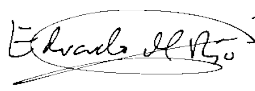



Making the railway system
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Clarification note

Content of the EC declarations

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<i>Date</i>	26/08/2021	27/08/2021	27/08/2021
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Document History

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1.0	26/08/2021	Initial version

The purpose of this document is to provide applicants and other external stakeholders of the vehicle authorisation business with information in regards to the specific topic referenced in the title. The clarifications contained in this document may be integrated in the next revision of the guidelines for the practical arrangements for the vehicle authorisation process, without prejudice of the formal process foreseen for updating the guideline.

The present document is a non-legally binding guidance of the European Union Agency for Railways. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

1. Description of the issue

The Directive (EU) 2016/797¹, as amended by Directive (EU) 2020/700², imposes an obligation for subsystems and interoperability constituents (hereinafter IC) to have an EC declaration before being placed on the market:

- › Subsystems: the applicant for placing on the market of the subsystem shall establish an EC declaration of verification
- › ICs: the manufacturer (or its authorised representative) shall establish an EC declaration of conformity and/or suitability for use

According to Regulation (EU) 2019/250³, as amended by Regulation (EU) 2020/779⁴, the EC declarations shall mention;

- › Union law and national rules that the subsystem/IC complies with;
- › Reference to the outcomes foreseen by each applicable rule (e.g. certificate, report etc.), and
- › Conditions for use of the vehicle and other restrictions.

In case of applications for a new authorisation and/or for an extension of the area of use, there are doubts concerning the applicable rules, the references to the evidence required by the rules and the conditions for use of the subsystem/IC that should be listed in the EC declarations:

- › Whole subsystem/IC;
- › Changed parts and interfaces with the unchanged parts, and/or
- › Extended area of use

Furthermore, when the vehicle that is going to be modified or whose area of use is going to be extended was placed in service long time ago without an EC declaration of verification, it is not always possible to determine the rules that it complied with originally.

It is also not clear whether mentioning a previous EC declaration (which in principle should have listed all the elements required by the legal text) is enough or whether there is a need to mention all the elements again in the new EC declarations.

Finally, the Regulation (EU) 2016/919⁵ (CCS TSI), as amended by Regulations (EU) 2019/776⁶, 2020/387⁷ and 2020/420⁸, introduces the concept of ESC/RSC statements. However, the Regulation (EU) 2019/250 does not explicitly mention these statements, raising doubts on whether they should be mentioned in the EC declaration of verification for the CSS subsystem or not.

¹ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJEU L138, 26.5.2016, p.44-101)

² Directive (EU) 2020/700 of the European Parliament and of the Council of 25 May 2020 amending Directives (EU) 2016/797 and (EU) 2016/798, as regards the extension of their transposition periods (OJ L 165, 27.5.2020, p.27–30)

³ Commission Implementing Regulation (EU) 2019/250 of 12 February 2019 on the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, on the model of declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems in accordance with Directive (EU) 2016/797 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 201/2011 (OJ L 42, 13.2.2019, p. 9–24)

⁴ Commission Implementing Regulation (EU) 2020/779 of 12 June 2020 amending Implementing Regulation (EU) 2019/250 as regards the dates of application following the extension of the transposition deadline of Directive (EU) 2016/797 of the European Parliament and of the Council (OJ L 188, 15.6.2020, p. 6–7)

⁵ Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union (OJ L 158, 15.6.2016, p. 1–79)

⁶ Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474 (OJ L 139I, 27.5.2019, p. 108–311)

⁷ Commission Implementing Regulation (EU) 2020/387 of 9 March 2020 amending Regulations (EU) No 321/2013, (EU) No 1302/2014 and (EU) 2016/919 as regards the extension of the area of use and transition phases (OJ L 73, 10.3.2020, p. 6–18)

⁸ Commission Implementing Regulation (EU) 2020/420 of 16 March 2020 correcting the German language version of Regulation (EU) 2016/919 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union (OJ L 84, 20.3.2020, p. 5–6)

2. Line to take

The EC declaration(s) established after 31 October 2020 shall meet the requirements in Regulation (EU) 2019/250. In Member States that have not yet transposed the Directive (EU) 2016/797, Annexes IV and V of Directive 2008/57/EC may have been applicable until 31 October 2020 (depending on the transposition date in the concerned Member State).

To determine which is the applicable legal text there are 2 cumulative criteria:

- › Member State of establishment/seat of the applicant/manufacturer (declarant), and
- › The date of issuing of the declaration

As a result, an EC declaration shall:

- › be in conformity to Regulation (EU) 2019/250 in case the declaration is issued after 31 October 2020, no matter of the Member State in which the issuer is established or has its seat;
- › be in conformity to Regulation (EU) 2019/250 in case the issuer of the declaration was established or had its seat in a Member State which had transposed the Directive (EU) 2016/797 and the declaration was issued after the transposition date;
- › meet the requirements of Annexes IV or V of Directive 2008/57/EC in case the issuer of the declaration was established or had its seat in a Member State which had not transposed the Directive (EU) 2016/797 and the declaration was issued before 30 October 2020;
- › meet the requirements of Annexes IV or V of Directive 2008/57/EC in case the declaration was established before 16 June 2019.

