TITLE	
CONTENT OF EC CERTIFICATE/ QMS-APPROVAL/ ISV	
ORIGINATOR	**SUBJECT RELATED TO**
NB-RAIL SUB-GROUP STRATEGY	DIRECTIVE 2008/57/EC (AS AMENDED BY 2009/131/EC, 2011/18/EU, 2010/713/EU, 2013/9/EU, 2014/38/EU, 2014/106/EU), (EU)2016/797 DECISION 768/2008/EC

AMENDMENT RECORD:

ISSUE 07 INCLUDES MODIFICATIONS DERIVING FROM THE AMENDMENTS DONE TO RFU-STR-060 AT STR044

ISSUE 08 INCLUDES MODIFICATIONS TO THE ISV TITLES

ISSUE 09 BETTER DEFINES THE CERTIFICATES LABELLING, CONTENTS AND THE "CONDITIONS AND LIMITS OF USE" CONCEPTS

ISSUE 10 AMENDS SOME EDITORIAL ERRORS AND BETTER CLARIFIES THE CERTIFICATE TITLES IN ANNEX 4

DESCRIPTION AND BACKGROUND EXPLANATION

Harmonisation of EC Certificate/ QMS-Approval/ ISV Content

The EU legislative documents 768/2008/EC, 2008/57/EC and 2010/713/EU establish a number of requirements on the content of EC Certificates. These requirements have been extracted and summarised in Annex 1 of this RFU. In Annexes 2 to 6 the minimum content (as well as a proposed layout) of a Certificate and its Annex are provided.

Furthermore, this RFU regulates the EC Certificate/ QMS-Approval/ ISV Content ID Numbers to be used by Notified Bodies.

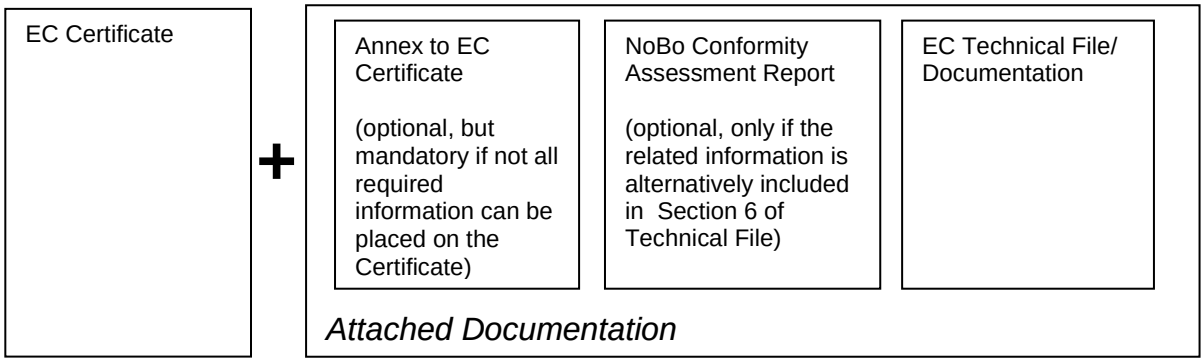
It is also noted, that Directive (EU) 2016/797" and a future "Implementing Act on 'EC' declaration of verification of subsystems and templates referred to in Articles 9(4), 15(9) and 24(4) of Directive (EU) 2016/797" will establish requirements in this context.

RFU PROPOSAL

A – Content of EC Certificate and Attached Documentation

Due to the broad range of possible certification activities, NB-Rail cannot propose to fully standardise the content of the EC Certificates and Annexed Documentation. However, it is judged that at least the following information shall be contained as minimum content on the EC Certificates and in the Attached Documentation.

A.1 General Overview:



The Attached Documents – with exception of the EC Technical File/Documentation (these names are defined within legislative documents) - may have different names than those indicated here, as long as they contain the relevant information required by EU legislation.

The use of the Annex to the EC Certificate is optional. It is only required, if the related information could not be included on the cover page of the EC Certificate.

The information in the Annex to the EC Certificate may instead be called page No 2/2 of the EC Certificate or be the backpage of the EC Certificate cover page.

The NoBo Assessment Report and the NoBo Technical File/Documentation may be a combined document called the EC Technical File/Documentation. In this case, the information to be contained in the EC Assessment Report must be contained in the EC Technical File/Documentation Section 6.

It is highly recommended to apply the requirements on content of Technical File defined by RFU-STR-011 in a similar matter to the content of the Technical Documentation. In the following only the term Technical File is used.

It was noted that current legislation requires EC Certificates to be part of the technical file as well as the technical file to be attached to the EC Certificate. To solve this inconsistency we propose that every EC Certificate shall have a technical file (or an addendum and reference to an existing technical file) attached to it. If a certificate is updated it will require at least section 2 of the technical file to be updated.

