedures already assessed by the quality management system certification body. In addition to experience gained in the quality management system, the evaluation team has at least one other member with the experience of the evaluator in the area of ​​the appropriate interoperability constituent / element of the structural subsystem and the technology of a particular product and knowledge of the TSI requirements and / or national railway technical rules. Checking includes a visit to the manufacturer's business premises for evaluation.<0}

The manufacturer or his authorized representative shall be informed on the decision.

The notice contains the conclusions of the control and a substantiated assessment decision. If the assessment of the quality management system provided satisfactory evidence that the requirements of point 3.2. are met, the conformity assessment body issues the approval of the quality management system to the Applicant.

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3.4. {0>The manufacturer shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.<}96{> The manufacturer undertakes to fulfill the obligations arising out of the approved quality management system, and shall provide that the system remains adequate and efficient. <0}

3.5. {0>The manufacturer shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the interoperability constituent, including changes of quality management system certificate.<}96{>The manufacturer shall notify the conformity assessment body that has approved the quality management system about the planned changes in the quality management system affecting the interoperability constituent, including changes in the quality management system certificate.

The conformity assessment body assesses the proposed changes and decides whether the changed quality management system will continue to meet the requirements from item 3.2. or re-evaluation is needed.

The manufacturer is notified about the decision. The notice contains the conclusions of the review and a substantiated assessment decision.<0}

3.6. {0>Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.<}96{>Each notified body shall notify its reporting authorities on the quality management system approvals issued or withdrawn, and periodically or upon request, shall make available to its authorities a list of rejected, suspended or otherwise limited quality management systems.

Each notified body shall notify other notified bodies on the quality management system approvals which the body has refused, suspended or withdrawn, and, upon request, on the approvals of the issued quality management system.

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4. Project Testing <0}

4.1. {0>The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.<}0{> The manufacturer submits a request for examination of the project referred to in point 3.1 to the conformity assessment body.<0}

4.2. T{0>The application shall make it possible to understand the design, manufacture, maintenance and operation of the interoperability constituent, and to assess the conformity with the requirements of the TSI that apply to it.<}0{>he request allows understanding of the design, production, maintenance and operation of the interoperability constituent / element of the structural subsystem and assessment of compliance with the TSI requirements or applicable national railway technical rules.

<0}{0>It shall include:<}0{>ЗThe request also includes:<0}

- the name and address of the manufacturer;

- a written statement that the same request was not submitted to another body for conformity assessment;

- technical file. The technical file enables the assessment of the conformity of the interoperability constituents / elements of the structural subsystem with the TSI requirements or the national railway technical rules. The technical file defines the requirements and, to the extent necessary for evaluation, includes the design and operation of the interoperability constituent / element of the structural subsystem. <0} {0>The technical documentation shall, wherever applicable, contain at least the following elements:<}0{> The technical file, if possible, contains at least the following elements:<0}

* + - {0>- a general description of the interoperability constituent,<}96{>a general description of the interoperability constituent / element of the structural subsystem;
    - conceptual design, production plans and components schemes, sub-assemblies, circuits, etc;
    - descriptions and explanations necessary for understanding drawings and schemes, and operation (including conditions of use) and maintenance of the interoperability constituent / element of the structural subsystem;
    - the conditions for integrating the interoperability constituent / element of the structural subsystem into the system environment (sub-assembly, circuit, subsystem) and the necessary interface conditions;
    - a list of national railway technical rules applied;
    - a list of recognized standards and / or other relevant technical specifications applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements or national railway technical rules, if the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that have been applied;
    - results of project budgets, test executed, etc. and
    - Test reports;<0}

{0>- the supporting evidence for the adequacy of the technical design.<}87{>- supporting evidence on the adequacy of the technical project. All supporting documents shall be mentioned as supporting evidence, in particular when the relevant TSI, or national railway technical rules, recognized standards and technical specifications are not applied in full. Supporting evidence shall include, where appropriate, the results of testing carried out by the appropriate laboratory of the manufacturer or other laboratory on his behalf and under his responsibility.

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4.3. {0>The notified body shall examine the application, and where the design meets the requirements of the TSI that apply to the interoperability constituent it shall issue an EC design examination certificate to the manufacturer.<}0{>ТТТТThe Conformity Assessment Body reviews the requirements and, if the project meets the TSI requirements or national railway technical rules, referring to the interoperability constituent, issues the manufacturer a certificate of project testing. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) related to its validity and data necessary for identifying the approved project, and if necessary, a description of the product functioning. The certificate may have one or more annexes.<0}

The certificate and its annexes contain all relevant information for assessing the conformity of the interoperability constituent / element of the structural subsystem with the tested project.

When a project does not meet the TSI requirements or national railway technical rules, the conformity assessment body refuses to issue a project review certificate and informs the applicant thereof with a detailed explanation for refusal.

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4.4. Before the certificate validity date, t{0>The manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the TSI or the conditions for validity of the certificate until the expiry of the validity of the certificate.<}0{>he manufacturer shall notify the conformity assessment body issuing the project review certificate of any changes to an approved project that may affect compliance with the TSI requirements or the national railway technical rules or the conditions related to the validity of the certificate. <0}

4.5. {0>Each notified body shall inform its notifying authorities of the EC design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.<}93{>Each notified body shall notify its registration authorities about the project review certificates and / or their addenda issued or withdrawn, and periodically or upon request, make available a list of certificates and / or their additions rejected, suspended or otherwise limited, to their registration authorities.

Each notified body shall notify other notified bodies about the project review certificates and / or any addenda that were refused, withdrawn, suspended or otherwise restricted, and, upon request, on the certificates and / or their addenda.<0}

OTIF, OTIF member states and other notified bodies may, upon request, obtain a copy of the project review certificate and / or its supplements. OTIF and OTIF Member States may, upon request, obtain a copy of the technical file and the results of the inspection carried out by the notified body.

The conformity assessment body shall keep a copy of the project review certificate, its annexes and addenda as well as the technical file, including documentation submitted by the manufacturer, until the expiry date of the certificate.

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4.6. {0>The manufacturer shall keep a copy of the EC design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}95{>The manufacturer shall keep a copy of the project review certificate, its annexes and addenda together with the technical file available to the national authorities within a period of ten years from the date of manufacture of the last interoperability constituent / element of the structural subsystem.

5. {0>Surveillance under the responsibility of the notified body<}96{> Supervision in jurisdiction of the conformity assessment body <0}

5.1. {0>The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality management system.<}96{> The purpose of the supervision is to verify that the manufacturer duly fulfills the obligations arising from the approved quality management system.

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5.2. For the purpose of periodic verification, the manufacturer shall enable the body assessing the conformity access to production, inspection, and testing and storage sites and provide all necessary information, in particular:

- documentation for the quality management system,

- the quality records provided for in the part of the quality management system related to the project, such as the results of analyzes, calculations, tests, etc. and

- the quality records provided for in the part of the quality management system related to production, such as inspection reports and test data, calibration data, sealing reports, reports on staff training, etc. {0>The manufacturer shall, for periodic audits purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:<}96{><0}

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5.3. The conformity assessment body performs periodic audits to ensure that the manufacturer maintains and applies the quality management system, and provides the manufacturer with a verification report.

Periodic audits are carried out at least once every two years.

  If a manufacturer applies a certified quality management system, the conformity assessment body takes this into account during periodic audits.

<0}

5.4. {0><}96{>In addition, the conformity assessment body may pay a visit to the manufacturer without a prior announcement. During such visits, the conformity assessment body may, if necessary, carry out tests of the interoperability constituents / elements of the structural subsystem or impose their performance in order to verify the proper functioning of the quality management system. The conformity assessment body shall provide the manufacturer with a visit report and, in case of tests carried out, a test report.<0}

6. {0>EC declaration of conformity<}96{>Declaration of Conformity<0}

6.1. {0>The manufacturer shall draw up a written EC declaration of conformity for the interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}96{>The manufacturer shall draw up a written declaration of conformity for the interoperability constituent / element of the structural subsystem and shall keep it available to the national authorities for a period of ten years from the date of manufacture of the last interoperability constituent / element of the structural subsystem. The Declaration of Conformity identifies the interoperability constituent / element of the structural subsystem for which it was compiled and enlists the certificate number on project testint.<0}

{0>A copy of the EC declaration of conformity shall be made available to the relevant authorities upon request.<}96{>Примерак A copy of the Declaration of Conformity is provided at the request of the competent authorities.

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6.2. {0>The EC declaration of conformity shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.<}96{> {0>The certificates to be referred to are:<}96{>The certificates referred to in the Declaration of Conformity are:

- approval of the quality management system referred to in point 3.3. and the audit reports referred to in point 5.3, if any, and

- certificate of examination of the project referred to in point 4.3. and its addenda.

7. {0>The manufacturer shall, for the period defined in the relevant TSI and, where the TSI does not define this period, for a period ending at least 10 years after the last interoperability constituent has been manufactured, keep at the disposal of the national authorities:<}96{> The manufacturer shall, for a period of at least ten years from the date of manufacture of the last interoperability constituent / element of the structural subsystem, keep the following at the disposal of the national authorities:

- documentation related to the quality management system referred to in point 3.1;

- change from point 3.5 and the way of approval and

- the decisions and reports of the conformity assessment body referred to in points 3.5, 5.3. and 5.4.

8. {0>Authorised representative<}96{>Authorised Representative

The manufacturer's authorized representative may, on his behalf and under his responsibility, apply as per requirements listed in items 4.1. and 4.2. and fulfill the obligations under points 3.1, 3.5, 4.4, 4.6, 6 and 7, provided that they are listed in the authorization.<0}

**MODULES FOR ASSESSMENT OF THE BENEFITS FOR THE USE OF THE INTEROPERABILITY CONSTITUENTS, RELATED TO THE ELEMENTS OF STRUCTURAL SUBSYSTEM** <0}

**{0>Module CV.<}96{>Module CV.<0} {0>Type validation by in-service experience (suitability for use)<}96{>** **Validation of type based on testing in exploitation**

**(usage convenience)**

**<0}**

1. {0>Type validation by in-service experience is the part of assessment procedure in which a notified body ascertains and attests that a specimen, representative of the production envisaged meets the requirements for suitability for use of the technical specification for interoperability (TSI) that apply to it.<}0{>Validation of type based on testing in exploitation is part of the assessment procedure in which the conformity assessment body establishes and certifies that a representative sample for the intended production meets the suitability requirements for the TSIs use or applicable national railway technical rules.

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2. {0>The manufacturer shall lodge an application for type validation by in-service experience with a notified body of his choice.<}71{>The manufacturer submits a request for type validation based on testing in exploitation to the conformity assessment body of his choice.

Request includes:

- the name and address of the manufacturer, and if the request was made by an authorized representative, his name and address;

- a written statement that the same request was not submitted to another body for the conformity assessment;

- the technical file referred to in point 3;

- a validation program based on testing in exploitation, as described in point 4;

- the name and address of the enterprise (infrastructure manager and / or railway carrier) with whom the applicant has entered into an agreement on participation in the suitability for use assessment based on the basis trial in exploitation: <0}

{0>- by operating the interoperability constituent in service,<}0{>

* + - {0>- by monitoring the in-service behaviour, and<}0{>using the interoperability constituent / element of the structural subsystem;
    - monitoring behavior during operation and
    - publishing a report on the exploitation test; <0}

{0>- the name and the address of the company undertaking the maintenance of the interoperability constituent during the time period or running distance required for in-service experience, and<}0{>- the name and address of the enterprise undertaking the maintenance of the interoperability constituent / element of the structural subsystem over a period of time or the distance traveled necessary for the exploitation test,

- the type examination certificate when the CB module for the design phase was used, or the project test certificate when the CH1 module was used for the design phase. <0}

The manufacturer shall make available to the organization that has taken the interoperability constituent / element of the structural subsystem into the exploitation, sample or sufficient number of samples representating the planned production which is hereinafter referred to as the "type". The type may include several versions of the interoperability constituent / element of the structural subsystem, provided that all differences between the versions are covered by the above-mentioned certificates.

The conformity assessment body may request additional samples if necessary to perform validation based on exploitation tests.

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3. {0>The technical documentation shall make it possible to assess the interoperability constituent’s conformity with the requirements of the TSI.<}93{>The technical file should enable the assessment of conformity of the interoperability constituent / element of the structural subsystem with the TSI requirements or the national railway technical rules. The technical file includes the design, production, maintenance and operation of the interoperability constituent / element of the structural subsystem.

The technical file contains the following elements:

- the technical file referred to in item 9 of the CB Module or in item 4.6. Module CH1 and

- conditions for usage and maintenance of the interoperability constituent / element of the structural subsystem (e.g. the limit values ​​of driving or distance times, wear limits, etc.).

If the TSI, or national railway technical rules require additional information in the technical file, such information will also be included.

4. {0>The programme for the validation by in-service experience shall include:<}0{> The validation program based on exploitation tests includes:

- required performance or behavior of the interoperability constituent / element of the structural subsystem during trial work;

- preparations for installation;

- duration of the program - time or distance;

- expected conditions and program;

- maintenance program;

- special tests to be carried out during work, if any;

- the size of the sample series - if there are more than one;

- control program (type, number and frequency, documentation);

- criteria for authorisation ted defects and their impact on the program; and

- the information to be found in the organization's report using the interoperability constituent / element of the structural subsystem (see point 2 of the item 5).

5. {0>Type validation by in-service experience<}0{> Validation of type based on testing in exploitation

Compliance Assessment Body {0>The notified body shall:<}96{>:<0}

5.1. {0>examine the technical documentation and the programme for validation by in-service experience;<}0{> reviews technical file and validation program based on testing in exploitation;<0}

5.2. {0>verify that the type is representative and has been manufactured in conformity with the technical documentation;<}0{> checks whether the type is representative and manufactured in accordance with the technical file;<0}

5.3. {0>verify that the programme for validation by in-service experience is well adapted to assess the required performance and in-service behaviour of the interoperability constituents;<}0{>verifies that the validation program based on testing in exploitation is well adapted to assess the required performance and behavior during the use of the interoperability constituent / element of the structural subsystem;<0}

5.4. {0> agree with the applicant and the company(ies) undertaking the operation of the interoperability constituent referred to in point 2 the programme and the location where the inspections will be carried out and if necessary, the test(s) and the body performing the test(s);<}0{>arranges both with the applicant and the organization that has taken over the exploitation of the interoperability constituent / element of the structural subsystem referred to in point 2, the program and the place where the audits shall be carried out and, if necessary, the tests and the body carrying out the tests;<0}

5.5. {0>monitor and inspect the progress of in-service running, operation and maintenance of the interoperability constituent;<}0{> monitors and controls the behavior of the interoperability constituent / element of the structural subsystem during exploitation and maintenance;<0}

5.6. {0>assess the report, to be issued by the company(ies) undertaking the operation the interoperability constituent referred to in point 2, and all other documentation and information, collected during the procedure (test reports, maintenance experience etc.);<}0{> evaluates a report published by an organization that has taken over the exploitation of the interoperability constituent / element of the structural subsystem referred to in point 2 and all other documentation and information collected during the process (test reports, maintenance experience, etc.);<0}

5.7. {0>evaluate whether the in-service behaviour results meet the requirements of the TSI.<}0{> assesses whether the performance results during operation meet the TSI requirements or national railway technical rules.

6. {0>Where the type meets the requirements of the TSI that apply to the interoperability constituent concerned, the notified body shall issue an EC certificate of suitability for use to the manufacturer.<}84{>When the type meets the TSI requirements, i.e., the national railway technical rules applicable to the relevant interoperability constituent / element of the structural subsystem, the body for conformity assessment issues a certificate of convenience for use to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the validation, the conditions (if any) for its validity and necessary data for identification of the approved type. The certificate may have one or more annexes.<0}

{0>A list of the relevant parts of the technical documentation shall be annexed to the EC certificate of suitability for use and a copy kept by the notified body.<}0{>A list of the relevant parts of the technical file is provided in the annex with the certificate of convenience for use, and the copy is kept by the conformity assessment body.

When the type does not meet the TSI requirements or the national railway technical rules, the conformity assessment body refuses to issue a certificate of convenience for use and informs the applicant thereof with a detailed explanation.