EC declaration(s) meeting the requirements of Regulation (EU) 2019/250 also meet the requirements of Annexes IV or V of Directive 2008/57/EC. The Agency, when acting as authorising entity, will accept EC declarations according to Regulation (EU) 2019/250 even if the legal text formally applicable in the concerned Member State for the content of the declaration is the Directive 2008/57/EC.

2.1. First authorisation

The EC declarations shall:

- › List all the applicable rules (TSIs, national rules and other Union law)
- › Make reference to all the certificates, reports or other outcomes required by the applicable rules at subsystem level (only when the applicable rules require directly some sort of certificate, report, statement, etc., issued by a conformity assessment body, inspection body, competent body etc.; when the outcomes relate to CE marking and/or self-declarations to be issued by the manufacturer, it is not necessary to mention them in the EC declaration). It is not necessary to list the EC certificates and EC declarations related to interoperability constituents incorporated into the subsystem.
- › For the CCS subsystem, make reference to the ESC/RSC statements where applicable, see clarification note ERA1209/143 ([link](#))
- › List all conditions for use and other restrictions. Special attention should be paid to avoid describing all possible aspects that impact the use of the subsystem/IC (e.g. everything described in the driver manual or the maintenance plan).

Conditions for use and other restrictions should be focused on important aspects that shall be respected in order to ensure that the essential requirements are met (including technical compatibility with the network) and that the subsystems are technically compatible with each other and safely integrated into a vehicle, e.g. operational constraints (speed limitations in degraded modes, pantograph configurations allowed etc.).

For the majority of the railway vehicle types there are other Directives that apply (e.g. Simple Pressure Vessels Directive (SPVD) 2014/29/EU, Electromagnetic Compatibility (EMC) Directive 2014/30/EU, Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation EC 1907/2006, Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive 2011/65/EU, etc.). Therefore EC declarations not covering any Union law in the framework of an application for a first authorisation of a vehicle and/or vehicle type will normally be subject to issues through the OSS.

2.2. New authorisation (upgrade/renewal of a subsystem)

If the subsystem was placed on the market with an EC declaration of verification, a reference to such EC declaration in the new EC declaration covering the modified subsystem is sufficient to cover the unmodified parts:

- › It is not necessary to transfer the applicable rules, the references to certificates/reports or the conditions for use and other restrictions from the previous EC declaration of verification to the new one;
- › Only the rules, certificates, reports and/or conditions for use related to the modified parts (and the interfaces with the unchanged parts) shall be listed in the new EC declaration of verification.

If the subsystem was placed on the market without an EC declaration of verification, or the vehicle was placed in service before Directive 2008/57/EC, only the rules, certificates, reports and/or conditions for use related to the modified parts shall be listed in the new EC declaration of verification.

See section 2.1 for further details on which certificates, reports or other outcomes need to be mentioned in the EC declaration.

2.3. Extension of the area of use

If the subsystem was placed on the market with an EC declaration of verification, a reference to such EC declaration in the new EC declaration covering the extension of the area of use is sufficient to cover the original area of use:

- › It is not necessary to transfer the applicable rules (in particular national rules), the references to certificates/reports or the conditions for use and other restrictions to the new EC declaration of verification;
- › Only the rules, certificates, reports and/or conditions for use related to the extended area of use shall be listed in the new EC declaration of verification covering the extension of the area of use.

If the subsystem was placed on the market in the original area of use without an EC declaration of verification, or the vehicle was placed in service in the original area of use before Directive 2008/57/EC, only the rules, certificates, reports and/or conditions for use related to the extension of the area of use shall be listed in the new EC declaration of verification.

See section 2.1 for further details on which certificates, reports or other outcomes need to be mentioned in the EC declaration.

2.4. Authorisation for placing on the market in conformity to an authorised type

When assessing an application for vehicle authorisation for placing on the market in conformity to an authorised type, the Agency does not evaluate if the content of the EC declaration(s) of verification (that should be included in the annexes of the declaration of conformity to type) fulfils the requirements of the Regulation (EU) 2019/250. The verifications are limited to the traceability between the EC declaration(s), the EC certificate(s), the file accompanying the application, ERATV and ERADIS.

From the date of issuing of this clarification note, when there is a need for a new or updated EC declaration of verification (e.g. in case of changes to the vehicle type that can be classified pursuant to Article 15(1)(b) of Regulation (EU) 2018/545), such EC declarations of verification shall respect all the requirements of the legal texts, taking into account paragraphs above. In such cases, the Agency will assess if the new or updated EC declaration of verification fulfils the requirements of the Regulation.

2.5. ICs already placed on the market

The Regulation (EU) 2019/250 requires that the EC declarations of conformity and/or suitability for use describes the relevant Union law complied with, the references to the evidence required by the relevant Union law and the conditions for use and other restrictions.

However, EC declarations of conformity and/or suitability for use of ICs:

- › already placed on the market;
- › integrated in subsystems also placed on the market, and
- › being part of vehicle types and/or vehicles already authorised and in operation

do not always respect the concerned provisions of the Regulation (EU) 2019/250.

This is considered correct if the concerned EC declaration was following the requirements of the Annex IV of Directive 2008/57/EC when the IC was placed on the market and this was the applicable legal text in the Member State where the manufacturer was established.

For other cases, if the applicant for vehicle authorisation can demonstrate and provide evidence that the concerned ICs, with the associated EC declarations of conformity and/or suitability for use not fulfilling the requirements of Regulation (EU) 2019/250, are already integrated into vehicle types and/or vehicles already authorised, the Agency, when acting as authorising entity, will exceptionally accept such deviations.