Only the Content on the Certificate Templates in the Annex to this RFU is binding as minimum content. The Format and Layout are presented only to propose and encourage a common layout to be used in order that certificates across Europe might appear similar and contain the same information in the same places. The precise layout and any additional information given on the Certificate, including any legal attestations, is the responsibility of the issuing Notified Body.

A.1.1 Concept of "Conditions and Limits of Use":

This terminology has been introduced with (EU) 2016/797 and replaces various similar terms (e.g. compatibility, restrictions, constraints) which have been used in 2008/57/EC and 2010/713/EC and several TSIs to represent the same concept.

"Conditions and Limits of Use" define any information necessary to enable and ensure the intended use of a constituent or a subsystem in its surrounding (the intended Placing in Service). This information can e.g. be minimum or maximum values, technical scope, the 'Area of Use' parameters as included in the TSIs, technical interfaces or operational and maintenance requirements. A limitation is a special kind of condition and both can be included under the same headline and no distinction between limitations and conditions is necessary or useful. Conditions and Limits of Use may typically be a combination of those which were pre-defined and those which resulted from the conformity assessment process.

Conditions and Limits of Use shall never be abused if the object of assessment does not comply with the TSI requirements; this situation represents a non-conformity, in this case only an ISV can be issued to those remaining parts, which are conform. The correction of non-conformities with TSI requirements shall be carried out by the applicant until conformity is reached (unless a non-application of TSI in accordance with Articles 9 or 20 of Directive (EU) 2008/57 has been granted).

A.2 Information to be provided on the Certificate and Attached Documentation:

Based on the requirements listed in Annex1 of this RFU, the following information shall be included on the EC Certificate and in the Attached Documentation [Text in square brackets indicates the requirements covered]. The Attached Documentation shall always be regarded as part of and delivered with the EC Certificate.

A.2.1 Certificate

1. Type and identification number of the Certificate (see below Section C and D) [R25]
2. Scope of Certification by reference to the Certification Scheme (2008/57/EC and its Amendments). [R3.a,R34]
3. Scope of Certification by reference to **Object of Assessment**: Designation of the certified Interoperability Constituent/ Subsystem Type(s) and variant(s)/versions(s)

included in the certification. Identified by industry-typical and un-ambiguous denomination. This may include a reference to a separate Attached Document which provides a more detailed definition (e.g. a Product Type Drawing, the Technical File/ Documentation, the EC Assessment Report.) [R4,R12,R28]

4. Name and address of **Applicant** (or of his authorized representative established within the Community.) [R9]
5. Name and address of the **Manufacturer** (or of his authorized representative established within the Community. If Applicant and Manufacturer are the same entity, it is sufficient to have a single entry for "Applicant/Manufacturer".) [R1,R8,R33]
6. Scope of Certification by reference to **Location of manufacturer** (only if relevant (e.g. for all QMS approvals), only if different from address of Manufacturer. May also be a list of several locations.) [R3.a,R33]
7. Scope of Certification by reference to **Assessment Requirements**: TSIs and their identification number to which conformity was assessed, including any Amendments. (Format as given here: TSI CR L&P 2011/321/EU, amended by xxxxxx.) For Harmonised Standards, Voluntary Standards and Alternative Solutions (= AMOC, Acceptable Means Of Compliance) reference to the relevant section of Technical File/Documentation shall be made. [R3.a,R16,R35]
8. Scope of Certification by reference to **Exemptions from Assessment** [R17]
9. Scope of Certification by reference to Assessment **Module(s) applied** for Conformity Assessment. [R3.a,R34]
10. Statement about the **Assessment Results** (NoBo statement declaring the conformity of the Interoperability Constituent/ Subsystem or its phase/part, or quality management system with the appropriate Assessment Requirements. This is the central statement of the certificate.) [R2,R10,R16,R21,R30]
11. Conditions and Limits of Use (See section A.1.1 above). E.g. minimum or maximum values, technical scope, the 'Area of Use' parameters as included in the TSIs, technical interfaces or operational and maintenance requirements. These are often partly contained in evidence documents supplied by the applicant and partly require documentation by the NoBo.