7. {0>The manufacturer shall inform the notified body that holds the technical documentation relating to the EC certificate of suitability for use of all modifications to the approved type that may affect the suitability for use of the interoperability constituent or the conditions for validity of the certificate.<}0{>The manufacturer shall notify the conformity assessment body that keeps the technical file regarding the certificate of suitability for use of any type of change of an approved type that may affect the suitability for the use of the interoperability constituent / element of the structural subsystem or the certificate’s validity conditions. Such changes require additional approval in the form of an addendum to the original certificate of convenience for use. Only relevant examinations and tests are performed for necessary changes.

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8. {0>Each notified body shall inform its notifying authorities concerning the EC certificate of suitability for uses and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.<}86{>Each notified body shall notify its authorities for registration of the certificates of convenience for use and / or their addenda issued or withdrawn, and periodically or if requested make available a list of certificates and / or their addenda that have been rejected, suspended or otherwise limited to their registration authorities.

9. {0>Each notified body shall inform the other notified bodies concerning the EC certificate of suitability for uses and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.<}85{> Each notified body shall notify other bodies about the certificates of convenience for use and / or any addenda refused, withdrawn, suspended or otherwise restricted, and, if requested, about the certificates and / or the addenda issued.

10. OTIF, OTIF member states and other notified bodies may, upon request, obtain a copy of the certificate of convenience for use and / or its addenda. OTIF and OTIF member states may, upon request, obtain a copy of the technical file and the results of the examination carried out by the notified body.

The conformity assessment body shall keep a copy of the certificate of convenience for use, its annexes and addenda up to the expiry date of the certificate.

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11. Declaration of convenience for use

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11.1. {0>The manufacturer shall draw up a written EC declaration of suitability for use for an interoperability constituent and keep it at the disposal of the national authorities for the period defined in the relevant TSI and, where the TSI does not define this period, for 10 years after the last interoperability constituent has been manufactured.<}90{>The manufacturer shall draw up a written declaration of convenience for use of an interoperability constituent / element of the structural subsystem and shall keep it available to the national authorities for a period of ten years from the date of manufacture of the last interoperability constituent / element of the structural subsystem. The Declaration of Convenience for Use identifies the interoperability constituent / element of the structural subsystem for which it was compiled.

  A copy of the declaration of convenience for use is provided upon the request of the competent authorities.<0}

11.2. {0>The EC declaration of suitability for use shall meet the requirements of Article 13(3) and point 3 of Annex IV to Directive 2008/57/EC.<}88{> {0>The certificate to be referred to is:<}96{> The certificate referred to in the declaration of convenience for use is:

- certificate of convenience for use.

<0}

11.3. {0>The interoperability constituent may be placed on the market only after the following EC declarations have been drawn up:<}0{> The interoperability constituent / element of the structural subsystem may be released to on the market only after compiling the following declarations:

- Declaration of convenience for use referred to in point 11.1. and

- Declaration of conformity.

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12. {0>Authorised representative<}96{>Authorized representative<0}

{0>The manufacturer’s obligations set out in points 2, 7 and 11.1 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}90{> Manufacturer’s duties referred to in points 2, 7 and 11.1 may be, on his behalf and under his responsibility, fulfilled by his authorized representative, provided that they are listed in the authorization.

**Annex 3**

**DECLARATION OF COMPLIANCE OF**

**THE INTEROPERABILITY CONSTITUENT / ELEMENT OF THE STRUCTURAL SUBSYSTEM**

CC/RRRRRRRRRRRRRR/YYYY/NNNNNN – *Declaration number\**

**Applicant:** **Authorized representative:**

*Business name Business name*

*Full address Full address*

**Applicant:**

*Business name*

*Full address*

**We declare under full responsibility that an interoperability constituent / element of a structural subsystem:**

*Name/type/designation/constituent description/element of the structural subsystem*

**to which this declaration relates is in conformity with the following laws and technical rules:**

*Name(s) of the laws and technical rule(s)*

**has been assessed by the conformity assessment body:**

*Business name*

*Full address*

**according to the following approval(s) and/or certificate(s):**

*Certificate(s) number, date of issue*

**with following limitations and conditions of use:**

*List of limitations and conditions*

**The following procedures have been applied in order to obtain a declaration of conformity:**

*Modules selected by the manufacturer for the conformity assessment of the interoperability constituent / element of the structural subsystem*

**Referral to standards:**

*List of standards*

**List of annexes:**

*Annex title (technical file)*

**Valid until:** *date DD/MM/YYYY* (in case of temporary declaration)

**In**: *Location*

**Dated:** *date DD/MM/YYYY*

**Applicant:****Authorized representative:**

**Name and surname** *Signature*  **Name and surname** *Signature*

*Stamp Stamp*

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\*) CC – state code (two letters) according to ISO 3166; for Republic of Serbia - RS;

RRRRRRRRRRRRRR – company registration number (14-digit number); if the CR number is shorter, first digits are 0;

YYYY – year of issue (four digits) and

NNNNNN – counter (six digits) increases by one digit with each issued declaration and refers to the person who issued the declaration; every year the counter starts again from zero.

**DECLARATION OF APPLICATION FOR USE OF**

**THE INTEROPERABILITY CONSTITUENT / ELEMENT OF STRUCTURAL SUBSYSTEM**

CC/RRRRRRRRRRRRRR/YYYY/NNNNNN – *Declaration\**

**Applicant:** **Authorized representative:**

*Business name Business name*

*Full address Full address*

**Applicant:**

*Business name*

*Full address*

**We declare under full responsibility that an interoperability constituent / element of a structural subsystem:**

*Name/type/designation/constituent description/element of the structural subsystem*

**to which this declaration relates is in conformity with the following laws and technical rules:**

*Name(s) of the laws and technical rule(s)*

**has been assessed by the conformity assessment body:**

*Business name*

*Full address*

**according to the following certificate of convenience for use:**

*Certificate number, date of issue*

**with following limitations and conditions of use:**

*List of limitations and conditions*

**The following procedures have been applied in order to obtain a declaration of conformity:**

*Modules selected by the manufacturer for the conformity assessment of the interoperability constituent / element of the structural subsystem*

**Declaration of conformity of the relevant interoperability constituent / element of the structural subsystem:**

*Declaration of Conformity, number*

**List of annexes:**

*Annex title (technical file)*

**Valid until:** *date DD/MM/YYYY* (in case of temporary declaration)

**In**: *Location*

**Dated:** *date DD/MM/YYYY*

**Applicant:****Authorized representative:**

**Name and surname** *Signature*  **Name and surname** *Signature*

*Stamp Stamp*

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\*) CC – state code (two letters) according to ISO 3166; for Republic of Serbia - RS;

RRRRRRRRRRRRRR – company registration number (14-digit number); if the CR number is shorter, first digits are 0;

YYYY – year of issue (four digits) and

NNNNNN – counter (six digits) increases by one digit with each issued declaration and refers to the person who issued the declaration; every year the counter starts again from zero.

**Annex 4**

**STRUCTURAL SUBSYSTEMS AND MODULES TO BE APPLIED**

**FOR THEIR VERIFICATION**

1. **Subsystem infrastructure:**

Module SG - Verification based on unit verification or

Module SH1 - Verification based on complete quality management system with project testing

1. **Subsystem energy:**

Module SG - Verification based on unit verification or

Module SH1 - Verification based on complete quality management system with project testing

1. **Subsystem control, management and signalization – track part:**

Module SG - Verification based on unit verification or

Module SB + SD -Type testing + Verification based on quality management system of the production process or

Module SB + SF - Type testing + verification based on product verification or

Module SH1 - Verification based on complete quality management system with project testing <0}

{0>Module SD.<}0{> <0}

1. **Subsystem control, management and signalization – car part:**

Module SB + SD - Type testing + Verification based on quality management system of the production process or

Module SB + SF - Type testing + verification based on product verification or

Module SH1 - Verification based on complete quality management system with project testing

**5) Subsystem train cars:**

Module SB + SD - Type testing + Verification based on quality management system of the production process or

Module SB + SF - Type testing + verification based on product verification or

Module SH1 - Verification based on complete quality management system with project testing

**Annex 5**

**MODULES FOR VERIFICATION OF STRUCTURAL SUBSYSTEMS**

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**{0>Module SB.<}96{>Module SB.<0} Type testing{0>EC-type examination<}96{>ИИИИИи**

**<0}**

1. Type testing is a part of the verification process in which the conformity assessment body reviews the technical design of the subsystem and checks and confirms that the technical design of the subsystem meets the relevant TSI requirements, or the national railway technical rules and all other applicable rules.

2. The type testing is carried out:

- by assessing the adequacy of the technical project of the subsystem through the review of the technical file and the supporting evidence referred to in point 3 (type of project) and

- by examining a sample representative of the intended production of the whole subsystem (type of production).

The type may include several versions of the subsystem, provided that differences between versions do not affect the provisions of the relevant TSIs or national railway technical rules.

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3. {0>The applicant shall lodge an application for EC-type examination with a notified body of his choice.<}91{>The Applicant submits a request for examination of the type to the conformity assessment body of his choice.

Request includes:

- the name and address of the applicant, and if the request has been submitted by an authorized representative, and his name and address,

- a written statement that the same request was not submitted to another body for the assessment of conformity;

- technical file. The technical file enables the assessment of the conformity of the subsystem with the TSI requirements or the national railway technical rules.<0} The technical file shall state the relevant TSI requirements or national railway technical rules and shall include the design, manufacture and operation of the subsystem, to the extent relevant for the type examination procedure. The technical file contains the following elements:<0}

* + - {0>- a general description of the subsystem, its overall design and structure,<}96{>a general description of the subsystem, its overall design and structure,
    - the documentation necessary for the establishment of the technical file prescribed in Article 17 of this Rulebook,
    - a separate file with the set of data required by the TSI / national railway technical rules for each appropriate register provided by the law governing the safety and interoperability of the railway,
    - a copy of the declaration of transitional declaration of verification (hereinafter: PIV) issued for the subsystem, if any,
    - descriptions and explanations necessary for understanding the operation and maintenance of the subsystem, if necessary,
    - the conditions for integrating the subsystem into its system environment and necessary interface conditions,
    - a list of national railway technical rules applied,
    - a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements / national railway technical rules, if the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that were applied,

* + - {0>- results of design calculations made, examinations carried out, etc.,<}96{>results of implemented project calculations, performed tests, etc.,
    - program testing and test reports,
    - evidence of compliance with other rules (including certificates, if any),
    - accompanying production and subsystem assembly documentation,
    - a list of manufacturers that participated in the design, manufacture, assembly and installation of the subsystem,
    - conditions for subsystems use (limit values ​​of operating time or distance traveled, wear limit values, etc.),
    - maintenance conditions and technical file on maintenance of the subsystem,
    - all technical requirements defined by the relevant TSI / national railway technical rules that need to be considered during the production, maintenance or operation of the subsystem,
    - any other appropriate technical evidence showing that previous checks or tests have been successfully carried out by the competent authorities under similar conditions and
    - any additional information, if provided for in the relevant TSI / national railway technical rules;<0}

{0>- the specimens representative of the production envisaged.<}96{>- representative samples for the intended production. The conformity assessment body may request additional samples if necessary for the execution program testing,

- it is necessary to provide a sample or samples of subassembly or assembly or a subsystem model in a pre-assembled state, if necessary for certain tests or test methods defined by the relevant TSI / national railway technical rules,

- supporting evidence on the adequacy of the technical design solution. In these supporting evidence, all documentation used is indicated, especially when the relevant recognized standards and / or technical specifications have not been applied in full. The supporting evidence shall include, where appropriate, the results of testing performed by the appropriate body as requested by the applicant or other testing body on his behalf and under his responsibility.

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4. Body for Assessment Compliance <0}

{0>For the design type:<}96{>for project type:<0}

4.1. {0>examine the technical documentation and supporting evidence to assess whether the technical design of the subsystem is adequate to fulfil the requirements of the relevant TSI(s);<}96{> reviews the technical file and supporting evidence to assess whether the technical design of the subsystem meets the TSI requirements or national railway technical rules;

<0}

4.2. {0>where a design review is requested in the relevant TSI(s), examine design methods, the design tools and the design results to assess compliance with the requirements of the relevant TSI(s).<}96{>when the relevant TSI / national railway technical rules require a review of the project, review the methods, tools and design results for the assessment of conformity with the TSI requirements / national railway technical rules.<0}

{0>For the production type:<}96{>for the production type:<0}

4.3. {0>verify that the specimen(s) have been manufactured in conformity with the requirements of the relevant TSI(s) and with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant TSI(s), harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;<}96{>confirms that the specimen is manufactured in accordance with the requirements of the relevant TSI / national railway technical rules and identifies elements that have been designed in accordance with recognized standards and / or technical specifications, as well as elements that have been designed without the application of the relevant provisions of the standard;<0}

4.4. {0>carry out appropriate examinations and tests, or have them carried out, to check whether, where the applicant has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;<}96{>изводи performs or orders the execution of appropriate examinations and tests to verify, if the applicant has decided to apply the solutions in the relevant recognized standards and / or technical specifications, whether they were appropriately applied;<0}

4.5. {0>carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the relevant TSI(s);<}96{>изводи performs or orders the execution of appropriate examinations and tests to verify that if the solutions in the relevant recognized standards and / or technical specifications have not been applied, whether the solutions adopted by the manufacturer meet the relevant TSI requirements / national railway technical rules;<0}

4.6. {0>agree with the applicant on a location where the examinations and tests will be carried out.<}96{> mutually agrees with the applicant about the location of examination and tests. <0}

5. {0>When the subsystem referred to in point 3 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.<}96{>When the subsystem referred to in item 3 is subject to deviation from the TSI application, the applicant shall inform the notified body thereof.

The Applicant also submits a precise referral to the TSI (or parts thereof) for which the deviation is requested to the notified body.

The Applicant shall inform the notified body about the outcome of the deviation proceedings.

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6. {0>The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes.<}96{>ТТе The conformity assessment body shall draw up an assessment report indicating the activities undertaken in accordance with point 4 and their results. Without prejudice to its obligations to the reporting authorities, the conformity assessment body shall publish the content of such report, in whole or in part, only with the applicant’s consent.<0}

7. {0>Where the type meets the requirements of the relevant TSI(s) that apply to the subsystem concerned, the notified body shall issue an EC-type examination certificate to the applicant.<}78{>When the type meets the requirements of the relevant TSI / national railway technical rules applicable to the subsystem concerned, the conformity assessment body issues the type-examination certificate to the applicant. The certificate shall contain the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes.<0}

{0>The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems with the examined type to be evaluated.<}88{>The certificate and its annexes shall contain all relevant information for assessing the conformity of the manufactured subsystems with the type tested.

When the type does not meet the relevant TSI requirements / national railway technical rules, the conformity assessment body refuses to issue a type-examination certificate and informs the applicant thereof with a detailed explanation for the refusal.

When the subsystem referred to in point 3 is subject to deviation from the application of the TSI, improvement, renewal or a specific case, the type examination certificate also contains precise references to the TSI or parts thereof according to which compliance has not been tested in the verification process.

If only certain parts or individual stages of the subsystem are covered and they meet the relevant TSI requirements / national railway technical rules, the conformity assessment body issues the PIV certificate.

The applicant shall draw up the PIV Declaration.

8. {0>The applicant shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the subsystem with the requirements of the relevant TSI(s) or the conditions for validity of the certificate.<}86{>The applicant shall notify the conformity assessment body holding the technical file for the type-examination certificate about any type-approved changes that may affect the subsystem's compliance with the TSI requirements / national technical rules or the certificate’s conditions of validity. Such changes require additional approval in the form of an addendum to the original type-examination certificate.<0}

9. {0>Each notified body shall inform its notifying authorities concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.<}96{>Each notified body shall inform its authorities on the type-examination certificates and / or their addenda issued or withdrawn, and periodically or if requested make available a list of certificates and / or their additions to their registry authorities, that have been rejected, suspended or otherwise restricted.

Each notified body shall inform other notified bodies of type examination certificates and / or any additions that have been refused, withdrawn, suspended or otherwise restricted and, upon request, about certificates and / or their addenda issued.

OTIF, OTIF member states and other notified bodies may, upon request, obtain a copy of the type-examination certificate and / or its addenda. OTIF and OTIF member states may, upon request, obtain a copy of the technical file and the results of the examination carried out by the notified body.

The conformity assessment body shall keep a copy of the type examination certificate, its annexes and addenda, including the technical file submitted by the applicant, until the expiration date of the certificate.