From the date of issuing of this clarification note, when there is a need for a new or updated EC declaration of conformity and/or suitability for use (e.g. when the validity of an EC certificate of conformity and/or suitability for use expires), such EC declaration shall respect all the requirements of the legal texts. Otherwise, as a general rule, they will not be accepted by the Agency for issuing vehicle type authorisations and/or vehicle authorisation for placing on the market.

3. Legal background

3.1. Directive (EU) 2016/797 (as amended)

› Article 2 Definitions

[...]

(5) ‘subsystems’ means the structural or functional parts of the Union rail system, as set out in Annex II;

[...]

(7) ‘interoperability constituents’ means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly, including both tangible objects and intangible objects;

[...]

(9) ‘essential requirements’ means all the conditions set out in Annex III which must be met by the Union rail system, the subsystems, and the interoperability constituents, including interfaces;

[...]

(22) ‘applicant’ means a natural or legal person requesting an authorisation, be it a railway undertaking, an infrastructure manager or any other person or legal entity, such as a manufacturer, an owner or a keeper; for the purpose of Article 15, the ‘applicant’ means a contracting entity or a manufacturer, or its authorised representatives; for the purpose of Article 19, the ‘applicant’ means a natural or legal person requesting the Agency’s decision for the approval of the technical solutions envisaged for the ERTMS track-side equipment projects;

[...]

(35) ‘placing on the market’ means the first making available on the Union’s market of an interoperability constituent, subsystem or vehicle ready to function in its design operating state;

(36) ‘manufacturer’ means any natural or legal person who manufactures a product in the form of interoperability constituents, subsystems or vehicles, or has it designed or manufactured, and markets it under his name or trademark;

(37) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer or a contracting entity to act on behalf of that manufacturer or contracting entity in relation to specified tasks;

[...]

(41) ‘conformity assessment’ means the process demonstrating whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled;

[...]”

› Article 3 Essential requirements

“1. The Union rail system, subsystems and interoperability constituents including interfaces shall meet the relevant essential requirements.

[...]”

› Article 13 Conformity with TSIs and national rules

“1. The Agency and the national safety authorities shall consider as **meeting the essential requirements**, those **structural subsystems** constituting the rail system which are **covered**, as appropriate, by the **‘EC’ declaration of verification** established by reference to **TSIs**, in accordance

with Article 15, or the declaration of verification established by reference to **national rules** in accordance with Article 15(8), or both.

[...]"

› Article 15 Procedure for establishing the 'EC' declaration of verification

"1. In order to establish the 'EC' declaration of verification necessary for placing on the market and placing in service referred to in Chapter V, the applicant shall request the conformity assessment body or bodies that it has selected for that purpose to apply the 'EC' verification procedure set out in Annex IV.

2. The applicant shall establish the 'EC' declaration of verification of a subsystem. The applicant shall declare on his sole responsibility that the subsystem concerned has been **subject to the relevant verification procedures and that it satisfies the requirements of relevant Union law and any relevant national rule**. The 'EC' declaration of verification and the accompanying documents shall be dated and signed by the applicant.

4. The applicant shall be responsible for compiling the technical file that is to accompany the 'EC' declaration of verification. That technical file shall contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It shall also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.

5. In the event of the renewal or upgrading of a subsystem resulting in an amendment to the technical file and affecting the validity of the verification procedures already carried out, the applicant shall assess the need for a new 'EC' declaration of verification.

[...]

9. The Commission may specify, by means of implementing acts:

- a) the details of the 'EC' verification procedures for subsystems, including the verification procedure in the case of national rules and the documents to be submitted by the applicant for the purposes of that procedure;
- b) the templates for the 'EC' declaration of verification, including in the case of a modification of the subsystem or in the case of additional verifications, the intermediate statement of verification, and templates for documents of the technical file that is to accompany those declarations as well as templates for the certificate of verification.

Those implementing acts shall be adopted in accordance with the examination procedure referred to Article 51(3)."

› Article 20 Placing on the market of mobile subsystems

"1. **Mobile subsystems shall be placed on the market** by the applicant only if they are designed, constructed and installed in such a way as to **meet the essential requirements**.

2. In particular, the applicant shall ensure that the **relevant declaration of verification** has been provided."

› Article 21 Vehicle authorisation for placing on the market

"[...]"

3. The application for a vehicle authorisation for placing on the market shall be accompanied by a file concerning the vehicle or vehicle type and including documentary evidence of:

(a) the **placing on the market of the mobile subsystems** of which the vehicle is composed in accordance with Article 20, on the **basis of the 'EC' declaration of verification**;

[...]"

› Annex IV 2.3 Certificate of verification

[...]

2.3.1. *The notified bodies responsible for the verification assess the design, production and final testing of the subsystem and draw up the certificate of verification intended for the **applicant who in turn draws up the 'EC' declaration of verification**. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.*

[...]"