    The set of relevant Conditions and Limits of use must be contained in the Technical File section 3. On the Certificate the following shall be provided:

    - the most relevant Conditions and Limits of Use in plain text and
    - a reference to the Technical File section 3 for the set of relevant Conditions and Limits of Use related to the object of assessment. [R3.c, R11,R22]
12. (Where applicable) **Reference to Annex** of EC Certificate (where used) [R5, R14]
13. **Reference to attached EC Assessment Report** [R5,R14,R22,R27,R31,R32]

14. **Reference to attached EC Technical File/Documentation** [R3.c,R5,R6,R7,R13,R14,R15,R18,R19,R35]
15. **Validity** of the Certification: any timeframes/conditions of validity shall be stated.[R3.b,R11,R36]
16. (Where applicable) **Reference to superseded EC Certificate** in case of replacement and withdrawn of EC Certificate. [R37]
17. Name and address of the **Notified Body** and its registration number at the European Commission. [R24]
18. **Date of issue, Signature** of the authorized signatory of the Notified Body.[R20,R26,R29]

A.2.2 Annex of Certificate

1. Type and identification number of the **related Certificate** (see below Section B and C) [R25]
2. Scope of Certification by reference to **Object of Conformity Assessment**: Scope of Certification by reference to **Object of Assessment**: Designation of the certified Interoperability Constituent/ Subsystem Type(s) and variant(s)/versions(s) included in the certification. Identified by industry-typical and un-ambiguous denomination. This may include a reference to a separate Attached Document which provides a more detailed definition (e.g. a Product Type Drawing, the Technical File/ Documentation, the EC Assessment Report.) [R4,R12,R28]
3. **Conditions and Limits of use** (Follow on from the same topic on the Certificate Cover page).
4. Name and address of the **Notified Body** and its registration number at the European Commission.
5. **Date of issue, signature** of the authorized signatory of the Notified Body.

A.2.3 Content which must be contained in the NoBo Conformity Assessment Report or Technical File/Documentation

1. The Attached Documentation shall contain all relevant information to allow the conformity of Interoperability Constituents/Subsystems with the examined type/design to be evaluated. This shall be contained by the Technical File/Documentation section 5. [R6,R15]
2. All relevant information to allow for in-service control. (Note: “In service control” is considered to cover:
    a. the provisions for operation and maintenance (these may be required by TSIs, 2004/49/EC and other regulations derived from the EU Treaty)
    b. and the Conditions for use of the subsystem.) [R3.c,R7]

These shall be contained by the Technical File/Documentation sections 3 and 5.5/5.6.

3. If relevant, a description of the product's functioning [R13]; this shall be contained by the Technical File/Documentation sections 5.2 or 5.5/5.6 as considered most appropriate by the NoBo.
4. Calculation notes [R19] This is considered to relate to design documentation, which shall be contained by the Technical File/Documentation section 5.2.
5. Date of inspection/audit. This shall be contained by the EC Assessment (or Audit) Report or the Technical File/Documentation section 6. [R27]
6. Inspection results. This shall be contained by the EC Assessment (or Audit) Report or the Technical File/Documentation section 6. [R31,R32]
7. Scope of certification relating to the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply. This shall be contained by the EC Assessment (or Audit) Report or the Technical File/Documentation section 5.2. [R35]

In addition to this minimum set of information, the Notified Body is free to complete the EC Certificate and its Attached Documentation with any additional information deemed to be appropriate for comprehensive information and to improve a mutual recognition.

B) Languages

Certificates including their annex can be issued in monolingual or bilingual version. At bilingual versions, English shall be the second language to enable information exchange between Notified Bodies as required by Decision 2010/713/EU and between other stakeholders.

For the EC Technical File/Documentation a monolingual version is sufficient to avoid translation errors.

Any **Translations** of Certificates shall bear the **original Certificate ID Number** and be marked as a Translation.

NoBos shall ensure that the object of assessment is unambiguously identified on the certificate and in the attached documentation. If this information is not originally provided in Latin script (e.g. drawings codes in annexes of Technical file), NoBos shall place the translation in the Latin script, along with the original script in brackets (or vice versa if required), on the certificate and in the attached documentation.

C) Types of certification level documents – EC Certificate/ QMS-Approval/ ISV

EC-Certificates: Directive 2008/57/EC, as amended by Directive 2014/106/EU, refers to certificates omitting the label 'EC', but this is not coherent with Decision 2010/713/EU and Directive (EU) 2016/797 where 'EC' is used. For simplification and consistency NB-Rail has decided to keep the term 'EC' in front of 'Certificates' where this related to the types 1+2+5+6+7.

QMS-Approval: The Quality Management System Approval of type 4 is not named EC-Certificate by the European legislation, even though it is a certification level document and according to ISO17065 in combination with the relevant aspects of ISO17021 all related requirements to a certificate shall apply also to this document.

ISVs: ISVs although having, as documents, a different scope, purpose and legal status, shall follow the same technical and administrative approach as for Certificates.

Each ISV shall clearly identify the stages and parts covered.

The second digit of the ISV type refers to the type of certificate/ QMS-Approval as described under section C.