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10. {0>The applicant shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities throughout the service life of the subsystem.<}0{> The applicant shall provide a copy of the type examination certificate, its annexes and addenda together with the technical file at the request of the national authorities during the lifetime of the subsystem.<0}

11. {0>The applicant’s authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 5, 8 and 10, provided that they are specified in the mandate.<}88{> The authorized representative of the applicant may file a request from item 3 and fulfill the obligations under items 5, 8 and 10, provided that they are defined in the authorization.

**<0}{0>Module SD.<}96{>Module SD.<0} Verification based on the production process quality management system**

**<0}**

1. Verification based on the production process quality management system is part of the verification process where the applicant fulfills the obligations laid down in points 2 and 8 and confirms and declares under full responsibility that the subject subsystem conforms to the type described in the type examination certificate and meets the relevant TSI requirements / national railway technical rules and all other applicable rules. <0}

2. {0>Manufacturing<}96{>Production<0}

{0>The production, final subsystem inspection and testing of the subsystem concerned shall be covered by approved quality management system(s) as specified in point 3, and shall be subject to surveillance as specified in point 7.<}0{>The production, final control and testing of the subsystem concerned are covered by an approved quality management system, as defined in point 3, and subject to the control referred to in point 7.<0}

3. {0>Quality management system<}96{>Quality management system<0}

3.1. {0>The applicant shall lodge an application for assessment of the quality management system with the notified body of his choice, for the subsystem concerned.<}81{>The applicant submits a request to the Body for Evaluation of Conformity of Optional Quality Management System Assessment for the subsystem concerned.

Request includes:

- the name and address of the applicant, and if the request has been submitted by an authorized representative, his name and address;

- a written statement that the same request was not submitted to another body for the assessment of conformity;

- a detailed project management structure and the name and address of all persons involved in the project;

- all relevant information for the subsystem envisaged;

- documentation on the quality management system;

- a copy of the PIV declaration for the subsystem, if applicable;

- the technical file of the approved type and a copy of the type examination certificate and its annex.

3.2. {0>The quality management system shall ensure that the subsystem is in conformity with the type described in the EC-type examination certificate and comply with the requirements of the relevant TSI(s) that apply to it.<}79{>The quality management system ensures that the subsystem conforms to the type described in the type examination certificate and meets the TSI requirements / applicable national railway technical rules.

All elements, requirements and provisions adopted by the applicant are documented systematically and organized in the form of written policies, procedures and instructions. The documentation for the quality management system enables a consistent interpretation of programs, plans, manuals and quality records, and in particular contains the detailed descriptions of:<0}

{0>- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to subsystem quality,<}92{>- quality goals and organizational structure, responsibilities and authorizations of the management regarding the quality of the subsystem,

- appropriate techniques, processes and systematic actions to be used in production, quality control and quality management,

- examinations and tests carried out before, during and after manufacture, and their frequency,

- quality records, such as inspection reports and test data, calibration data, reports on the professional training of staff, etc. and

- how to monitor the achievement of the desired product quality and the efficient operation of the quality management system.

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3.3. The conformity assessment body assesses the quality management system to determine whether it meets the requirements from section 3.2.

It assumes compliance with these requirements with respect to the elements of a quality management system that comply with the relevant national standard specifications that implement the applicable quality management standard, recognized standards and / or technical specifications.

If the subsystem's compliance with the relevant TSI requirements / national railway technical rules is based on more than one quality management system, the conformity assessment body shall in particular review:<0}

{0>- whether the relations and interfaces between the quality management systems are clearly documented, and<}0{>- whether the relationships and interfaces between the quality management system are clearly documented and

- whether the overall responsibility and powers of the management for the approval of the whole subsystem are clearly assigned and accepted by all participants in the project. <0}

{0>The audit shall be specific for the subsystem concerned, taking into consideration the specific contribution of the applicant to the subsystem.<}0{>КонтролаКоПровераП The check is adapted to the subsystem concerned, taking into account the specific contribution of the applicant to the subsystem.

<0}{0>When the applicant operates a certified quality management system certified by an accredited certification body, for the manufacturing and final testing of the relevant subsystem, the notified body shall take this into account in the assessment.<}83{>When the applicant in the production and final testing of the respective subsystem implements a quality management system certified by the accredited body, the conformity assessment body takes this into account. In this case, the conformity assessment body carries out a detailed assessment of the specific documentation and records of the quality management system only for that subsystem. The conformity assessment body does not re-evaluate the entire quality manual and all procedures already assessed by the certification body for the quality management system.<0}

{0>In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant subsystem field and product technology concerned, and knowledge of the requirements of the relevant TSI(s).<}86{>In addition to experience in the quality management system, the evaluation team has at least one other member experienced in the assessment of the respective subsystem and technology of a particular product, and knowledge of the TSI requirements / national railway technical rules. Checking includes a visit to the business premises of the persons concerned for evaluation. The review team shall review the technical file referred to in point 3.1, second paragraph, item seven, in order to check the ability of certain persons to recognize the TSI requirements / national railway technical rules and carry out the necessary tests to ensure compliance of the subsystem with these requirements. <0}

{0>The decision shall be notified to the applicant.<}85{>The applicant shall receive the information on the decision. The notice contains the verification findings and a substantiated assessment decision. When the assessment of the quality management system provides satisfactory evidence that the requirements of point 3.2 are met, the conformity assessment body issues the approval of the quality management system to the applicant.

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3.4. {0>The applicant shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.<}92{> The applicant undertakes to fulfill the obligations arising from the approved quality management system, and to maintain the system adequate and efficient.<0}

3.5. {0>The applicant shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any changes of quality management system certificate.<}0{>The applicant shall notify the conformity assessment body that has approved the quality management system on all planned changes in the quality management system which have an impact on the design, manufacture and final inspection, testing and operation of the subsystem, as well as any changes to the quality management system certificate.

The conformity assessment body assesses the proposed changes and decides whether the changed quality management system will continue to meet the requirements from item 3.2. or the re-evaluation is needed.

The applicant shall be informed about the decision. The notice contains the conclusions of the review and substantiated assessment decision.

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4. {0>Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.<}96{>Each notified body shall notify its reporting authorities of the quality management system about the approvals issued or withdrawn, and periodically or upon request, shall make available to its filing authorities a list of rejected, suspended or otherwise limited quality management systems.

Each notified body shall inform other notified bodies of the quality management system about the approvals which have been refused, suspended, withdrawn or otherwise restricted, and, upon request, about the issued approvals of the quality management system.

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5. Subsystem verification{0>EC verification<}0{>ВВ<0}

5.1. {0>The applicant shall lodge an application for the EC verification of the subsystem with a notified body of his choice.<}71{> The applicant submits a request for verification of the subsystem to the conformity assessment body of his choice.

Request contains:<0}

{0>- name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well,<}92{>- the name and address of the applicant and, if the request has been submitted by an authorized representative, his name and address and

- the technical file pertaining to the approved type, including the type-examination certificate, issued upon the completion of the procedure defined in the SB module.

The request also contains, if it has not already been covered by technical file:

- general description of the subsystem, its overall design and structure;

- the documentation necessary for the establishment of the technical file prescribed in Article 17 of this Rulebook;

- a separate file with the set of data required by the relevant TSI / national railway technical rules for each appropriate register provided for by the law governing the safety and interoperability of the railway;

- a list of national railway technical rules applied;

- a list of recognized standards and other relevant technical specifications, applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements / national railway technical rules, if the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that have been applied;

- conditions for the subsystem use (limit values ​​of operating time or distance traveled, wear limit value, etc.);

- descriptions and explanations necessary for understanding the functioning and maintenance of the subsystem,

- maintenance conditions and technical file related to maintenance of the subsystem;

- all technical requirements defined by the relevant TSI / national railway technical rules that must be considered during the production, maintenance or operation of the subsystem; <0}

{0>- other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies,<}88{>- other appropriate technical evidence showing that previous checks or tests have been successfully carried out by the competent authorities under similar conditions;

- the conditions for integrating the subsystem into its system environment and the necessary interface conditions with other subsystems;

- results of implemented project calculations, performed tests, etc.;

- test reports, if any;

- documentation relating to the production and assembly of the subsystem;

- a list of manufacturers that participated in the production, assembly and installation of the subsystem;

- evidence that the production and final testing referred to in point 2 is covered by the applicant's quality management system and evidence of its effectiveness;

- the name of the body for assessing the conformity of the person responsible for the approval and supervision of the quality management system;

- evidence of compliance with the provisions of other rules (including certificates, if any); and

- any additional information, if provided for in the relevant TSI / national railway technical rules.

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5.2. The Compliance Assessment Body selected by the applicant shall first review the requirement relating to the validity of the type examination certificate and its annexes.

If the conformity assessment body considers that the type-examination certificate is no longer valid or is not appropriate and that a new type-examination certificate is required, the conformity assessment body refuses to assess the quality management system of the applicant, with an explanation provided.

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6. {0>When the subsystem referred to in point 5.1 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.<}96{>When the subsystem referred to in item 5.1. subject to deviation from the TSI application, the applicant shall inform the conformity assessment body thereof.

The Applicant also submits a precise reference to the conformity assessment body about the TSI (or parts thereof) for which the deviation is requested.

The Applicant shall notify the Compliance Body on the outcome of the proceedings concerning the deviation.

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7. {0>Surveillance under the responsibility of the notified body<}96{> Supervision jurisdiction of the conformity assessment body <0}

7.1. {0>The purpose of surveillance is to make sure that the applicant duly fulfils the obligations arising out of the approved quality management system.<}92{> The purpose of the supervision is to ensure that the applicant duly fulfills the obligations arising from the approved quality management system.<0}

7.2. {0>The applicant shall, for periodic audits purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:<}94{>For the purpose of periodic checks, the applicant enables the conformity assessment body access to production, inspection, testing and storage sites and provides all necessary information, in particular:

- documentation for the quality management system and

- quality records such as inspection reports and data on testing, calibration data, reports on professional staff training, etc.

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7.3. The conformity assessment body performs periodic checks to confirm that the applicant maintains and applies the quality management system, providing the applicant with a verification report.

Periodic checks are carried out at least once every two years.

  If the applicant applies a certified quality management system, the conformity assessment body takes this into account during the periodic check.

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7.4. {0>In addition, the notified body may pay unexpected visits to the applicant.<}89{>In addition, the conformity assessment body may pay an unannounced visit to the applicant. During such visits, the conformity assessment body may, if necessary, test the subsystem or impose its testing to determine that the quality management system functions properly. The conformity assessment body shall submit a visit report to the applicant and, if tests have been carried out, a test report.<0}

7.5. The conformity assessment body responsible for the verification of the subsystem, if it does not control all the quality management systems referred to in point 3, coordinates the supervisory activities of the other body for assessing the compliance of the responsible person for the task, in order to:

- ensure proper interface management between different management quality systems related to integration of the subsystem,

- collect, together with the applicant, necessary elements for evaluation in order to ensure consistency and overall control of the various quality management systems.

 This coordination includes the right of the conformity assessment body to:

- obtain all documentation (approval and supervision) issued by another body for the assessment of conformity,

- attend the supervisory checks referred to in item 7.3. and

- launch additional checks from point 7.4. under their full responsibility and together with another body for the conformity assessment.

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8. Certificate of verification and declaration of verification{0>EC certificate of verification and EC declaration of verification<}0{>ССсс<0}

8.1. {0>Where the subsystem meets the requirements of the relevant TSI(s), the notified body shall issue an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.<}0{>When the subsystem meets the requirements of the relevant TSI / national railway technical rules, the conformity assessment body issues the certificate of subsystem verification.

When the subsystem referred to in item 5.1. subject to deviation from the TSI application, upgrade, renewal or is a specific case, the certificate also contains precise references to the TSI or parts thereof according to which compliance has not been tested in the verification process.

If only certain parts or individual stages of the subsystem are covered and they meet the relevant TSI requirements / national railway technical rules, the body for conformity assessment issues the PIV certificate.

8.2 <0}8.2. {0>The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem.<}0{>The Applicant shall draw up a written declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the subsystem’s lifetime. The verification declaration identifies the subsystem for which it is compiled.

When the subsystem referred to in item 5.1. subject to deviation from the TSI application, upgrade, update, or is a specific case, the declaration for the subsystem also contains a reference to the TSI or parts thereof according to which the conformity has not been tested in the verification process. <0}

{0>In case of ISV procedure the applicant shall draw up a written EC ISV declaration.<}0{>In the case of PIV procedure, the applicant shall draw up a written PIV declaration.

The declaration of verification and the supporting documentation shall be drawn up in the manner prescribed by Articles 14 and 17 of this Rulebook.

Related certificates are:

- approval of the quality management system referred to in point 3.3. and examination reports from point 7.3, if applicable, and

- type examination certificate and its addenda.

A copy of the declaration of verification and the PIV declaration, if applicable, shall be provided upon the request of the competent authorities.

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8.3. The conformity assessment body is responsible for the preparation of the technical file attached to the declaration of verification and the PIV declaration. The technical file shall be drawn up in accordance with Article 17 of this Rulebook.<0}

9. {0>The applicant shall, throughout the service life of the subsystem, keep at the disposal of the national authorities:<}0{> Throughout the subsystem’s service life, the applicant the following documents at the disposal to the national authorities:<0}

{0>- the documentation referred to in point 3.1,<}96{>- documentation from item 3.1,<0}

{0>- the change(s) referred to in point 3.5, as approved,<}88{>- ammendments from item 3.5, as they were approved,<0}

{0>- the decisions and reports of the notified body referred to in points 3.5, 7.3 and 7.4, and<}87{>- decisions and reports of the bodies for conformity assessment from items 3.5., 7.3. and 7.4. and<0}

{0>- the technical file referred to in point 8.3.<}80{>- technical file from item 8.3.

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10. {0>Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.<}79{>Each notified body shall inform its reporting authorities about the issued or withdrawn verification certificates, and periodically or upon request, make available to its registry authorities a list of refused, suspended or otherwise restricted verification certificates. Each notified body shall inform other notified bodies about certificates of verification which has been refused, suspended, withdrawn or otherwise restricted, and, upon request, about the verification certificates that have been issued. <0}

11. {0>Authorised representative<}96{>Authorised Representative

Obligations of the Applicant referred to in points 3.1, 3.5, 6, 8.2. and 9. may be met by his authorized representative on his behalf and under his responsibility, provided that they are listed in the authorization.

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**{0>Module SF.<}96{>Module SF.<0} Verification based on product verification**

**<0}**

1. Verification based on product verification is part of the verification process where the applicant fulfills the obligations set out in points 2 and 5 and confirms and declares under full responsibility that the subject subsystem, for which the provisions of paragraph 4 apply, is in accordance with the type described in the type testing certificate and that it meets the relevant TSI requirements / national railway technical rules and all other applicable rules. <0}

2. {0>Manufacturing<}96{>Production

<0}{0>The manufacturing process and its monitoring shall ensure conformity of the manufactured subsystem with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s) that apply to it.<}0{>The production process and its supervision ensure the conformity of the manufactured subsystem with the approved type described in the type-examination certificate and with the relevant TSI requirements / applicable national railway technical rules.<0}

3. {0>The applicant shall lodge an application for the EC verification of the subsystem with a notified body of his choice.<}96{>The applicant submits a request for the subsystem verification to the conformity assessment body of his choice.

The request includes:

- the name and address of the applicant, and if the request was made by an authorized representative, his name and address and

- the technical file pertaining to the approved type, including the type-examination certificate and its annex, issued upon the completion of the procedure defined in the SB module.

It also contains the following, unless already covered by technical file:

- a general description of the subsystem, its overall design and structure,

- the documentation necessary for the establishment of the technical file prescribed in Article 17 of this Rulebook;

- a separate file with a set of data required by the relevant TSI / national railway technical rule for each appropriate register provided for by the law governing the safety and interoperability of the railway;

- a list of national railway technical rules applied;

- a list of recognized standards and other relevant technical specifications, applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements / national railway technical rules, if the recognized standards are not applied. In case of partially applied recognized standards, the technical file lists the parts that have been applied;

- conditions for the subsystem usage (limit values ​​of operating time or distance traveled, wear limit values, etc.);

- descriptions and explanations necessary for understanding the operation and maintenance of the subsystem;

- maintenance conditions and technical file related to maintenance of the subsystem;

- all technical requirements defined by the relevant TSI / national railway technical rules which need to be taken into account during the production, maintenance or operation of the subsystem;

- other relevant technical evidence indicating that previous checks or tests have been successfully carried out by the competent authorities under similar conditions;

- the conditions for integrating the subsystem into its system environment and the necessary interface conditions with other subsystems;

- evidence on compliance with other rules (including certificates, if any);

- results of implemented project calculations, tests executed, etc.;

- test reports;

- documentation on the production and assembly of the subsystem;

- a list of manufacturers who participated in the design, manufacture, assembly and installation of subsystems and

- any additional information, if provided for in the relevant TSI / national railway technical rules.

