CERTIFICATION RULES

GRUPPO
ISTITUTO ITALIANO DELLA SALDATURA

RULES FOR ISSUING CERTIFICATE OF CONFORMITY IN ACCORDANCE WITH EUROPEAN DIRECTIVES/REGULATIONS

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CONTENTS

1 SCOPE AND FIELD OF APPLICATION

1.1 This Rule defines the criteria that IIS CERT applies in the evaluation of conformity activities in response to the European directives and the issue of the relative certificates.

In particular, the Rule describes the criteria implemented by IIS CERT for:

- the issue of approvals required by Directive 2014/68/UE (hereinafter PED) regarding pressure equipment, limited to the activities of European approval of the materials, the approval of non-destructive testing personnel, the approval of welding personnel and procedures relative to the execution of permanent joints;
- the issue of the certificates of conformity required by Directive 2014/29/UE (hereinafter SPV), regarding simple pressure vessel;
- the issue of the certificate of conformity in the field of the construction products (or materials) as certification Body as provided by Art. 9 of Legislative Decree No. 106/2017;
- the issue of certificates of conformity or eligibility for use of the railway interoperability components and the completion of the EC assessment procedure of the subsystems of the European Community railway system, as provided of Legislative Decree N. 57/2019

1.2 The Rule is divided in:

- one General Part;
- five Annexes relative specifically to the Directives PED (two Annexes), SPV and railway interoperability and to the Regulation CPR.

The Annexes refer, in the numbering of the paragraphs, to the corresponding paragraphs of the Rule for which additional requirements have been introduced.

1.3 For anything not provided in this document, please refer to the general contract terms and conditions established in the rule CER_QAS 017 R (see § 2) which can be found on the IIS CERT website.

In particular, IIS CERT implements all the actions to guarantee:
- the impartiality;
- the absence of conflict of interest;
- the confidentiality of any information owned by the customer.

1.4 For the activities covered by this Rule, IIS CERT operates, in accordance with the authorizations granted by the competent authorities and according to the requirements of the standard EN ISO/IEC 17020, as Type “A” inspection organization and therefore applies the criteria of independence, impartiality, integrity and confidentiality provided by that standard.

1.5 Access to the IIS CERT services is open to all Organizations and is not conditioned by their affiliation or otherwise to any Association or Group.
IIS CERT applies its own current rates, guaranteeing fairness and uniformity of application, for these services.

IIS CERT is legally entitled to refuse requests for certification by organizations that are subject to, or whose production or activities have been subject to restriction, suspension or proscription by a public authority.

1.6 ACCREDIA and the concerned Ministries may request, where applicable, the participation of their own observers in the audits performed by IIS CERT, in order to ascertain that the assessment methods adopted by IIS CERT itself comply with the applicable rules; the participation of these observers is previously agreed between IIS CERT and the Organization.

The refusal by the Organization to grant its approval for the above mentioned checks may result in the suspension and subsequently revocation of the certification.

2 REFERENCES

CER_QAS 002 R	Rules for the use of the IIS CERT marking
CER_QAS 017 R	Rules for the assessments of systems, personnel, products – General Contract Conditions
EN ISO/IEC 17020	Requirements for the operation of various types of bodies performing inspections
EN ISO/IEC 17021-1	Conformity assessment – Requirements for bodies providing audits and certification of management systems – Part 1: Requirements
EN ISO/IEC 17024	Conformity assessment – General requirements for bodies operating certification of persons
EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
EN ISO/IEC 17065	Conformity assessment – Requirements for bodies certifying products, processes and services
EN ISO 9000	Quality Management Systems – Fundamentals and vocabulary
EN ISO 9001	Quality management systems – Requirements
EN ISO 9712	Non-destructive tests – Qualification and certification of the personnel assigned to the non-destructive tests
EN ISO 14731	Coordination of the welding activities – Tasks and responsibilities

In general, the documents of reference cited are applicable in the latest valid and/or revised edition.

In any case, considering that the national implementation decrees of the European directives cited in § 1 sometimes listed outdated references to standards of reference (now obsolete), following please find a correlation table between the standards listed above, including the issue date, and the outdated references of the aforementioned European directives.

Current standards di reference	Outdated references to implementation decrees of European directives
EN ISO/IEC 17020:2012	EN 45004 (ed. 1996)
EN ISO/IEC 17021-1:2015	EN 45012 (ed. 1998)
EN ISO/IEC 17024:2012	EN 45013 (ed. 1990)
EN ISO/IEC 17025:2018	EN ISO/IEC 17025 (ed. 2000)
EN ISO/IEC 17065:2012	EN 45011:1999
EN ISO 9000:2015	EN ISO 9000 (ed. 2000 and 2005)
EN ISO 9001:2015	EN ISO 9001 (ed. 2000 and 2008)
EN ISO 9712:2012	EN 473 (--)
EN ISO 14731:2007	EN 719 (--)

In addition, the references listed in the relative Attachments are applicable for the PED, SPV and railway interoperability, and for the CPR regulation.

3 DEFINITIONS

In general the definitions apply of the standards of the ISO/IEC 17000 series (see § 2), with the additions listed below, when they are of a general nature, and in the Annexes, when they refer to the individual directives.

Company:	Applicant requesting certificate of conformity (manufacturer, authorized representative, user, etc.)
Finding:	Observations made by IIS CERT during audits conducted on the Company and formalized in its audit reports. For the purposes of this Rule, the findings are divided into non-conformities, observations and comments.
Non-conformity:	The Company's failure to satisfy a requirement established by the applicable regulatory references. For the purposes of the provisions contained in these Rules, a finding is classified as non-conformity when the failure to meet the corresponding requirement is such that it may compromise the compliance with the RES anticipated by the directive.

Observation:	A finding formalized by IIS CERT in regards to the Company is classified as an observation when the failure to satisfy the requirement, even when indicative of unsatisfactory behaviour on the part of the Company and, as such, requires correction, is not such as to immediately compromise the value of the certifications issued under the aforementioned terms.
Comment:	A finding raised by IIS CERT in regards to the Company is classified as a comment when it is not followed when it is not the result of a finding of an objective situation of non-fulfillment of a requirement, but it is intended to prevent this situation from occurring (as potentially achievable) and/or provide guidance for improvement in the performance of the Company.

4 VERIFICATION OF CONFORMITY PROCEDURES

4.1 Overview

4.1.1 The verification of conformity procedures, for the PED, SPV and railway interoperability and for the CPR regulation, are listed in detail in the relative Attachments.

4.1.2 IIS CERT generally used in-house inspectors. If it uses outside inspectors, they are always asked to act as sole agent.

4.1.3 If laboratory tests are required, IIS CERT uses outside laboratories with which it has an agreement of willingness to conduct tests on behalf of IIS CERT or a special agreement.

4.1.4 The applicant Company must take all the measures necessary so that the IIS CERT inspectors can conduct the visits in complete safety. The Company assumes all responsibility vis-a-vis the inspectors that an employer would for its employees in order to comply with all the conditions of the applicable legislation.
Usually, during the audits, the IIS CERT personnel must be constantly accompanied by the Company's personnel.

4.2 Phases of the activity

The verification of conformity procedures always includes the following phases:

a) request for proposal from the Company, with the certification application filled out;
b) economic proposal by IIS CERT and subsequent ODA issue by the Customer;
c) compilation of the certification application form by the Customer and relative review (see in detail the § 4.2.1)
d) assessment or investigation activity (see § 4.2.2 for details);
e) audits and tests;
f) notification of possible non-conformities (preventing the issuance of the certificate of conformity);
g) issue of the certification or a report;
h) changes in the conditions that led to the issue;
i) management of other certificates relative to the product.

If applicable, the following can also be carried out before phase d):

-) document review;
-) approval of the project;
-) approval and assessment of the application of the quality system to the project;
-) if required, in application of the interoperability directive to the European Community railway system, the assessment of the appropriateness of using the interoperability components.

4.2.1 Review of the application

The Project Manager carries out a review of the information verifying the congruence between the ODA and the certification application to ensure that:

a) the information relative to the customer and certificate requested are sufficient to conduct the activity;
b) possible differences in understanding between IIS CERT and the customers regarding the standards of reference are resolved;

c) the field of application of the certificate of conformity is defined;
d) all the means to perform all the certificate of conformity activity are available;
e) that IIS CERT is competetent and has the capacity to undertake the activity expected (see the following notes).

If a positive outcome occurs, the certification process proceeds; otherwise PM reviews the economic / technical offer to make it congruent with the certification application.

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Note 1 *The activities covered by this rule are only those listed in § 1.1 and therefore IIS CERT does not undertake assessment of conformity activities relative to other European directives.*

Note 2 *If it should rely, in order to leave out any activity, on certificates of conformity already issued to the customer, IIS CERT will refer to the certificates included in its registrations and, if requested by the customer, will provide justification for omitting the activity.*

4.2.2 Assessment Activity

IIS CERT carries out its assessment activity by implementing the following:

a) has an appropriate plan for the assessment activities;
b) directly assigns internal or external personnel to perform each of the assessment tasks to be undertaken (the Company can object to the appointment of the appointed assessors, within 5 days of the relevant communication, justifying the reasons);
c) makes sure that all the information and/or the documentation necessary are made available for the implementation of the assessment tasks;
d) predominantly uses its own internal resources and, should outside resources be used, manages them directly depending on the assessment plan (see also § 4.1.2);
e) informs the Customer of any deficiencies resulting from the examination of the documentation, requesting appropriate additions (via e-mail communication);
f) in case of assessment/certification activity already performed by other bodies, it relies on the relative results only if those bodies are accredited/notified;
g) informs the customer of all the non-conformities found;
h) if non-conformities are found, provides information on the additional assessment tasks necessary to make sure that the non conformities have been corrected (see also § 4.3);

4.3 Management of the findings

When non-conformities are present, the certification is not granted until confirmation has been received that the necessary processes have been applied (the Company's proposal must be received by IIS CERT within 30 days of the formalization of the finding), the corresponding corrective actions have been closed and the relative verification of effectiveness by IIS CERT.