Rail Notified Bodies may issue certification level documents of the following types:

1. EC Type Examination Certificate (B, CB,SB)
2. EC Design Examination Certificate (CH1, H2, SH1, SH2)
4. Quality Management System Approval (CD, CH, CH1, D, SD, H1, H2, SH1, SH2)*
5. EC Certificate of Conformity (A1, CA1, CA2, CF, F)
6. EC Certificate of Verification (SD, SF, SG, SH1, SH2)
7. EC Certificate of Suitability for Use (CV, V)**

8.1. Intermediate Statement of Verification – EC Type Examination (SB)

8.2. Intermediate Statement of Verification - EC Design Examination (SH1, SH2)

8.4. Intermediate Statement of Verification – Quality Management System Approval (SD, SH1, SH2)

8.6. Intermediate Statement of Verification (SD, SF, SG, SH1, SH2)

In brackets the Modules that lead to the indicated types are given.

Notes:

- *The previously used type 3, Design examination report, is now incorporated within type 2, Design Examination Certificate and is no longer supported. Certificates of type 3 that have been issued continue to remain valid until their normal expiry.*
- *Certificate type 6, EC Certificate of Verification, was incorporated within Certificate type 5, Certificate of Conformity, and was therefore no longer supported after the first revision of the high speed TSIs. With Decision 2010/713/EU Certificates of type 6 have been introduced again for subsystem certification.*
- **This is not an approval for the overall Quality Management System of the designer/ manufacturer but of its specific suitability for the intended purpose to deliver the object of assessment in compliance with the interoperability Directives and TSIs*
- *** Suitability for use is defined in module V to be equivalent with conformity by in service experience*
- *An Interim Statement of Conformity ISC as previously defined in RFU-0-000-17 should not be mistaken as an ISV as defined by 2008/57/EC or (EU) 797/2016 and as referred to in this document.*

E) Certificate numbering

A certificate shall to be numbered as follows:

NNNN / T / M / YEAR / SSS / C1C2 / #

NNNN: Notified Body Registration number at the European Commission

T: Type number of certificate – See C) and D) above.

M: Module (SB, SH2 etc.) as appropriate 1, 2 or 3 characters

YEAR: Year of issue of the first version (4 digits). See also the note for #

SSS: Subsystem concerned:

- INF Infrastructure (*INS has been used formerly according to previous TSI versions)*
- RST Rolling Stock
- ENE Energy
- CCO Control Command and Signalling (on-board)
- CCT Control Command and Signalling (trackside)

Note: CCS Control-Command and Signalling is no longer used since the subsystem has been split into a trackside and an on-board subsystem according to Directive 2011/18/EU

C1: Master Language of Certificate and Technical File (use EU codes)
e. g. DE = German, EN = English, FR = French etc.

C2: Second language of certificate (where used) shall be English. If the certificate is monolingual, C2 is not used, so the language indication is C1 only (2 digits)

#: Unique number(s) and version as defined by each NoBo.

Note: The original issuing Notified Body may continue to use a previously issued number on reissue of a certificate, provided that there is no change to scope, there are no changes to the product, the product continues to comply with the TSI in force and there has been no break in certification from the previously issued certificate. Where a previous number is retained, the Certificate number must include an issue reference.

List of Annexes to this RFU

Annex 1 - Requirements for Content of EC Certificates
Annex 2 - Content of EC Certificates (other than QMS Approval)
Annex 3 - Content of QMS Approval
Annex 4 – Content of ISV (other than QMS Approval)
Annex 5 - Content of ISV (QMS Approval)
Annex 6 - Content of Annex to an EC Certificate

THIS RFU WAS AGREED ON
PLENARY MEETING 53
THIS RFU ENTERS INTO FORCE ON
DATE OF PUBLICATION: 08/06/2018
RFU APPLICATION IS MANDATORY STARTING FROM
01/09/2018 AT THIS DATE ANY PREVIOUS VERSIONS OF THIS RFU WILL BE WITHDRAWN.
ERA COMMENTS
PLE 53 – 23/05/2018: NO COMMENTS

Annex 1 of RFU - Requirements for Content of EC Certificate

The Decision 768/2008/EC on a common framework for the marketing of products (which is repealing and replacing Decision 93/465/EC) defines general requirements for the content of EC Certificates provided by NoBos.

These general requirements for an EC Certificate are (Summary of relevant requirements from 768/2008 Annex II):

R1. **The certificate shall contain the name and address of the manufacturer,**

R2. **the conclusions of the examination,**

R3. **the conditions (if any) for its validity** (Validity is considered to cover 3 Aspects:

a. **The Scope of certification,**

b. **the term or expiry date of certification,**

c. **the Conditions for the Use of the Subsystem.**

It is proposed that the Requirement R3.c may be covered by reference to the Technical File (i.e. Section 3 as defined by RFU-STR-011).)

