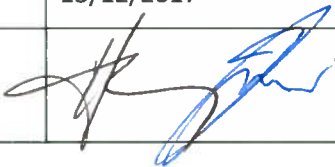




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*Accompanying report to the Agency proposal for the Commission Implementing Acts on 'EC' declaration of verification of subsystems and templates referred to in Articles 9(4), 15(9) and 24(4) of Directive (EU) 2016/797*

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## Executive Summary

This report is intended to document the activity performed for the project “‘EC’ declaration of verification of subsystems and templates”.

The objective of this report is to describe the working methodology used to develop the deliverables.

This is a project under the project on the Implementing Act on Vehicle Authorisation. Several workshops on practical arrangements for the vehicle authorisation process were organized and held in Valenciennes.

During the workshop held on 19-20 July 2016, a proposal for content for the Implementing Act on ‘EC’ declaration [10] and templates was agreed.

A working paper [11] was proposed for discussion during the workshop held on 8-10 December 2016, but due to other priorities the envisaged discussions were postponed to the workshop held on 28-29 March 2017.

The “Subgroup on the implementing act on ‘EC’ declaration” was established in July 2017, composed of representatives from NSAs, manufacturers, railway undertakings and infrastructure managers who had been involved in the workshops. The subgroup developed an updated working paper [12] which was sent on 16 November 2017 for exchange of views with stakeholders.

The working paper [12] covers the templates and the details of the verification procedure that need to be followed in order to deliver the ‘EC’ declaration of verification for a subsystem requested by the Directive (EU) 2016/797 [2].

Feedback on the working paper received from stakeholders was compiled into document ERA-PRG-005-02\_263 [13] and used to develop a draft Agency proposal for the Commission Implementing Acts ERA-PRG-005-02\_293 [14]. A written consultation process was followed to obtain comments from stakeholders, which were recorded in ERA-PRG-005-02\_297 [15]. These were taken into account in the final proposal [16] which was sent to DG MOVE on 18 December 2017.

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## Section 1 – References, definitions and abbreviations

### 1.1 Reference Documents

Table 1 : Table of Reference Documents

[Ref.]	Title	Reference	Version / date
[1]	REGULATION (EU) 2016/796 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004	(EU) 2016/796	11-05-2016
[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)	(EU) 2016/797	11-05-2016
[3]	DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety (recast)	(EU) 2016/798	11-05-2016
[4]	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)	2008/57/EC	17-06-2008
[5]	COMMISSION IMPLEMENTING REGULATION (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	(EU) 402/2013	30-06-2013
[6]	COMMISSION REGULATION (EU) No 201/2011 of 1 March 2011 on the model of declaration of conformity to an authorised type of railway vehicle	(EU) 201/2011	01-03-2011
[7]	COMMISSION DECISION of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council (2010/713/EU)	2010/713/EU	09-11-2010
[8]	DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC	768/2008/EC	09-07-2008
[9]	DIRECTIVE 2001/16/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 March 2001 on the interoperability of the trans-European conventional rail system	2001/16/EC	19-03-2001
[10]	Working paper on the structure and content of the Implementing Act on Declaration of verification	ERA-PRG-005-02_172	0.1
[11]	Working paper on Implementing Act on EC Declaration of verification of subsystems - Section 4. 5. 6 and 7 – 0.1	ERA-PRG-005-02_243	0.1
[12]	Working paper on Implementing Act on EC Declaration of verification of subsystems - Section 4. 5. 6 and 7 – 0.3	ERA-PRG-005-02_243	0.3
[13]	Compiled comments for EC Declaration and templates (ERA-PRG-005-02_243)	ERA-PRG-005-02_263	0.3
[14]	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	ERA-PRG-005-02_293	1.0

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Table 1 : Table of Reference Documents

[Ref.]	Title	Reference	Version / date
[15]	Compiled comments to the document ERA-PRG-005_02-293 - 1.0	ERA-PRG-005-02_297	1.0
[16]	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	ERA-PRG-005/02- 298	1.0
[17]	COMMISSION NOTICE The 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01)	Blue Guide	26-07-2016
[18]	Working document - Draft Commission Implementing Regulation establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council	16/797 - DV11	Version EN06
[19]	ERADIS Application Guide	ERA/GUI/02-2010/INT	Version 3.0
[20]	'REPORT MNB PROJECT - Proposal for EC Certificates Content and Templates	ERA-REP-154-CERT	Version 1.0
[21]	Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the member states relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)	Directive 2014/34/EU	26-04-2010

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## 1.2 Definitions and Abbreviations

The general terms and abbreviations used in the present document can be found in a standard dictionary. The Agency website contains a glossary of railway terms that focuses primarily on safety and interoperability terminology, but also on other areas that the Agency can use in its day-to-day activities as well as in its Workgroups for the development of future publications (<http://www.era.europa.eu/Document-Register/Pages/Glossary-of-railway-terms.aspx>).

Specific terms and abbreviations are defined below.

Table 2 : Table of Terms

Term	Definition
Agency	The European Railway Agency (ERA) such as established by the Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European railway agency, as last amended by Regulation (EC) No 1335/2008 [2].
Applicant	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.
Area of use	A network or networks within a Member State or a group of Member States in which a vehicle is intended to be used
Commission	The European Commission, in particular DG MOVE

Table 3 : Table of Abbreviations

Term	Definition
CSM	Common Safety Methods
EC	European Commission
EIN	European Identification Number
ERADIS	European Railway Agency Database of Interoperability and Safety
ERATV	European Register of Authorised Types of Vehicles
EU	European Union
IA	Implementing Act
IM	Infrastructure Manager
ISV	Intermediate Statement of Verification
MS	Member State
NoBo	Notified Body
NSA	National Safety Authority
RA	Risk Assessment
TSI	Technical Specification for Interoperability

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## Section 2 – Introduction

This report is a deliverable of the project “Implementing act on the template of the ‘EC’ verification of subsystem and other templates”

### 2.1 Legal base

The legislation that supports the activity is the “technical pillar” of the Fourth Railway Package that was published in the Official Journal (OJL 138/2016).

The technical pillar covers the update of the three existing pieces of legislation:

- › EU Regulation 2016/796 [1] on the European Union Agency for Railways repealing ‘EC’ Regulation 881/2004.
- › EU Directive 2016/797 [2] on the interoperability of the rail system within the European Union
- › EU Directive 2016/798 [3] on railway safety

Based on this legislation of the technical pillar, the Agency will be provided with new responsibilities including, among others, the issuing of vehicle authorisations.