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4. Subsystem v{0>EC verification<}96{>erification<0}

4.1. The conformity assessment body selected by the applicant shall first review the requirement related to the validity of the type examination certificate. If the conformity assessment body considers that the type-examination certificate is no longer valid or is not appropriate and that a new type-examination certificate is required, the conformity assessment body refuses to carry out the verification of the subsystem, providing an explanation.

The conformity assessment body shall carry out appropriate examinations and tests to verify conformity of the subsystem with the approved type described in the type-examination certificate and with the TSI requirements / national railway technical rules.

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4.2. {0>All subsystems shall be individually examined and appropriate tests set out in the relevant TSI(s), harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s).<}85{>All subsystems shall be individually examined and appropriate tests set out in TSI / national railway technical rules, recognized standards and / or technical specifications or equivalent tests shall be carried out in order to verify conformity with the approved type described in the type-examination certificate and with the relevant TSI requirements / national railway technical rules.

If such recognized standard does not exist, the applicant and the notified body decide on the appropriate tests. <0}

4.3. The conformity assessment body shall mutually agree with the applicant the location of the examinationss and final subsystem testingand, if required by the relevant TSI / national railway technical rules, the applicant shall, under direct supervision and in the presence of the conformity assessment body, perform tests or validation under full operating conditions.

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The conformity assessment body has access to, in order to carry out testing and verification, manufacturing workshops, assembly and installation sites and, where appropriate, prefabrication and testing facilities, in order to carry out its tasks provided for in the relevant TSI / national railway technical rules.

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4.4. {0>When the subsystem referred to in point 3 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.<}96{>When the subsystem referred to in item 3 is subject to deviation from the application of the TSI, the applicant shall inform the notified body thereof.

The Applicant also submits to the notified body a precise referral to the TSI (or parts thereof) for which the deviation is requested.

The Applicant shall inform the notified body about the outcome of the deviation proceedings.

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4.5. The conformity assessment body issues a certificate of verification based on examinations and tests carried out.

When the subsystem referred to in point 3 is subject to deviation from the TSI application, improvement, renewal or is subject to a specific case, the certificate also contains precise references to the TSI or parts thereof according to which the conformity has not been tested in the verification process. If only certain parts or individual stages of the subsystem are covered and meet the relevant TSI requirements / national railway technical rules, the notified body issues the PIV certificate.

The Applicant provides a certificate of verification for the inspection needs of national authorities during the service life of the subsystem.

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5. Declaration of verification{0>EC declaration of verification<}71{>ДД<0}

5.1. {0>The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities, throughout the service life of the subsystem.<}95{>The Applicant shall draw up a written declaration of verification for the subsystem and shall keep it at the disposal for the national authorities throughout the operating life of the subsystem. Declaration of verification identifies the subsystem for which it was compiled.

When the subsystem referred to in point 3 is subject to deviation from the application of the TSI, improvement, renewal or is a specific case, the declaration for the subsystem also contains a reference to the TSI or parts thereof for which the conformity has not been examined during the verification process.

In the case of the PIV procedure, the Applicant shall draw up a written PIV declaration.

Declaration of verification and accompanying documents shall be drawn up in the manner prescribed by Articles 14 and 17 of this Rulebook.

Examples of the declaration of verification and the PIV declarations, if any, shall be provided if requested by the competent authorities.

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5.2. The conformity assessment body is responsible for drawing up the technical file that shall be attached to the declaration of verification and the PIV declaration. The technical file shall be drawn up in accordance with Article 17 of this Rule.<0}

6. {0>Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.<}96{>Each notified body shall inform its reporting authorities about the issued or withdrawn verification certificates, and periodically or upon request, make available a list of refused, suspended or otherwise restricted verification certificates to its registry authorities.

Each notified body shall inform other notified bodies about the verification certificates which have been refused, suspended, withdrawn or otherwise restricted, and, upon request, about the verification certificates that have been issued.

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7. {0>Authorised representative<}96{>Authorized representative

<0}{0>The applicant’s obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}93{> Applicant’s obligations may be fulfilled by his authorized representative on his behalf and under his responsibility, provided that they are listed in the authorization. The authorized representative may not execute the applicant’s obligations referred to in point 2.

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**{0>Module SG.<}96{>Module SG.<0} Verification based on unit verification**

**<0}**

1. Verification of the subsystem based on unit verification represents the verification procedure where the applicant fulfills the obligations set out in points 2, 3, 4, 6.2. and 6.4. and confirms and declares under full responsibility that the subsystem concerned, subject to the provisions of paragraph 5, meets all relevant TSI requirement / applicable national railway technical rules.

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2. {0>The applicant shall lodge an application for the EC verification of the subsystem with a notified body of his choice.<}96{>The applicant submits a request for the subsystem verification to the conformity assessment body of his choice.

The request includes:

- the name and address of the applicant, and if the request was submitted by an authorized representative, his name and address and

- technical file.

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3. Technical file{0>Technical documentation<}96{><0}

{0>The applicant shall establish the technical documentation and make it available to the notified body referred to in point 5.<}0{>The Applicant prepares technical file and makes it available to the conformity assessment body referred to in point 5. The documentation enables the conformity assessment of the subsystem with the relevant TSI requirements / national railway technical rules. Technical file defines the requirements and, to the extent necessary for evaluation, includes the design, manufacture, installation / construction and operation of the subsystem. <0}

{0>The technical documentation shall, wherever applicable, contain the following elements:<}80{>The technical file shall include, where possible, the following elements:

- general description of the subsystem, its overall design and structure;

- necessary documentation for the establishment of the technical file prescribed in Article 17 of this Rulebook;

- a separate set of data required by the relevant TSI / national railway technical rule for each appropriate register provided for by the law governing the safety and interoperability of the railway;

- a list of national railway technical rules applied;

- a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements / national railway technical rules, in case that recognized standards are not applied. In case of partially applied recognized standards, technical file contains information ons the parts applied; {0>In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,<}96{>

{0>,- conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.),<}95{>- conditions for the subsystem usage (limit values for operating time or the distance traveled, the wear limit value, etc.);

- descriptions and explanations necessary for understanding the operation and maintenance of the subsystem;

- maintenance conditions and technical file related to maintenance of the subsystem;

- all technical requirements defined by the relevant TSI / national railway technical rules which need to be taken into account during the production, maintenance or subsystem operation;

- other relevant technical evidence indicating that previous checks or tests have been successfully carried out by the competent authorities under similar conditions;

<0}{0>- conditions of integration of the subsystem in its system environment and the necessary interface conditions with other subsystems,<}96{>- conditions for the integration of the subsystem into its system environment and necessary interface conditions with other subsystems;

 - evidence of compliance with other rules (including certificates, if applicable);

 - conceptual design and production plans, structural drawings and schemes of components, sub-assemblies, circuits, etc.;

 - descriptions and explanations necessary for understanding the drawings;

 - results of implemented project calculations, executed tests, etc.;

 - test reports;

 - documentation on the production and assembly of the subsystem;

 - list of manufacturers participating in the design, manufacture, assembly and installation of the subsystem and

 - any additional information, if provided for in the relevant TSI / national railway technical rules.

 Applicant shall keep the technical file available to the competent national authorities during the operational life of the subsystem.

4. {0>Manufacturing<}96{>Production

<0}{0>The applicant shall take all measures necessary so that the manufacturing and/or installation/construction process and its monitoring ensure conformity of the subsystem with the requirements of the relevant TSI(s).<}0{>Applicant shall take all necessary measures to ensure that the manufacturing and / or installation / construction process and its supervision ensure the conformity of the subsystem with the relevant TSI requirements / national railway technical rules.<0}

5. Subsystem verification{0>EC verification<}96{>ВВ<0}

5.1. The conformity assessment body selected by the applicant shall carry out or impose appropriate checks and tests as specified in the relevant TSI / national railway technical rules, recognized standards and / or technical specifications, or equivalent tests, to verify compliance of the subsystem with the relevant TSI requirements / national railway technical rules. If such standards and / or technical specifications do not exist, the applicant and the conformity assessment body shall decide on the appropriate tests to be carried out.

Checks, examinations and tests shall be carried out in phases prescribed in Article 11 of this Rulebook.

The conformity assessment body may take into consideration checks, examinations or tests that have been successfully carried out under other conditions by other conformity assessment bodies or by the applicant (or made in its name), as defined by the relevant TSI / national railway technical rules. The conformity assessment body then decides whether to use the results of those checks or tests.

Evidence gathered by the conformity assessment body is appropriate and sufficient to demonstrate conformity with the relevant TSI requirements / national railway technical rules and to demonstrate that all necessary and appropriate checks and tests have been carried out.

The extent to which the conformity assessment body takes into account evidence obtained from other parties is explained by a documented analysis of the factors referred to in point 5.2.

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5.2. The conformity assessment body examines:

- use of existing equipment and systems:

• used in the same way as before,

• used earlier, but adapted to new use;

- use of existing projects, technologies, materials and production techniques;

- design solutions, production, testing and commissioning;

- previous approval issued by other competent bodies and

- accreditation of other participating bodies:<0}

* + - {0>- it is permissible for the notified body to take account of valid accreditation to relevant European standards, provided that no conflict of interest exists, that accreditation covers the testing being performed and that accreditation is current,<}0{>conformity assessment body may take into account valid accreditation according to the relevant standards, provided that there is no conflict of interest, that the accreditation is both valid and that includes the tests executed,
    - when the formal accreditation is missing, the conformity assessment body confirms that the systems for process of expertise control, independence, testing and handling of materials, facilities and equipment and other processes important for contributing to the subsystem, are subject to supervision and
    - in all cases, the conformity assessment body considers the adequacy of the decision and decides to what extent its presence is necessary.<0}

{0>In all cases, the notified body keeps the responsibility of final results of the examinations, tests and checks.<}0{> In all cases, the conformity assessment body is responsible for the final results of the examinations, checks and tests. <0}

5.3. {0>The notified body shall agree with the applicant the locations where the tests will be carried out and shall agree that final subsystem tests and, whenever required in the TSI, tests under full operating conditions, are carried out by the applicant under direct supervision and attendance of the notified body.<}79{>The conformity assessment body shall agree with the applicant the location for the examinations and the final subsystem testing, and if required by the relevant TSI / national railway technical rule, the applicant shall, under the direct supervision and in the presence of the conformity assessment body, perform tests under full operating conditions.

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5.4 . {0>When the subsystem referred to in point 2 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.<}96{> When the subsystem referred to in item 2 is subject to deviation from the TSI, the applicant shall notify the conformity assessment body thereof.

Applicant also submits a precise reference to the conformity assessment body about the TSIs (or parts thereof) for which the deviation is requested.

Applicant shall notify the compliance body on the outcome of the proceedings regarding the deviation.

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6. Declaration of verification{0>EC declaration of verification<}96{>ДД<0}

6.1. {0>Where the subsystem meets the requirements of the relevant TSI(s), the notified body shall issue an EC certificate of verification in compliance with point 3 of Annex VI to Directive 2008/57/EC.<}96{>When the subsystem meets the requirements of the relevant TSI / national railway technical rule, the conformity assessment body issues a certificate of verification.

When the subsystem referred to in point 2 is subject to deviation from the application of TSIs, upgrades, updates, or is a specific case, the certificate also contains precise references to the TSI or parts thereof with which the conformity has not been examined during the verification process.

If only certain parts or individual stages of the subsystem are covered and they meet the relevant TSI requirements / national railway technical rules, the conformity assessment body issues the PIV certificate. <0}

6.2. {0>The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem.<}96{>Applicant shall draw up a written declaration of subsystem verification and shall keep it at the disposal for the national authorities throughout the subsystem lifecycle. Declaration of verification identifies the subsystem for which it was compiled.

When the subsystem referred to in point 2 is subject to deviation from the application of the TSI, upgrade, renewal or is a specific case, the declaration for the subsystem also contains a reference to the TSI or parts thereof with which the conformity has not been examined in the verification process.

In case of PIV procedure, applicant shall draw up a written PIV declaration.

Declaration of verification and accompanying documents shall be drawn up in the manner prescribed in Articles 14 and 17 of this Rulebook.

Examples of the declaration of verification and the PIV declaration, if applicable, shall be provided upon the request of competent authorities.

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6.3. {0>The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification and the EC ISV declaration.<}96{>The conformity assessment body is responsible for drawing up the technical file that is attached to the declaration of verification and the PIV declaration. Technical file shall be drawn up in accordance with Article 17 of this Rulebook.

6.4. {0>The technical file accompanying the EC certificate of verification shall be lodged with the applicant.<}0{>The technical file enclosed with the verification certificate is kept by the applicant. Examples of certificates of verification and technical dossier shall be provided upon the request made by OTIF, OTIF contracting party and competent authorities.

Applicant keeps a copy of the technical file throughout the lifecycle of the subsystem; it shall be available upon the request made by any other OTIF member.

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7. {0>Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.<}96{>Each notified body shall inform its reporting authorities about the issued or withdrawn verification certificates, and periodically or upon request, make available to its registry authorities a list of refused, suspended or otherwise restricted verification certificates. Each notified body shall inform other notified bodies about all certificates of verification which have been refused, suspended, withdrawn or otherwise restricted, and, upon request, about the certificates of verification that have been issued. <0}

8. {0>Authorised representative<}96{>Authorized representative <0}

Applicant’s {0>The applicant’s obligations set out in points 2, 3, 5.3, 5.4, 6.2 and 6.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.<}90{>obligations referred to in points 2, 3, 5.3, 5.4, 6.2. and 6.4. may be fulfilled by the authorized representative on his behalf and under his responsibility, provided that they are listed in the authorization.

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**{0>Module SH1.<}96{>Module SH1.<0} Verification based on a complete quality management system and project testing**

**<0}**

1. Verification process based on a complete quality management system and project verification represents a process where the applicant fulfills the obligations stipulated in items 2 and 6 confirming and declaring under full responsibility that the subsystem complies with the relevant TSI requirements / national railway technical rules and all other applicable rules. <0}

2. {0>Manufacturing<}96{>Production<0}

{0>The design, manufacture and final subsystem inspection and testing of the subsystem concerned shall be covered by approved quality management system(s) as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the subsystem shall have been examined in accordance with point 4.<}71{> Design, production, final control and testing of the subsystem are covered by an approved quality management system as defined in item 3 and subject to the control referred to in item 5. The adequacy of the technical project of the subsystem shall be examined in accordance with item 4.

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3. {0>Quality management system<}96{>Quality management system<0}

3.1. {0>The applicant shall lodge an application for assessment of the quality management system with the notified body of his choice, for the subsystem concerned.<}96{>Applicant submits the request for assessment of the quality management system for the subsystem in question to the body for compliance assessment.

Request includes:

- the name and address of the applicant, and if the request was submitted by an authorized representative, his name and address;

- a detailed project management structure and the name and address of all participants in the project;

- all relevant information for the subsystem envisaged;

- documentation on the quality management system;

- a copy of the PIV declaration for the subsystem, if applicable

- written statement that the same request has not been submitted to the other body for conformity assessment.