R4. **and the necessary data for identification of the approved type.**

R5. **The certificate may have one or more annexes attached.** (This is considered to mean BOTH: either an "Annex to the EC Certificate" OR other documentation attached to the Certificate such as a NoBo Conformity Assessment Report or the Technical File/Documentation.) (Note: Conformity Assessment Reporting includes Inspection Reports as well as Audit Reports)

R6. **The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated.** (Note: Due to the significant number of assessment requirements relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate. Further 2008/57/EC and 2013/713/EU specifically require this information be included in the Technical File/ Documentation. This requirement shall therefore be satisfied by inclusion of the required information in the Technical File/Documentation (i.e. Section 5 as defined by RFU-STR-011) and referencing the Technical File/Documentation on the Certificate.)..

R7. **The certificate and its annexes shall contain all relevant information to allow for in-service control.** (Note: "In service control" is considered to cover:

a. **the provisions for operation and maintenance** (these may be required by TSIs, 2004/49/EC and other regulations derived from the EU Treaty)

b. and the Conditions for use of the subsystem. (Already covered under R3 above.)

For reasons similar to those stated at R6 above, this requirement shall be satisfied by inclusion of the relevant information in the Technical File/Documentation (i.e. Section 3, 5.5 and 5.6 as defined by RFU-STR-011) and referencing the Technical File/ Documentation on the Certificate.)

Within the scope of the Interoperability Directive (IOD) 2008 /57/EC (which is repealing and replacing the earlier Interoperability Directives) specific assessment Modules for IOD have been defined.

Initially these Modules were defined in the Annexes of TSIs. For TSIs published after 2010, these Modules are defined in the separate Decision 2010/713/EU and no longer inside the Annexes of the TSIs. At the same time new or updated definitions of assessment Modules for IOD were introduced. These new/updated Modules for IOD are incorporated in this RFU.

Note: The previous Modules for IOD will remain applicable according to the applicability of that TSI in which they are defined. Certificates must adhere in content and validity to that assessment Module for IOD which was used in the project.

The IOD and the definitions of the Modules for IOD contain a number of specific requirements (i.e . 2008/57/EU Annex VI , 2010/713/EU (description of modules) CB, CH1, CV, SB, SD, SF, SG, SH1) for EC Certificates:

R8. The certificate shall contain the name and address of the manufacturer (same as R1),

R9. the certificate shall contain the name and address of the Applicant,

R10. the conclusions of the examination (same as R2),

R11. the conditions (if any) for its validity (variant of R3) and

R12. the necessary data for identification of the **approved type/design** (variation of R4) and

R13. **if relevant, a description of the product's functioning.** (Note: It is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the required information in the Technical File (i.e. Section 5.2 as defined by RFU-STR-011) and referencing the Technical File on the Certificate.)

R14. The certificate may have one or more annexes attached (same as R5).

R15. The certificate and its annexes shall contain all relevant information to allow the conformity of **Interoperability Constituents/Subsystems with the examined type/ design** to be evaluated. (variation of R6) (Note: Due

to the significant number of assessment requirements relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate. Further 2008/57/EC and 2010/713/EU specifically require this information be included in the Technical File/Documentation. This requirement shall therefore be satisfied by inclusion of the information in the Technical File/Documentation (i.e. Section 5.2 as defined by RFU-STR-011) and referencing the Technical File/Documentation on the Certificate.)

R16. The 'EC' verification certificate must provide reference to the TSIs with which the conformity has been assessed.

In case of TSI with additional optional technical requirements to quote whether it is inclusive of the optional requirements or not.

R17. Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case)**, the 'EC' certificate shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the Notified Body during the 'EC' certification procedure**

R18. A list of the relevant parts of the Technical Documentation shall be annexed to the EC certificate of suitability for use. (This supports the argument given in R5.)

R19. 'EC' certificate of Verification, accompanied by corresponding calculation notes (Note: It is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the required information in the Technical File (i.e. Section 5.2 as defined by RFU-STR-011) and referencing the Technical File on the Certificate.)

R20. and signed by the Notified Body responsible for the 'EC' verification,

R21. stating that the subsystem complies with the requirements of the relevant TSI(s) (Core Statement of the Certificate.)

R22. and mentioning any reservations recorded during performance of the activities and not withdrawn;

R23. **the 'EC' certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body** (This supports the argumentation provided at R5.)

Further NoBos must adhere to requirements based on their Accreditation or Recognition or are voluntary following the same requirements as good industry practice. These are contained in the ISO standards for Conformity Assessment Bodies (ISO 17020, 17021, 17065).

Any certificate shall include all of the following:

R24. **Identification of the issuing body;**

R25. **unique identification and**

R26. **date of issue;**

R27. **date of inspection** (Note: Due to the significant number of inspections relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the information in the NoBo Conformity Assessment Report and by referring to this Report on the Certificate.)