The Directive (EU) 2016/797 [2], in Articles 9(4), 15(9) and 24 (4), specifies that the Commission shall adopt by means of an Implementing Act:

- (a) the template of the ‘EC’ declaration of conformity or suitability for use of interoperability constituents and the list of accompanying documents;
- (b) 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;
- (c) 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.
- (d) the model of declaration of conformity to type (to an authorised type of a railway vehicle).

The Commission has asked the Agency to prepare a proposal for the above described Implementing Acts.

### 2.2 Scope

The scope of these Implementing Acts is:

- Subsystem for placing on the market
  - Mobile subsystems according to Articles 15 and 20 of the Directive (EU) 2016/797 [2]
- Subsystem for placing in service
  - Fixed installations according to Article 15 and 18 of the Directive (EU) 2016/797 [2]



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- Interoperability constituents
  - o Interoperability constituents according to chapter III of Directive (EU) 2016/797 [2]
- Vehicles
  - o Vehicles in conformity with an authorised type according to Article 24(5) of the Directive (EU) 2016/797 [2]

### 2.3 Objectives

The objective of this report is to describe the working methodology used to develop the deliverable:

- Agency Proposal for the Commission Implementing Acts on 'EC' declaration of verification of subsystems and templates referred to in Article 9(4), 15(9) and 24(4) of Directive (EU) 2016/797 [2]

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## Section 3 – Working methodology

### 3.1 Workshops

The development of the Implementing Acts for ‘EC’ declaration of verification of subsystems and templates was carried out as a subproject within the overall project for the implementation of the fourth railway package.

At the end of 2015 the Agency took the decision to set up a series of workshops, involving NSA and sector representatives, for the purpose of drawing up its technical proposals for the practical arrangements for vehicle authorisation. The workshops were arranged on a regular basis at key phases of the development of the proposals in order to report on progress and to exchange views and positions among the interested parties.

As part of the workshop held on 19-20 July 2016, a proposal for the content of the Implementing Act on ‘EC’ declaration and templates [10] was presented and agreed.

“Working paper on Implementing Act on ‘EC’ Declaration of verification of subsystems - Section 4, 5, 6 and 7 – Version 0.1” [11] was proposed for discussion during the workshop held on 8-10 December 2016, but due to other priorities the envisaged discussions were postponed to the workshop held on 28-29 March 2017. During the latter workshop the proposed working paper [11] was partially discussed with no major update.

### 3.2 Subgroup – Implementing Act on ‘EC’ declaration of subsystem and templates

In July 2017 it was decided to establish a subgroup in order to expedite progress and bring more experts’ knowledge within the project.

Representatives of the stakeholders that were attending the vehicle authorisation workshops were invited to attend the subgroup. Three meetings were held between July and October 2017 with an average attendance of 12 persons representing the NSAs, the manufacturers, the railway undertakings and the infrastructure managers. The contributors to the subgroup were: NSA DE, NSA DK, NSA FI, NSA FR, NSA UK, UNIFE, CER, EIM and NB Rail.

The working methodology applied for these three subgroup meetings was:

The documents were made available to the participants (on the extranet workspace) and by email three weeks before the meeting. The participants were asked to provide their comments two days before the

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subgroup meeting at the latest in order for the comments to be taken into account for the organisation of the meeting. The Agency provided a template to be used for the comments.

The comments received were evaluated by the Agency using the categories provided for in the template. Those comments that were categorised as “D” (Discussion necessary) were collated for the subgroup meetings. The other comments were dealt with by means of written responses.

During the subgroup meetings the work was organised as follows:

1. The Agency made introductory presentations of the documents and the comments received.
2. A proposal from the Agency was presented for discussions.
3. The comments that were compiled for the meeting were discussed.
4. Based on activity 3 the subgroup arrived at conclusions.
5. Summary by the Agency staff.

After the meetings the Agency:

1. Finalised the written answers to all comments received (including those comments received after the deadline) taking into account the discussions. The answers to the comments were uploaded to the extranet workspace within one week of the meeting.
2. Updated the documents taking into account the comments received and the conclusions reached at the subgroup meetings. The amended documents were uploaded to the extranet workspace.

The documents proposed for discussions and the conclusions can be found on the ERA Extranet dedicated workspace for managing the activity of the subgroup:

<https://extranet.era.europa.eu/4RWPW/Meetings/Forms/meeting.aspx>

- Meeting No.1 – [6 July 2017](#)
- Meeting No.2 – [7 September 2017](#)
- Meeting No.3 – [19 October 2017](#)

### 3.3 Working papers

Several working papers were developed during the timeframe of the sub-project.

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### 3.3.1 Working paper-The structure and content of the Implementing Act on ‘EC’ Declarations and templates

The intention of this working paper [10] was to propose and collect the requirements for change to the part of the ‘EC’ verification procedure that mandates the applicant to establish the ‘EC’ declaration of verification of a subsystem and for some harmonised templates required for the applicant to use within the authorisation process.

### 3.3.2 Working paper-Implementing Act on ‘EC’ Declaration of verification of subsystems - Section 4, 5, 6 and 7

The intention of this working paper [11] was to propose and collect the requirements for change to the part of the ‘EC’ verification procedure that mandates the applicant to establish the ‘EC’ declaration of verification of a subsystem and for some harmonised templates required for the applicant to use within the authorisation process.

This working paper [11] was the basis for discussions within the work performed by the subgroup.

Several updates have been made following the comments sent by the members of the subgroup and the discussions during the subgroup meetings.

The comments have been compiled and processed in the document: ERA-PRG-005-02\_263 Compiled comments for ‘EC’ Declaration and templates (ERA-PRG-005-02\_243)

An updated working paper [12] has been developed in conjunction with the “Subgroup on the implementing act on ‘EC’ declaration”.

### 3.3.3 Working paper-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

The working paper [12] was updated according to the internal discussions in the Agency. The updated version “Agency proposal for the Commission Implementing Acts” [14] was sent on 16 November 2017 for exchange of views with stakeholders.

The latter working paper [14] covers the templates and the details of the verification procedure that needs to be followed in order to deliver the ‘EC’ declaration of verification for a subsystem requested by the Directive (EU) 2016/797 [2].

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### 3.3.4 Working paper–Final 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

The working paper [14] was amended by incorporating the comments [15] received from the stakeholders, and the final proposal [16] was sent to DG MOVE on 18 December 2017.

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## Section 4 – The details of the ‘EC’ Verification Procedure for subsystems

### 4.1 Introduction

The ‘EC’ verification procedure is the process carried out by the applicant for the placing on the market or in service of the subsystem to demonstrate that the requirements of the relevant Union law and any relevant national rules relating to that subsystem have been fulfilled and the subsystem may be authorised to be placed on the market or in service.