<0}

3.2. {0>The quality management system shall ensure compliance of the subsystem with the requirements of the relevant TSI(s) that apply to it.<}72{> The quality management system ensures compliance of the subsystem with the TSI requirements / applicable national railway technical rules.<0}

{0>All the elements, requirements and provisions adopted by the applicant shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.<}96{>All elements, requirements and provisions adopted by the applicant are documented systematically and organized in the form of written policies, procedures and instructions. The documentation for the quality management system enables a consistent interpretation of programs, plans, manuals and quality records.<0}

{0>It shall, in particular, contain an adequate description of:<}96{>In particular, it contains matching descriptions on:

- the quality goals and organizational structure, responsibilities and authorizations of the management regarding the project and the subsystem quality;

- the project technical specification, including the standards to be applied and, where the standards and / or technical specifications are recognized, are not applied in full, the means to be used to meet the TSI requirements / applicable national railway technical rules;

- techniques, procedures and systematic actions to be used for the control and verification of the project during subsystems designing that belong to the covered product category;

- appropriate techniques, processes and systematic actions that will be used in production, quality control and quality management;

- inspections and tests carried out before, during and after manufacture, and their frequency;

- quality records, such as inspection reports and test data, calibration data, reports on professional staff training, etc. and

- the way of monitoring the achieving the desired project and subsystem quality and the quality management system effectiveness.

3.3. {0>The notified body shall assess the quality management system to determine whether it satisfies the requirements referred to in point 3.2.<}96{>The conformity assessment body assesses the quality management system to determine whether it meets the requirements from item 3.2.

It assumes compliance with the requirements for all components of the quality management system that meet the relevant specifications of national standards implementing the applicable quality management standards, recognized standards and / or technical specifications.

If the conformity of the subsystem with the relevant TSI requirements / national railway technical rules is based on more than one quality management system, the conformity assessment body shall in particular examine:<0}

{0>- whether the relations and interfaces between the quality management systems are clearly documented, and<}96{>- if the relations and interfaces between the quality management system are clearly documented and

- if the overall responsibility and authorizations of the management for compliance of the whole subsystem are clearly assigned and accepted by all participants in the project. <0}

{0>The audit shall be specific for the subsystem concerned, taking into consideration the specific contribution of the applicant to the subsystem.<}0{>КонтролаКПровера Провера се прилагођава предметном subsystemу и узима се у обзир посебан допринос подносиоца захтева subsystemу.<0}

{0>When the applicant operates a certified quality management system certified by an accredited certification body for the design, manufacturing and final testing of the relevant subsystem, the notified body shall take this into account in the assessment.<}92{>When the applicant during the design, manufacture and final testing of the respective subsystem implements the quality management system certified by the accredited body, the conformity assessment body shall take this into account. In this case, the conformity assessment body carries out a detailed assessment of specific documentation and records of the quality management system related to the subsystem. The conformity assessment body does not re-evaluate the entire quality manual and all procedures already assessed by the certification body for the quality management system in question.<0}

{0>In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant subsystem field and product technology concerned, and knowledge of the requirements of the relevant TSI(s).<}89{>In addition to experience in the quality management system, the evaluation team has at least one member with relevant experience in the area of ​​the respective subsystem and a particular product technology, as well as knowledge in relevant TSI requirements / national railway technical rules. Evaluation process includes a visit to the business premises for evaluation.

Applicant or his authorized representative shall be informed about the decision.

The notice contains the verification findings and a substantiated assessment decision. If the assessment of the quality management system provides satisfactory evidence that the requirements of point 3.2 are met, the conformity assessment body issues the approval for the quality management system to the applicant.

<0}

3.4. {0>The applicant shall undertake to fulfil the obligations arising out of the quality management system as approved and to maintain it so that it remains adequate and efficient.<}95{> Applicant undertakes to fulfill the obligations arising from the approved quality management system, and maintain the system adequate and efficient.

<0}

3.5. {0>The applicant shall keep the notified body that has approved the quality management system informed of any intended change to the quality management system having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any changes of quality management system certificate.<}96{>Applicant shall notify the conformity assessment body approved by the quality management system on all planned changes in the quality management system that have an impact on the design, production and final inspection, testing and operation of the subsystem, as well as any changes to the quality management system certificate.

The conformity assessment body assesses the proposed changes and decides whether the changed quality management system still meets the requirements from section 3.2. or re-evaluation is needed.

Applicant shall be informed about the decision. The notice contains the conclusions of the review and a substantiated assessment decision.

<0}

3.6. {0>Each notified body shall inform its notifying authorities of quality management system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality management system approvals refused, suspended or otherwise restricted.<}96{>Each notified body shall inform its reporting authorities about the quality management system approvals issued or withdrawn, and periodically or upon request, shall make available to its filing authorities a list of rejected, suspended or otherwise limited quality management systems.

Each notified body shall inform other notified bodies about the quality management system approvals which were refused, suspended or withdrawn, and, upon request, about the approvals of the quality management system that were issued. <0}

4. {0>EC verification<}96{>Verification of the subsystem

4.1 <0}4.1. {0>The applicant shall lodge an application for EC verification of the subsystem (through full quality management system plus examination of the design) with the notified body referred to in point 3.1.<}0{>Applicant submits a request for verification of the subsystem (through a full quality management system and examination of the project) to the conformity assessment body referred to in item 3.1.

4.2. The request should allow for understanding of the design, production, maintenance and operation of the subsystem and the assessment of compliance with the TSI requirements / applicable national railway technical rules.<0}

{0>It shall include:<}96{>ЗахтевRequest includes:

- name and address of the applicant;

- a written statement that the same request was not submitted to another body for the assessment of conformity;

- technical file. The documentation enables assessment of the conformity of the subsystem with the relevant TSI requirements / national railway technical rules. The technical file shall specify the relevant TSI requirements / national railway technical rules and, to the extent relevant to the assessment, include the design and operation of the subsystem. <0}{0>The technical documentation shall, wherever applicable, contain at least the following elements:<}96{>Technical file shall contain, where possible, at least the following elements:

• a general description of the subsystem, its overall design and structure,

• the documentation necessary for the establishment of the technical file prescribed in Article 17 of this Rulebook;

• a separate file with a set of data required by the relevant TSI / national railway technical rules for each appropriate register provided for by the law governing the safety and railway interoperability;

• descriptions and explanations necessary for understanding the operation and maintenance of the subsystem,

• the conditions for integrating the subsystem into its system environment and the required interface conditions;

• a list of national railway technical rules applied;

• a list of recognized standards and other relevant technical specifications, which are applied in full or in part, as well as descriptions of the solutions adopted to meet the TSI requirements / national railway technical rules, if the recognized standards are not applied. In the case of partially applied recognized standards, the technical file lists the parts that were applied; {0>In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,<}96{>

* + - {0>- results of design calculations made, examinations carried out, etc.,<}96{>results of implemented project calculations, examinations carried out, etc.;
    - testing program and test reports;
    - evidence of compliance with other rules (including certificates, if any);
    - documentation on the production and subsystem assembly;
    - a list of manufacturers that took part in subsystem design, manufacture, assembly and installation;
    - conditions for subsystems use (limit values ​​for operating time or distance traveled, wear limit values, etc.);
    - maintenance conditions and technical file for maintenance of the subsystem;
    - all technical requirements defined by the relevant TSI / national railway technical rules that need to be considered during the production, maintenance or operation of the subsystem;
    - any other appropriate technical evidence showing that previous checks or tests have been successfully carried out by the competent authorities under similar conditions and
    - any additional information, if provided for in the relevant TSI / national railway technical rules;

- supporting evidence for the adequacy of the technical project. Within the supporting evidence, all the documentation used is indicated, especially when the relevant rules and standards are applied in full. The supporting evidence shall include, where appropriate, test results (including those in operating conditions) carried out by the appropriate body for testing the applicant or other testing body on his behalf and under his responsibility.

<0}

4.3. {0>When the subsystem referred to in point 4.1 is subject to derogation(s) procedure according to Article 9 of Directive 2008/57/EC, the applicant shall inform the notified body thereof.<}96{>Once the subsystem referred to in point 4.1 is subject to deviation from the TSI application, the applicant shall inform the notified body thereof.

Applicant also submits a precise referral to the TSI (or parts thereof) for the deviation requested to the notified body.

Applicant shall inform the notified body about the outcome of the deviation proceedings.

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4.4. The conformity assessment body reviews the requirements and if the project meets the TSI requirements / national railway technical rules applicable, issues a certificate of project examination to the applicant. This certificate shall contain the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and data necessary for the identification of the approved project. The certificate may have one or more annexes.<0}

{0>The certificate and its annexes shall contain all relevant information to allow the conformity of the subsystem with the examined design to be evaluated.<}87{>The certificate and its annexes contain all relevant information for assessing the conformity of the subsystem with the project tested.

Once the subsystem referred to in point 4.1 is subject to deviation from the TSI application, renewal, improvement or is a specific case, the project test certificate shall also contain precise references to the TSI or parts thereof according to which the conformity has not been tested in the verification process.

If only certain parts or sub-stages of the subsystem are covered and they meet the relevant TSI requirements / national railway technical rules, the conformity assessment body issues a PIV certificate.

If the project does not meet the relevant TSI requirements / national railway technical rules, the conformity assessment body shall not issue a project test certificate and shall inform the applicant thereof with a detailed explanation for the refusal.

Applicant shall draw up the PIV Declaration.

<0}

4.5. {0>The applicant shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the relevant TSI(s) or the conditions for validity of the certificate until the expiry of the validity of the certificate.<}90{>Prior to the certificate expiration date, the applicant shall notify the conformity assessment body issued by the project examination certificate of all changes to the approved project that may affect the compliance with the TSI requirements / national railway technical rules or the conditions of certificate’s validity. Such changes require additional approval, from the conformity assessment body that had issued the project review certificate, in the form of an appendix to the original project examination certificate. Only examinations and tests that are relevant and necessary for the performed changes are performed. <0}

4.6. {0>Each notified body shall inform its notifying authorities of the EC design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.<}96{> Each notified body shall inform its registration authorities about the project review certificates and / or their addenda issued or withdrawn, and periodically or upon request, make available a list of certificates and / or their additions rejected, suspended or otherwise limited to their registration authorities.

Each notified body shall inform other notified bodies about the project review certificates and / or any additions that have been refused, withdrawn, suspended or otherwise restricted and, upon request, about certificates and / or their addenda.

<0}{0>The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC design examination certificates and/or additions thereto.<}96{>ОТИФОО OTIF, OTIF member states and other notified bodies may, upon request, obtain a copy of the project examination certificate and / or its supplements. OTIF and OTIF member states may, upon request, obtain a copy of the technical file and the results of the examination carried out by the notified body.

The conformity assessment body shall keep a copy of the project examination certificate, its annexes and appendices, as well as the technical file, including documentation submitted by the applicant, until the certificate’s expiry date.

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4.7. {0>The applicant shall keep a copy of the EC design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities throughout the service life of the subsystem.<}93{>Applicant shall keep a copy of the project review verification, its annexes and addenda together with the technical file, available to the national authorities throughout the subsystem’s lifetime.

5. Supervision of the conformity assessment body

5.1. The purpose of the supervision is to confirm that the applicant duly fulfills the obligations arising from the approved quality management system.<0}

5.2. {0>The applicant shall, for periodic audits purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:<}94{>For the purpose of periodic checks, the applicant enables the access to the conformity asseement body to production, inspection, testing and storage sites and provides all necessary information, in particular:

- documentation for the quality management system;

- the quality records provided for in the part of the quality management system related to design, such as results of analysis, calculations, tests, etc. and

- the quality records provided for in the part of the quality management system related to production, such as inspection reports and test data, calibration data, reports on the professional training of personnel, etc.

<0}

5.3. The conformity assessment body performs periodic checks to confirm that the applicant maintains and applies the quality management system providing the applicant with a verification report.

Periodic checks shall be carried out at least once in two years, with at least one check during the period of performing certain activities (design, manufacture, assembly and installation) for the subsystem subject to the project review referred to in point 4.4.

If a manufacturer applies a certified quality management system, the conformity assessment body, during the periodic verification takes this into account.

<0}

5.4. {0>In addition, the notified body may pay unexpected visits to the applicant.<}96{>In addition, the Compliance Assessment Body may pay an unscheduled visit to the applicant. During such visits, the conformity assessment body may, if necessary, carry out subsystem testing or upload the performance to verify the proper functioning of the quality management system. The compliance assessment body shall submit a visit report to the applicant and, in case of tests have been carried out, a test report.

<0}

5.5. If the body responsible for the subsystem verification does not control all the quality management systems referred to in point 3, shall coordinate the supervisory activities of the other body for assessing the compliance of the person responsible for the task, in order to:

- ensure proper interface management between different quality management systems related to subsystem integration and

- together with the applicant, collect the necessary elements for the assessment in order to ensure consistency and overall control for the different quality management systems.

This coordination includes the right of the conformity assessment body to:

- obtain all documentation (approval and supervision), issued by another body for the assessment of conformity;

- attend the supervisory checks referred to in item 5.2

- start additional checks from point 5.3. under full responsibility and together with another body for the assessment of conformity.

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6. Certificate of verification and declaration of verification

6.1. When the subsystem meets the relevant TSI requirements / national railway technical rules, the conformity assessment body issues a certificate of verification.

Once the subsystem referred to in point 4.1. is subject to deviation from TSI implementation, upgrade, renewal or is a specific case, the certificate also contains precise references to the TSI or parts thereof with which the conformity has not been tested in the verification process.

If only certain parts or phases of the subsystem are tested and they meet the requirements of the relevant TSI / national railway technical rules, the conformity assessment body issues the PIV certificate.

<0}

6.2. {0>The applicant shall draw up a written EC declaration of verification for the subsystem and keep it at the disposal of the national authorities throughout the service life of the subsystem.<}96{> Applicant shall draw up a written declaration of verification for the subsystem and shall keep it at the disposal to the national bodies throughout the subsystem’s lifetime.

The verification declaration identifies the subsystem for which it was compiled and the number of the project examination certificates is indicated.

Once the subsystem referred to in point 4.1. is the subject of deviation, improvement, renewal or is a specific case, the declaration of verification for the subsystem shall contain reference to the TSIs or parts thereof with which the conformity has not been tested in the verification process.

In case of the PIV procedure, the applicant shall draw up a written PIV declaration.

The declaration and the supporting documents shall be drawn up in the manner prescribed by Articles 17 and 24 of this Rulebook.

Certificates to which the declaration refers are:

- approval of the quality management system referred to in point 3.3. and examination reports from point 5.3, if applicable

- project review certificate referred to in item 4.4. and its addenda.

A copy of the verification declaration and the PIV declaration, if applicable, shall be provided upon the request of the competent authority. <0}

6.3. The conformity assessment body is responsible for drawing up the technical file attached to the verification declaration and the PIV declaration. Technical file shall be drawn up in accordance with Article 17 of this Rulebook.

7. {0>The applicant shall, throughout the service life of the subsystem, keep at the disposal of the national authorities:<}96{> During the subsystem’s lifetime, the applicant keeps the following documentation at the disposal of the national authorities:

- documentation related to the quality management system referred to in point 3.1;

- the change from point 3.5 as approved;

- the decisions and reports of the conformity assessment body referred to in points 3.5, 5.3. and 5.4. and

- technical file referred to in point 6.3.

<0}

8. {0>Each notified body shall inform its notifying authorities of EC certificates of verification issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of EC certificates of verification refused, suspended or otherwise restricted.<}96{>Each notified body shall inform its reporting authorities about the issued or withdrawn verification certificates, and periodically or upon request, make available a list of refused, suspended or otherwise restricted verification certificates to the registry authorities.

Each notified body shall inform other notified bodies about certificates of verification which have been refused, suspended, withdrawn or otherwise restricted to and upon request, and certificates of verification issued.

<0}

9. {0>Authorised representative<}96{>Authorized representative<0}

{0>The applicant’s authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.3, 4.5, 4.7, 6.2 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.<}91{>Applicant's authorized representative may file a request from item 4.1. and 4.2. and fulfill the obligations from points 3.1, 3.5, 4.3, 4.5, 4.7, 6.2. and 7. on his behalf and under his full responsibility, provided that they are listed in the authorization.

