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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/250

of 12 February 2019

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 9(4), Article 15(9) and Article 24(4) thereof,

Whereas:

(1) Manufacturers or their authorised representatives, applicants, notified bodies and designated bodies should use harmonised templates for documents that accompany the application for an authorisation for the placing in service of fixed installations or a vehicle authorisation for placing on the market in order to streamline the assessment by the European Union Agency for Railways ('the Agency') or a national safety authority of those applications and in order to facilitate the supervision of the Union rail system by national safety authorities.

(2) There is a need to facilitate the establishment of 'EC' declarations provided for in Directive (EU) 2016/797. In particular, there is a need to facilitate the establishment of 'EC' declaration of conformity or suitability for use of interoperability constituents, 'EC' declaration of verification of subsystems, intermediate statement of verification of subsystems, declaration of conformity to an authorised vehicle type.

(3) There is also a need to facilitate the establishment of the technical file that is to accompany the 'EC' declarations by setting templates for 'EC' certificate of conformity or suitability for use of an interoperability constituent, 'EC' certificate of verification of a subsystem delivered by a notified body and certificate delivered by a designated body.

(4) 'EC' declaration of conformity and 'EC' declaration of suitability for use and their accompanying documents should provide evidence that the interoperability constituents have been subject to the procedures laid down in the corresponding technical specifications for interoperability ('TSI') for assessing conformity or suitability for use and indicate the references of those TSIs and other relevant Union acts.

(5) An 'EC' declaration of suitability for use of interoperability constituents being issued on the basis of in-service experience should be considered as a supplementary declaration to the 'EC' declaration of conformity of interoperability constituent.

(6) The nature of information to be provided should allow for one template to be used to accommodate both 'EC' declaration of the conformity of the interoperability constituent and 'EC' declaration of the suitability for use of the interoperability constituent.

(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.

(10) One template should be used to accommodate the 'EC' declaration of verification and potential changes that could affect its elements during the lifecycle of the subsystem.

(11) Intermediate Statement of Verification of subsystem, its annex and accompanying documentation should provide evidence of the completion of a stage of the relevant verification procedure of a subsystem, or of a part of a subsystem, in accordance with the applicable Union law and relevant national rules. It should also indicate the references of the Directives, TSIs and other relevant Union acts as well as relevant national rules.

(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.

(14) On 19 December 2017, the Agency issued a recommendation on 'EC' declaration of verification of subsystems and templates referred to in Article 9(4), Article 15(9) and Article 24(4) of Directive (EU) 2016/797.

(15) Annexes IV and V to Directive 2008/57/EC of the European Parliament and of the Council[(2)] on the content of 'EC' declaration of conformity or suitability for use and 'EC' declaration of verification are repealed by Directive (EU) 2016/797, the provisions concerned should therefore be replaced.

(16) Commission Regulation (EU) No 201/2011[(3)] should be repealed.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 51(1) of Directive (EU) 2016/797,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down:

(a) the template for the 'EC' declaration of conformity or suitability for use of an interoperability constituent as referred to in Article 9(2) of Directive (EU) 2016/797;

(b) the details of the 'EC' verification procedures of subsystems and the template for the 'EC' declaration of verification as referred to in Article 15(9) of Directive (EU) 2016/797;

(c) the template for the Intermediate Statement of Verification of the subsystem as referred to in Article 15(9) of Directive (EU) 2016/797;

(d) the template for the certificates of conformity or suitability for use of an interoperability constituent as referred to in Article 9(2) and the template for the certificates of verification of a subsystem as referred to in Article 15(9) of Directive (EU) 2016/797;

(e) the model of declaration of conformity to an authorised vehicle type as referred to in Article 24(4) of Directive (EU) 2016/797.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/250. (See end of Document for details)*

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(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.

(e) 'Intermediate Statement of Verification' means the document established either by the notified body selected by the applicant, in the case of TSI requirements, or by a designated body, in the case of requirements stemming from national rules, which registers the results of a stage of the verification procedure;

(f) '"EC" certificate of conformity' means the certificate delivered for an interoperability constituent by the notified body of the conformity of an interoperability constituent, considered in isolation, with the Union technical specifications to be met;

(g) '"EC" certificate of suitability for use' means the certificate delivered for an interoperability constituent by the notified body of the suitability for use of an interoperability constituent considered within its railway environment;

(h) 'certificate of verification' means the certificate delivered for a subsystem either by the notified body or by the designated body regarding the verification of conformity respectively with relevant TSIs or with relevant national rules from the design stage to the acceptance stage before the subsystem is placed on the market or in service and which covers verification of the interfaces of the subsystem in question with the system into which it is incorporated;

(i) '"EC" certificate of verification' means the certificate delivered for a subsystem by the notified body regarding solely the verification of conformity with relevant TSIs;

(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.

(k) 'ERADIS ID' means the alphanumeric code used to identify an 'EC' declaration of conformity or suitability for use of interoperability constituent or an 'EC' declaration of verification of subsystem and which is established in accordance with Annex VII.

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[(6)].

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.