› Annex IV 2.4. Technical file accompanying the 'EC' declaration of verification

"The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following:

- a) *technical characteristics linked to the design including general and detailed drawings with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned;*
- b) *a list of interoperability constituents, referred to in point (d) of Article 4(3), incorporated into the subsystem;*
- c) *the files referred to in Article 15(4), compiled by each of the notified bodies involved in the verification of the subsystem, which shall include:*
 - *copies of the 'EC' declarations of verification and, where applicable, 'EC' declarations of suitability for use established for interoperability constituents referred to in point (d) of Article 4(3) and accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications,*
 - *where available, the ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity,*
 - *the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;*
- d) ***certificates of verification issued in accordance with other legal acts of the Union;***
- e) *when verification of safe integration is required pursuant to in point (c) of Article 18(4) and in point (c) of Article 21(3), the relevant technical file shall include the assessors' report(s) on the CSMs on risk assessment referred to in Article 6(3) of Directive."*

3.2. Regulation (EU) 2019/250 (as amended)

› Recitals

[...]

(7) *'EC' declaration of verification of subsystems and its accompanying documents should provide evidence of the completion of the relevant procedures for verification in accordance with the applicable Union law and relevant national rules, and indicate the references of the Directives, TSIs and other relevant Union acts as well as relevant national rules.*

(8) *In order to ensure that a subsystem continues to meet the essential requirements over time the 'EC' declaration of verification should reflect any change which affects it and the applicant should have procedures in place to continuously update the 'EC' declaration of verification.*

(9) ‘EC’ verification procedure for a modified subsystem should be in accordance with Article 15 of Directive (EU) 2016/797 and provisions applicable to existing subsystems and vehicles which are set out in TSIs. Existing subsystems may have been placed in service before ‘EC’ verification procedure was applicable to them and thus without an ‘EC’ declaration of verification. ‘EC’ verification procedure regarding changes to those subsystems placed in service without an ‘EC’ declaration of verification should be limited to the parts of the subsystem that are changed, and their interfaces to the unchanged parts of the subsystem. An ‘EC’ declaration of verification should then cover the changed subsystem.

[...]

(12) The nature of information to be provided allows for one template to be used to accommodate ‘EC’ certificate of verification delivered by a notified body for a subsystem, ‘EC’ certificate of conformity delivered by a notified body for an interoperability constituent, ‘EC’ certificate of suitability for use delivered by a notified body for an interoperability constituent as well as certificate delivered by a designated body for a subsystem.

(13) The annexes to the declaration of conformity to an authorised vehicle type should provide evidence of the completion of the relevant procedures for verification in accordance with the applicable Union law and relevant national rules, and indicate the references of the Directives, TSIs and other relevant Union acts as well as relevant national rules.

[...]”

› Article 2 Definitions

“(a) **“EC” declaration of conformity**’ means the declaration established for an interoperability constituent by the manufacturer or its authorised representative in which the **manufacturer or its authorised representative declares** on its sole responsibility that the **interoperability constituent** concerned, which has been subject to the relevant verification procedures, **complies with the relevant Union law**;

(b) **“EC” declaration of suitability for use**’ means the supplementary declaration to the ‘EC’ declaration of conformity of the interoperability constituent established for an interoperability constituent by the manufacturer or its authorised representative in which the **manufacturer or its authorised representative declares** on its sole responsibility that the **interoperability constituent** concerned, which has been subject to the relevant verification procedures, **satisfies the requirements for suitability for use specified in the relevant TSI**;

(c) **“EC” declaration of verification**’ means the declaration established for a subsystem by the applicant in which the applicant **declares** on its sole responsibility that the **subsystem** concerned, which has been subject to the relevant verification procedures, **satisfies the requirements of the relevant Union law and any relevant national rules**;

(d) ‘Subsystem placed in service without an “EC” declaration of verification’ means a subsystem, fixed or mobile, that has been placed in service before ‘EC’ verification procedure was applicable to it in accordance with Council Directive 96/48/EC (4), Directive 2001/16/EC of the European Parliament and of the Council (5) or Directive 2008/57/EC, and thus without an ‘EC’ declaration of verification.

[...]

(j) **‘declaration of conformity to an authorised vehicle type**’ means the declaration established for a vehicle by the applicant in which the **applicant declares** on its sole responsibility that the **vehicle** concerned, which has been subject to the relevant verification procedures, **conforms to an authorised vehicle type and satisfies the requirements of the relevant Union law and relevant national rules**.

[...]”

- › Article 3 ‘EC’ declaration of conformity or ‘EC’ declaration of suitability for use

*“1. The **manufacturer or its authorised representative shall establish ‘EC’ declaration of conformity of interoperability constituent or ‘EC’ declaration of suitability for use of interoperability constituent** in accordance with the template set out in Annex I.*

2. An ‘EC’ declaration of conformity or ‘EC’ declaration of suitability for use shall be written in one of the official languages of the Union and it shall be in the same language as its accompanying documents.”
- › Article 4 Accompanying documents for ‘EC’ declaration of conformity or ‘EC’ declaration of suitability for use

“An ‘EC’ declaration of conformity or suitability for use of interoperability constituents shall be accompanied by the following documents:

 - a) ‘EC’ certificate of conformity and, where appropriate, ‘EC’ certificate of suitability for use;*
 - b) technical documentation in accordance with Commission Decision 2010/713/EU.”*
- › Article 5 ‘EC’ declaration of verification

*“1. An ‘EC’ declaration of verification shall be based on the information resulting from the verification procedures for subsystems set out in Article 15 of Directive (EU) 2016/797 and Annex IV to that Directive. One **‘EC’ declaration of verification shall comprise the verification in respect with Union law and, where appropriate, national rules.***

2. The applicant shall establish ‘EC’ declaration of verification in accordance with the template set out in Annex II, and in accordance with the template set out in Annex III when it relates to a subsystem initially placed in service without an ‘EC’ declaration of verification.