Waivers from the actions proposed by the company are not allowed unless conceded by IIS CERT for justified reasons.

IIS CERT reserves the option to check the implementationof the actions proposed by the Company, also by carrying out unscheduled audits, if the process, the identification of the causes and the possible corrective actions/preventive actions cannot be assessed just from the document proof proposed.
In this case it is IIS CERT's duty to give the Company adequate warning in order to prepare the visit.

The observations formalized by IIS CERT must undergo the necessary processes and corrective actions by the Organizations and these must be sent to IIS CERT if requested for their approval.

Comments do not require an immediate and official response; however, IIS CERT verifies the level of implementation of the instructions provided during the first appropriate audit.
If the aforementioned instructions are not adequately considered, the comment may be turned into an observation. In that case the aforementioned conditions apply.

4.4 Results of the certification procedure

Only the files of Companies for which the Inspector responsible has expressed a positive opinion (see also following Note) and which meet the following conditions, are submitted to the Deliberating Body:

a) any non-conformities have been resolved, providing proof that they have been processed and the implementation of the corrective actions within the time agreed;

b) the observations have been processed submitting to the inspector an adequate plan that defines the processes (when applicable), the causes, the corrective actions and the relative implementation times.

Should the inspector decide not to require the aforementioned plan, he records the reason in the deliberation document.

In case of negative evaluation of the documentation, even after appropriate additions, the "denial" of the certification is recorded (see also Note 2 below); the Company may however request a new assessment, for which a new procedure will be applied.

The Deliberating Body analyzes at least the following requirements and documentation:

- document review;
- purpose of the certification;
- inspection reports;
- reports of non-conformity;
- observations;
- proposals for corrective actions;
- documentation regarding disputes that may have arisen.

Should the Deliberating Body not consider the file complete, including that which is reported by the inspector or the plan defined by the Company inadequate, it suspends the decision, waiting for clarifications, recording the reasons in the specific document.
The inspector informs the Company of the reasons and takes actions to correct the deficiencies and then again propose another decision; if still unsuccessful, the Deliberating Body records the “denial” of the certification, recording also the reasons (see also note 2).

If the decision of the Body is favorable, the Company is notified along with any limitations/conditions (i.e. request for additional visit) and determines the issue, for the file in question, of a certificate of conformity with validity defined in the attachments relative to the specific certificates of conformity: the certificate is made available to theOrganizationin electronic format in the reserved area of the IIS CERT website (for the certificates issued according to the EWF/IIW schemes, see also § A.10).

The Company is required to accept the decisions of the Deliberating Body. If it considers the reason unjustified and does accept the decisions, it can start the appeal procedure.

IIS CERT will record the issue of the certificates of conformity in a special list, including any suspensions and/or revocations of the certification, sending at least once a year an extract of that register to the Competent Authorities (this applies in particular for the Factory Production Control certificates of conformity).

Nota 1 *With reference to §§ 7.5 and 7.6 of EN ISO/IEC 17065, the deliberating Body conducts at the same time the review activity of the files presented by the Inspector and the decision-making activity relative to the certification/certificate.*

Nota 2 *For certain activities of attestations of conformity (eg SPV and PED directives), in case of refusal it is necessary to inform also the competent authorities concerned: in this regard, please refer to the individual Annexes.*

4.5 Obligations of the Certified Companies

The certified Company is required to respect the following conditions:

- not use the IIS CERT and ACCREDIA trademarks in a way which could be interpreted as product approval (i.e. mark applied to the product, etc.), abiding by what is provided in the specific rule CER QAS 002 R (see § 2);
- not advertise the certification in such a way as to give the impression that it is valid for activities other than those for which it was issued, or in any case in a way which could be misleading;

- promptly notify IIS CERT of any changes to the Company or changes in ownership, or other changes which could affect its ability to satisfy the certification requirements;
- accept, at its own expense, even unscheduled audits which may become necessary to keep the certification valid following changes in ownership, organizational modifications or other situations considered significant by IIS CERT;
- allow access to its premises to IIS CERT's Auditors (or its authorized representatives) and the Accreditation Agencies, providing them with the necessary assistance during their audits;
- implement the corrections for a correct management of the quality requirements for the welding following deviations detected;
- not use the certification when it has been suspended, revoked, or has expired;
- keep records of all claims relative to the its activity, as well as the corrective actions that ensued as a result;
- manage the copies of the certificate that are no longer valid as an obsolete document;
- keep the documentation sent by IIS CERT updated.

Note *Furthermore, the Company also take into account the following requirements taken from EN ISO/IEC 17065:*
- *always meet the certification requirements, including implementation of necessary modifications notified by IIS CERT;*
- *under suspension, revocation or expiration of the certification discontinue use of all advertising material that contains any reference to it*;
- *in the case of delivery of certificates to others, to reproduce them in their entirety.*

4.6 Waiver by the Company

If the certified Company intends to waive the certification, it must give formal notice to waive the contract at least 6 months before the date (month/day) of expiry of the certificate.
The Company may also waive certification in the case of changes to these rules and variations of the reference standard certification.
The withdrawal by the Company entails the simultaneous and automatic revocation of the certification. This situation is reported to the Accreditation Bodies, which will provide the necessary arrangements.

Following the waiver, the Company must:
- not use the certification;
- remove any reference to the IIS CERT certification from the letterhead and technical and advertising documentation.

IIS CERT will delete the Company from the list of certified Companies and make public the waiver using the means by which the certification had been advertised.
Furthermore, the certificate already issued to the Company will be removed from the restricted area of the IIS CERT website after prior and formal notification.

The company, which after waiver wishes to be re-certified must submit a new application repeating the whole process.

4.7 Suspension or revocation of the certification

4.7.1 The certification may be suspended in the following cases:

4.7.1.1 non-conformity and/or observation, for which no treatment has been completed nor corrective actions implemented within the specified time;

4.7.1.2 non-conformity and/or observations for which IIS CERT had not defined, nor accepted, within the terms of the contract, the treatment, the corrective actions and the times of implementation;

4.7.1.3 repeated delays in the processing of the non-conformities and/or observations and in the implementation of the resulting corrective actions;

4.7.1.4 changes to the organization of the Company that had not been accepted by IIS CERT;

4.7.1.5 in the case of major restructuring of the Company which were not communicated to IIS CERT;

4.7.1.6 refusal or obstruction of monitoring visits;

4.7.1.7 improper use of certification and/or the IIS CERT marking;

4.7.1.8 delinquency in the payments of the IIS CERT services;

4.7.1.9 verified claims received for IIS CERT that the Company had not properly managed;

4.7.1.10 due to refusal or barrier to the participation in the audits by the observers of an Accreditation Agency;

4.7.1.11 any other circumstance that IIS CERT, in its opinion, believes have a negative influence on the certification granted;

4.7.1.12 The Company can also request IIS CERT, justifying the reasons, to suspend the certification.

The suspension procedure is preceded by a written warning setting out the terms which, if not met, would trigger a suspension.

The suspension is decided by the Deliberating Body and cannot last more than six months (after that, the revocation becomes effective).

The suspension starts from the date of the decision and is notified in writing, by registered letter to the Company, specifying the conditions for restoring the certification and the deadline by when they must e implemented. This notification is submitted to the IIS CERT Committee to Safeguard Impartiality which has the power of ratification.

As a result of the suspension, the Company must inform its customers of the situation.

The suspension of the certificate's validity may be made public by IIS CERT.

The restoration of the certification is subject to certification of the elimination of the deficiencies which caused the suspension. It is notified in writing by registered letter to the company and made public by IIS CERT if the news of the suspension had been made public at the time.

4.7.2 The revocation of the certificate may be decided in the following cases:

4.7.2.1 failure to satisfy the requirements listed in the preceding point (4.7.1);

4.7.2.2 suspension that continues longer than six months;

4.7.2.3 misuse of the certificate and/or IIS CERT marking;

4.7.2.4 failure by the Company to adopt the new rules expressed by IIS CERT following changes to the Regulation;

4.7.2.5 persistent delinquency in the payments of the IIS CERT services;

4.7.2.6 Company's failure to implement the measures requested by IIS CERT following incorrect use of the logo and the certification;

4.7.2.7 termination of the activity certified;

4.7.2.8 proof that the scheme certified does not ensure compliance with the binding laws and regulations applicable to the characteristics of the product supplied;

4.7.2.9 Company's failure to accept the new financial conditions established by IIS CERT for the possible change in the contract;

4.7.2.10 for any other justified reason, in the opinion of IIS CERT.

The revocation is decided by the Deliberating Body and ratified by the Committee to Safeguard Impartiality.
Withdrawal of the certificate shall be notified in writing by registered letter to the Company.

IIS CERT notifies the Accreditation Bodies the name of the organizations whose certifications have been revoked, specifying the reasons.

The Company which has had the certification revoked must:

- not use copies or reproductions of the certificate revoked;
- remove any reference to the IIS CERT certification from the letterhead and technical and advertising documentation.