### 4.2 ‘EC’ Verification procedure

The ‘EC’ verification procedure for subsystems – Annex IV of Directive (EU) 2016/797 [2] – mandates the verification procedure in the case of TSIs and national rules, including Intermediate Statements of Verification and documents to be submitted by the applicant.

The Decision 2010/713/EU [7] makes mandatory the modules for procedures for assessment of conformity and suitability for use of the interoperability constituents and for ‘EC’ verification of subsystems, without detailing the part of verification procedure for establishing the ‘EC’ declaration of verification of subsystems.

Current Commission Decision 2010/713/EU [7] on modules makes mandatory in its scope that “The modules shall be applicable to all TSIs which enter in force on or after January 2011”.

Today’s common understanding is that the modules should also be applicable to National Rules, therefore there is a need to include them in the scope either by updating the above Decision or by supplementing the legal text.

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## Section 5 – ‘EC’ Declaration of verification for subsystems

### 5.1 Introduction

Much of Annexes IV and V of the Directive 2008/57/EC [4] and of the current regulation 201/2011/EU [6] are still valid but require updating to cover new developments and to take account of the changes introduced by the Fourth Railway Package with regard to the legal references and terminology.

Changes are necessary:

1. To ensure consistency with EU legal texts:
  - Directive (EU) 2016/797 [2], in respect of Article 15, “Procedure for establishing the ‘EC’ declaration of verification”, and Annex IV, “‘EC’ verification procedure for subsystems”, in particular with Articles 15(1), 15(2), 15(8), 21(5) and 21(8).
  - Annex III of Decision 768/2008/EC [8], “EC Declaration of conformity”
2. To allow the update and development of new templates specified in Article 15(9) of the Directive (EU) 2016/797 [2] based on the existing templates proposed by the Agency in 2011:
  - “‘EC’ declaration of conformity of interoperability constituents”
  - “‘EC’ declaration of verification of subsystems”
  - “Model of declaration of conformity to an authorised type of vehicle”
3. To accommodate the provisions of Article 20 of Directive (EU) 2016/797 [2], “Placing on the market of mobile subsystems”.
4. To be consistent with the proposal for the Commission Implementing Regulation [18]

During the Workshop No. IV on vehicle authorisation, held in Valenciennes on 19 and 20 July 2016, the ID 24 – “Key principles for ‘EC’ Declaration of Verification of subsystems” was discussed within subgroup No.2. One of the main conclusions was that there is a need to update the provisions in Annex V.2 of Directive 2008/57/EC [4] “‘EC’ Declaration of verification of subsystems in the case of modifications.

It was also agreed, for the intermediate statement of verification, that *mutatis mutandis* principle could allow the same approach used by notified body to be used by designated body.

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## 5.2 Changes necessary to the current Annex V.1 of Directive 2008/57/EC

Each requirement from Annex V.1 of Directive 2008/57/EC [4] has been analysed during the Subgroup meetings:

- The text in the boxes is the text of Annex V of Directive 2008/57/EC [4].
- An explanation is given for the proposed changes compared to the text of Annex V.

### *‘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.*

Article 18 is replaced by article 15.

“Union Legislation” is replaced by “Union Law”

*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 shall be written in the same language as the technical file accompanying the ‘EC’ declaration of verification and must contain at least the following:*

The sentence: “The ‘EC’ declaration of verification and the accompanying documents must be dated and signed” was transferred in Article 15(2) of the Directive (EU) 2016/797 [2], therefore it shall not be repeated.

Annex IV of Directive (EU) 2016/797 [2] replaces the Annex VI of the Directive 2008/57/EC [4], therefore Annex IV shall be mentioned instead of Annex VI.

*a) the reference to this Directive, TSIs and applicable national rules,*

The reference to these acts should be part of the applicant’s statement when declaring that the subsystem meets the Union law.

This statement is included now in the elements that are captured by the declaration.

*(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,*



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Derogation is replaced by “non–application of the TSI(s)”.

*(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 authorized representative, specifying also the trade name of the contracting entity or the manufacturer),*

This section identifies the applicant by different means, therefore it will be changed to “Identification of the applicant for ‘EC’ declaration of verification of subsystem” in order to allow more possibilities for identification.

Article 18 is replaced by Article 15.

*(d) a brief description of the subsystem,*

Identification of the subsystem is missing, therefore will be added in the template.

*(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,*

This is changed to “Identification of notified body(ies) which conducted the verification(s) referred in Article 15(1)”, to be in line with Directive (EU) 2016/797 [2].

*(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,*

This is changed to “Identification of notified body(ies) which conducted the conformity assessment with other Union law”, to be in line with Directive (EU) 2016/797 [2].

*(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),*

This is changed to “Identification of the designated body(ies) which conducted the verification(s) referred to in Article 15(1)”, to be in line with Directive (EU) 2016/797 [2].

*(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,*

This is changed to “Identification 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”, to be in line with Directive (EU) 2016/797 [2].

*(i) the references of the documents contained in the technical file accompanying the ‘EC’ declaration of verification*

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This requirement does not include a direct reference to the technical file, therefore it is changed to “Identification of the technical file accompanying the ‘EC’ Declaration of verification pursuant to Article 15(4) of Directive (EU) 2016/797” [2].

*(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*

This requirement remains unchanged.

*k) the identity of the signatory (i.e. the physical person or persons authorised to sign the declaration)*

This requirement is considered as incomplete, therefore it is changed to “the identity of the signatory of the ‘EC’ declaration of verification of subsystem (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.*

This is removed due to the need to have a specific template for ISV.

1. Additional elements introduced:

I. Identification of the document by using ERADIS codification

Annex V of the Directive 2008/57/EC [4] does not required the provision of an identification number or a code for the declaration, therefore this was considered. Identification of the document will be made based on the ERADIS identification number.

II. A statement from the Applicant expressly declaring:

- that the subsystem has been subject to the relevant verification procedures
- the conformity of the subsystem with all relevant Union law, including relevant TSI(s) and National Rules.

This statement is not present in Annex V of Directive 2008/57/EC [4], therefore it needs to be introduced in order to reflect the provisions of Article 15(2) of Directive (EU) 2016/797 [2].

III. Reference to the procedures followed to declare conformity

The following text has been added: “*The following procedures have been followed in order to declare conformity: (The modules chosen by applicant for the verification of the subsystem)*”

IV. The place and date of issue of the declaration of verification of subsystem

2. Other elements addressed but not retained for the template

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## I. Validity

A subsystem is considered to be completed and finished when an 'EC' declaration is established, therefore the 'EC' declaration shall have unrestricted validity and shall remain valid in accordance with the conditions under which has been granted.