3. An ‘EC’ declaration of verification shall be written in one of the official languages of the Union and it shall be in the same language as its accompanying documents.”
- › Article 6 Verification procedure in case of a change to a subsystem

“1. In the event of a change to a subsystem, the applicant shall analyse the change and assess the impact on the ‘EC’ declaration of verification.

2. Where the validity of an element of the relevant ‘EC’ declaration of verification is impacted by that change, the applicant shall update the ‘EC’ declaration of verification or shall establish a new ‘EC’ declaration of verification. A new ‘EC’ declaration of verification shall be established whenever a new authorisation according to criteria set out in Articles 18(6) and 21(12) of Directive (EU) 2016/797 is required.

3. Where a change affects a basic parameter, the applicant shall assess the need for, and where required carry out the ‘EC’ verification procedure set out in Article 15 of Directive (EU) 2016/797 and Annex IV to that Directive for the changed subsystem.”
- › Article 7 Verification procedure in case of a change to a subsystem placed in service without an ‘EC’ declaration of verification

“1. In the event of a change to a subsystem placed in service without an ‘EC’ declaration of verification, the applicant shall analyse the change and assess the impact on the existing design and maintenance documentation.

2. Where a change is made to a subsystem that affects a basic parameter, the applicant shall assess the need for, and where required carry out the ‘EC’ verification procedure in accordance with Article 15 of Directive (EU) 2016/797.

3. The conformity assessment body shall only assess the parts of the subsystem that are changed, and assess the interfaces to the unchanged parts of the subsystem

4. An ‘EC’ declaration of verification shall be established by the applicant for the whole subsystem by declaring under its sole responsibility that:

- a) *the changed part and the interfaces to the unchanged parts of the subsystem have been subject to the relevant verification procedures and comply with the relevant Union law and any relevant national rules.*
- b) *the unchanged part has been brought into use in the railway system and has been maintained in its design operating state since the date of bringing into use in the railway system until the date of the establishment of EC declaration of verification.”*
- › Annex I Template for ‘EC’ Declaration of Conformity or Suitability for use of Interoperability Constituents
- “[...]
- We, *Manufacturer or Authorised representative***
- [Business name]
- [Complete postal address]
- Declare** under our sole responsibility that the following **interoperability constituent**:
- [Name/short description of interoperability constituent, unique identification of the interoperability constituent]
- to which this declaration refers **complies with the relevant Union law**:
- [Title(s) of the Directive(s); Title(s) of the TSI(s); Title(s) of European Specifications]
- [...]
- In accordance with the following approval(s) and/or certificate(s):
- [Approval(s), date of issue][Certificate number(s), date of issue]
- The following conditions of use and other restrictions apply:
- [List or reference to the list of conditions of use and other restrictions]
- [...]
- [Titles of the Annexes (Technical documentation or technical file accompanying the ‘EC’ declaration of conformity or suitability for use)] (4)
- [...]”
- › Annex II Template for ‘EC’ Declaration of Verification of Subsystem
- “[...]
- We, *Applicant***:
- [Business name]
- [Complete postal address]
- Declare** under our sole responsibility that the following **subsystem**:
- [Name/short description of the subsystem, unique identification of the subsystem]
- to which this declaration refers has been subject to the relevant verification procedures and **complies with the relevant Union law and any relevant national rules**:
- [Reference to: the Directive(s); TSI(s); Relevant national rules;]**
- [...]
- In accordance with the following certificate(s) and or report(s):
- [Certificate(s) number(s), report(s) number(s), date(s) of issue]
- The following conditions of use and other restrictions apply:

[List or reference to the list of conditions of use and other restrictions]

[...]

Identification of the technical file accompanying this declaration

[Reference to the technical file accompanying the 'EC' declaration of verification of subsystem in accordance with Article 15(4) of Directive (EU) 2016/797]

Reference to former 'EC' declaration of verification (where applicable)

[Yes/No]

[...]"

- › Annex III Template for 'EC' Declaration of Verification for Subsystem initially placed in service without an 'EC' Declaration

"[...]

We, Applicant:

[Business name]

[Complete postal address]

Declare under our sole responsibility that for the **subsystem** to which this declaration refers (2):

[Name/short description of the subsystem, unique identification of the subsystem]

The changed part of the subsystem:

[Name/short description of the parts of the subsystem]

*has been subject to the relevant verification procedures and **complies with the relevant Union law and any relevant national rules:***

[Reference to: the Directive(s); TSI(s); Relevant national rules;]

[...]

In accordance with the following certificate(s) and or report(s):

[Certificate(s) number(s), report(s) number(s), date(s) of issue]

The unchanged part of the subsystem to which this declaration refers has been brought into use in the railway system and has been maintained in its design operating state since the date of bringing into use in the railway system until the date of the establishing the 'EC' declaration of verification.

The following conditions of use and other restrictions apply:

[List or reference to the list of conditions of use and other restrictions]

[...]

Identification of the technical file accompanying this declaration

[Reference to the technical file accompanying the 'EC' declaration of verification of subsystem in accordance with Article 15(4) of Directive (EU) 2016/797]

Reference to former 'EC' declaration of verification (where applicable)

[Yes/No]

[...]"