**Annex 6**

**DECLARATION ON SUBSYSTEM VERIFICATION**

CC/RRRRRRRRRRRRRR/YYYY/NNNNNN – *Declaration number*\*

**Applicant:** **Authorized representative:**

*Business name Business name*

*Full address Full address*

**Applicant:**

*Business name*

*Full address*

**We declare under full responsibility that a subsystem**:

*Title /short description of the subsystem*

**To which this declaration applies is in conformity with the following laws and technical rules:**

*Name(s)of the law and technical rules*

**Assessed by body for conformity assesment:**

*Business name*

*Full address*

**By following approval(s) and /of certificate(s):**

*Number(s) of certificates, date of issue*

**Under following restritions and conditions for use:**

*List of restrictions and conditions, in case of deviation from TSI list the parts of TSI that are not included*

**The following steps have been applied in order to issue the declaration:**

*Modules chosen by the applicant for the subsystem verification*

**List of annexes:**

*Title of annexes (technical file)*

**Valid until:** date *DD/ММ/YYYY* (in case of temporary declaration)

In: *Location*

**Dated:** date *DD/ММ/YYYY*

**Applicant:****Authorized representative:**

**Full name** *Signature* **Full name** *Signature*

*Stamp Stamp*

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\*) CC – state code (two letters) according to ISO 3166; for Republic of Serbia - RS;

RRRRRRRRRRRRRR – company registration number (14-digit number); if the CR number is shorter, first digits are 0;

YYYY – year of issue (four digits) and

NNNNNN – counter (six digits) increases by one digit with each issued declaration and refers to the person who issued the declaration; every year the counter starts again from zero.

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**TEMPORARY DECLARATION ON SUBSYSTEM VERIFICATION**

CC/RRRRRRRRRRRRRR/YYYY/NNNNNN – *Declaration number*\*

**Applicant:** **Authorized representative:**

*Business name Business name*

*Full address Full address*

**Applicant:**

*Business name*

*Full address*

**We declare under full responsibility that a subsystem**:

*Title /short description of the subsystem*

**To which this declaration applies is in conformity with the following laws and technical rules:**

*Name(s)of the law and technical rules*

**Assessed by body for conformity assesment:**

*Business name*

*Full address*

**By following approval(s) and /of certificate(s):**

*Number(s) of certificates, date of issue*

**Under following restritions and conditions for use:**

*List of restrictions and conditions, in case of deviation from TSI list the parts of TSI that are not included*

**The following steps have been applied in order to issue the declaration:**

*Modules chosen by the applicant for the subsystem verification and particular steps*

**List of annexes:**

*Title of annexes (technical file)*

**Valid until:** date *DD/ММ/YYYY* (in case of temporary declaration)

In: *Location*

**Dated:** date *DD/ММ/YYYY*

**Applicant:****Authorized representative:**

**Full name** *Signature* **Full name** *Signature*

*Stamp Stamp*

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\*) CC – state code (two letters) according to ISO 3166; for Republic of Serbia - RS;

RRRRRRRRRRRRRR – company registration number (14-digit number); if the CR number is shorter, first digits are 0;

YYYY – year of issue (four digits) and

NNNNNN – counter (six digits) increases by one digit with each issued declaration and refers to the person who issued the declaration; every year the counter starts again from zero.

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**DECLARATION OF CONFORMITY WITH APPROVED VEHICLE TYPE**

Applicant (1): Authorized representative:

*Business name Business name*

*Full address Full address*

Applicant:

*Business name*

*Full address*

*]*

*We declare with full responsibility that the vehicle [Vehicle Identification Number] (2) to which this declaration applies*

*- corresponds to vehicle type [vehicle type identification] approved in:*

*[Country name 1] license number [European Vehicle Identification Number (EIN) Vehicle Type License]*

*[name of country 2] license number [European Vehicle Identification Number (EIN) Vehicle Type License],*

*... (indicate all countries where the type of vehicle is approved)*

*- meets the legal requirements, the TSI requirements and the applicable national railway technical rules, listed in the annex to this declaration,*

*- passed all verification procedures necessary for the submission of this declaration*

List of annexes: (3)

*[Annexes title]*

On behalf *[applicants name]*

In *[place], [ date DD/MM/YYYY ]*

*[full name,position] [signature] [stamp]*

(field reserved for issuing authority)

Unique vehicle number allocated*: [12-digit number]*



(1) Applicant may be a contracting authority or a manufacturer or their authorized representative in the Republic of Serbia

(2) If at the time of issuing this declaration the vehicle has not yet been assigned a unique number, the vehicle will be identified in a manner agreed between the applicant and the safety authority (Railway Directorate). In such case, once a unique number is assigned to the vehicle, it will be entered into the box reserved for that purpose

(3) Enclosures contain copies of all documents proving that all the erification procedures have been applied in accordance with the applicable rules (TSIs and national declaration of verification)

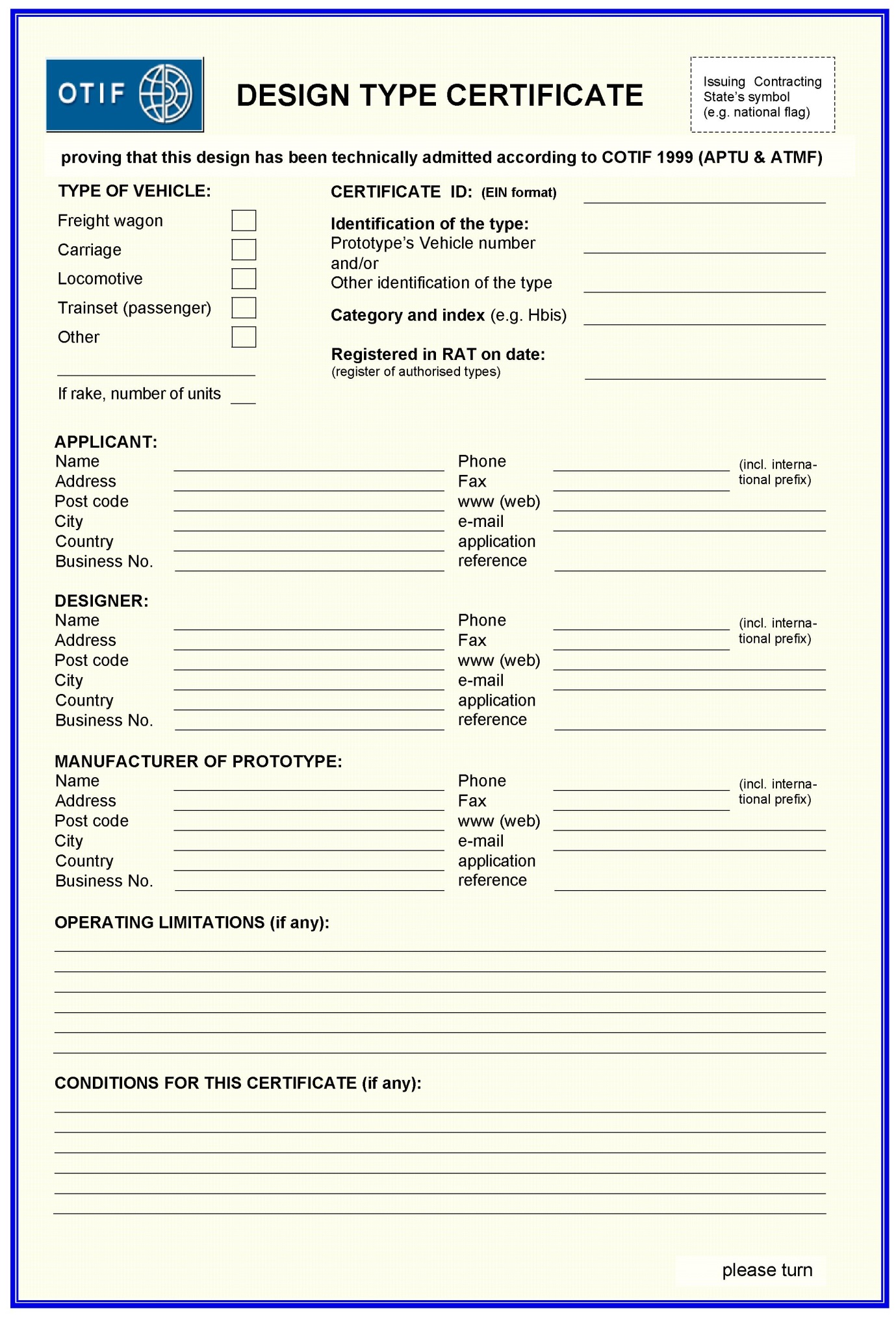
**Annex 7**

**LICENSE FOR THE SUBSYSTEM USE**

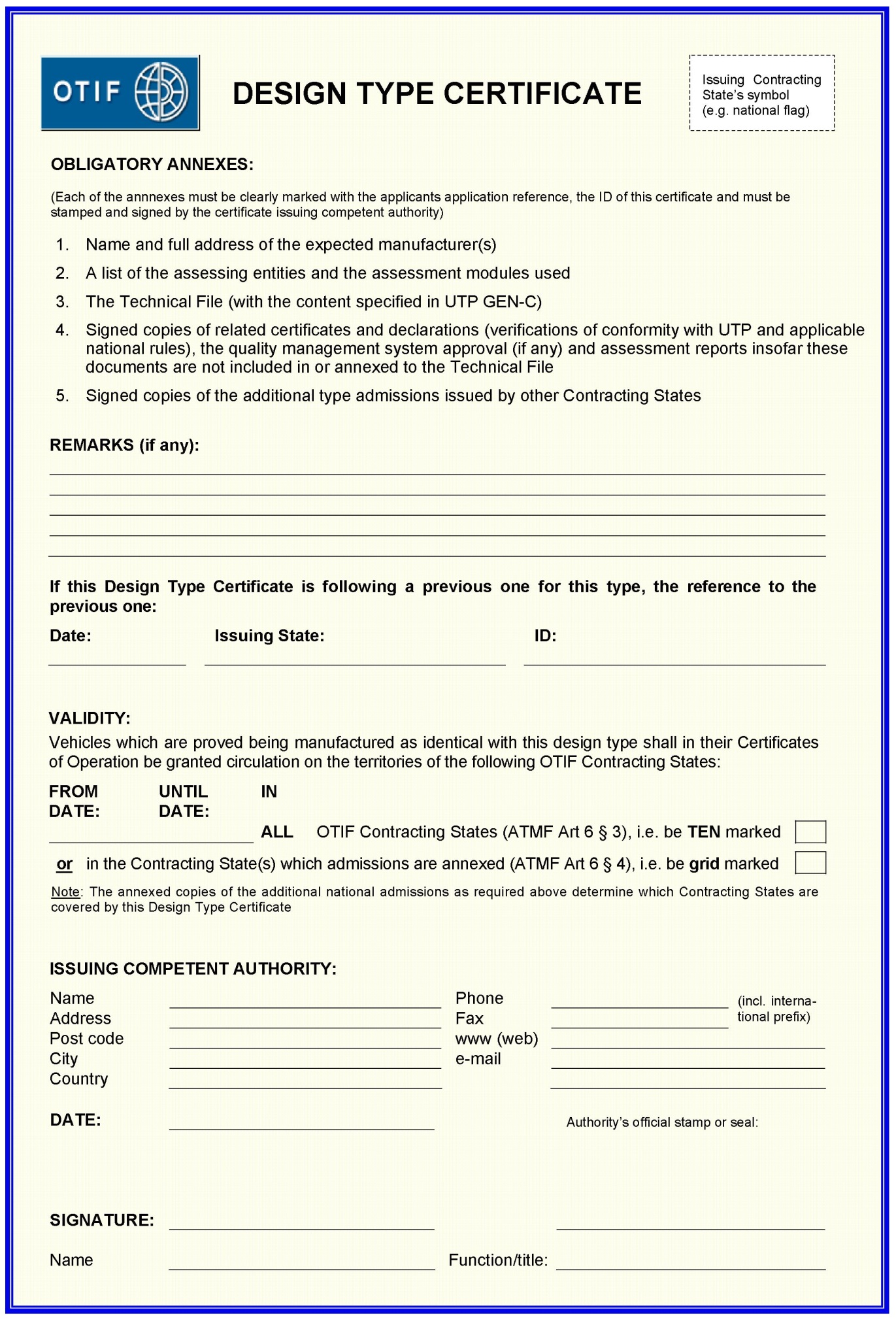
|  |
| --- |
| **Grb-Srbija_2004**  **REPUBLIC OF SERBIA**  **DIRECTORATE FOR RAILWAYS**    **LICENSE FOR SUBSYSTEM USE**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  *(name f the subsystem, type, designation, location and etc.)*  License number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(EIN)*  Date of issue: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Valid until: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(if of limited validity)*  Issued to the Applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Business name, аdress and ID number)*  Refferal to the declaration(s) оf verification: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *( declaration (s) number(s))*  Terms and conditions of use: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  List of documents in technical file: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Director**  *(Full name, signature)*  *(stamp)* |

**License for type of vehicle intended for international traffic**

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| OTIF_logo **LICENSE FOR VEHICLE TYPE**  suing Contracting State’s symbol  (e.g. national flag)     |  |  | | --- | --- | | **TYPE OF VEHICLE:** |  | | Freight wagon |  | |  |  | | Carriage |  | |  |  | | Locomotive |  | |  |  | | Trainset |  | |  |  | | Other |  | |  |  | |  |  | | If rake number of units |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **APPLICANT:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  |  | | --- | --- | | **CERTIFICATE ID: (EIN формат)** |  | |  |  | | Idenfication of the type**:** | | | Prototype’s vehicle number |  | | and/or  other idenfication of the type |  | |  |  | | **Category and index**(i.e. Hbis) |  | |  |  | | **Registered in RAT on date:** |  | |  |   **proving that this design has been technically addmited according to COTIF 1999 (APTU & ATMF)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **DESIGNER:** |  |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **PROTOTYPE MANUFACTURER:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  | | --- | | **RESTRICTIONS FOR USE(if any):** | |  | |  | |  | |  | |  |  |  | | --- | | **CERTIFICATE CONDITIONS (if any):** | |  | |  | |  | |  |   Turn page |
| OTIF_logo**LICENSE FOR VEHICLE TYPE**  suing Contracting State’s symbol  (e.g. national flag)    **MANDATORY APPENDICES:** (integral part of the certificate)  (Each annex must be: clearly marked with a link with the applicant's request, the number of this license, certified and signed by the authority issuing the license)  1. Name and address of expected manufacturer(s)  2. A list of the assessed conformity assessment bodies and applied conformity assessment modules  3. Technical file  4. Certified copy of the Certificate and Declaration of Conformity (with TSI and national rules), quality management system approvals (if any) and evaluation reports, if these documents are not attached to the technical file  5. Certified copies of additional License for vehicle type issued in other contracting states   |  | | --- | | **NOTE (if any):** | |  | |  | |  | |  | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **If this license is issued after the previous one for the vehicle in question, the link to the previous license:** | | | | | | | **Date:** |  | | **Country of issue:** | | **Number:** | |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **VALIDITY:** | | | | | | | | | | Vehicles manufactured in accordance with this approved type for which a license has been issued may be moved to the territories of the following OTIF contracting states: | | | | | | | | | | **From**  **Date:** | **To**  **Date:** | **In** |  |  |  |  | | | |  |  | **All** contracting states (ATMF art. 6§3), e.g.. **TEN** | | | | | |  | |  | | | | | | |  |  | | **or** in contracting states with licenses submitted (ATMF Art 6 § 4), e.g. **растер** | | | | | | | |  | | Explanation: The attached copies of the additional national licenses, as specified above, determine in which country the contracting states are subject to this License for vehicle type | | | | | | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | |  |  |  | | **ISSUING COMPETENT AUTHORITY:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  |  |  | |  |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | **DATE:** |  |  | Stamp: | |  |  |  | |  |  |  | |  |  | |  |  | | **SIGNATURE:** |  | | Full name |  | Position: |  | |