IIS CERT will delete the company from the list of certified Companies and make public the revocation using the means by which the certification had been advertised.
Furthermore, the certificate already issued to the Company will be removed from the restricted area of the IIS CERT website after prior and formal notification.

The Company, which after revocation wishes to be re-certified must submit a new application repeating the whole process.

4.8 Registration Documents

The registrations of the activities performed are generally stored electronically.
In particular, for each of the activities specified, the registrations specified in the applicable individual Attachment are stored.

5 CONTRACTUAL CONDITIONS

For the contractual conditions, the provisions contained in the "Rules for the assessments of systems, personnel, products – General Contract Conditions" (see § 2) are applicable in the latest revised edition.

ANNEX A Particular aspects for the PED directive - European approval of the materials and the manufacturer's quality system

A.1 Scope and Field of Application

A.1.1 The additional, not replacement, rules applied by IIS CERT in the case of assessments of conformity relative to Directive 2014/68/UE (PED), compared to what has already been defined previously in the General Part, are defined in this Annex specifically for:

- the issue of the European approval of the materials destined for repeated used in the manufacture of pressurized equipment, not falling under a harmonized standard;
- the integration for the issue of the certification of a quality system for the manufacturer of the equipment.

Only the points of the General Part are included for which additional rules are applicable and the relative numbering corresponds.

A.2 References

Directive 2014/68/UE

A.3 Definitions

In general, the definitions listed in the standard EN ISO 9000 and in the reference Directive, supplemented by the following definitions, apply for the terminology.

prEAM:	Preliminary European approval for materials. It is a document that has to be submitted to the Member States and to the European Commission for approval of the materials.
EAM:	European approval for materials. It is the final document approved by the responsible competent bodies.
OJEC:	Official Journal of the European Community.

A.4 Verification of Conformity procedures

A.4.1 Overview

A.4.1.1 Certification requirements

To earn the certificate of conformity from IIS CERT, the Company must satisfy, initially and over time, the requirements of the standard or the regulatory document of reference and those indicated in the following points.

In particular, in order to obtain the certificate of conformity, the Company must guarantee continuity in the production methods and in the quality of the products subject of the certificate of conformity.

A.4.2 Phases of the activity

A.4.2.1 Application for Certification

A.4.2.1.1 European approval of the materials

The application for approval of the material, submitted by the manufacturer of the material or the pressurized equipment, is received by IIS CERT, which makes sure that it is complete and in particular that it contains the following information (if applicable):

- designation of the material;
- references to specifications of origin;
- type of product;
- size limitations (if significant in terms of the approval);
- regulatory references of support (non-destructive controls, assessments specific requests, etc.);
- terms of supply (i.e. heat treatments);
- manufacture method;
- deoxidation mechanisms;
- chemical composition;
- mechanical characteristics (tensile test at room temperature and at high temperature, resilience test, bending test, hardness test, etc.);
- surface conditions;
- other properties (i.e. creep).

Should IIS CERT determine that the aforementioned documentation is incomplete, it asks the applicant to add the missing documentation.

Based on this information, IIS CERT drafts a financial proposal, with reference to the applicable unit rates in effect. This proposal will take into consideration all the activities which at the discretion of IIS CERT should become necessary to complete assessments of the certificate of conformity.

If the proposal is accepted, the Company formalizes the request for certification, by filling out the relative form attached to the proposal, and guaranteeing that no conformity certification activities of that product are being carried out with other Notified Bodies.

Upon receipt of the aforementioned application, IIS CERT will formalize the confirmation of acceptance of the application, notifying the name of the Responsible for the file by fax, letter of email.

A.4.2.1.2 Certification of the quality system of the manufacturer

The application for Issue of the certification of the quality system, submitted by the manufacturer of the material or the pressurized equipment, is received by IIS CERT, which makes sure that it is complete and in particular that it contains the following information (if applicable):

- designation of the material;
- references to specifications of origin;
- regulatory references of support (non-destructive controls, assessments specific requests, etc.);
- manufacture method manual;
- quality manual;
- any certifications already granted.

Should IIS CERT determine that the aforementioned documentation is incomplete, it asks the applicant to add the missing documentation.

Based on this information, IIS CERT drafts a financial proposal, with reference to the applicable unit rates in effect. This proposal will take into consideration all the activities which at the discretion of IIS CERT should become necessary to complete assessments of the certificate of conformity.

If the proposal is accepted, the Company formalizes the request for certification, by filling out the relative form attached to the proposal, and guaranteeing that no conformity certification activities of that product are being carried out with other Notified Bodies.

Upon receipt of the aforementioned application, IIS CERT will formalize the confirmation of acceptance of the application, notifying the name of the Responsible for the file by fax, letter of email.

A.4.2.2 Operating Modes

A.4.2.2.1 European approval of the materials

The Responsible of the file, having reviewed the application, identifies among the inspectors those who, based on specific skills, will perform the assessments of the materials subject of the European approval of materials.
Based on the results of the verifications performed, IIS CERT prepares the PrEAM to be submitted to the Committee to Safeguard Impartiality for ratification. Once this ratification has been obtained, IIS CERT forwards the PrEAM to the Member States and to the European Commission and enters the technical data relative to the tests conducted in the specific electronic database of the European Community (CIRCA EAM).
If the verifications performed by the competent European bodies listed above give rise to comments, they will be notified to IIS CERT by the deadlines established by those bodies.
In that case, IIS CERT, with the cooperation of the Product Inspectors who participated in the preparation of the prEAM, answers the comments received, issued the review of the prEAM and changes the data entered in the CIRCA EAM database.

A.4.2.2.2 Certification of the quality system of the manufacturer

The Responsible of the file checks that the documentation sent by the Company is complete and consistent and then sends notification of the start of the certification process, by fax, letter of email, together with the name of the inspector responsible for the auditing activities (RGV).

Should the documentation received by incomplete or non-compliant, the Company will be asked to supplement or modify it to render it complete and compliant. In the meantime, the process remains suspended for a maximum of twelve months, after which the entire process can be repeated starting with a new proposal, if in the opinion of IIS CERT situations occurred making it impossible to comply with the contract.

The initial audit (assessment) can only take place when the documentation is considered compliant and after the requirements defined by the standard of reference are fully operational.

IIS CERT then informs the Company of the completion of the document review, pointing out possible observations and/or comments and agreed on the date of the visit with the Company.
The Company can delivery the correct documentation during the opening meeting of the assessment visit.

A.4.2.2.3 Preliminary visit

If agreed with the Company, IIS CERT can perform, before the assessment visit, a preliminary visit to assess the overall status of the application of the quality system.

This visit, notified by the RGV to the Company, is conducted in order to review the required documents of reference, without following the procedures anticipated for the evaluation activity (for example, the opening meeting is not held and check lists are not used).

The Company is informed of the result in the visit report which may be delivered at the end of the visit or sent later.

A.4.2.2.4 Assessment visit

At the same time or separately from the closure of the document review, the RGV agrees with the Company on the date and notifies the representative of the inspectors appointed to perform the activity, forwarding the audit plan.

IIS CERT can ask the Company for authorization to allow observers and/or auditors in training to participate in the visit.
The Company has the right to request the replacement or recuse the individual appointed, in case of justified conflict of interest, within 5 days of the notification date.

Before performing the evaluation visit, the assessment team (GV) holds and opening meeting, recording on the audit report the meeting with the Company’s Management or its Representative and those responsible for the main departments.

During the audit, the Company is required to make available the staff and to grant free access to the company areas, the information, the documentation relative to the product for which the certification has been requested, and to assist the IIS CERT Auditors.

The application of the requirements is checked through:

- the assessment includes a visit to the production units;
- the assessment includes a review of:
  - production technology adopted,
  - equipment used,
  - principal parameters to be kept under control,
  - tasks of the personnel responsible for applying the quality system and all the related production activities.

In addition, the GV must assess that:

- the equipment used for the production and the control devices of the essential parameters of the process are operational;
- there is competent personnel present, assigned to the operation and maintenance of the equipment, the supervision of the manufacturing process and the inspection and verification activities;
- possible exclusions are justified;
- the the definition of the purpose of the certificate of conformity is correct.

At the end of the audit and before the closing meeting the AG will meet to;

- make sure that they have considered all the requirements applicable to the standard subject of the certification of conformity;
- prepare the visit report in which possible observations and/or comments are listed.

The evaluation audit ends with the closing meeting, during which the RGV explains to the representatives of the Company:

- possible findings;
- the possible observations and/or comments (described in the Audit Report);
- the “Audit Report” document.

The documents listed above are handed over to the Company representative who, if in agreement, will sign them for acceptance and will keep a copy. If not in agreement he will express the reservations in the space provided in the audit report.

A.4.2.2.5 Surveillance Audit

During the validity of the certificate, the Company is required to maintain its production process in compliance with the Standards of Reference.

IIS CERT performs period audits at the Manufacturers in order to:

- assess the maintenance of the conformity of the FPC with the requirements of the standards of reference;
- assess the correct implementation of the corrective actions (if applicable) in regards to the non-conformities found in the course of the previous visit.

The frequency of these audits is defined by the harmonized standards of reference, at least annually.

A.4.2.2.6 Extraordinary or Additional Surveillance Audit

The Deliberating Body reserves the right to require additional surveillance audits at the Company (or based on documentation at the IIS CERT office) in the following cases:

- receives claims or reports received by IIS CERT, considered particularly significant, relative to the non-compliance of the Manufacturer to the requirements of the Standard of Reference and this Regulation;
- processing of non-conformities or observations found during an audit or corrective actions which cannot be evaluated just through review of the documentation;
- organizational and/or technical changes (new machinery, new processes, change in management personnel, etc.).