› Annex VI Model of declaration of conformity to an authorised vehicle type

“We,

Applicant

[Business name]

[Full address]

Declare under our sole responsibility that vehicle [European Vehicle Number/pre-reserved Vehicle Number/agreed means of identification] (2) to which this declaration refers

- conforms to authorised vehicle type [ERATV identification of the type/version/variant of vehicle]
- **complies with the relevant Union law and relevant national rules, as indicated in the annexes to this declaration,**
- has undergone all verification procedures necessary for establishing this declaration.

List of annexes ⁽³⁾

[Titles of the annexes]

Signed for and on behalf of [name of the applicant]

Done at [place], [date DD/MM/YYYY]

[name, function] [signature]

[...]

⁽³⁾ Annexes shall include copies of EC declaration(s) of verification of subsystem(s).”

3.3. Directive 2008/57/EC

› Article 18 Procedure for establishing the ‘EC’ declaration of verification

“1. In order to establish the ‘EC’ declaration of verification, the applicant shall invite the notified body that it has selected for that purpose to apply the ‘EC’ verification procedure referred to in Annex VI. The applicant may be the contracting entity or the manufacturer, or their authorised representative within the Community.

2. The task of the notified body responsible for the ‘EC’ verification of a subsystem shall begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the subsystem is placed in service. It shall also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated, based on the information available in the relevant TSI and in the registers provided for in Articles 34 and 35.

3. The notified body shall be responsible for compiling the technical file that has to accompany the ‘EC’ declaration of verification. This technical file must contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It should also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.

4. The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem. In such a case, the procedure set out in Annex VI shall apply.

5. If the relevant TSIs allow, the notified body may issue certificates of conformity for a series of subsystems or certain parts of those subsystems.”+

› Annex IV 'EC' Declaration of conformity and suitability for use of interoperability constituents*"3. Contents of the 'EC' declaration*

The 'EC' declaration of conformity or of suitability for use and the accompanying documents must be dated and signed.

That declaration must be written in the same language as the instructions and must contain the following:

- the **Directive references**,*
- name and address of the manufacturer or its authorised representative established within the Community (give trade name and full address; in the case of the authorised representative, also give the trade name of the manufacturer),*
- description of interoperability constituent (make, type, etc.),*
- description of the procedure followed in order to declare conformity or suitability for use (Article 13),*
- all the relevant descriptions met by the interoperability constituent and, in particular, its conditions of use,*
- name and address of the notified body or bodies involved in the procedure followed in respect of conformity or suitability for use and date of examination certificate together with, where appropriate, the duration and conditions of validity of the certificate,*
- where appropriate, **reference to the European specifications**,*
- identification of the signatory empowered to enter into commitments on behalf of the manufacturer or of the manufacturer's authorised representative established within the Community."*

› Annex V 1. 'EC' Declaration of Verification of Subsystems

*"The 'EC' declaration of verification of a subsystem is a declaration established by the 'applicant' within the meaning of Article 18 in which he declares on his sole responsibility that the subsystem concerned, which has been subject to the relevant verifications procedures, **satisfies the requirements of the relevant Union legislation, including any relevant national rules.***

The 'EC' declaration of verification and the accompanying documents must be dated and signed.

The 'EC' declaration of verification must be based on the information resulting from the 'EC' verification procedure for subsystems set out in Annex VI. It must be written in the same language as the technical file accompanying the 'EC' declaration of verification and must contain at least the following:

- a) the **reference to this Directive, TSIs and applicable national rules**,*
- b) the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure and to the **national rules** which have been applied in case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case,*
- c) name and address of the 'applicant' within the meaning of Article 18 (specifying the trade name and full address; in the case of the authorised representative, specifying also the trade name of the contracting entity or the manufacturer),*
- d) a brief description of the subsystem,*
- e) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the 'EC' verification(s) referred to in Article 18,*
- f) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the assessment of conformity with **other regulations deriving from the Treaty**,*
- g) name(s) and address(es) of the designated body(ies) which conducted the verification(s) of conformity with national rules referred to in Article 17(3),*
- h) name and address of the assessment body(ies) which established the safety assessment reports related to the use of the CSM on risk assessment where required by this Directive,*

- i) *the references of the documents contained in the technical file accompanying the 'EC' declaration of verification,*
- j) *all the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any **operating restrictions or conditions**,*
- k) *the identity of the signatory (i.e. the physical person or persons authorised to sign the declaration) Where reference is made in Annex VI to the 'intermediate statement of verification' (ISV), the provisions of this Section shall apply to that declaration."*

› Annex V 2. 'EC' Declaration of Verification of Subsystems in the case of modifications

"In a case of a modification, which is not a substitution in the framework of maintenance, of a subsystem covered by an 'EC' declaration of verification, without prejudice to Article 20, the following provisions apply.

2.1. If the entity introducing the modification demonstrates that the modification does not affect the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning the basic parameters:

- a) *the entity introducing the modification shall update the references of the documents contained in the technical file accompanying the 'EC' declaration of verification;*
- b) *no new 'EC' declaration of verification needs to be established.*

2.2. If the entity introducing the modification demonstrates that the modification affects the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning some basic parameters:

- a) *the entity introducing the modification shall establish a complementary 'EC' declaration of verification with reference to the basic parameters concerned;*
- b) *the complementary 'EC' declaration of verification shall be accompanied by a list of documents of the original technical file accompanying the original 'EC' declaration of verification that are no more valid;*
- c) *the technical file accompanying the 'EC' declaration of verification shall include a demonstration that the impact of modifications is limited to the basic parameters referred to in point (a);*
- d) *provisions of Section 1 of this Annex shall apply mutatis mutandis to this complementary 'EC' declaration of verification;*
- e) *the original 'EC' declaration of verification shall be considered valid for the basic parameters not concerned by the modification.*

› Annex VI 'EC' Verification procedure for Subsystems

"[...]