**License for vehicle type нaмењеног међународном саобраћају**

 **(на енглеском језику)**

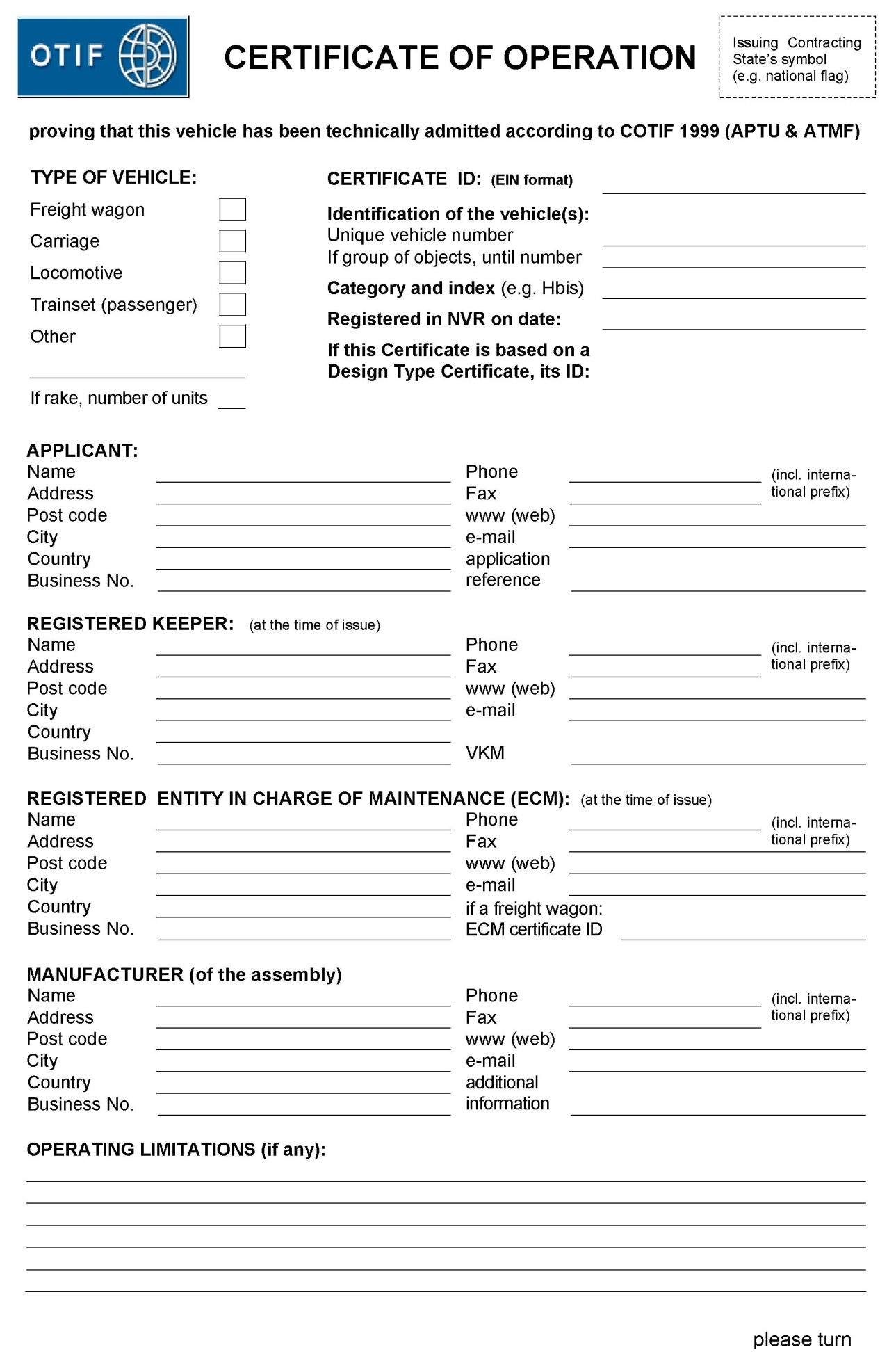


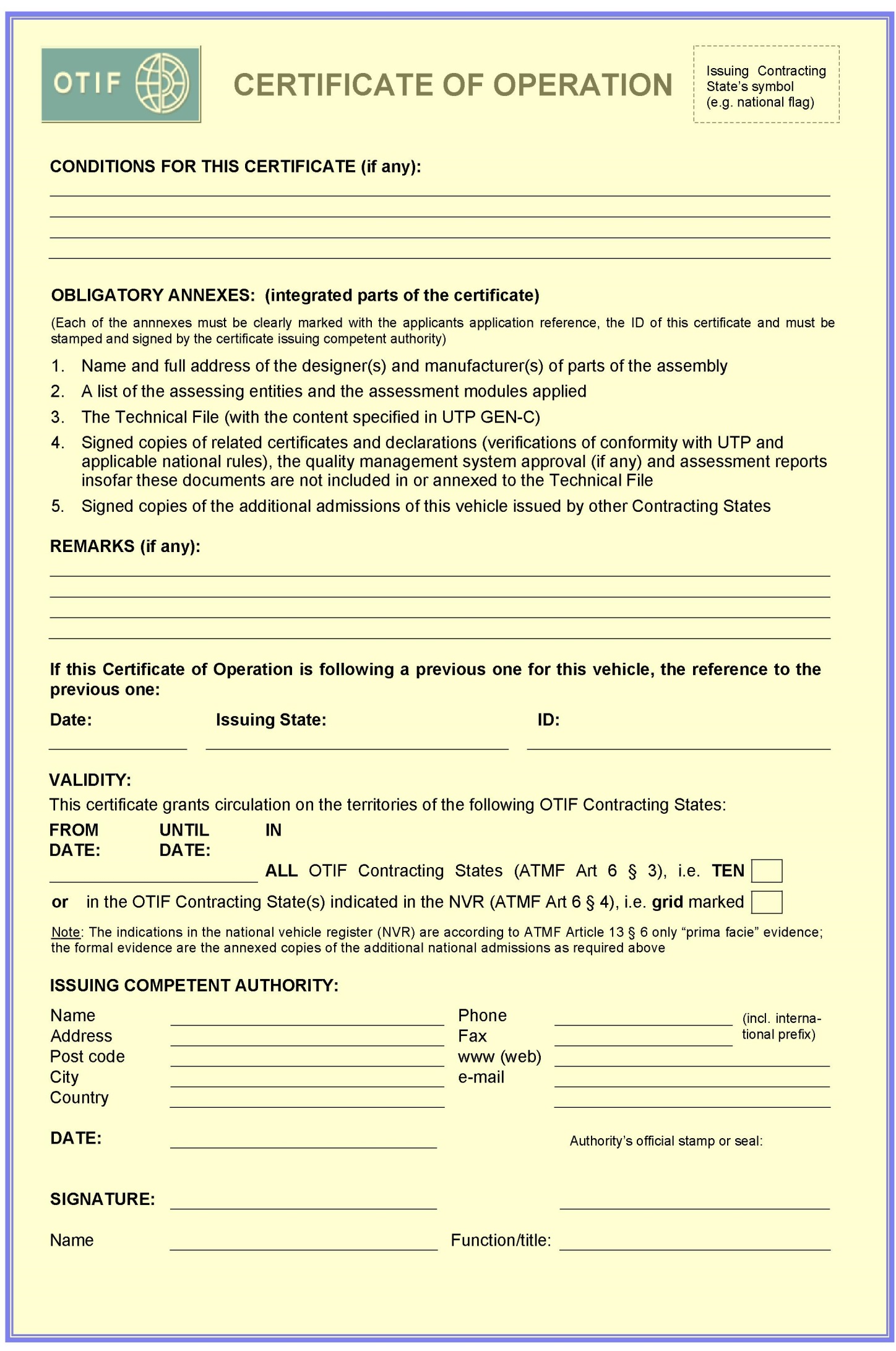
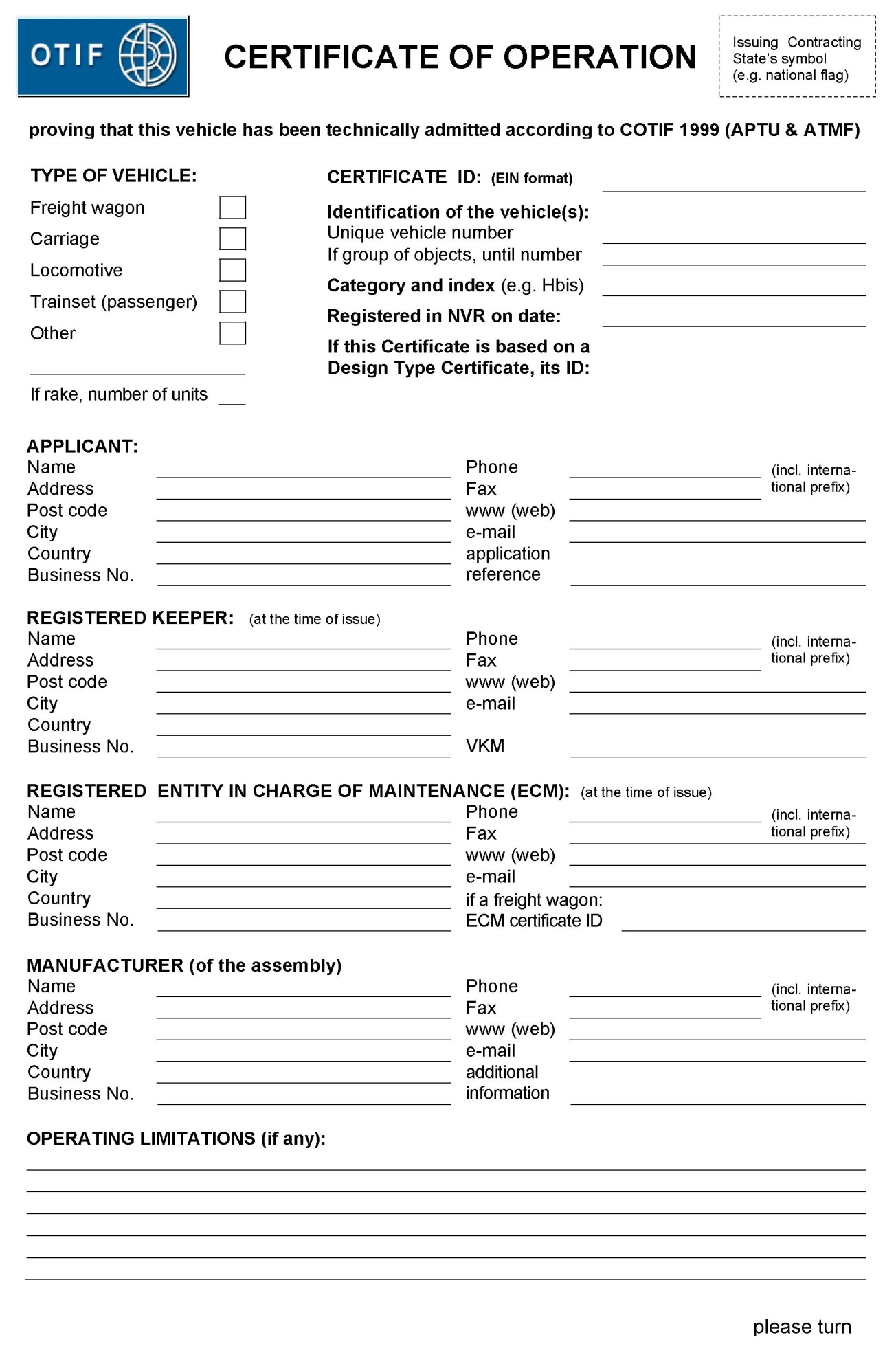
**Дозвола за коришћење возила намењеног међународном саобраћају**

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| OTIF_logo**LICENSE FOR VEHICLE OPERATION**  suing Contracting State’s symbol  (e.g. national flag)    **Proving that the vehicle is technically approved according to COTIF 1999 (APTU & ATMF)**   |  |  | | --- | --- | | **VEHICLE TYPE:** |  | | Freight wagon |  | |  |  | | Carriage |  | |  |  | | Locomotive |  | |  |  | | Trainset |  | |  |  | | Other |  | |  |  | |  |  | | If rake number of units |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **APPLICANT:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  |  | | --- | --- | |  |  | | **LICENSE NUMBER: (EIN fоrmat)** |  | |  |  | | **Vehicle identification:** | | | Unique vehicle number |  | | For group, up to No. |  | |  |  | | **Category and index** (Hbis) |  | |  |  | | **Реgistered in НРВ (date):** |  | |  |  | | **If this license is based on a license type, its number:** |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **REGISTERED OWNER:** (at time of issue) | | | |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | Owner code (VKM) |  | | | Business no. |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **PERSON REGISTERED FOR INSURANCE (ECM):** (at time of issue) | | | | |  | | Name |  | Tel. |  | | (incl. international prefix) | | Address |  | Fax |  | | | Post code |  | www (web) |  | | | | City |  | e-mail |  | | | | Country |  | For freight wagon:  ECM cеrtificate no. | |  | | | Business no. |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **MANUFACTURER (of assembled vehicle)** | | | |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | Additional information |  | | | Business no. |  |  |  | | --- | | **RESTRICTIONS FOR USE(if any):** | |  | |  |   Turn page | |
| OTIF_logo**LICENSE FOR VEHICLE OPERATION**  http://www.srbija.gov.rs/view_image.php?id=30968&cache=crsuing Contracting State’s symbol  (e.g. national flag)     |  | | --- | | **CERTIFICATE CONDITIONS (if any):** | |  | |  | |  | |  | | **MANDATORY APPENDICES:** (integral part of the certificate)  (Each annex must be: clearly marked with a link with the applicant's request, the number of this license, certified and signed by the authority issuing the license)  1. Name and address of expected manufacturer(s)  2. A list of the assessed conformity assessment bodies and applied conformity assessment modules  3. Technical file  4. Certified copy of the Certificate and Declaration of Conformity (with TSI and national rules), quality management system approvals (if any) and evaluation reports, if these documents are not attached to the technical file  5. Certified copies of additional License for vehicle type issued in other contracting states  **NOTE (if any):** | |  | |  | |  | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **If this license is issued after the previous one for the vehicle in question, the link to the previous license:** | | | | | | | **Date:** |  | | **Country of issue:** | | **Number:** | |  | |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **VALIDITY:** | | | | | | | | | | This license allows movement in the territories of the following OTIF contracting countries: | | | | | | | | | | **From**  **Date:** | **To**  **Date:** | **In** |  |  |  |  | | | |  |  | **All** contracting countries (ATMF art. 6§3), **TEN** | | | | |  |  | |  | | | | | | |  |  | | **or** in contracting countries listed in НРВ (ATMF art. 6 § 4), **растер** | | | | | | |  |  | | Explanation: Information within the national vehicle register (НРВ) is considered as, according to ATMF art. 13 § 6, “prima facie” proof; formal evidence is a copy of additional national license, as required above. | | | | | | | | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **ISSUING COMPETENT AUTHORITY:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  |  |  | |  |  |  |  |  | | --- | --- | --- | --- | | **DATE:** |  |  | Stamp: | |  |  |  | |  |  |  | | **SIGNATURE:** |  | | Full name |  | Position: |  | |

**License за коришћење возила намењеног међународном саобраћају**

**(на енглеском језику)**





**License for vehicle type нaмењеног унутрашњем саобраћају**

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| OTIF_logo**LICENSE FOR VEHICLE TYPE**  suing Contracting State’s symbol  (e.g. national flag)     |  |  | | --- | --- | | **VEHICLE TYPE:** |  | | Freight wagon |  | |  |  | | Carriage |  | |  |  | | Locomotive |  | |  |  | | Trainset |  | |  |  | | Other |  | |  |  | |  |  | | If rake number of units |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **APPLICANT:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  |  | | --- | --- | | **БРОЈ ДОЗВОЛЕ: (EIN формат)** |  | |  |  | | **Idenfication of the type:** | | | Prototype’s vehicle number |  | | and/of  other idenfication of the type |  | |  |  | | **Category and index** (нпр. Hbis) |  | |  |  | | **Registered in the approved type register, date:** |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **DESIGNER:** |  |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **PROTOTYPE MANUFACTURER:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  | | --- | | **RESTRICTIONS FOR USE(if any):** | |  | |  | |  | |  | |  |  |  | | --- | | **CERTIFICATE CONDITIONS (if any):** | |  | |  | |  | |  |   Turn page |
| OTIF_logo**LICENSE FOR VEHICLE TYPE**  suing Contracting State’s symbol  (e.g. national flag)    **MANDATORY APPENDICES:** (integral part of the certificate)  (Each annex must be: clearly marked with a link with the applicant's request, the number of this license, certified and signed by the authority issuing the license)  1. Name and address of expected manufacturer(s)  2. A list of the assessed conformity assessment bodies and applied conformity assessment modules  3. Technical file  4. Certified copy of the Certificate and Declaration of Conformity (with TSI and national rules), quality management system approvals (if any) and evaluation reports, if these documents are not attached to the technical file  5. Certified copies of additional License for vehicle type issued in other contracting states   |  | | --- | | **NOTE (if any):** | |  | |  | |  | |  | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **If this license is issued after the previous one for the vehicle in question, the link to the previous license:** | | | | | | | **Date:** |  | | **Country of issue:** | | **Number:** | |  | |  |  |  |  |  |  | | --- | |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | |  |  |  | | **ISSUING COMPETENT AUTHORITY:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  |  |  | |  |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | **DATE:** |  |  | Stamp: | |  |  |  | |  |  |  | |  |  | |  |  | | **SIGNATURE:** |  | | Full name |  | Position: |  | |