R28. identification of the item(s) inspected (variation of R4+R12);

R29. signature or other indication of approval, by authorized personnel (variation of R20);

R30. a statement of conformity where applicable (variation of R21);

R31. **the inspection results, except where detailed in a separate report.** (Note: Due to the significant number of inspections relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate. This requirement shall therefore be satisfied by inclusion of the information in the NoBo Conformity Assessment Report and by referring to this Report on the Certificate.)

R32. **An inspection body shall issue an inspection certificate that does not include the inspection results only when the inspection body can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other.** (This supports the argumentation provided at R31.)

R33. **The scope of certification relating to the** product(s), **process(es) or service(s) for which the certification is granted** (in relation to products same as R4+R12). It is considered that scope of certification relating process or service is only relevant for modules including Quality Management System Assessment. Due to the large number processes/services relating to a QMS, it is not considered reasonable to include this information directly on the Certificate. This requirement shall therefore be covered by stating the Manufacturer and the Location(s) of manufacture on the Certificate, as this is considered to identify suitably the related QMS.

R34. **The scope of certification relating to the applicable certification scheme.** The Certification Scheme is considered to be defined by 768/2008, 2008/57/EC and 2010/713/EC, in each case including amendments. The Modules for IOD are part of the Scheme. For clarity, it is considered that the reference to 2008/57/EC including amendments and to the Module(s) used at this Certification shall suffice.

R35. The scope of certification relating to the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply. (Note: This covers

a. standards or other documents referred to in the TSI's (and hence mandatory),

b. where applicable other Standards or other documents not referred to in the TSI's which give presumption of conformity with the TSI Requirements (Harmonised Standards and Voluntary Standards),

c. Alternative Solutions to b. if proposed by the Applicant. (see 2010/713/EU)

Due to the significant number of assessment requirements relating to an IC/Subsystem, it is not considered reasonable to provide this information directly on the Certificate, other than the references to TSIs. As 2008/57/EC and 2013/713/EU specifically require this information be included in the Technical File/ Documentation, this requirement shall be satisfied by inclusion of the information in the Technical File/ Documentation (Section 5.1 as defined by RFU-STR-011) and by referencing the Technical File/ Documentation on the Certificate.

R36. The term or expiry date of certification, if certification expires after an established period (variation of R3.c);

R37. An amended certificate shall identify the replaced certificate.

R38. Any other information required by the certification scheme (covered by R1 to R23 above).

Annex 2 of RFU

EC *[Type Examination Certificate][Design Examination Certificate][Certificate of Conformity][Certificate of Verification] [Suitability for Use Certificate]*

Certificate Number: NNNN / T / M / YEAR / SSS / C1C2 / #

In accordance with Directive 2008/57/EC of 17 June 2008 (as amended).

Object of Assessment	[Interoperability Constituent][Subsystem] [Part of the Subsystem] (DESIGNATION) (and for A1, F, SF, SG UNIQUE SERIAL NUMBERS –) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer]	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer, only relevant for CD, CH, CH1, D, H2, SD, SH1, SH2)
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with those Harmonised Standards, Voluntary Standards (or parts thereof), other European or national rules authorized by TSI's and Alternative Solutions as identified in the EC Technical [File/Documentation] (Section 5.1)
[Scope of /Exemptions from Assessment]	(optional) Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/ renewal, transitional period or specific case). This section contains precise reference to the TSI(s)/parts assessed or not assessed. May be done by reference to Attached Documentation.
Module applied	[A1, B, CA1, CA2, CB, CD, CF, CH, CH1, CV, D, F, H2, V, SB, SD, SF, SG, SH1, SH2] of 2010/713/EU or the relevant TSI.
Assessment Result	The Object of Assessment as identified above was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the attached [EC Assessment Report or EC Technical File/Documentation section 6]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	(Required by 2008/57/EC 18(3) for Subsystems. Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment. Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of Certificate or to the Assessment Report or to the Technical File section 3.))
Annex of EC Certificate	(Only if used at issue of Certificate) (identifier, revision (if used), date)
EC Assessment Report	(identifier, revision (if used), date) The report is an integral part of this Certificate.
EC Technical File / Documentation	(identifier, revision (if used), date)

Validity	This certificate is valid [until (if applicable, duration according to relevant TSI/ Module)] for the object of assessment as mentioned above and a s long as the Object of Assessment and the relevant technical documentation are not modified. [The NoBo must be informed about any modifications without delay (not relevant for SF and SG)]. [(only for SD, SH1 modules) Within the validity duration of this Certificate the applicant can perform production/installation and final product/installation inspection of the object of the assessment as long as the product/installation conforms to the EC Type/Design Examination Certificate. This validity duration may be extended on the basis of future auditing.]
	(Where applicable:) This certificate supersedes (that means replaces and withdraws) certificate number xxxxx (and, if needed: dated xx/xx/xx)

DATE of Issue:_____

Signature:_____
Name: (printed) Title: (printed)
On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

Annex 3 of RFU (only for CD, CH, CH1, D, H2, SD, SH1, SH2)

Quality Management System Approval

Number: NNNN / T / M / YEAR / SSS / C1C2 / #

In accordance with Directive 2008/57/EC of 17 June 2008 (as amended).