*"'EC' verification' means a procedure carried out by the applicant within the meaning of Article 18 to demonstrate that the **requirements of the relevant Union legislation including any relevant national rules** relating to a subsystem have been fulfilled and the subsystem may be authorised to be placed in service.*

[...]

2.3. Certificate of verification

2.3.1. The notified bodies responsible for the verification assesses the design, production and final testing of the subsystem and draw up the certificate of verification intended for the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), who in turn draws up the 'EC' declaration of verification. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.

[...]

2.4. Technical file accompanying the EC declaration of verification

The technical file accompanying the EC declaration of verification shall be assembled by the applicant (in the meaning of Article 18) and must contain the following:

- a. technical characteristics linked to the design including general and detailed drawings with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned;
- b. a list of interoperability constituents, referred to in Article 5(3)(d), incorporated into the subsystem;
- c. the technical files referred to in Article 18(3), compiled by each of the notified bodies involved in the verification of the sub-system, which shall include:
 - copies of the 'EC' declarations of conformity and, where applicable, 'EC' declarations of suitability for use established for interoperability constituents referred to in Article 5(3)(d) and accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications, where available, the ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity,
 - the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;
- d. certificates of verification issued in accordance **with other legislation deriving from the Treaty**;
- e. when verification of safe integration is required pursuant to Article 15, the relevant technical file shall include the assessors' report(s) on the common safety methods (CSM) on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.

[...]"

3.4. Regulation (EU) 2018/545 (as amended)

- › "Article 2(3) '**configuration management**' means a systematic organisational, technical and administrative process put in place throughout the lifecycle of a vehicle and/or vehicle type to ensure that the consistency of the documentation and the traceability of the changes are established and maintained so that:
 - a) **requirements from relevant Union law and national rules are met**;
 - b) changes are controlled and documented either in the technical files or in the file accompanying the issued authorisation;
 - c) information and data is kept current and accurate;
 - d) relevant parties are informed of changes, as required;"
- › "Article 2(11) '**requirements capture**' means the process of identification, assignment, implementation and validation of requirements performed by the applicant in order to ensure that **relevant Union and national requirements are complied with**. Requirements capture may be integrated in the product development processes;"
- › "Article 2(15) '**vehicle authorisation for placing on the market**' means the decision issued by the authorising entity based on a **reasonable assurance** that the applicant and the entities involved in the design, manufacture, verification and validation of the vehicle have fulfilled their respective obligations and responsibilities in order to ensure **conformity with essential requirements of the**

applicable legislation or to ensure conformity with the authorised type enabling that the vehicle may be placed on the market and may be used safely in the area of use according to the conditions for use and other restrictions, when applicable, specified in the vehicle authorisation and in the vehicle type authorisation;”

- › “Article 2(16) ‘**vehicle type authorisation**’ means the decision issued by the authorising entity based on **reasonable assurance** that the applicant and the entities involved in the design, manufacture, verification and validation of the vehicle type have fulfilled their obligations and responsibilities in order to **ensure conformity with the essential requirements of the applicable legislation** enabling that a vehicle manufactured according to this design may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions for use of the vehicle and other restrictions, when applicable, specified in the vehicle type authorisation and to be applied to all vehicle authorised in conformity to this type;”

- › Article 3 Responsibilities of the applicant

“The applicant shall submit its application for vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with the provisions of this Regulation.

It is the responsibility of the applicant to **ensure that the relevant requirements from applicable legislation are identified and met** when submitting its application for vehicle type authorisation and/or vehicle authorisation for placing on the market.”

- › Article 26 Perform verifications and establish evidence

“1. The applicant shall, as applicable per authorisation case, perform the necessary checks in order to establish the evidence referred to in Annex I.

[...]”

- › Article 28 Establishment of evidence for the application

“The **applicant** for a vehicle type authorisation and/or a vehicle authorisation for placing on the market **shall establish the evidence** for the application by:

- a) putting together the **EC declarations of verification for the subsystems** composing the vehicle and providing the evidence, in the technical file accompanying the EC declarations, of the conclusions of the conformity assessments done following the identification carried out pursuant to Article 21;

[...]”

- › Article 38 Assessment of the application

“The assessment of the application shall be carried out by the authorising entity and the concerned NSAs for the area of use to establish a **reasonable assurance** that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities in the design, manufacture, verification and validation stages of the vehicle and/or vehicle type in order to ensure **conformity with the essential requirements of the applicable legislation** so that it may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions of use and other restrictions specified within the application.”

- › Article 48 The information in the issued vehicle type authorisation

“The vehicle type authorisation issued by the authorising entity shall contain the following information:

[...]”

- d) an identification of:
 - i. the vehicle type ID, in accordance with Annex II to Commission Implementing Decision 2011/665/EU (1);
 - ii. the vehicle type variants, where applicable;

- iii. *the vehicle type versions, where applicable;*
- iv. *values of the parameters set out in the TSIs and, where applicable, in the national rules, for checking the technical compatibility between the vehicle and the area of use;*
- v. *the **vehicle type's compliance with the relevant TSIs and sets of national rules**, relating to the parameters referred to in paragraph 1(d)(iv);*
- e) *reference to the **EC declarations of verification** for the subsystems;*
- f) *reference to **other Union or national law** with which the vehicle type is compliant;*

[...]"