The aforementioned decision is notified to the Company together with the relative reason and the deadlines by when it must be conducted.

It is preferable that the audit be conducted by one of the Auditors who participated in the preceding audit. The requirements of the standard being reviewed are at least those considered non-compliant and/or indicating a weakness in the system, found during the preceding audit.

The methods of conduct are the same as those defined for the surveillance audits.

The cost of the supplemental audit will be borne by the Company.

In case of refusal, without valid reasons, by the Company, IIS CERT can start the suspension process of the certification.

The additional Audit does not affect the frequency of the surveillance audits.

A.4.2.2.7 Unscheduled Audit

IIS CERT reserves the right to conduct unscheduled audits on certified Companies to investigate claims or following changes or as actions resulting from the suspension of the certification.
The cost for the implementation of these audits must be considered contractually like those of additional surveillance audits and therefore must be borne by the Company.

The Company cannot raise objections with the members of the audit group.

In case of refusal, without valid reasons, by the Company, IIS CERT can start the suspension process of the certification.

The audit without notice does not affect the frequency of the surveillance audits.

A.4.2.2.8 Validity and renewal of the certification

The validity of the certification is three years.

At the expiry of the certification a renewal audit is performed, with the same procedures applied during the assessment visit.

The renewal is subject to a new order before a new quotation prepared with the assistance of the information in IIS CERT's possession.

The Company must send IIS CERT, should changes have occurred since the last visit, the following documentation:

- application for certification and everything listed therein,
- the procedures(s) if modified in respect to the previous documentation sent to IIS CERT.

In the case of changes, IIS CERT formalizes the acceptance of the application and appoints the RGV for the contractual period defined.
If there are no changes, the RGV is appointed directly for the contractual period defined.
The RGV conducts the review of the documentation only in the case of changes, notifying the customer of the audit schedule and the possible nomination of other auditors.

A.4.2.2.9 Amendment of extension of the certification

During the period of validity of the certification, the Company must promptly inform IIS CERT of every significant change concerning its organization, activities, and the family of products it creates. In this case, IIS CERT will arrange to inform the Company of the audit activities which will be necessary and the relative pricing.

A.4.2.3 Laboratory Tests

In the case of initial-type testsIIS CERT reserves the right to perform additional tests on samplestaken at the factory, on the market and in the work sites; these tests will be conducted at authorized Laboratories.

The cost of performing these tests must be considered contractually the responsibility of the Company.

A.4.4 Issue of the certification

A.4.4.1 European approval of the materials

Once the phase listed in § 4.3.1 has been completed and the subsequent verifications have been conducted by the Member States and the European Commission, IIS CERT definitely updates the CIRCA

EAM database, and if charged to do so by the Committee to Safeguard Impartiality, formally issues a definitive EAM appropriately identified.
The European Commission will publish the EAM in the Official Journal of the European Community (OJEC).

The certificate, in the name of the manufacturer of the material or the equipment, is issued to him.
In case of changes in the rules of the certification system, the bearers of the certificate of approval are informed of the changes which have occurred and possible actions necessary to maintain the approval.
In the case of failure to obtain the approval, the decision is notified in writing with the relative reason.

IIS CERT collects the approval certificate of the material issued if it determines that it should not have been issue or if the type of material has already been included in a harmonized standard. In this case, IIS CERT immediately notifies the other Member States, the other Bodies notified and the European Commission of the revocation of the approval.

A.4.4.2 Certification of the quality system of the manufacturer

The validity of the certification is three years.

At the expiry of the certification a renewal audit is performed, with the same procedures applied during the assessment visit.

The renewal is subject to a new order before a new quotation prepared with the assistance of the information in IIS CERT's possession.

The Company must send IIS CERT, should changes have occurred since the last visit, the following documentation:

- application for certification and everything listed therein,
- the procedures(s) if modified in respect to the previous documentation sent to IIS CERT.

In the case of changes, IIS CERT formalizes the acceptance of the application and appoints the RGV for the contractual period defined.
If there are no changes, the RGV is appointed directly for the contractual period defined.
The RGV conducts the review of the documentation only in the case of changes, notifying the customer of the audit schedule and the possible nomination of other auditors.

A.4.8 Registration Documents

The registration documents listed in §§ A.4.2.1.1 (in the case of European Approval of the Materials) or A.4.2.1.2 and A.4.2.2.2 (in the case of certification of the quality system of the manufacturer) are stored electronically.

ANNEX B Particular aspects for the PED directive - Approval of personnel and procedures

B.1 Scope and Field of Application

B.1.1 The additional, not replacement, rules applied by IIS CERT in the case of assessments of conformity relative to Directive 2014/68/UE (PED), compared to what has already been defined previously in the General Part, are defined in this Annex specifically for:

- the approval of the personnel and the procedures concerning permanent joints;
- approval of the non destructive testing personnel (NDT).

Only the points of the General Part are included for which additional rules are applicable and the relative numbering corresponds.

B.2 References

Directive 2014/68/UE

UNI CEN / TR 15589	Non-destructive tests - Guidelines for the approval of personnel assigned to non-destructive tests carried out by third parties recognized according to the provisions of Directive 97/23 / EC

B.3 Definitions

In general, the definitions listed in the standard EN ISO 9000 and in the reference directive, supplemented by the following definitions, apply for the terminology:

approval:	recognition, through a specific procedure, that a particular skill (knowledge an experience) is adequate for a specific product/activity.
certification:	third party proof, made obvious through a specific procedure for maintaining over time a qualification obtained in a certain area on a certain date.
qualification:	proof, made obvious through a specific procedure (which often defines a shared training path), of a specific level of knowledge, achieved in a certain area on a certain date.

B.4 Approval procedures

B.4.1 General requirements

Based on the application and the information received from the manufacturer, IIS CERT drafts a financial proposal, with reference to the applicable unit rates in effect. This proposal will take into consideration all the activities which at the discretion of IIS CERT should become necessary to complete the approval activities.

The acceptance of the offer also applies as a certification application and guarantees that no approval activities are in progress relating to that same product with other Third Party Organizations/Notified Bodies.

Upon receipt of the aforementioned application, IIS CERT will formalize the confirmation of acceptance of the application, notifying the name of the Responsible for the file by fax, letter of email. The documentation required to proceed with the approval activities is provided in §§ B.4.2.1 and B.4.2.2.

To earn the approval from IIS CERT, the Company must satisfy, initially and over time, the requirements of the standard or the regulatory document of reference and those indicated in the following points. In particular, to obtain the approval, the Company must guarantee continuity in the application of the manufacturing and control procedures by the personnel subject of the approval.

B.4.1.1 Personnel and procedures for permanent joints

Generally, IIS CERT takes into consideration certifications of personnel and procedures issued by Certification Bodies accredited by Accreditation Bodies belong to EA pursuant to the EN ISO/IEC 17024 and EN ISO/IEC 17065 standards or from Third Entities recognized for Directive 2014/68 / EU. Should the Company not be able to provide documentation that satisfied these requirements, IIS CERT will arrange to conduct the qualification/certification activities at a production facility of the Company. The charges for this activity are the responsibility of the Company.

B.4.1.2 Non Destructive Testing Personnel

IIS CERT will consider the following cases:

a) certifications according to ISO 9712 issued by certification bodies recognized as Third Entities (Route A of UNI CEN / TR 15589);
b) certifications according to ISO 9712 issued by certification bodies not recognized as Third Parties (Route B of UNI CEN / TR 15589);
c) qualifications issued using criteria equivalent to those of ISO 9712 (Route C of UNI CEN / TR 15589).

B.4.2 Phases of the activity

B.4.2.1 Requirements for the approval of the personnel and procedures for permanent joints

The Company must provide the following information/documentation:

- personal data of the Manufacturer;
- equipment/set subject of assessment of conformity and name of the ON in charge of that activity;
- code and product standards applied, with possible special requests;
- construction drawings;
- welding notebook, including the map of the typical joints and the production joint procedures (for example in the case of welding WPS);
- certificates of qualification supporting the production joint procedures;
- list of operators assigned to carrying out the permanent joints and the relative valid certifications.

Should IIS CERT determine that the aforementioned documentation is incomplete, it asks the Company to add the missing documentation.

B.4.2.2 Requirements for the approval of the NDT personnel

One of the following routes applies:

B.4.2.2.1 Route A

The certification is according to ISO 9712, in a relevant sector, issued by a certification body recognized as a Third Entity, the person is considered approved without further action: IIS CERT will therefore inform the applicant that will not proceed with the procedure;

B.4.2.2.2 Route B

The certification is according to ISO 9712, in a relevant sector, issued by a certification body that is not recognized as a Third Entity, IIS CERT may consider the opportunity to stipulate with such Body a subcontract contract for evaluation activities: in this case, the applicant can be approved after IIS CERT has received satisfactory documented evidence of the qualification and certification by the aforementioned Body.

B.4.2.2.3 Route C

A qualified person in a relevant sector according to a standard equivalent to ISO 9712 can be approved by IIS CERT, provided that the qualification criteria are effectively equivalent to those of ISO 9712. Applying Route C, an on-site audit is still required: IIS CERT will then appoint one or more assessors, among whom at least one is in possession of a level 3 certification issued by a certification body, covering the relevant sectors and methods equivalent to those applied by the applicant. In particular, the aforementioned assessors must verify during the audit that the applicant fulfills the following criteria:

- satisfactory vision and perception of colors;
- general and specific training completed before the examination;
- appropriate industrial experience acquired in the method and sectors covered by the application;
- passing of written qualification exams, general and specific;
- passing specific practical examinations relating to CND on the welding of pressure equipment;

- continuation, without significant interruptions, in the activities of CND on the welding of pressure equipment;
- familiarity and ability to carry out procedures / instruction of CND on welding of pressure equipment.