For an intermediate statement of verification the limited validity is allowed because the subsystems or part of them are still under development. This approach will allow subsystems to be perform on site and on track testing.

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### 5.2.1 Provisions for 'EC' Declaration of verification for subsystems

The 'EC' declaration of verification of a subsystem is a declaration established by the 'applicant' within the meaning of Article 15 of the Directive (EU) 2016/797 [2] 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 law, including any relevant national rules.

The 'EC' declaration of verification must be based on the information resulting from the 'EC' verification procedure(s) for subsystems set out in Annex IV of the Directive (EU) 2016/797 [2]. It shall be written in the same language as the technical file accompanying the 'EC' declaration of verification and must contain at least the following:

1. Identification of the document (ERADIS identification)
2. Identification of the applicant for 'EC' declaration of verification of subsystem:
  - Legal denomination
    - Applicant's name
    - Complete postal address
3. Identification of the technical file(s) accompanying the 'EC' Declaration of verification for subsystem pursuant Article 15(4) of Directive (EU)2016/797 [2]
4. Statement from the Applicant expressly declaring:
  - That the subsystem has been subject to the relevant verification procedures
  - The conformity of the subsystem with all relevant Union law including relevant TSIs and relevant national rules,
5. A brief description and identification of the subsystem
6. Identification of the Certificate(s) of verification from NoBos and/or DeBos and Assessment body report.
7. Identification of the notified body(ies) which conducted the verification(s) of conformity with TSI(s) referred to in Article 15(1)
  - Legal denomination
    - Notified Body name
    - Notified Body ID number
8. Where appropriate, identification of the notified body(ies) which conducted the assessment of conformity with other regulations deriving from the Treaty,
9. Where appropriate, identification of the designated body(ies) which conducted the verification(s) of conformity with national rules referred to in Article 15(8):
  - Legal denomination
  - Designated Body name
  - Full postal address
10. Where appropriate, identification of the assessment body(ies) (CSM RA) which established the safety assessment reports related to the use of the CSM on risk assessment where required by this Directive:
  - Legal denomination
  - Assessment Body CSM name

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- Full postal address
11. All the relevant temporary or final provisions, including any conditions of use and other restrictions, to be complied with by the subsystems.
  12. The procedures that have been followed in order to declare conformity with the modules chosen by applicant for the verification of the subsystem.
  13. The place and date of issue the declaration of verification of subsystem

Based on the results of the analysis the template to be used is laid down in section 2.1 – Annex I – Template of ‘EC’ Declaration of verification of subsystem of Working Paper [14].

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### 5.3 Changes necessary to the current Annex V.2 of Directive 2008/57/EC

Each requirement from Annex V.2 of Directive 2008/57/EC [4] has been analysed during the Subgroup meetings:

- The text in the boxes is the text of the Annex V.2 of Directive 2008/57/EC [4].
- An explanation is given for the proposed changes compared to the text of Annex V.

#### *'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.*

*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.*

#### Conclusions after work of the Subgroup

In the light of last developments:

- Word "modification" is replaced by "change"
- A change is considered to affect a vehicle type not a vehicle, therefore "substitution in the framework of maintenance" is considered to be wrongly used in this context.  
Moreover, Article 15(1)(a) of 16/797-DV11 [18] uses as a first threshold "a change that does not introduce a deviation from the technical files"  
In addition "there is no need for verification by a conformity assessment body, and the initial 'EC' declarations of verification for the subsystems and the vehicle type authorisation remain valid and unchanged;
- Article 20 of Directive 2008/57/EC [4] is replaced by Article 21(2) of Directive (EU) 2016/797 [2]

The Article 15.1(a) of the document 16/797- DV 11 [18] covers this situation, therefore there is no need for it to be addressed again here.

The following situation is not covered: when a reference needs to be changed in an 'EC' declaration, following an update of a certificate of verification, for example a Quality Management System Approval

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Certificate that is renewed biannually, the 'EC' Declaration needs also to address the change, therefore to be updated.

*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.*

#### Analysis performed by the Subgroup

According to Article 15(5) of Directive (EU) 2016/797, the applicant shall assess the need for a new 'EC' declaration of verification, in case of renewal or upgrading of a subsystem that results in an amendment of the technical file and affecting the validity of the verification procedures already carried out.

There are two possible scenarios for the applicant who can assess this need:

- the applicant who has contractual rights to use the original 'EC' declaration
- the applicant who has no rights over the original 'EC' Declaration

In the first scenario the applicant should be sufficiently competent to assess the implications of the change, and where appropriate to supplement the original declaration.

In the second scenario the applicant would need to establish the competency to assess the change. This can be done only if the full process from Article 15 of Directive is followed, which requires the applicant to provide all requested documents, including a complete new 'EC' Declaration of verification. In this case it is not necessary to repeat the tests performed for the elements of the subsystems not affected by the change, but the applicant should have access to the records of such tests. The applicant shall take full responsibilities for the changed subsystem.

This was in line with Article 15 of the Implementing Regulation on Vehicle Authorisation where an entity managing the change who is also the holder of the vehicle type authorisation needs only create a new vehicle type version or a new version of a vehicle type variant and provide the relevant information to the authorising entity. An entity managing the change who is not the holder of the vehicle type authorisation must follow the process for a new or first authorisation.

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The Blue Guide [17] recommends the same approach: “In any case, ***a modified product sold under the name or trademark of a natural or legal person different from the original manufacturer***, should be considered as new and subject to Union harmonisation legislation. The person who carries out important changes to the product carries the responsibility for verifying whether or not it should be considered as a new product in relation to the relevant Union harmonisation legislation. If the product is to be considered as new, this person becomes the manufacturer with the corresponding obligations. Furthermore, in the case the conclusion is that it is a new product, the product has to undergo a full conformity assessment before it is made available on the market. However, the technical documentation has to be updated in as much as the modification has an impact on the requirements of the applicable legislation. It is not necessary to repeat tests and produce new documentation in relation to aspects not impacted by the modification, as long as the manufacturer has copies (or access to copies) of the original test reports for the unchanged aspects. It is up to the natural or legal person who carries out changes or has changes carried out to the product to demonstrate that not all elements of the technical documentation need to be updated.”