Object of Assessment	Quality Management System for the [design and] (only for CH1, H2, SH1, SH2) production of the [Interoperability Constituent][Subsystem] [Part of Subsystem] (DESIGNATION) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer])	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer, only relevant for CD, CH, CH1, D, H2, SD, SH1, SH2)
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with the Harmonised Standards, Voluntary Standards (or parts thereof) and Alternative Solutions as identified in the EC Technical [File/Documentation] (Section 5.1)
[Scope of /Exemptions from Assessment]	(optional) (Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/renewal, transitional period or specific case), precise reference to the TSI(s)/parts not assessed.) (May be done by reference to Attached Documentation.)
Module applied	[CD, CH, CH1, D, H2, SD, SH1, SH2] of the relevant decision adopted pursuant to the Directive.
Assessment Result	The Quality Management System of the aforementioned Manufacturer [at the indicated Location(s)] has been audited and was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the attached [EC Audit Report or EC Technical File/Documentation section 6]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	(Required by 2008/57/EC 18(3) for Subsystems. Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment. Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of the QMS Approval or to the Assessment Report or to the Technical File section 3.))
Annex of QMS Approval	(Only if used at issue of QMS Approval) (identifier, revision (if used), date)
EC Audit Report	(identifier, revision (if used), date) The report is an integral part of this QMS Approval.
EC Technical File/Documentation	(identifier, revision (if used), date)

Validity	The validity of this QMS Approval is subject to (continued compliance with the [Design][Type] Examination Certificate(s) as listed on the attached annex, which forms part of this certificate and - CD, CH1, D, H2, SD, SH1, SH2 only) the continued maintenance of the Quality Management System in accordance with the requirements of the above Directive as monitored through regular and unannounced surveillance. This QMS Approval is valid [until (duration according to relevant TSI/ Module)] as long as the Object of Conformity Assessment, the Quality Management System and the relevant technical documentation are not modified. The NoBo must be informed about any modifications without delay. Within the validity duration of this QMS Approval the applicant can perform production/installation and final product/installation inspection of the object of the assessment. This validity duration may be extended on the basis of future auditing.
	(Where applicable:) This QMS Approval supersedes (that means replaces and withdraws) QMS Approval number xxxxx (and, if needed: dated xx/xx/xx)
DATE of Issue:_____	Signature:_____ Name: (printed) Title: (printed) On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

Annex 4 of RFU (only for ISV and SB, SD, SF, SG, SH1, SH2)

[Intermediate Statement of Verification]
[Intermediate Statement of Verification - EC Type Examination]
[Intermediate Statement of Verification - EC Design Examination]

Number: NNNN / T / M / YEAR / SSS / C1C2 / #

In accordance with Directive 2008/57/EC of 17 June 2008 (as amended).

Object of Assessment	[Part of the Subsystem] (DESIGNATION) (and for SF, SG UNIQUE SERIAL NUMBERS –) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer]	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer, only relevant for SD, SH1, SH2)
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with those Harmonised Standards, Voluntary Standards (or parts thereof), other European or national rules authorized by TSI's and Alternative Solutions as identified in the EC Technical [File/Documentation] (Section 5.1)
[Scope of /Exemptions from Assessment]	(optional) Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/ renewal, transitional period or specific case). This section contains precise reference to the TSI(s)/parts assessed or not assessed. May be done by reference to Attached Documentation.
[Stages]	Only applicable for ISVs, it is used to clearly define which project stage(s) are covered by this ISV.
Module applied	[SB, SD, SF, SG, SH1, SH2] of 2010/713/EU or the relevant TSI.
Assessment Result	The Object of Assessment as identified above was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the attached [EC Assessment Report or EC Technical File/Documentation section 6]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	(Required by 2008/57/EC 18(3) for Subsystems. Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment. Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of ISV or to the Assessment Report or to the Technical File section 3.)
Annex of ISV	(Only if used at issue of Certificate) (identifier, revision (if used), date)
EC Assessment Report	(identifier, revision (if used), date) The report is an integral part of this ISV.
EC Technical File / Documentation	(identifier, revision (if used), date)