Auditors will have to evaluate all applicants, including through a practical exam during which each applicant will be monitored while satisfactorily applying a relevant CND procedure / instruction covering each of the methods covered by the request.

B.4.4 Results of the certification procedure

B.4.4.1 Approval

Procedures described in the preceding points, IIS CERT keeps a register relative to the corporate practices started and saves a copy of the documentation received.

Having checked that the aforementioned documentation is complete, the file is transferred for the approval of the Inspector in charge who review the requirements of the directive:

In particular, the Inspector in charge (included in the CPM 006 list) performs the following actions:

- in the case of approval of personnel and procedures for permanent joints, he assesses the documentation pursuant to § B.4.2.1, completing the special form CPM 007;
- in the case of approval of NDT personnel, he assesses the documentation pursuant to § B.4.2.2 (Route B and C), completing the special form CFP 102.

The file is then reviewed by the Technical Director who, in the case of a positive outcome, signs for approval the form filled out by the Inspector in charge.

Lastly IIS CERT issues the Certificate of Approval signed by the Technical Director.

B.4.4.2 Validity and renewals

The approvals issued by IIS CERT concerning the permanent joint personnel and procedures and the NDT personnel will refer to the single family of pressurized equipment/sets being verified.

The approvals issued by IIS CERT concerning the personnel assigned to the NDTs can refer to the family of pressurized equipment/assembly verified.

The approvals issued by IIS CERT regarding the personnel assigned to the CND may refer to more families of equipment / pressure units; in this case the certificate has the same validity as the certificate for the operator assigned to the NDT (Route B) and therefore expires at the same time as the certificate itself

The Approval must therefore be repeated after the renewal or recertification of the operator; once the operator has renewed or re-certified and the constancy of the conditions that led to the release of the first Approval is verified by IIS CERT, a new Certificate is issued.

Failure to maintain the declared requirements and / or any changes must be communicated by the Company to IIS CERT which, according to what described in the previous points, will proceed with the suspension and / or integration of the certificate already issued. The duration of the approvals is 5 years for routes A and B and 3 years for Route C. In the case of Route B and C (and also in the case of Route A, upon explicit request by the customer), IIS CERT issues an approval certificate which includes:

a) IIS CERT logo;

b) name of the approved person;

c) name of the certification body for Route B or the applicant's employer for Route C;

d) NDT methods for which the person is approved;

e) the purpose and limits of the approval (such as those defined in ISO 9712);

f) reference to § 3.1.3 of Directive 2014/68 / EU;

g) conditions for the maintenance and validity of the approval;

h) he expiry date of the approval (aligned with that of the certificate / relative qualification);

i) signature of the Technical Director of IIS CERT.

After the deadline, the approval can be renewed if the criteria of the initial approval remain, according to the following:

- Route A: the approval is automatically renewed together with the renewal or re-certification of the relevant ISO 9712 certificate;

- Route B: the approval can be renewed upon receipt of documented evidence, by the subcontracted certification body, relating to the renewal or re-certification of the relevant ISO 9712 certificate;

- Route C: the approval can be renewed if the criteria defined in § 4.2.2.2 are met.

B.4.8 Registration Documents

The registration documents listed in §§ B.4.2.1 (in the case of approval of the personnel and procedures for permanent joints) or B.4.2.2 (in the case of approval of NDT personnel) are stored electronically.

ANNEX C Particular aspects for the SPV directive

C.1 Scope and Field of Application

C.1.1 The additional, not replacement, rules applied by IIS CERT in the case of assessments of conformity relative to the SPV Directive, compared to what has already been defined previously in the General Part. Only the points of the General Part are included for which additional rules are applicable and the relative numbering corresponds.

This Annex of the regulation establishes the general procedures and administrative terms and conditions for the EC certification of the simple pressurized containers pursuant to Directive 2014/29/UE.
For the purposes of this Annex to the regulation, by notified agency or control body we mean IIS CERT while by Manufacturer (manufacturer or his representative) we mean the Company requesting the certification.

This Rule applies to simple pressure vessels (hereafter referred as 'vessels') manufactured in series with the following characteristics:

a) the vessels are welded, intended to be subjected to an internal gauge pressure greater than 0,5 bar and to contain air or nitrogen, and are not intended to be fired;

b) the parts and assemblies contributing to the strength of the vessel under pressure are made either of non-alloy quality steel or of non-alloy aluminium or non-age hardening aluminium alloys;

c) the vessel is made of either of the following elements:

i) a cylindrical part of circular cross-section closed by outwardly dished and/or flat ends which revolve around the same axis as the cylindrical part,

ii) two dished ends revolving around the same axis;

(d) the maximum working pressure of the vessel does not exceed 30 bar and the product of that pressure and the capacity of the vessel (PS × V) does not exceed 10000 bar x l;

(e) the minimum working temperature is no lower than – 50 °C and the maximum working temperature is not higher than 300 °C for steel and 100 °C for aluminium or aluminium alloy vessels.

C.2 References

Directive 2014/29/UE

C.3 Definitions

Definition of Art. 2 of Directive 2014/29/UE apply.

C.4 Conformity assessment procedures

Prior to their manufacture, vessels of which the product of PS × V exceeds 50 bar x l shall be subject to the EU-type examination (Module B, see § C.4.1.1), as follows:

(a) for vessels manufactured in accordance with the harmonised standards referred to in Art. 12 of the Directive, at the choice of the manufacturer, in either of the following two manners:

(i) assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence without examination of a specimen (Module B – design type);

(ii) assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence, plus examination of a prototype, representative of the production envisaged, of the complete vessel (Module B – production type).

(b) for vessels not manufactured, or manufactured only partly, in accordance with the harmonised standards referred to in Art. 12 of the Durective, the manufacturer shall submit for examination a prototype, representative of the production envisaged, of the complete vessel and the technical documentation and supporting evidence for examination and assessment of the adequacy of the technical design of the vessel (Module B – production type).

Prior to their placing on the market, vessels shall be subject to the following procedures:

(a) where the product of PS × V exceeds 3000 bar x l, to conformity to type based on internal production control plus supervised vessel testing (Module C1, see § C.4.1.2;

(b) where the product of PS × V does not exceed 3000 bar x l but exceeds 200 bar x l, at the choice of the manufacturer, to either of the following:

(i) conformity to type based on internal production control plus supervised vessel testing (Module C1, see § C.4.1.2);

(ii) conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2, see § C.4.1.3);

(c) where the product of PS × V does not exceed 200 bar x l but exceeds 50 bar x l, at the choice of the manufacturer, to either of the following:

(i) conformity to type based on internal production control plus supervised vessel testing (Module C1, see § C.4.1.2);

(ii) conformity to type based on internal production control (Module C, see § C.4.1.4).

The records and correspondence relating to the conformity assessment procedures above referred to shall be drawn up in italian or english.

C.4.1 Applicable Modules and relevant assessment procedures

C.4.1.1 EU-Type examination (Module B)

General

EU-type examination is the part of a conformity assessment procedure in which IIS CERT examines the technical design of a vessel and verifies and attests that the technical design of the vessel meets the requirements of this Directive that apply to it.

EU-type examination shall be carried out in either of the following manners in accordance with Art. 13 of the Directive:

- assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of a prototype, representative of the production envisaged, of the complete vessel (production type);
- assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a prototype vessel (design type).

Obligations of the manufacturer

The manufacturer shall lodge an application for EU-type examination to IIS CERT.

The application shall include:

a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation.

The technical documentation shall make it possible to assess the vessel's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the vessel; it shall contain, wherever applicable, at least the following elements:

(i) a general description of the vessel;

(ii) conceptual design and manufacturing drawings and schemes of components, etc.;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the vessel;

(iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out, etc.;

(vi) test reports;

(vii) the instructions and safety information referred to in point 2 of Annex III;

(viii) a document describing:

- the materials selected,
- the welding processes selected,
- the checks selected,
- any pertinent details as to the vessel design;

d) where applicable, the prototype vessels representative of the production envisaged (IIS CERT may request further prototype vessels if needed for carrying out the test programme);

e) the supporting evidence for the adequacy of the technical design solution; this supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

When a prototype vessel is examined, the technical documentation shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed or a description of the proposed checks.

The manufacturer shall inform IIS CERT, that holds the technical documentation relating to the EU-type examination certificate, of all modifications to the approved type that may affect the conformity of the vessel with the essential safety requirements of this Directive or the conditions for validity of that certificate; such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the vessel has been placed on the market.

The manufacturer's authorised representative may lodge the application and fulfil the obligations set out in the previous points, provided that they are specified in the mandate.

Obligations of IIS CERT

IIS CERT shall:

a) for the vessel:
   - examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the vessel;

b) for the prototype vessel(s):
   - verify that the prototype vessel(s) has/have been manufactured in conformity with the technical documentation, that it may safely be used under its intended working conditions and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
   - carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
   - carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive;
   - agree with the manufacturer on a location where the examinations and tests will be carried out.

IIS CERT will draw up an evaluation report that records the activities undertaken in accordance with previous point and their outcomes; without prejudice to its obligations vis-à-vis the notifying authorities, IIS CERT will release the content of that report, in full or in part, only with the agreement of the manufacturer.