#### Proposal analysed by the Subgroup

If the entity managing the change, having in the same time the rights on the ‘EC’ declaration of verification of subsystem, demonstrates that the change affects the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning some basic parameters:

- (a) it shall establish a supplementary ‘EC’ declaration of verification with reference to the basic parameters concerned;
- (b) the supplementary ‘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 is no longer valid for the parameters concerned;
- (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) same provisions for ‘EC’ Declaration of verification of subsystems shall apply to this supplementary ‘EC’ declaration of verification to the necessary extent to address the change;

If the entity managing the change, without having the rights on the ‘EC’ declaration of verification of subsystem, demonstrates that the change affects the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning some basic parameters:

- (a) it shall establish a new ‘EC’ declaration of verification
- (b) it shall apply the “Procedure for establishing the ‘EC’ declaration of verification” from Article 15 of the Directive (EU) 2016/797 for the new ‘EC’ declaration of verification of subsystem

The original ‘EC’ declaration of verification shall be considered valid for the basic parameters not concerned by the modification.



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### Conclusions after work of the Subgroup

- In both cases there is a need for a new 'EC' Declaration of verification of subsystem and same procedure should be followed in order to address the change. Therefore, there is no need to split between the holder and non-holder of the rights on the 'EC' Declaration of verification of subsystem.
- Verifications already done for the original 'EC' Declaration of verification should not be repeated and only those related to changes need to be addressed.
- A change that could affect the declaration has a wide range , such us: changes in the subsystem, changes in the vehicle that affect the subsystem, changes in the legislation, changes in the rules, changes in the certificates that accompany the declaration.
- In order to capture all these types of changes any impact on the elements that define the declaration needs to be addressed.
- In addition, in other industries it is requested to continuously update the 'EC' declaration of conformity for the product.

Based on the results of the analysis the text in section 2 of the Working Paper [16] was agreed.

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## 5.4 Changes necessary to the current Annex V.3 of Directive 2008/57/EC

Each requirement from Annex V.3 of Directive 2008/57/EC [4] has been analysed during the Subgroup meetings:

- The text in the box is the text of the Annex V.3 of Directive 2008/57/EC [4].
- An explanation is given for the proposed changes compared to the text of Annex V.

### *‘EC’ DECLARATION OF VERIFICATION OF SUBSYSTEMS IN THE CASE OF ADDITIONAL VERIFICATIONS*

*An ‘EC’ declaration of verification of a subsystem may be complemented in the case of additional verifications carried out, in particular when such additional verifications are necessary for an additional authorisation for placing in service. In this case the scope of the complementary declaration shall be limited to the scope of the additional verifications.*

#### Analysis performed by the Subgroup

Article 14(1)(c) of the Implementing Act on Vehicle Authorisation lays down the “extended area of use” vehicle authorisation case : the vehicle type authorisation and/or the vehicle authorisation for placing on the market issued by the relevant authorising entity for an already authorised vehicle type and/or vehicle in order to extend the area of use without a change of the design, pursuant to Article 21(13) of Directive (EU) 2016/797 [2].

When such authorisation is sought, the applicant shall provide evidence that the technical compatibility between the vehicle and the network that forms the new part of the area of use has been checked. This means that the vehicle shall comply with the relevant rules in the scope of the extended area of use.

After additional verifications performed to demonstrate such compliance a new ‘EC’ Declaration of verification of subsystem needs to be provided.

#### Proposal analysed by the Subgroup

*‘EC’ Declaration of verification of subsystems in the case of additional verifications*

*An ‘EC’ declaration of verification of a subsystem shall be supplemented in the case of additional verifications carried out, in particular when such additional verifications are necessary for an extended area of use. In this case the scope of the supplementary declaration shall be limited to the scope of the additional verifications.*

During the 3<sup>rd</sup> meeting of the subgroup that was held on 19<sup>th</sup> of October it was proposed:

- to extend the scope of a change and to include a possible change in the legal framework
- not to limit only to a change in the subsystem caused by a change in the vehicle

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The new proposal was laid down in order to include changes in the subsystem that are caused by:

- the upgrading or renewal of the vehicle
- the extension of area of use of the vehicle
- a change in the legal framework

Based on the results of the analysis the text in section 2 of the Working Paper [16] was agreed.

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## 5.5 Changes to the 'EC' Declaration of conformity of Interoperability Constituents

The current Annex IV of the 2008/57/EC [4] lays down the provisions for 'EC' Declaration of conformity and suitability for use of Interoperability Constituents. Based on that, ERA developed in 2011 a template for such declaration. This template is available in the ERADIS Application Guide: ERA/GUI/02-2010/INT Version 3.0 [19] and on the Agency website: <http://www.era.europa.eu/Document-Register/Pages/EC-declaration-of-conformity-of-IC-template-in-EU-languages-.aspx>. The current provisions and template need to be updated due to legislative changes.

According to Decision 2010/713/EU [7] there are two declarations:

- EC declaration of conformity, and where appropriate
- EC declaration of suitability for use

The latter is issued only when module CV is required by the TSI and is always supplementary to 'EC' declaration of conformity. Therefore, the provisions for the 'EC' declaration of conformity will be sufficient to be mandated and one template can accommodate both declarations.

Each requirement from Annex IV of Directive 2008/57/EC [4] has been analysed during the Subgroup meetings:

- The text in the boxes is the text of Annex IV of Directive 2008/57/EC [4].
- An explanation is given for the proposed changes compared to the text of Annex IV.

### *Annex IV EC' DECLARATION OF CONFORMITY AND SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS*

#### *1. Interoperability constituents*

*The 'EC' declaration applies to the interoperability constituents involved in the interoperability of the rail system, as referred to in Article 3. These interoperability constituents may be:*

##### *1.1. Multiple-use constituents*

*These are constituents that are not specific to the railway system and which may be used as such in other areas.*

##### *1.2. Multiple-use constituents having specific characteristics*

*These are constituents which are not, as such, specific to the railway system, but which must display specific performance levels when used for railway purposes.*

##### *1.3. Specific constituents*

*These are constituents that are specific to railway applications.*

Sections 1.1 to 1.3 are considered redundant and therefore removed from the proposal. In addition explanations on Interoperability Constituents are given in each TSI.

Text proposal: *The 'EC' declaration applies to the interoperability constituents involved in the interoperability of the rail system, as referred to in Article 1(2) of the Directive (EU) 2016/797 [2]*

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#### *Annex IV.2 Scope*

*The ‘EC’ declaration covers: — either the assessment by a notified body or bodies of the intrinsic conformity of an interoperability constituent, considered in isolation, to the technical specifications for interoperability to be met, — or the assessment/judgement by a notified body or bodies of the suitability for use of an interoperability constituent, considered within its railway environment and, in particular in cases where the interfaces are involved, in relation to the technical specifications for interoperability, particularly those of a functional nature, which are to be checked.*

*The assessment procedures implemented by the notified bodies at the design and production stages will draw upon the modules defined in Decision 93/465/EEC, in accordance with the conditions referred to in the TSIs.*

This requirement is now covered by Directive (EU) 2016/797 [2] in its Article 9(2), therefore there is no need for it to be repeated.

