

Agency proposal

For the Commission Implementing Acts on 'EC' declaration of verification of subsystems and templates referred to in Articles 9(4), 15(9) and 24(4) of Directive (EU) 2016/797

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Introduction

This document is the final proposal for future Regulations sent by the Agency to DG MOVE.

This final proposal includes three sections that mirror the Implementing Acts requested by articles 9(4), 15(9) and 24(4) of Directive (EU) 2016/797 in relation to the creation of templates for the ‘EC’ declaration of conformity or suitability for use of interoperability constituents, for the ‘EC’ declaration of verification of subsystems and for the model of declaration of conformity to type.

The final proposal has been developed following the written procedure for exchanging of views with the stakeholders.

1. *Template of the ‘EC’ declaration of conformity or suitability for use of interoperability constituents and list of accompanying documents referred to in Article 9(4) of Directive (EU) 2016/797*

Recitals

- (1) The accompanying documents to the declaration of conformity or suitability for use should provide evidence of the completion of the relevant procedures for verification in accordance with the applicable Union law, and indicate the references of the directives, technical specifications for interoperability and European specifications.
- (2) The ‘EC’ declaration of suitability for use of interoperability constituents is issued on the basis of in-service experience; it should be seen as a supplementary declaration to the ‘EC’ declaration of conformity of interoperability constituents.
- (3) One template will be used to accommodate both ‘EC’ declarations:
 - ‘EC’ declaration of conformity of interoperability constituent; and
 - ‘EC’ declaration of suitability for use of interoperability constituents

Article 1

Subject matter

This Regulation establishes the template for the ‘EC’ declaration of conformity or suitability for use of interoperability constituents referred to in Article 9(4) of Directive (EU) 2016/797¹.

Article 2

Definitions

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

- (a) ‘elements of the declaration’ means the information or data that shall be provided according to the template.
- (b) ‘‘EC’ declaration of conformity of interoperability constituent’ means the declaration established by the applicant in which the applicant declares on his sole responsibility that the interoperability constituent concerned, which has been subject to the relevant verifications procedures, satisfies the requirements of the relevant Union law and other requirements relevant for compliance with essential requirements.
- (c) ‘‘EC’ declaration of suitability for use of interoperability constituents’ means the supplementary declaration to the ‘EC’ declaration of conformity of interoperability

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 (recast) (OJ L 138, 26.5.2016, P. 44 202)

constituent established by the applicant in which the applicant declares on his own responsibility that the interoperability constituent concerned, which has been subject to the relevant verification procedure, satisfies the requirements for suitability for use specified in the relevant TSI.

Article 3

Template of certificate

1. The ‘EC’ declaration of conformity or suitability for use of interoperability constituents shall have the template set out in Annex I of this Regulation.
2. The elements in Annex I specify the mandatory minimum information that shall be provided by the manufacturer or its authorised representative when establishing the ‘EC’ declaration of conformity or suitability for use of interoperability constituent.

Article 4

Establishing the ‘EC’ declaration

1. The ‘EC’ declaration of conformity or suitability for use of interoperability constituents and the accompanying documents shall be dated and signed by the manufacturer or its authorised representative.
2. The ‘EC’ declaration shall be written in one of the official languages of the Union and it shall be in the same language as the accompanying documents.

Article 5

Accompanying documents

The following documents shall accompany the ‘EC’ declaration of conformity or suitability for use of interoperability constituents:

1. Certificate(s) of verification of interoperability constituent¹.
*[‘EC’ Design Examination Certificate; ‘EC’ Type Examination Certificate; Quality Management System approval certificate; other certificates]*²
2. Technical documentation³.

Article 6

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

¹ According to Article 9(2) of Directive (EU) 2016/797.

² The information in square brackets [] is provided to support the user in correctly and exhaustively compiling the list.