Where the type meets the requirements of this Directive, IIS CERT will issue an EU-type examination certificate to the manufacturer; that certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type; the EU-type examination certificate may have one or more annexes attached.
The EU-type examination certificate and its annexes will contain all relevant information to allow the conformity of manufactured vessels with the examined type to be evaluated and to allow for in-service control.
That certificate will also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

Where the type does not satisfy the applicable requirements of this Directive, IIS CERT will refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

IIS CERT keeps itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and will determine whether such changes require further investigation: if so, IIS CERT will inform the manufacturer accordingly.

IIS CERT will inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

IIS CERT will inform the Ministry of Economic Development, ACCREDIA and the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto; on request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

IIS CERT keeps a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

C.4.1.2 Conformity to type based on internal production control plus supervised vessel testing (Module C1)

General

Conformity to type based on internal production control plus supervised vessel testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in following points, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

Obligations of the manufacturer

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall provide IIS CERT of his choice with all necessary information, and in particular:

a) the technical documentation, which shall also include:
   - the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
   - the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
   - a report on the examinations and tests performer;
b) the inspection document, describing the appropriate examinations and tests to be carried out during

manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

c) the EU-type examination certificate.

The manufacturer shall present his vessels in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

Il fabbricante presenta i propri recipienti in lotti omogenei e prende tutte le misure necessarie affinché il processo di fabbricazione assicuri l'omogeneità di ciascun lotto prodotto.

During the manufacturing process, the manufacturer shall, under the responsibility of IIS CERT, affix the identification number of IIS CERT itself.

The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market; the EU declaration of conformity shall identify the vessel model for which it has been drawn up.

The manufacturer shall be able to supply on request by the relevant authorities the certificates of conformità issued by IIS CERT.
A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

The manufacturer's obligations set out in previous points may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Obligations of IIS CERT

For each individual vessel manufactured, IIS CERT will carry out the appropriate examinations and tests in order to verify the conformity of the vessel with the type described in the EU-type examination certificate and with the corresponding requirements of this Directive in accordance with the following points.

When a batch is examined, IIS CERT will ensure that the vessels have been manufactured and checked in accordance with the technical documentation, and shall perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in the batch at a pressure Ph equal to 1,5 times the vessel's design pressure in order to check its strength; the pneumatic test shall be subject to acceptance of the test safety procedures by the Member State in which the test is performed.

Moreover, IIS CERT wil carry out tests on test-pieces taken from a representative production test- piece or from a vessel, as the manufacturer chooses, in order to examine the weld quality; the tests shall be carried out on longitudinal welds; however, where differing weld techniques are used for longitudinal and circumferential welds, the tests shall be repeated on the circumferential welds.

For the vessels subject to the experimental method referred to in point 2.1.2 of Annex I of the Directive, these tests on test-pieces shall be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the essential safety requirements set out in point 2.1.2 of Annex I of the Directive.

In the case of accepted batches, IIS CERT will affix its identification number, or cause that number to be affixed, to each vessel and shall draw up a written certificate of conformity relating to the tests carried out; all vessels in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test.

If a batch is rejected, IIS CERT will take appropriate measures to prevent the placing on the market of that batch; in the event of frequent rejection of batches, IIS CERT may suspend the statistical verification.

IIS CERT will supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

C.4.1.3 Conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2)

General

Conformity to type based on internal production control plus supervised vessel checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the following obligations, and ensures and declares on his sole responsibility that the vessels concerned are in

conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

Obligations of the manufacturer

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall provide IIS CERT of his choice with all necessary information, and in particular:

(a) the technical documentation, which shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed;

(b) the EU-type examination certificate;

(c) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate, including:

- a description of the means of manufacture and checking appropriate to the construction of the vessels;
- an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;
- an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;
- the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

The manufacturer shall affix the n identification number of IIS CERT during the manufacturing process.

The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the Directive.

The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.
A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

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.

Obligations of IIS CERT

Before the date on which any manufacture begins, IIS CERT examines those documents in order to certify their conformity with the EU-type examination certificate.

IIS CERT carries out vessel checks or has them carried out on random samples at random intervals determined by IIS CERT itself, in order to verify the quality of the internal checks on the vessel, taking into account, inter alia, the technological complexity of the vessels and the quantity of production; in particolar, an adequate sample of the final vessels, taken on site by IIS CERT before the placing on the market, will be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or equivalent tests set out in other relevant technical specifications, will be carried out to check the conformity of the vessel with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.

IIS CERT will also ensure that the manufacturer actually checks series-produced vessels in accordance with previous clause.
Where a sample does not conform to the acceptable quality level, IIS CERT will take appropriate measures.
The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the vessel performs within acceptable limits, with a view to ensuring conformity of the vessel.
IIS CERT will supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

C.4.1.4 Conformity to type based on internal production control (Module C)

General

Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in following points, and ensures and declares that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

Obligations of the manufacturer

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall provide the notified body which issued the EU-type examination certificate with all necessary information, and in particular:

a) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;
b) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel;
c) a report on the examinations and tests performed;
d) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate.
   That document shall include:
   i) a description of the means of manufacture and checking appropriate to the construction of the vessels;
   ii) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;
   iii) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;
   iv) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the Directive.
The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market.
The EU declaration of conformity shall identify the vessel model for which it has been drawn up.
A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

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.

Obligations of IIS CERT

IIS CERT will, before the date on which any manufacture begins, examine the documents listed in point C.4.4.2 in order to certify their conformity with the EU-type examination certificate.

C.4.2 Stages of the activity

The stages of the conformity assessment activity are those described in detail in the previous paragraphs C.4.1.1 to C.4.1.4, depending on the applicable Module.

In the simplest cases, the stage of the application review can be attested by affixing an appropriate stamp on the application itself.

C.4.3 Management of findings

The management of any formalized findings during the activity phases is that described in detail in the preceding paragraphs C.4.1.1 to C.4.1.4, according to the applicable Module.

C.4.4 Results of the assessment process

At the end of the conformity assessment phase, the inspector in charge carries out a comprehensive review of the documentation, as detailed in the appropriate IIS CERT software called "Perinomos_Simplex" in its current revision.

The decision making Body will then make an independent review of the practice, using the same software "Perinomos_Simplex", compiling it in the applicable parts and recording the final outcome.

Nota *In case of refusal of certification, IIS CERT informs the Ministry of Economic Development, ACCREDIA and the other notified bodies (see § C.4.1.1 in detail).*

ANNEX D Particular aspects for the CPR regulation

D.1 Scope and field of application

D.1.1 The additional, not replacement, rules applied by IIS CERT in the case of assessments of conformity relative to the EU Regulation No. 305/2001, known as CPR, are defined in this Annex.
Only the points of the General Section for which supplementary rules are applicable are included.
The Annex refers in general to activities pertaining to the field of application of Mandate 120 - Structural Metallic Products and Ancillaries, and in particular to the 2+ certification of conformity system.
Achieving the conformity of the product to the directive by the Manufacturer is however subordinate to the complete compliance with the prerequisites included in the harmonized technical standards of reference.

D.2 References

Regulation (EU) 305/2011	Regulation (EU) No. 305/2011 of the European Parliament and the Council of 9 March 2011 which establishes the harmonized terms and conditions for the marketing of construction products and repeals Directive 89/106/CEE of the Council
Directive 93/68/CEE	
Law Decree No. 106/2017	Adaptation of national legislation to the provisions of EU Regulation No. 305/2011, which sets harmonized conditions for the marketing of construction products and which repeals Directive 89/106 / EEC
Pres. Decree 10-12-1997, No. 499	Regulation bearing implementation standards of Directive 93/68/CEE for the part that modifies Directive 89/106/CEE regarding construction products
EN 10025-1:2005	Hot rolled products of structural steels – Part 1: General technical delivery conditions
EN 13479:2017	Welding consumables - General product standard for filler metals and fluxes for fusion welding of metallic materials
EN 14399-1:2015	High-strength structural bolting assemblies for preloading – Part 1: General requirements
EN 1090-1:2012	Execution of steel and aluminium structures – Part 1: Requirements for conformity assessment of structural components

The documents of reference cited are applied in the latest valid and/or revised edition.

D.3 Definitions

Construction material/product:	Every product manufactured to be incorporated or assembled permanently into buildings and other civil engineering projects.
Verification of Conformity System (SAC):	Verification of conformity procedure pursuant to the CPR regulation to be applied to a product, according to the criteria established in the ZA annexes of the applicable harmonized technical regulations.
Product specifications:	Document of the Manufacturer and/or the Customer which gives all the information and technical requirements necessary to create the product.
Initial Type Tests (ITT):	Set of tests or other procedures, suitable for verifying the performance of the representative samples of the product type.
Factory Production Control (FPC):	Manufacturer's control system suitable for guaranteeing that the products introduced into the market comply with the stated performance characteristics.
Technical File:	Set of technical documents supplied by the Manufacturer which provide proof of the adequacy of the quality control systems and process for the production of products in compliance with the CPR regulation.

D.4 Verification of Conformity procedures of the FPC

D.4.1 Certification requirements

To earn the certificate of conformity of the FPC from IIS CERT, the Company must satisfy, initially and over time, the requirements of the standard or the regulatory document of reference and those indicated in the following points.

In particular, in order to obtain the certificate of conformity of the FPC, the Company must guarantee continuity in the production methods and in the quality of the products subject of the certificate of conformity.

The IIS CERT inspectors carry out their audits using the SAC established for the specific product, assessing in general the coherence of the product specification and the activities of the Manufacturer, with reference to the requirements of the applicable technical standards.