#### *Annex IV.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:*

In order to be consistent with the language requirements the text needs to be changed.

The ‘EC’ Declaration of conformity comes together with accompanying documentation, therefore “accompanying documentation” shall be mention and not to limit the accompanying documentation only to “instructions”.

Text changed:

“That declaration must be written in one of the European languages and in the same language as the accompanying documentation and must contain the following”:

*— the Directive references,*

Correct text is: “the Directive and TSI references”

Reference to relevant TSIs is missing.

*— 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),*

The decision of the subgroup was to remove this requirement as it duplicates information that is already provided.

*— description of interoperability constituent (make, type, etc.),*

Requirement kept unchanged.

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— *description of the procedure followed in order to declare conformity or suitability for use (Article 13),*

- The text “where necessary” was introduced due to the sequence that needs to be followed.
- Article 10 of Directive (EU) 2016/797 [2] needs to be mentioned.
- Text to be used: “Description of the procedure followed in order to declare conformity or, where necessary, the suitability for use (Article 10)”,

— *all the relevant descriptions met by the interoperability constituent and, in particular, its conditions of use,*

Requirement kept unchanged.

— *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,*

It should be only “Identification of notified body or bodies”. The additional requirements in this text are covered already by the previous requirements.

— *where appropriate, reference to the European specifications,*

Requirement kept unchanged

— *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.*

The identity of the signatory of the ‘EC’ declaration of conformity of interoperability constituent is considered to be sufficient. The competency of the signatory is mentioned in the Decision 2010/713/EU [7], therefore no need for it to be repeated here.

Missing requirements:

1. Identification of the document by using ERADIS codification
2. A statement from the signatory of the declaration that the interoperability constituent complies with the EU Directives and relevant Technical Specifications for Interoperability
3. The place and the date of issue of the ‘EC’ declaration of conformity of interoperability constituent

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### 5.5.1 Provisions for the 'EC' Declaration of conformity or suitability for use of Interoperability Constituents

#### Interoperability constituents

The 'EC' declaration of conformity or suitability for use of interoperability constituents applies to the interoperability constituents involved in the interoperability of the rail system, as referred to in Article 1(2) of the Directive (EU) 2016/797 [2]. The declaration of conformity and the declaration of suitability for use are combined in a single template.

The assessment procedures implemented by the notified bodies at the design and production stages will draw upon the modules defined in Decision 2010/713/EU [7], in accordance with the conditions referred to in the TSIs.

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 one of the European languages and in the same language as the accompanying documentation and must contain the following:

1. Identification of the document by using ERADIS coding or EIN
2. A statement from the signatory of the declaration that the interoperability constituent complies with the EU Directives and relevant Technical Specifications for Interoperability
3. The Directive and TSIs references
4. Description of interoperability constituent (name, short description, type, etc.),
5. Description of the procedure followed in order to declare conformity or, where necessary, the suitability for use (Article 10),
6. All the relevant descriptions met by the interoperability constituent and, in particular, its conditions of use
7. Identification of the notified body
8. Where appropriate, reference to the European specifications,
9. The identity of the signatory of the 'EC' Declaration of conformity of interoperability constituent
10. The place and the date of issue of the 'EC' Declaration of conformity of interoperability constituent

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## 5.6 Changes necessary to adapt the 'EC' Declaration template to ISV template

The intermediate statement of verification of a subsystem is a document established by the Notified Body recording the results of a stage of the verification procedure.

The ISV must be based on the information resulting from the 'EC' verification procedure for subsystems set out in Annex IV of the Directive (EU) 2016/797 [2].

There is no mandatory template in the EU legislation for the Intermediate Statement of Verification. Existing legislative text in Annex V of the Directive 2008/57/EC [4] Directive specifies that the provisions for 'EC' declaration of verification apply mutatis mutandis to ISV. There is a need to adapt such provisions to the ISV in order to introduce more clarity.

In addition, the generic template proposed by the NB RAIL – see the MNB Report [20] - is a common practice among many Notified Bodies.

In order to accommodate applicable provisions from the 'EC' declaration of verification and current practice an analysis was performed by the Subgroup.



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The table below details the results of adaptation of the provisions of 'EC' declaration of verification for subsystems to fit the purpose of the ISV:

<i>Provisions of 'EC' declaration</i>	<i>Kept? Y/N</i>	<i>Adaptation</i>
Identification of the document.	Y	<p>Information retained for the template</p> <p>Note Identification is done in the NB RAIL template via a number that is structured as follows:</p> <ul style="list-style-type: none"> <li>• Number: NNNN / T / M / YEAR / SSS / C1C2 / #</li> </ul> <p>Where:            NNNN = Notified Body Registration number at the European Commission            T = Type number of certificate            M = Module (SB, SH2 etc.) as appropriate 1, 2 or 3 characters            Year = Year of issue (4 digits)            SSS = Subsystem concerned (INF, RST, ENE, CCO*, CCT**)            C1 = Master Language of Certificate and NoBo Technical File (EU codes)            C2 = Second language of Certificate (where used) shall be EN            # = Unique number(s) as desired by each NoBo</p> <p>* Control Command and Signalling on-board            ** Control Command and Signalling trackside</p>
Identification of the Applicant for ISV	Y	<p>Information retained for the template</p> <p>In the NB RAIL template the Applicant identification is also addressed</p>
Identification of the Applicant for the placing on the market of the mobile subsystem	Y	The Applicant, and where applicable the Manufacturer and Manufacturer location to be retained
Modules applied	Y	Information is retained for the template

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Identification of the assembled technical file accompanying this ISV	N	This information is not necessary at this stage, therefore it is not retained
Applicant's statement	N	No statement is necessary at this stage, information is not retained
Brief description of the subsystem and identification of the subsystem	Y	Information to be retained and if possible identification of the subsystem (object of assessment)
Parts into which the subsystem is split (object of assessment)	Y	Information needed for ISV
Parts checked at each stage (object of assessment)	Y	Information needed for ISV
Identification of the 'EC' Certificate of verification	N	The 'EC' Certificate is not yet issued, information is not retained
Reference to EU Directives, TSIs and applicable National Rules	Y	Information to be retained Same existing information in NB RAIL template
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 non-application of the TSI(s), partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case	Y	Information to be retained Same existing information in NB RAIL template
Identification of the notified body(ies) which conducted the "EC" verification(s) referred to in Article 15(1)	Y	Information to be retained
Where appropriate, identification of the notified body(ies) which conducted the assessment of conformity with other regulations deriving from the Treaty	Y	Information to be retained
Where appropriate, identification of the designated body(ies) which conducted the verification(s) of conformity with national rules referred to in Article 15(8)	Y	Information to be retained
Where appropriate, identification 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,	Y	Information field to be retained

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References of the documents contained in the assembled technical file accompanying the ISV	Y	Documents are partially available, information field to be retained
All the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,	Y	Information to be retained
Validity of the Intermediate Statement of Verification	Y	Information field to be introduced, available only for ISV
The place and date of issue of the ISV	Y	Information to be retained
The identity of the signatory (i.e. the physical person or persons authorised to sign the ISV)	Y	Information to be retained
Additional information to be retained		
Result of assessment		

The template is presented in section 2.2 of the Working Paper [16].