³ According to the Article 24(6) of Directive (EU) 2016/797.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797. It shall apply in all Member States from 16 June 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I

TEMPLATE OF 'EC' DECLARATION OF CONFORMITY OR SUITABILITY
FOR USE OF INTEROPERABILITY CONSTITUENTSEC declaration identification number – *[ERADIS ID]*¹

We,
Manufacturer or Authorised representative
[Business name]
[Complete postal address]

Declare under our own responsibility that the following interoperability constituent:
[Name/short description of interoperability constituent/type]

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]

has been assessed by Notified Body:
[Business name]
[Registration number]
[Full address]

In accordance with the following approval(s) and/or certificate(s):
[Approval(s), date of issue]
[Certificate number(s), date of issue]

The following restrictions or conditions of use apply:
List of restrictions or conditions of use

The following procedures have been followed in order to declare conformity:
[The modules chosen by manufacturer for the assessment of the interoperability constituent]

List of Annexes
[Titles of the Annexes (Technical documentation or technical file accompanying the 'EC' declaration of conformity or suitability for use)]

Done on:
[Date DD/MM/YYYY]

Signature of Manufacturer/Authorised representative
[First Name, Surname]

¹ The information in square brackets [] is provided to support the user in correctly and exhaustively compiling the template.

2. *‘EC’ verification procedure for subsystems and the templates referred to in article 15(9) of the Directive (EU) 2016/797*

2.1 ‘EC’ declaration of verification of subsystems and the template for the ‘EC’ declaration of verification

Recitals

- (1) Directive (EU) 2016/797 will repeal Directive 2008/57/EC¹, however the provisions of the Annex V regarding the ‘EC’ declaration of verification of subsystems and for its related template should not be lost.
- (2) The technical file accompanying the ‘EC’ declaration of verification of subsystems 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, technical specifications for interoperability, national rules and other requirements.
- (3) One template will be used to accommodate the ‘EC’ declaration and potential changes that could affect its elements during the lifecycle of the subsystem.

Article 1 Subject matter

This Regulation lays down the requirements for the ‘EC’ declaration of verification of subsystems and its related template referred to in Article 15(9) of Directive (EU) 2016/797².

Article 2 Definitions

For the purpose of this Regulation, the following definition shall apply:

- (a) ‘elements of the declaration’ means the information or data that shall be provided according to the template.
- (b) ‘‘EC’ declaration of verification of a subsystem’ means the declaration established by the applicant in which the applicant 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 law, any relevant national rules and other requirements relevant for compliance with essential requirements.

¹ Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the Interoperability of the rail system within the Community (Recast) (OJ L 191, 18.7.2008, p. 1)

² 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 (recast) (OJ L 138, 26.5.2016, P. 44 202)

Article 3

‘EC’ declaration of verification of subsystem

1. The ‘EC’ declaration of verification shall be based on the information resulting from the verification procedure(s) for subsystems set out in Article 15 of the Directive (EU) 2016/797.
2. The ‘EC’ declaration of verification of subsystem referred to in Article 15 (9) of Directive (EU) 2016/797 shall contain the elements specified in the template set out in Annex I to this Regulation.
3. The ‘EC’ declaration of verification of subsystems shall be written in one of the official languages of the Union and it shall be in the same language as the accompanying file.
4. The elements in Annex I specify the mandatory minimum information that shall be provided by the applicant when establishing the ‘EC’ declaration of verification of subsystem.

Article 4

‘EC’ declaration of verification of subsystem in case of changes

1. In the event that an element of the initial ‘EC’ declaration of verification of subsystem is changed the applicant shall establish a new ‘EC’ declaration of verification of subsystem.
2. When a new ‘EC’ declaration of verification of the subsystem is issued by the applicant the procedure for establishing the ‘EC’ declaration of verification set out in article 15 of the Directive (EU) 2016/797 shall apply to the changed elements of the relevant ‘EC’ declaration of verification of subsystem.
3. The initial ‘EC’ declaration of verification of a subsystem remains valid for the subsystem until there is a change either to the conditions under which it was established or to the legislation that was applicable when the subsystem was placed on the market or in service.