The assessment of the FPC of the manufacturer carried out by the IIS CERT inspectors includes the following activities:

- document review;
- assessment visit and issue of the certificate of conformity of the FPC;
- periodic surveillance visits in order to maintain the certificate of conformity of the FPC;

D.4.2 Phases of the activity

D.4.2.1 Application for Certification

The Companies who want to obtain the certificate of conformity of the FPC must give the following information to IIS CERT:

- personal data of the Manufacturer;
- number and location of the production units specifying the activities performed and the employees involved;
- type of product (description, commercial name, etc.), its intended use and regulations of reference;
- possible possession of certifications relative to its quality management system and the production processes;

Based on this information, IIS CERT drafts a financial proposal, with reference to the applicable unit rates in effect. This proposal will take into consideration all the activities of the SAC for which the organization notified is responsible and possible additional assessment or test, which at the discretion of IIS CERT may become necessary to complete the assessments of the verification of conformity of the FPC.

If the proposal is accepted, the Company formalizes the application for certification, by filling out the relative form attached to the proposal, and guaranteeing that no conformity certification activities of the FPC of that product are being carried out with other Notified Bodies.

Upon receipt of the aforementioned application, IIS CERT will formalize the confirmation of acceptance of the application, notifying the name of the Responsible for the file by fax, letter of email.

D.4.2.2 Document review

Together with the application for certification or during the subsequent phase, the Company sends a controlled copy of the Technical File relative to the product subject of the application.
This file must in general include the following documentation:

- Product specifications;
- Management procedure of the FPC;
- Description and registration of the ITT results;
- the list of the possible processes outsourced, when they are essential for the conformity of the FPC with the applicable technical requirements.

The Responsible of the file checks that the documentation sent by the Company is complete and consistent and then sends notification of the start of the certification process, by fax, letter of email, together with the name of the inspector responsible for the auditing activities (RGV).

Should the documentation received by incomplete or non-compliant, the Company will be asked to supplement or modify it to render it complete and compliant. In the meantime, the process remains suspended for a maximum of twelve months, after which the entire process can be repeated starting with a new proposal, if in the opinion of IIS CERT situations occurred making it impossible to comply with the contract.

The initial audit (assessment) can only take place when the documentation is considered compliant and after the requirements defined by the standard of reference are fully operational.

IIS CERT then informs the Company of the completion of the document review, pointing out possible observations and/or comments and agreed on the date of the visit with the Company.

The Company can delivery the correct documentation during the opening meeting of the assessment visit.

In the case of assessments of conformity relative to the CPR Regulation, no preliminary visit is anticipated.

D.4.2.3 Assessment visit

At the same time or separately from the closure of the document review, the RGV agrees with the Company on the date and notifies the representative of the inspectors appointed to perform the activity, forwarding the audit plan.

IIS CERT can ask the Company for authorization to allow observers and/or auditors in training to participate in the visit.
The Company has the right to request the replacement or recuse the individual appointed, in case of justified conflict of interest, within 5 days of the notification date.

Before performing the evaluation visit, the assessment team (GV) holds and opening meeting, recording on the audit report the meeting with the Company's Management or its Representative and those responsible for the main departments.

During the audit, the Company is required to make available the staff and to grant free access to the company areas, the information, the documentation relative to the product for which the certificate of conformity of the FPC has been requested, and to assist the IIS CERT Auditors.

The application of the requirements is checked through:

- assessment of the resources available and the procedures relative to the design process (if applicable);
- assessment of the operation of the production process at the factory;
- assessment of the criteria implemented for the definition, implementation and monitoring of the Initial Type Tests (ITT) and the Sampling in Production Tests;
- interviews with personnel involved in the activities (at all levels);
- examination of the documents, procedures, instructions, minutes of meetings, reports, etc. to assess the conformity of the FPC to the documents of reference;
- where applicable, verify the presence of documents of the qualification of the processes and the operators for each process for which the Builder seeks certification of conformity of the FPC, in accordance with the product object of the certificate (see following Note);
- verification of possible exclusions;
- correct definition of the purpose of the certificate of conformity of the FPC.

At the end of the audit and before the closing meeting the AG will meet to;

- make sure that they have considered all the requirements applicable to the standard subject of the certification of conformity of the FPC;
- prepare the visit report in which possible observations and/or comments are listed.

The evaluation audit ends with the closing meeting, during which the RGV explains to the representatives of the Company:

- possible findings;
- the possible observations and/or comments (described in the Audit Report);
- the "Audit Report" document.

The documents listed above are handed over to the Company representative who, if in agreement, will sign them for acceptance and will keep a copy. If not in agreement he will express the reservations in the space provided in the audit report.

Note *The certificate is drafted as provided by EN 1090-1 (see § 2) and, when the welding process is applicable it is composed as follows:*

- *in the case of a Company certified by IIS CERT in conformity with ISO 3834, on a single page, which represents the EC certificate of the FPC, with specific reference to that certification;*
- *in the case of a Company not certified by IIS CERT in conformity with ISO 3834, on two pages, the first of which represents the EC certificate of the FPC, while the second represents the Welding Certificates (at no additional cost to the Company).*

D.4.2.4 Surveillance Audit

During the validity of the certificate, the Company is required to maintain its production process in compliance with the Standards of Reference.

IIS CERT performs period audits at the Manufacturers in order to:

- assess the maintenance of conformity to the requirements of the Standard of reference;
- assess the correct implementation of the corrective actions (if applicable) in regards to the non-conformities found in the course of the previous visit.

The frequency of these audits is defined by the harmonized standards of reference and subordinately by the documents of the GNB CPD. If the preceding conditions do not exist, the contractual conditions apply.

D.4.2.5 Extraordinary or Additional Surveillance Audit

The Deliberating Body reserves the right to require additional surveillance audits at the Company (or based on documentation at the IIS CERT office) in the following cases:

- receives claims or reports received by IIS CERT, considered particularly significant, relative to the non-compliance of the Manufacturer to the requirements of the Standard of Reference and this Regulation;
- processing of non-conformities or observations found during an audit or corrective actions which cannot be evaluated just through review of the documentation;
- organizational and/or technical changes (new machinery, new processes, change in management personnel, etc.).

The aforementioned decision is notified to the Company together with the relative reason and the deadlines by when it must be conducted.

It is preferable that the audit be conducted by one of the Auditors who participated in the preceding audit. The requirements of the standard being reviewed are at least those considered non-compliant and/or indicating a weakness in the system, found during the preceding audit.

The methods of conduct are the same as those defined for the surveillance audits.

The cost of the supplemental audit will be borne by the Company.

In case of refusal, without valid reasons, by the Company, IIS CERT can start the suspension process of the certification.

The additional Audit does not affect the frequency of the surveillance audits.

D.4.2.6 Unscheduled Audit

In the case of assessments of conformity relative to the CPR Regulation, no unscheduled audit is anticipated.

D.4.2.7 Laboratory Tests

IIS CERT reserves the right to perform additional tests on samplestaken at the factory, on the market and in the work sites; in that case the tests will be conducted at authorized Laboratories approved by IIS CERT.

The cost of performing these tests must be considered contractually the responsibility of the Company.

D.4.2.8 Validity of the certification

The certificate remains valid until the conditions defined in the technical specifications of reference or the production conditions at the factory or its production control undergo significant changes.

The duration of the contract stipulated between IIS CERT and the Company is for three years if the activity is conducted together with the assessment of conformity to ISO 9001 and for five years in all other cases.
The renewal of the contract is subject to a new order before a new quotation prepared with the assistance of the information in IIS CERT's possession.

The Company must send IIS CERT, should changes have occurred since the last visit, the following documentation:

- application for certification and everything listed therein,
- the procedures(s) if modified in respect to the previous documentation sent to IIS CERT.

In the case of changes, IIS CERT formalizes the acceptance of the application and appoints the RGV for the contractual period defined.
If there are no changes, the RGV is appointed directly for the contractual period defined.
The RGV conducts the review of the documentation only in the case of changes, notifying the customer of the audit schedule and the possible nomination of other auditors.

D.4.2.9 Amendment or extension of the certification

During the period of validity of the certification, the Company must promptly inform IIS CERT of every significant change concerning its organization, activities, and the family of products it creates. In this case, IIS CERT will notify the Company of the assessment activities which will be necessary and the relative pricing.

D.4.2.10 Issue, withdrawal and cancellation of certificates

The certificate is issued following the positive outcome of the assessment audits.

If the obligations pursuant to § 4.5 are not observed or in the case of waiver by the Company (as explained in § 4.6), IIS CERT arranges to withdraw/cancel the certificate issued, as indicated in detail in § 4.7.

In particular, in the case of an established improper use of the certification, the provisions of the CER_QAS 005 P system document "Management of claims, appeals and improper use of the certification" apply.

D.4.8 Registration documents

The registration documents listed in §§ D.4.2.1, D.4.2.2 and D.4.2.3 are stored electronically.

ANNEX E Particular aspects for the directive of the Interoperability of the European Community Railway System and for the issue of the authorization to put vehicles, structural subsystems or parts of them into service on the national network

E.1 Purpose and field of application

E.1.1 This Annex defines the additional, not replacement, rules applied by IIS CERT in the case of assessments of conformity or eligibility for use of the interoperability components and the completion of the EC assessment procedure of the subsystems of the European Community railway system, as provided by Legislative Decree N.57/2019.

In addition, supplemental, not replacement, rules are included for the VIS (Independent Safety Assessor) activities, relative to the ANSF 03/2012 Guidelines (see § E.2).