Validity	This ISV is valid [until (if applicable, duration according to relevant TSI/ Module)] for the object of assessment as mentioned above and a s long as the Object of Assessment and the relevant technical documentation are not modified. [The NoBo must be informed about any modifications without delay (not relevant for SF and SG)]. [(only for SD, SH1 modules) Within the validity duration of this ISV the applicant can perform production/installation and final product/installation inspection of the object of the assessment as long as the product/installation conforms to the Type/Design Examination ISV. This validity duration may be extended on the basis of future auditing.]
	(Where applicable:) This ISV supersedes (that means replaces and withdraws) ISV number xxxxx (and, if needed: dated xx/xx/xx)

DATE of Issue:_____

Signature:_____

Name: (printed) Title: (printed)

On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

Annex 5 of RFU (only for ISV and SD, SH1, SH2)

Intermediate Statement of Verification - *Quality Management System Approval*

Number: NNNN / T / M / YEAR / SSS / C1C2 / #

In accordance with Directive 2008/57/EC of 17 June 2008 (as amended).

Object of Assessment	Quality Management System for the [design and] (only for SH1, SH2) production of the [Part of Subsystem] (DESIGNATION) (where required reference to Annex)
[Applicant] [Applicant/ Manufacturer])	(NAME, ADDRESS)
Manufacturer	(NAME, ADDRESS)
Manufacturing Location(s)	(NAME, ADDRESS) (only where different from Manufacturer, only relevant for SD, SH1, SH2)
Assessment Requirements	(TSI INF CR 2011/275/EU, amended by xxxx) in combination with the Harmonised Standards, Voluntary Standards (or parts thereof) and Alternative Solutions as identified in the EC Technical [File/Documentation] (Section 5.1)
[Scope of /Exemptions from Assessment]	(optional) (Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application for upgrade/renewal, transitional period or specific case), precise reference to the TSI(s)/parts not assessed.) (May be done by reference to Attached Documentation.)
Module(s) applied	[SD, SH1, SH2] of the relevant decision adopted pursuant to the Directive.
Assessment/ Audit Result	The Quality Management System of the aforementioned Manufacturer [at the indicated Location(s)] has been audited and was shown to comply with the Assessment Requirements, subject to any Conditions and Limits of use as listed below. The Assessment Results are provided in detail within the attached [EC Audit Report or EC Technical File/Documentation section 6]. The Essential Requirements have been assessed as being met through compliance with the requirements of the relevant TSI only.
Conditions and Limits of use	(Required by 2008/57/EC 18(3) for Subsystems. Text and/or reference to detailed information on Conditions and Limits of use (these may also be referred to as Limitations, Restrictions, Constraints, etc.) of the Object of Assessment. Where defined in a TSI this shall include the 'Area of Use' information as far as this is to be evaluated by the NoBo. Make reference to Annex of ISV or to the Assessment Report or to the Technical File section 3.))
Annex of ISV	(Only if used at issue of ISV) (identifier, revision (if used), date)
EC Audit Report	(identifier, revision (if used), date) The report is an integral part of this ISV.
EC Technical File	(identifier, revision (if used), date)
Validity	The validity of this ISV is subject to (continued compliance with the [Design][Type] Examination ISV(s) as listed on the attached annex, which forms part of this certificate and - SD, SH1, SH2 only) the continued maintenance of the Quality Management System in accordance with the

requirements of the above Directive as monitored through regular and unannounced surveillance.
This ISV is valid [until (duration according to relevant TSI/ Module)] as long as the Object of Conformity Assessment, the Quality Management System and the relevant technical documentation are not modified. The NoBo must be informed about any modifications without delay.
Within the validity duration of this ISV the applicant can perform production/installation and final product/installation inspection of the object of the assessment. This validity duration may be extended on the basis of future auditing.

(Where applicable:) This ISV supersedes (that means replaces and withdraws) ISV number xxxxx (and, if needed: dated xx/xx/xx)

DATE of Issue:_____

Signature:_____
Name: (printed) Title: (printed)
On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]

Annex 6 of RFU

Annex to (precise reference to related certification level document)

Number NNNN / T / M / YEAR / SSS / C1C2 / #

Object of Conformity Assessment	[Interoperability Constituent][Subsystem] [Part of Subsystem] (DESIGNATION) (and for A1, F, SF, SG UNIQUE SERIAL NUMBERS –) (where required reference to Annex)

Conditions and Limits of use	(follow up from related EC-Certificate/ QMS-Approval/ ISV)
[any other information which could not be placed on the EC Certificate]	(text or reference to detailed information)

DATE of Issue:_____ Signature:_____

Name: (printed) Title: (printed)

On behalf of [NAME/ ADDRESS/ EC-Identification No. of Notified Body]