- › Annex I Content of the application

"[...]

18.5 EC Declarations of Verification for the mobile subsystems, including accompanying technical files (Article 24 Directive (EU) 2016/797).

[...]"

- › Annex II Aspects for assessment by the authorising entity

"[...]

3. **The TSIs and other applicable Union law** identified by the applicant are correct

8. **EC Declarations of Verification and EC certificates** (Article 15 Directive (EU) 2016/797), check

[...]

8.6 All applicable legislation is covered, including other non-railway related legislation

[...]"

- › Annex III Aspects for assessment by the concerned NSAs for the area of use

"[...]

3. **The national rules and requirements for the concerned area of use** identified by the applicant are correct

[...]"

3.5 Guide for the application of the CCS TSI GUI/CCS TSI/2020

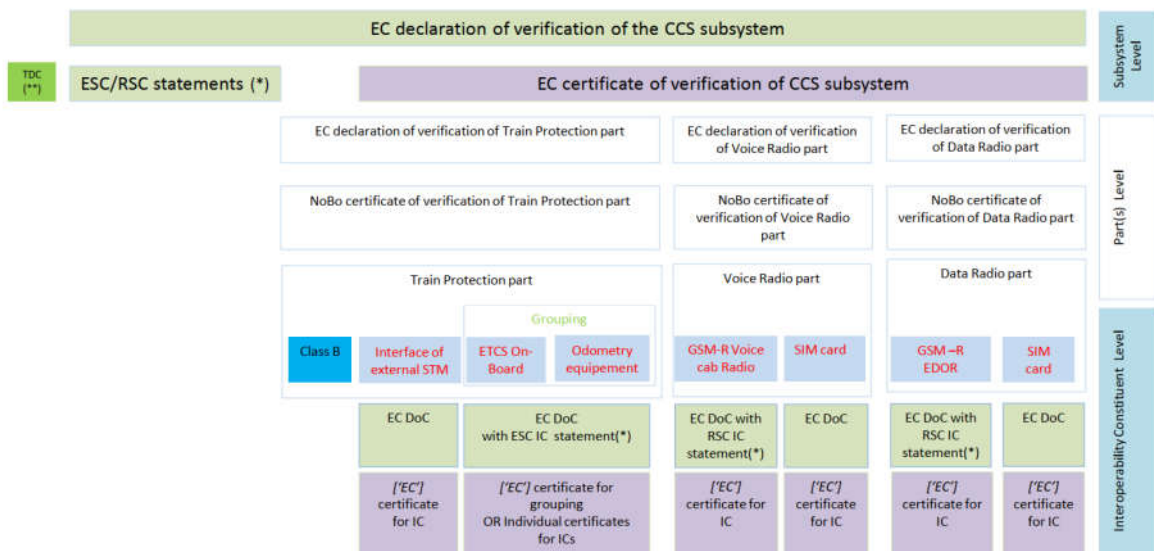
- › "2.6.57. It is required that at least one ESC/RSC Statement defined for each network inside the area of use is provided at the time of the requesting the vehicle authorisation. The provided ESC/RSC Statement must demonstrate the complete technical compatibility of the Class A systems, i.e. not limited to Level 0 or Level NTC operations. The ESC/RSC statement for the subsystem should include all the evidences (or proper justifications) for all the ESC/RSC type checks. If some of the checks have been done at the IC level, justification of their validity at subsystem level should be provided."
- › "2.6.58. The ESC/RSC Statements and the related NoBo ESC/RSC Statement Report should be included by the applicant of vehicle authorisation in the Technical File accompanying the EC Declaration of Verification. If there is any ESC /RSC IC Statements it should be included in the Technical File accompanying EC Declaration of Conformity. Each time the ESC/RSC Statements in a vehicle type are updated, this should be reflected in the Technical File accompanying the EC Declaration of Verification and therefore a new EC Declaration of Verification should be issued."
- › "2.6.59. The ESC/RSC checks successfully passed by the on-board subsystem and verified by a NoBo will be recorded in the authorisation as Basic Design Characteristics. They will also be included in ERATV in the relevant parameters (See Application Guide section 2.6.66 Basic Design Characteristics and ERATV)"
- › "2.6.76. The main task of the NoBo with regards to the ESC/RSC statement(s) and associated report is to verify the correctness and completeness of the check report for the subsystem, according to the

requirements in the CCS TSI Section 6.3.3.1. As indicated in Annex 6, it is possible to have checks passed at IC level test, but they should remain valid and reported in the final check report for the subsystem.”

- › “2.6.81. The NoBo will draw up a statement report with their check of the ESC / RSC check report, including the conditions (if any), to be attached to the vehicle technical file in the EC Declaration of verification drafted by the applicant of vehicle authorisation.”
- › “2.6.112. The following figure illustrate the components inside an EC declaration of verification of the on-board subsystem:



EC certification and the use of parts in CCS



(*) After checking by a NoBo; (**) Train Detection Compatibility is verified at LOC and PAS TSI subsystem level; Groupings and parts are OPTIONAL

Figure 7.- EC certification and the use of parts in CCS

”