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## 5.7 Changes necessary to adapt the ‘EC’ declaration of conformity to an authorised type of vehicle

Regulation (EU) 201/2011 [6] mandates in its Annex the model of declaration of conformity to an authorised type of vehicle.

Each requirement from the annex of the above Regulation has been analysed during the Subgroup meetings:

- The text in the boxes is the text of Regulation (EU) 201/2011 [6].
- An explanation is given for the proposed changes compared to the text of the Regulation

### *MODEL OF DECLARATION OF CONFORMITY TO AN AUTHORISED TYPE OF VEHICLE*

Article 24(4) of the Directive (EU) 2016/797 [2] mentions “model of declaration of conformity to type”, therefore word “authorised” shall be removed.

Clarification was brought by adding “for authorisation” after “The applicant”

We,  
*Applicant* <sup>(1)</sup>  
*[Business name]*  
*[Full address]*

*Authorised Representative:*  
*[Business name]*  
*[Full address]*

*of the applicant*  
*[Business name]*  
*[Full address]*

There is no need to mention all these entities, the Decision 2010/713/EC [7] mandates for the use of each of the modules the obligations of the manufacturer or authorised representative: for example “that the manufacturer’s obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate”.

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*Declare under our sole responsibility that vehicle [European Vehicle Number] (2) to which this declaration refers — conforms to vehicle type [ERATV identification of the type of vehicle] authorised in the following Member States: [Member State 1] under authorisation No [EIN of the type authorisation in MS 1] [Member State 2] under authorisation No [EIN of the type authorisation in MS 2] ... (indicate all MS where the vehicle type is authorised)*

There is no need to mention all Member States where the vehicle is authorised, the area of use of the vehicle is mentioned in the vehicle type authorisation.

The conformity can be declared with a version or a variant, therefore these two options should be mentioned together with the type.

*– complies with the relevant Union legislation, relevant technical specifications for interoperability and applicable national rules, as indicated in the annexes to this declaration,  
– has undergone all verification procedures necessary for establishing this declaration.*

No change

*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]  
Field reserved for NSA:  
EVN allocated to the vehicle: [EVN]*

No change

*(1) Applicant may be the contracting entity or the manufacturer or their authorised representative in the Union.  
(2) 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 competent NSA. In this case, when an EVN has been assigned to the vehicle, the NSA shall fill in the field reserved for this purpose.  
(3) Annexes shall include copies of the documents providing evidence on the completion of the relevant verification procedures in accordance with the applicable Union legislation (EC declarations of verification) and national rules.*

For footnote (3) the Subgroup considers that only the copies of 'EC' declaration(s) of verification of subsystem are sufficient to be provided. The additional information is accessible in the vehicle/version/variant type authorisation

The template is presented in section 3 of the Working Paper [16].

## Section 6 – Development of other templates

### 6.1 Provisions for templates in case of modification

Subgroup decision is that the template for ‘EC’ declaration of verification of subsystems can accommodate the following types of changes:

- Changes in the vehicle affecting the subsystem.
- Changes triggered by the extension of the area of use.
- Changes in the legislation
- Changes in the documents accompanying the ‘EC’ declaration

### 6.2 Provisions for templates for additional verifications

See section 6.1

### 6.3 Provisions for templates for ‘EC’ Certificate of verification

The basis for the ‘EC’ certificate of verification template was the existing template used and proposed by NB RAIL during the activity of the working group “Monitoring Notified Body”. The template is presented in Appendix 6 of the “REPORT MNB PROJECT Proposal for ‘EC’ Certificates Content and Templates” [20]. The NB RAIL template was adapted and made consistent with the other proposed templates.

### 6.4 Templates for Documents supporting the ‘EC’ Declaration

During its third meeting held on 19 October 2017 the Subgroup analysed the necessary templates for the documents supporting the ‘EC’ declaration of verification of subsystem.

Directive (EU) 2016/797 [2] Annex IV – Section 2.4 – “Technical file accompanying the ‘EC’ declaration of verification” was used as a basis for decision.

It was concluded that the necessary templates for documents of the technical file that is to accompany the ‘EC’ Declaration of subsystems are the following:

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1. Intermediate Statement of Verification
2. Certificate of verification issued by NoBo that checks the conformity with the TSI
3. Certificate of verification issued by NoBo that checks the conformity with other legal acts of the Union
4. Report of the assessor on the CSM on risk assessment
5. 'EC' Declaration of conformity of an IC
6. 'EC' Declaration of suitability for use

Items 1, 2, 5 and 6 are part of the proposal for this Implementing Act.

Agency cannot make a proposal for item 3 as long as such a certificate is issued under the scope of other Directive(s) of the Union.

For item 4 the Subgroup considers that the CSM Regulation on Risk Assessment (EU) 402/2013 [5] covers the content of the "Safety assessment report of the assessment body" in its Annex, therefore it is not necessary to address it here.

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## Section 7 – Stakeholder opinions

### 7.1 General opinions

All the comments received to Working Paper [14] have been compiled, processed and answered by the working document - ERA-PRG-005-02\_297 [15].

### 7.2 Minority opinions

The table below summarises the minority opinions expressed by the stakeholders in their comments. Subjects previously identified by the members of the subgroup and agreed during the meetings of the subgroups are not listed here. All the comments are captured in document ERA-PRG-005/02- 263 [13].

Language issues could not be resolved to the full satisfaction of the National Safety Authorities. Interoperability constituents and mobile subsystems are placed on the market without any involvement of National Safety Authorities. Therefore, is it for the manufacturer to choose the language in which they will write the declaration and the file accompanying the declaration? Moreover, a subsystem could incorporate several interoperability constituents for which the applicant shall decide according to their interests the language of the technical file accompanying the 'EC' declaration and of the 'EC' declaration. The only obligation is to use the same language for both.

At a later stage, the file accompanying the application for the authorisation can be submitted in one of the official languages of the Union. Nevertheless, parts of the documents shall be translated in the language determined by the NSA and indicated in their guidelines.