**License за коришћење возила намењеног унутрашњем саобраћају**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| OTIF_logo**LICENSE FOR OPERATION**  suing Contracting State’s symbol  (e.g. national flag)       |  |  | | --- | --- | | **VEHICLE TYPE:** |  | | Freight wagon |  | |  |  | | Carriage |  | |  |  | | Locomotive |  | |  |  | | Trainset |  | |  |  | | Other |  | |  |  | |  |  | | If rake number of units |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **APPLICANT:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | application reference |  | | | Business no. |  |  |  |  | | --- | --- | |  |  | | **LICENSE NUMBER: (EIN формат)** |  | |  |  | | **Vehicle identification:** | | | Unique vehicle number |  | | For group, up to No. |  | |  |  | | **Category and index** (Hbis) |  | |  |  | | **Registered in НРВ** (date)**:** |  | |  |  | | **License no for vehicle type:** |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **REGISTERED OWNER:** (at time of issue) | | | |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | Owner’s code (VKM) |  | | | Business no. |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **PERSON REGISTERED FOR INSURANCE (ECM):** (at time of issue) | | | | |  | | Name |  | Tel. |  | | (incl. international prefix) | | Address |  | Fax |  | | | Post code |  | www (web) |  | | | | City |  | e-mail |  | | | | Country |  | Freight wagon:  ECM certificate no. | |  | | | Business no. |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **MANUFACTURER (of assembled vehicle)** | | | |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  | Additional information |  | | | Business no. |  |  |  | | --- | | **RESTRICTIONS FOR USE (if any):** | |  | |  | |  | |  |   Turn page |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| OTIF_logo**LICENSE FOR OPERATION**  suing Contracting State’s symbol  (e.g. national flag)       |  | | --- | | **CERTIFICATE CONDITIONS (if any):** | |  | |  | |  | |  | | **MANDATORY APPENDICES:** (integral part of the certificate)  (Each annex must be: clearly marked with a link with the applicant's request, the number of this license, certified and signed by the authority issuing the license)  1. Name and address of expected manufacturer(s)  2. A list of the assessed conformity assessment bodies and applied conformity assessment modules  3. Technical file  4. Certified copy of the Certificate and Declaration of Conformity (with TSI and national rules), quality management system approvals (if any) and evaluation reports, if these documents are not attached to the technical file  5. Certified copies of additional License for vehicle type issued in other contracting states  **NOTE (if any):** | |  | |  | |  | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **If this license is issued after the previous one for the vehicle in question, the link to the previous license:** | | | | | | | **Date:** |  | | **Country of issue:** | | **Number:** | |  | |  |  |  |  |  |  | | --- | |  | |  | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **ISSUING COMPETENT AUTHORITY:** | |  |  |  | | Name |  | Phone |  | (incl. international prefix) | | Address |  | Fax |  | | Post code |  | www (web) |  | | | City |  | e-mail |  | | | Country |  |  |  | |  |  |  |  |  | | --- | --- | --- | --- | | **DATE:** |  |  | Stamp: | |  |  |  | |  |  |  | | **SIGNATURE:** |  | | Full name |  | Position: |  | |

**Annex 8**

**EXAMPLES OF STRUCTURAL SUBSYSTEM APPROVAL**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **New railway for international traffic, without stations and tunnels**  **(without open questions and TSI deviations)** | | | | |
| Applicant | Notified bodiesa (NoBo) | | | Directorate for Railways |
| NoBo for INF | NoBo for CCS | NoBo for ENE |
| Subsystem INF  - project  - production  - final testing  Full TSI implementation  **TSI Declaration of verification** | Verification of subsystem INF, compliance with:  TSI INF  **TSI Declaration of verification+**  **technical file** |  |  |  |
| Subsystem CCS  - project  - production  - final testing  Full TSI implementation  **TSI Declaration of verification** |  | Verification of subsystem CCS, compliance with:  TSI CCS – rail track part  **TSI certificate of verification**  **+ tech. documentation** |  |  |
| Subsystem ENE  - project  - production  - final testing  Full TSI implementation  **TSI Declaration of verification** |  |  | Verification of subsystem ENE, compliance with:  TSI ENE  **TSI certificate of verification**  **+ tech. documentation** |  |
| **- TSI declarations оf verification**  **- risk evaluation report**  **Commissioning** |  |  |  | Assessment of technical compatibility and safe integration  **Usage authorisation** |

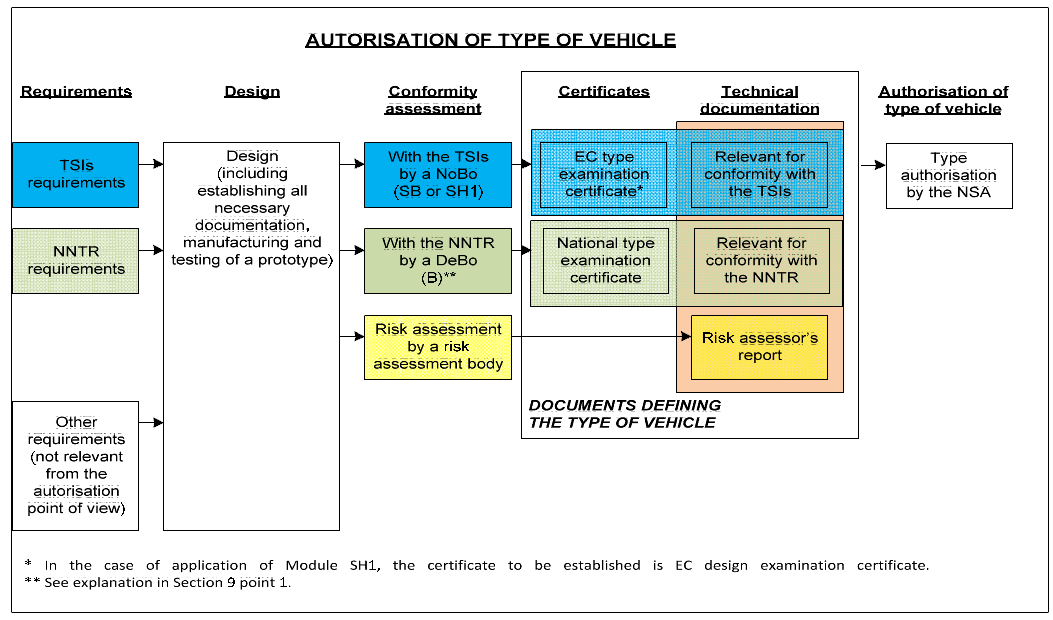
INF - subsystem infrastructure

CCS - subsystem supervision, management and signalization

ENE - subsystem energy

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **New railway for international traffic, without stations and tunnels**  **(without open questions and TSI deviations)** | | | | | |
| Applicant | Notified bodies (NoBo) | | | Compatibility evaluation with national rules  (Notified body) | Directorate for Railways |
| NoBo for INF | NoBo for CCS | NoBo for ENE |
| Subsystem INF  - project  - production  - final testing  Full TSI application, except for open issues and deviations  **TSI declaration of verification +**  **National declaration of verification** | Verification of subsystem INF, compliance with:  - TSI INF  - TSI PRM  - TSI SRT  **TSI Declaration of verification+ technical file** |  |  | Verification of  subsystem INF, compliance with national rules for open issues and deviations  **National declaration of verification+ technical file** |  |
| Subsystem CCS  - project  - production  - final testing  Full TSI application, except for open issues and deviations  **TSI declaration of verification +**  **National declaration of verification** |  | Verification subsystemа CCS, compliance with:  - TSI CCS  (rail track part)  - TSI SRT  **TSI declaration of verification+ technical file** |  | Verification of  subsystem CCS, compliance with national rules for open issues and deviations  **National declaration of verification+ technical file** |  |
| Subsystem ЕNE  - project  - production  - final testing  Full TSI application, except for open issues and deviations  **TSI declaration of verification +**  **National declaration of verification** |  |  | Verification of subsystem CCS, compliance with:  - TSI CCS  (rail track part)  - TSI SRT  **TSI Declaration of verification+ technical file** | Verification of  subsystem CCS, compliance with national rules for open issues and deviations  **National declaration of verification + technical file** |  |
| **- TSI declarations**  **- Nat. declarations**  **- risk evaluation report**  **Commissioning** |  |  |  |  | Assessment of technical compatibility and safe integration  **Usage authorisation** |

**Annex 9**



License for vehicle type (Directorate for Railways)

ТSI certificate ofcertificate of type-examination \*

ТSI requests

Required for national conformity assessment

National certificate ofcertificate of type-examination \*

**Documentation defining**

**vehicle type**

Risk grade – body for risk evaluation

With national rule – notified body( SB or SH1)

With TSI – registered body

( SB or SH1)

Project (including the prepraration of documentation, production and prototype testing)

National requests

**Certificates**

**License issue for vehicle type**

**VEHICLE TYPE APPROVAL**

**Тechnical documentation**

**Project**

\* In case of module SH1 application, Certificate of project examinationis issued

Risk evaluation report

Required for TSI conformity assessment

**Conformity grade**

**Requests**

**APPROVAL OF VEHICLES BASED ON COMPLIANCE WITH APPROVED TYPE**

**Requirements**

**Production and**

**final testing**

**Compliance grade**

**Certificates**

**Technical documentation**

**Declarations**

**License issue**

Technical documentation

for compliance with TSI

For compliance with nat. tech. rule

Risk evaluation report

Production and final testing acc. to technical documentation accompanying the type or project examination. Documentation proves the compliance with TSI, nat. tech. rules, technical compliance and safe integration

with type \*

(SD,SF or SH1)

Registered body

With type \*

(SD,SF or SH1)

Notified body

\* Compliance with the type implies compliance with both the TSI and the nat. tech. rules, if both apply

Risk evaluation report

TSI declaration of verification

National declaration of verification

Relevant for compliance with ТSI

Relevant for compliance with nat. reg..

ТSI declaration of verification

National declaration of verification

Declaration of conformity for type approval

Дозвола за

коришћење

(Дирекција)

Usage authorisation

(Directorate for Railways)

**Annex 10**

**STRUCTURE AND CONTENT OF EUROPEAN IDENTIFICATION NUMBER (EIN)**

The European Identification Number (EIN) consists of four fields, as given in the following example:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **R** | **S** | **5** | **3** | **2** | **0** | **1** | **6** | **0** | **0** | **0** | **5** |
| Country code  (2 letter) | | Documenttype  (2 digit) | | Year of issue  (4 digit) | | | | Counter  (4 digit) | | | |

field 1 field 2 field 3 field 4

**Field 1 – Country code (2 letter)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **COUNTRY** | **CODE** | **COUNTRY** | **CODE** | | **COUNTRY** | **CODE** |
| Republic of Аlbania | AL | Islamic Republic of Iran | IR | Republic of Poland | | PL |
| People’s Democratic Republic of Algeria | DZ | Republic of Iraq | IQ | Republic of Portugal | | PT |
| Republic of Armenia | АМ | Republic of Ireland | IE | Romania | | RO |
| Republic of Аustria | АТ | Israel | IL | Russian Federation | | RU |
| Republic of Azerbaijan | АZ | Republic of Italy | IT | Republic of Serbia | | RS |
| Republic of Belarus | BU | Republic of Kazakhstan | KZ | Republic of Slovakia | | SK |
| Belgium | BE | Republic of Kyrgyzstan | KG | Republic of Slovenia | | SI |
| Bosnia and Herzegovina | BA | Republic of Latvia | LV | Republic of Korea | | KR |
| Republic of Bulgaria | BG | Republic of Lebanon | LB | Kingdom of Spain | | ES |
| Republic of Croatia | HR | Principality of Liechtenstein | LI | Kingdom of Sweden | | SE |
| Czech Republic | CZ | Republic of Lithuania | LT | Swiss Confederation | | CH |
| Kingdom of Denmark | DK | Great Duchy of Luxembourg | LU | Syrian Arab Republic | | SU |
| Arab Republic of Egypt | EG | Republic of Macedonia | МK | Republic of Tajikistan | | ТЈ |
| Republic of Estonia | ЕЕ | Republic of Moldova | МD | Republic of Tunisia | | ТN |
| Republic of Finland | FI | Principality of Monaco | МC | Republic of Turkey | | ТR |
| Republic of France | FR | Mongolia | МN | Turkmenistan | | ТМ |
| Georgia | GE | Montenegro | МЕ | Republic of Ukraine | | UА |
| Federal Republic of Germany | DE | Kingdom of Morocco | МА | United Kingdom of Great Britain and Northern Ireland | | UK |
| Republic of Greece | EL | Kingdom of the Netherlands | NL | Republic of Uzbekistan | | UZ |
| Hungary | HU | Kingdom of Norway | NO |  | |  |

**FIELD 2 – Type of document (two-digit number)**

Two-digit number in field 2 allows the document identification:

1) the first digit indicates the general classification of the document and

2) the other digit indicates the document subtype

|  |  |  |
| --- | --- | --- |
| **Combination of digits for field 2** | **Type of document** | **Subtype of documents** |
| [51] and [55]\* | Usage authorisation | Tow cars |
| [52] and [56]\* | Usage authorisation | Towed carriage |
| [53] and [57]\* | Usage authorisation | Freight wagon |
| [54] and [58]\* | Usage authorisation | Special cars |
| [59]\*\* | License for vehicle type |  |
| [60] | Usage authorisation | Common license for fixed structural subsystems |
| [61] | Usage authorisation | Infrastructure subsystem |
| [62] | Usage authorisation | Energy subsystem |
| [63] | Usage authorisation | Supervision, management and signalization subsystem – railway track |

(\*)If the 4 digits foreseen in field 4 "current number" are completely used during one year, the first two digits in field 2 are changed as follows:

[51] becomes [55] for tow cars,

[52] becomes [56] for carriage cars,

[53] becomes [57] for freight wagon and

[54] becomes [58] for special cars.

(\*\*) Numbers in field 4:

from 1000 tо 1999 for tow cars,

from 2000 tо 2999 for carriage cars,

from 3000 tо 3999 for freight wagon and

from 4000 to 4999 for special cars.

**FIELD 3 – Year of issue (four-digit number)**

Field 3 states the уear of license issue.

**FIELD 4 - Counter**

Counter is increased by one unit with each license issuance, regardless of whether it is a new, extended or updated / revised license. In case of withdrawal or suspension of the license, the number referring to it may not be reused.

Each year, the counter starts again from zero.

**Annex 11**

**DOCUMENTS OF COMPLIANCE**

Depending on the module applied, documents of compliance include:

1) for interoperability constituents and elements of structural subsystems

|  |  |  |
| --- | --- | --- |
| Module | Compliance Assessment Body | Applicant |
| CA | - | Declaration of Conformity |
| CA1 | Certificate of Conformity | Declaration of Conformity |
| CA2 | Certificate of Conformity | Declaration of Conformity |
| CB | Assessment Report and  Type-examination certificate | - |
| CC | - | Declaration of Conformity |
| CD | *(Approval of the quality management system)* | Declaration of Conformity |
| CF | Certificate of Conformity | Declaration of Conformity |
| CH | *(Approval of the quality management system)* | Declaration of Conformity |
| CH1 | *(Approval of the quality management system)*  Certificate of project-examination | Declaration of Conformity |
| CV | Certificate of usage compliance | Declaration of usage compliance |

2) for structural subsystems

|  |  |  |
| --- | --- | --- |
| Module | Compliance Assessment Body | Applicant |
| SB | Assessment report,  Certificate of type-examination and  Transitional declaration of verification | Declaration on transitional declaration of verification |
| SD | *(Approval of the quality management system)*  Declaration of verification and  Transitional declaration of verification | Declaration of verification and  Transitional declaration of verification |
| SF | Declaration of verification and  Transitional declaration of verification | Declaration of verification and  Declaration on transitional declaration of verification |
| SG | Declaration of verification and  Transitional declaration of verification | Declaration of verification and  Declaration on transitional declaration of verification |
| SH1 | *(Approval of the quality management system)*  Certificate of project-examination,  Declaration of verification and  Transitional declaration of verification | Declaration of verification and  Declaration on transitional declaration of verification |