Article 5

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797. It shall apply in all Member States from 16 June 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I
TEMPLATE OF ‘EC’ DECLARATION OF VERIFICATION OF SUBSYSTEM

‘EC’ Declaration of Verification of Subsystem

‘EC’ declaration identification number *[ERADIS ID]*¹

We, Applicant:

Business name

Complete postal address

Declare under our own responsibility that the following subsystem:

[Name/short description of the subsystem 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;]

has been assessed by conformity assessment bodies:

Notified Body:

Business name

Registration number

Full address

Designated Body:

Business name

Identification number

Full address

Assessment body (CSM RA)

Business name

Identification number

Full address

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]

The following procedures have been followed in order to declare conformity:

[The modules chosen by applicant for the verification of the subsystem]

Identification of the technical file accompanying this declaration pursuant to article 15.4 of Directive (EU) 2016/797

[Reference to the technical file accompanying the ‘EC’ declaration of verification of subsystem]

Reference to former ‘EC’ declaration of verification (where applicable)

[Yes/No]

Done on:

[date DD/MM/YYYY]

Signature of Applicant

First Name Surname

¹ The information in square brackets [] is provided to support the user in correctly and exhaustively compiling the template.

2.2 Template of Intermediate Statement of Verification

Recitals

- (1) Directive (EU) 2016/797 will repeal Directive 2008/57/EC¹, however the provisions of Annex V of the latter directive regarding the ‘EC’ declaration of verification of subsystems and its related template should not be lost.
- (2) The annex and accompanying documents are integral parts of the Intermediate Statement of Verification of subsystem. They 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, and indicate the references of the directives, technical specifications for interoperability, national rules and other requirements.

Article 1

Subject matter

This Regulation establishes the template for the Intermediate Statement of Verification for subsystem referred to in Article 15(9) of Directive (EU) 2016/797².

Article 2

Definitions

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

- (a) ‘elements of the Intermediate Statement of Verification’ means the information or data that shall be provided according to the template.
- (b) ‘Intermediate Statement of Verification’ is established either by the notified body selected by the applicant, in case of TSI requirements, or by a designated body, in case of national rules requirements, and documents the results of a stage of the verification procedure.

Article 3

Intermediate Statement of Verification

1. The Intermediate Statement of Verification shall be based on the same relevant conformity assessment modules as those used for the certification of a subsystem.
2. The Intermediate Statement of Verification of subsystem referred to in Article 15(9) of Directive (EU) 2016/797 shall use the template set out in Annex II of this Regulation.
3. The elements in Annex II specify the mandatory minimum information that shall be provided when a notified body or a designated body establishes the Intermediate Statement of Verification.

¹ Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the Interoperability of the rail system within the Community (Recast) (OJ L 191, 18.7.2008, p. 1)

² 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 (recast) (OJ L 138, 26.5.2016, P. 44 202)

Article 4

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797. It shall apply in all Member States from 16 June 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX II

TEMPLATE OF INTERMEDIATE STATEMENT OF VERIFICATION

Intermediate Statement of VerificationNumber *[unique ISV identification number]*¹**Object of Assessment:***[Unique Identification of the subsystem or of the part of the subsystem: identification of whole or of the part of the subsystem, and stages of verification in accordance with Annex IV – Section 2.2.3 of Directive (EU) 2016/797²]***Applicant, where applicable also Manufacturer and Manufacturing Locations:***[Name(s), Address(es)]***Assessment Requirements:***[Reference to: the Directive(s), the TSI(s), the non-application of TSI(s), the relevant National Rules, European specifications, other Acceptable Means of Compliance]***Module(s) applied:***[The modules as chosen by the applicant for the assessment of the subsystem or of a part of the subsystem, and stages of verification]***Assessment/Audit result:***[Including reference to the assessment/audit report]***The following conditions and limits of use apply:***[List or reference to the list of conditions and limits of use]***Annex of ISV³ (where applicable)***[Yes/No]***Documentation accompanying this ISV:***[reference to accompanying documents; list or file of documents used for the assessment]***Validity:***[Time and conditions of validity of ISV]***Done on:***[date DD/MM/YYYY]***Notified Body***Signature**First Name, Surname**Business name**Registration number**Complete postal address**[OR]***Designated Body***Signature**First Name, Surname**Business name**Identification number**Complete postal address*

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¹ The information in square brackets [] is provided to support the user in correctly and exhaustively compiling the template.