The validity and the need for update of the 'EC' declaration were challenged by some entities in their comments. It is not necessary to mention the time validity for a subsystem or an interoperability because they should be considered as complete and finalized products. For the development of subsystems and on track testing the intermediate statement of verification is the tool to be used.



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The proposal introduces the idea that a new declaration is needed each time that an element of the declaration is changed. This includes cases where a subsystem is not physically changed but the declaration must be updated. For example: if a certificate of verification is updated then the element in the declaration referencing the certificate needs to be updated without affecting the verification procedure. Therefore, the declaration should be continuously updated. This principle is used in other industries. A short investigation in at least two European documents:

- ATEX Directive 2014/34/EU [21]
- Decision on marketing of the products [8]

shows also that the EC declaration of conformity '*... shall be continuously updated*'.

When an EC declaration is affected by a change in any of: legislation, vehicle or subsystem, technical file accompanying the declaration, etc. then the validity needs to be checked. A request for an authorisation in conformity to type based on a declaration that is affected by a change in a rule cannot be submitted. This is in line with article 24(3) of Directive (EU) 1016/797 [2].

An 'EC' declaration should have an indefinite time validity but is subject to updating according to Article 24(3) of Directive (EU) 2016/797 [2]. This does not mean that the existing subsystems placed on the market and integrated in a vehicle or a network will cease to be interoperable or that they will lose the authorisation that was already granted.

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Organisations	Reference to revised article	Comment/Proposal	Agency's response
NSA Spain	Section 1 - Article 4.2	A reference to Article 10 of the IA on Vehicle Authorisation and to point 2.6 of Annex IV of the IoD shall be added in order to make clear that, in the context of an authorisation, the documentation shall be presented in the language stated in the Guidelines of the NSA.	NSAs for the area of use have no involvement in the process of placing on the market of an interoperability constituent or a subsystem, therefore they cannot impose a language in which the documentation shall be written.
NSA Spain	Section 1 - Article 4.2	Why both documents EC declaration and the accompanying documents shall be in the same language? What is the reason for doing this particular request?	There is a direct link between the documentation and the declaration. A similar approach was taken for the language for the file accompanying the application for the authorisation.
NSA Poland	Section 1 - Article 4.2	The 'EC' declaration of conformity or suitability for use of interoperability constituents (Art. 4 (2), page 5) and the 'EC' declaration of verification of subsystem (Art. 3 (3), page 8) – According to the set out provisions, the documents shall be written in one of the official languages of the Union. In the case of Poland, the current provisions indicate that documents to be submitted to the National Safety Authority (in PL: UTK) must be written in Polish or have a notarized translation. However, bearing in mind the rule of the primacy of European Union law (here: IA), we may encounter a situation that, for example, the contractor for subsystem modernisation provides documents in a language other than Polish and based on these provisions he may not want to submit a translation into Polish, which in turn may cause problems on the infrastructure manager (PLK) – UTK line.	See previous two comments

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		Therefore, we would propose either to i) indicate that for the subsystem or interoperability constituent the documents were prepared also in the language of the country in which they are to be used, or ii) add the possibility of regulating additional matters regarding the language of these documents by national rules.	
NSA PL	Section 2 – Article 4	<p>‘EC’ declaration of verification of subsystem in case of renewal or upgrading of a subsystem</p> <p>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.</p> <p>According to Article 15 (5) of Directive (EU) 2016/797 applicant shall assess the need for a new ‘EC’ declaration of verification in case 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. Moreover “renewal” and “upgrading” are defined in Directive (EU) 2016/797 so we cannot require new ‘EC’ declaration always if subsystem is “changed”.</p>	<p>A new declaration is needed each time an element of the declaration is changed.</p> <p>There may be cases where a subsystem is not physically changed but the declaration must be updated.</p> <p>For example: if a certificate of verification is updated then the associated element in the declaration needs to be updated.</p> <p>The declaration should be continuously updated.</p> <p>This principle is used in all other industries.</p> <p>A conformity with an authorized type cannot be requested based on a declaration that is not updated.</p>
NSA PL	Section 2- Annex I	Before line with “signature manufacturer (...)” should be line with “Validity” [if applicable]. EC declaration can have specific conditions to issue identified in EC certificate by NoBo. Therefore manufacturer shall define this conditions used in EC declaration as well.	A subsystem is placed on the market only when it is complete and finalized. Therefore, there is no need to specify a time validity. An ‘EC’ declaration should not be seen as a temporary

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			document to be used for on track tests or for development of the subsystem. For such cases the ISV should be use, for which a limited time validity is envisaged.
EIM	Article 4(3) Page 8	<p>'EC' declaration of verification of subsystem (Art. 4 (3), page 8) – It is incomprehensible that the EC declaration of verification of a subsystem remains valid only until there is a change to the provisions on the basis of which is has been issued (the subsystem was put into service).</p> <p>In our opinion, the declaration remains valid as long as the conditions specified therein are kept, or the subsystem has not changed (as indicated in Art. 4(1)). It cannot be the case that, for example, if a TSI changes (which happens relatively often in the context of subsystem sustainability), the declaration for a built-in subsystem ceases to apply - In that event, the subsystem would not be interoperable any longer. In this context, it would be necessary to repeat the EC verification procedure for all subsystems being in service.</p>	<p>The update of a declaration does not necessarily make the existing subsystem not interoperable or the authorisation for the vehicle invalid. This is in accordance with article 4(2) of Directive (EU) 2016/797.</p> <p>The validity of the 'EC' Declaration for a subsystem is indefinite as long as no element is affected by the change.</p> <p>The declaration remains valid for an indefinite period but it requires to be updated, for example, if a change in the rules specifies that the existing vehicle type authorisation becomes invalid in respect of a specific parameter that will affect one of the elements of the declaration. Where a change is made to a TSI it should consider backwards compatibility, and explicitly state if an existing subsystem that does not comply with the changed requirement should have its authorisation revoked. This is not a common occurrence.</p>

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UNIFE	Section 2.1 Article 4(3)	The document states that the initial Declaration remains valid until there is a change [...] to the legislation that was applicable when the subsystem was placed on the market or in service. This approach is unfeasible and would either make the Declaration constantly invalid or require a constant change of the Declaration as the legislation constantly develops and changes overtime. However, the subsystem itself benefits from so-called orphan rights and provisions made to safeguard existing standards.	The subsystems already integrated in a vehicle will not lose their authorisation or will not become less interoperable. However, a type will lose its authorisation and therefore the authorisation will need to be renewed before further vehicles can be authorised using the type. As part of this, the 'EC' Declaration needs to be updated.
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