² 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 (recast) (OJ L 138, 26.5.2016, P. 44 202)

³ It is good practice to issue ISV as a single page document; if the relevant information for the ISV does not fit all on one page, the Annex provides sufficient space for any other relevant information to be considered.

Annex to Intermediate Statement of Verification [where applicable]

Number [unique ISV identification number]

Object of Assessment:

[Unique Identification of the subsystem or of the part of the subsystem: identification of whole or of the part of the subsystem, and stages of verification in accordance with Annex IV – Section 2.2.3 of Directive (EU) 2016/797⁴]

Done on:

[date DD/MM/YYYY]

Notified Body

Signature

First Name, Surname

Business name

Registration number

Complete postal address

[OR]

Designated Body

Signature

First Name, Surname

Business name

Identification number

Complete postal address

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⁴ 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 (recast) (OJ L 138, 26.5.2016, P. 44 202)

2.3 Template of the certificate of verification

Recitals

- (1) The template of the certificate of verification should be harmonised at European level and be used by conformity assessment bodies for the purpose of Article 30 of Directive (EU) 2016/797¹.
- (2) One template will be used to accommodate the:
 - a. ‘EC’ certificate of verification delivered by a notified body for a subsystem.
 - b. ‘EC’ certificate of conformity delivered by a notified body for an interoperability constituent.
 - c. ‘EC’ certificate of suitability for use delivered by a notified body for an interoperability constituent.
 - d. Certificate delivered by a designated body.

Article 1

Subject matter

This Regulation establishes the template for the certificates of verification of a subsystem, and for an interoperability constituent, as referred to in Article 9(4) and 15(9) of Directive (EU) 2016/797.

Article 2

Definitions

For the purpose of this Regulation, the following definition shall apply:

- (a) ‘‘EC’ certificate of verification’ mean the certificate delivered for a subsystem by the notified body.
- (b) Certificate of verification means’ the certificate delivered for a subsystem by the designated body.
- (c) ‘‘EC’ certificate of conformity means’ the certificate delivered for an interoperability constituent by the notified body.
- (d) ‘‘EC’ certificate of suitability for use is the certificate delivered for an interoperability constituent by the notified body supplementary to ‘EC’ certificate of conformity for an interoperability constituent.

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 (recast) (OJ L 138, 26.5.2016, P. 44 202)

Article 3

Template of certificate

1. The certificate and the ‘EC’ certificates mentioned in Article shall have the template structure set out in Annex III of this Regulation.
2. The elements in Annex III specify the mandatory minimum information that shall be provided by the notified body when issuing the ‘EC’ certificate of verification or ‘EC’ certificate of conformity or suitability for use and by a designated body when issuing a certificate of verification of subsystem.

Article 4

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797. It shall apply in all Member States from 16 June 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX III

TEMPLATE OF 'EC' CERTIFICATE OF VERIFICATION
 TEMPLATE OF 'EC' CERTIFICATE OF CONFORMITY OR SUITABILITY FOR USE
 TEMPLATE OF CERTIFICATE OF VERIFICATION

['EC']¹ Certificate

Number [unique ['EC'] Certificate identification number]²

Object of Assessment:

[Unique Identification of the Interoperability Constituent or of the Subsystem]

Applicant, where applicable also Manufacturer and manufacturing locations:

[Name(s), Address(es)]

Assessment Requirements:

[Reference to: the Directive(s), the TSI(s), the relevant National Rules, European specifications, other Acceptable Means of Compliance]

Module(s) applied:

[The module(s) as chosen by the applicant for the assessment of the Interoperability Constituent or of the Subsystem]

Assessment/Audit result:

[Including reference to the assessment/audit report]

The following conditions and limits of use apply:

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

Annex³ of [EC] Certificate (where applicable):

[Yes/No]

Documentation accompanying this [EC]¹ Certificate:

[reference to accompanying documents; list or file of documents used for the assessment]

Validity:

[Time and conditions of validity of [EC] Certificate]

Done on:

[date DD/MM/YYYY]

Notified Body

Signature
 First Name, Surname
 Business name
 Registration number
 Complete postal address

[OR]

Designated Body

Signature
 First Name, Surname
 Business name
 Identification number
 Complete postal address

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¹ 'EC' applies only to NoBo Certificates, to be omitted on DeBo Certificates

² The information in square brackets [] is just provided to support the user in correctly and exhaustively compiling the template.

³ It is good practice to issue certificates as a single page document; if the relevant information for the certificate does not fit all on one page, the Annex provides sufficient space for any other relevant information to be considered.

Annex to the ['EC']⁴ Certificate [where *applicable*⁵]Number [*unique* ['EC'] *Certificate identification number*]

Object of Assessment:

[Unique Identification of the Interoperability Constituent or of the Subsystem]

Done on:

*[date DD/MM/YYYY]***Notified Body***Signature**First Name, Surname**Business name**Registration number**Complete postal address**[OR]***Designated Body***Signature**First Name, Surname**Business name**Identification number**Complete postal address*

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⁴ 'EC' applies only to NoBo Certificates, to be omitted on DeBo Certificates.

⁵ It is good practice to issue certificates as a single page document; if the relevant information for the certificate does not fit all on one page, the Annex provides sufficient space for any other relevant information to be considered.

3. Model of declaration of conformity to a vehicle type referred to in article 24(4) of Directive (EU) 2016/797

Recitals

- (1) The annexes to the declaration of conformity to a 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, technical specifications for interoperability, national rules and other requirements.
- (2) The vehicle type authorisation including, where relevant, vehicle type variant or vehicle type version which is identified by the vehicle type number, should provide information on all the legal requirements on the basis of which the vehicle type authorisation has been issued by the Agency or a National Safety Authority for a specified area of use.

Article 1

Subject matter

This Regulation establishes the model of declaration of conformity to a vehicle type referred to in Article 24(4) of Directive (EU) 2016/797.

Article 2

Definitions

For the purpose of this Regulation, ‘element of the declaration’ means the information or data that shall be provided according to the template.

Article 3

Declaration of conformity to type

1. The declaration of conformity to type referred to in Article 24(4) of Directive (EU) 2016/797 shall have the model structure set out in the Annex to this Regulation.
2. The elements in the Annex specify the mandatory minimum information that shall be provided by the applicant when establishing the declaration of conformity to a vehicle type.

Article 4

Repeal

Regulation EU 201/2011 is repealed with effect from 16 June 2020.

Article 5

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797. It shall apply in all Member States from 16 June 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX

MODEL OF DECLARATION OF CONFORMITY TO A VEHICLE TYPE

We,

Applicant ¹

[Business name]²

[Full address]

Declare under our sole responsibility that vehicle [*European Vehicle Number*]³ 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 annexes⁴

[*Titles of the annexes*]

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

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

[*name, function*] [*signature*]

Field reserved for Authorising Entity

EVN allocated to the vehicle: [*EVN*]

¹ Applicant is defined in Article 2(22) of Directive (EU) 2016/797 and may be: a railway undertaking, an infrastructure manager, a manufacturer, a contracting entity or their authorised representative.

² The information in square brackets [] is to support the user in correctly and exhaustively compiling the template.

³ If at the moment of establishing this declaration the vehicle has not yet been assigned a European Vehicle Number (EVN), the vehicle shall be identified by another identification system agreed by the applicant and the authorising entity. In this case, when an EVN has been assigned to the vehicle, the authorising entity shall fill in the field reserved for this purpose.

⁴ Annexes shall include copies of EC declaration(s) of verification of subsystem(s)