This Annex therefore establishes the general procedures and administrative terms and conditions for the EC certification required by Directive (UE) 2016/797 concerning the interoperability if the European Community railway system (implemented in Italy with Law Decree D.Lgs. 14 maggio 2019, n.57) and for the application of the audit procedures with regard to the national standards relative to the issue of the authorization to put vehicles, structural subsystems or parts of them into service (with reference to the ANSF 01/2019 Guideline).

For the purposes of this Annex to the regulation, by notified agency or control body we mean IIS CERT while by Manufacturer (manufacturer or his representative) we mean the Company requesting the certification.

Nota *At the end of this Annex, a proper paragraph is adedd in order to take into account the additional requirements – in respect to those in the standards ISO/IEC 17065, ISO/IEC 17020 and ISO/IEC 17021 – provided in the accreditation scheme issued by ERA (European Railway Agency) for notification purposes according to directive* 2016/797 */EC, hereinafter also referred to as IOD (document ERA//MNB 000MRA1044 VER.1.1 "S"). "Sectorial scheme for accreditation of notified bodies under Directive 2016/797 /EC" – Part II: Harmonised Requirements for Accreditation of Notified Bodies").*

E.2 References

CER_QAS 075 I	Process of evaluation/certification of the conformity of a component/subsystem in the railway sector
CER_QAS 093 I	VIS (ISA) activity for the issue of the authorization to commission vehicles, structural subsystems and generic and first specification applications and the authorization to use generic products or components
CER_QAS 097 I	Documentation and requirements for commissioning Rolling Stock on the Italian rail network
Decree 14/05/19 n.57	Interoperability decree implementing the European Parliament and Council Directive (EU) 2016/797 of 11 May 2016 concerning the interoperability of the European Union railway system
Decree 14/05/19 n.50 Security	decree implementing Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety
EU Regulation No. 779/2019	EU Regulation No. 779 of 16 May 2019 published in the Official Journal of the European Union of 5/27/2019, which repeals Reg.445 / 2011 and which is related to a system of certification of subjects responsible for the maintenance of vehicles and railway wagons;
EU Regulation n.402 / 2013	EU Regulation n. 402/2013 of the Commission of 30 April 2013 on the common safety method for determining and assessing risks and repealing Regulation (EC) no. 352/2009;
MIT decree n.37 of 28/6/19	indications on the modalities through which the Qualification of the Evaluation Bodies in the railway field will be followed following the entry into force of the decrees interoperability and safety of transposition of the new directives both for the transition period than at regime

ERA Scheme of 2017/06/27	Decision n. 156 of the ERA Management Board, with which the provisions on audits were adopted for Notified Bodies under the art. 34 of the Regulation (EU) 2016/796.
96/48/EC	Directive 96/48/EC of the European Council of 23 July 1996 modified by Directive 2004/50/EC relative to the interoperability of the Trans-European High Speed rail system
2001/16/EC	Directive 2001/16/EC of the European Council of 19 March 2001 modified by Directive 2004/50/EC relative to the interoperability of the Trans-European Conventional rail system
2008/57/EC	Directive 2008/57/EC of the European Parliament and the Council of 17 June 2008 relative to the interoperability of the European Community rail system
2009/131/EC	Directive 2009/131/EC of the Commission of 16 October 2009 which modifies Annex VII of Directive 2008/57/EC of the European Parliament and the Council relative to the interoperability of the European Community rail system
ANSF - Decree 4/2012	Powers regarding safety of rail traffic
ANSF - Guidelines 06/2017	Guidelines for issuing authorization to put into service vehicles and structural subsystems and authorizing the use of generic applications, generic products and components
ANSF - Guidelines 03/2012	Guidelines for the qualification by the Agenzia Nazionale per la Sicurezza delle Ferrovie [National Agency for Rail Safety] of the Independent Safety Assessors

The documents of reference cited are applied in the latest valid and/or revised edition.

E.3 Definitions

Interoperability:	The ability of the rail system to permit safe traffic without interruption of trains performing the specified services. This ability is based on the regulatory, technical and operational regulations which must be satisfied to comply with the essential requirements.
Vehicle:	Rail vehicle suitable for travelling with its own wheels on the rail line, with or without traction. The vehicle includes one or more structural, function subsystems or parts of those subsystems
Network:	Lines, stations and terminals and all types of fixed equipment necessary to ensure the safe, continuous operation of the rail system.
Subsystem:	The result of the division of the rail system as indicated in Annex II. These subsystems, for which the essential requirements must be defined, are of a structural or functional nature;
Interoperability components:	Any basic component, group of components, subset or complete set of incorporated materials or destined to be incorporated in a subsystem on which the interoperability of the rail system depends directly or indirectly. The concept of “component” includes the tangible and intangible property, such as software.
Essential requirements:	All the conditions that must be satisfied by the railway system, the subsystems and the interoperability components, including interfaces.
European specification:	A common technical specification, a European technical approval or a national standard which implements a European standard, as defined in Annex XXI of Directive 2004/17/EC.
Technical Interoperability Specifications (STI):	A specification adopted in accordance with this directive covering every subsystem or subsystem part in order to satisfy the essential requirements and guarantee the interoperability of the rail system.

Fundamental parameters:	Every regulatory, technical or operational conditions, critical to interoperability, and specified in the relevant STI.
Specific case:	Every part of the rail system which requires particular provisions in the STI, temporary or definitive, due to geographic and/or topographic limitations, urban environment or coherence relative to the existing system. This may include in particular the lines and rail network isolated from the network of the rest of the European Community, the profile, gauge or wheelbase of the tracks, vehicles for strictly local, regional or historic use and vehicles coming from or going to third party countries.
Reorganization:	Large modification projects of a subsystem or a part of it which improves the services of the subsystem.
Renewal:	Large replacement projects of a subsystem or a part of it which modify the services of the subsystem.
Existing rail system:	All the railway infrastructures which include the lines and fixed installations of the existing rail network and the vehicles of every category and origin which travel on those infrastructures.
Commissioning:	All the operations through which a subsystem or a vehicle is put into the status of operation as designed.
Contracting body:	Any organization, public or private, that orders the design and/or construction, reorganization or renewal of a subsystem. The organization may be a railway company, an operator of the infrastructure or an owner, or the agent in charge of commissioning a project.
Infrastructure Manager:	1. Any body or business responsible in particular for the realization, maintenance of a railway infrastructure or the management of the control and safety systems of the infrastructure and rail traffic. The duties of the manager of an infrastructure or part of it can be assigned to various subjects with the obligations defined in the current European Community and national standards.
National Infrastructure Manager:	2. The subject indicated in Articles 3, paragraph 1, letter h) and 11 of Legislative Decree of 8 July 2003, No. 188.
Railway undertaking:	3. Any company that owns a license pursuant to Legislative Decree of 8 July 2003, No. 188 and any public or private undertaking whose main business is to provide services for the transport of goods and passengers, or goods or passengers by rail and must ensure traction. This also includes companies which provide only traction.
Agency:	4. National agency for rail safety, as national body assigned the duties of authority in charge of the safety of the Italian rail system pursuant to Chapter II of Legislative Decree No. 162 of 10 August 2007.
ERA:	5. European Rail Agency for rail safety and interoperability.
Holder:	6. The subject or entity using the vehicle as means of transport and is registered as such in the national register pursuant to Article 33: it can be the owner or have the right to use it.
Project in advanced phase of development:	7. Any project, the design and construction, or design or construction, of which has a reached a phase that a modification of the technical specifications would be unacceptable. This impossibility can be due to legal, contractual, economic, financial, social or environmental reasons, which must be duly justified.
Type:	8. The type of vehicle which defines the essential characteristics of design of the vehicle to which the single certificate of review of the type described in Form B of the decision 93/465/CEE refers.
Series:	9. A series of identical vehicles of a same type of project.
Subject responsible for maintenance:	10. Subject responsible for the maintenance of a vehicle registered as such in the national vehicle register.
Declaration of EC Conformity:	The procedure according to which the manufacturer declares that the container complies with the directive and the legislation of reference.

EC Assessment:	The procedure followed by the notified Organization to check that the certificates comply with the directive and the legislation of reference.
EC Surveillance:	The procedure followed by the notified Organization during the manufacture to ensure that the builder complies with the requirements of the Design and Production Plan and the legislation of reference.
Type of examination:	Procedure by which the notified Organization verifies and certifies that a model (sample) of the container of a given family satisfies the requirements of the legislation of reference and agrees with the PPF.
Certificate of Qualification:	Document issued by the notified Organization which certifies the conformity of the PPF with the Directive and the legislation of reference.
Design and Production Plan (PPF):	Document issued by the Manufacturer with the purpose of describing the project, the materials and the production of the containers of a single family.
Control Plan and Tests (PCP):	Document prepared by the Manufacturer on which are listed the controls and tests to be performed, the references to the relative standards and the possible interventions (points of presence).
Final Documentation Dossier (DDF):	Documentation issued and kept by the manufacturer regarding manufactured containers of a single family.
Control Statement and Tests (RCP):	Collection of the reports of the controls and tests conducted by the manufacturer.
Quality Plan:	Document which describes the manufacturing procedures as well as the set of established and systematic provisions which will be implemented to guarantee the conformity of the containers with the legislation of reference and/or the model approved.

For additional definitions, please see § 1.2 “Glossary” of Decree ANSF 4/2012 (see § E.2).

E.4 Verification of conformity procedures

E.4.1 Phases of the activity

E.4.1.1 Process of certification/assessment of the conformity of a component/subsystem

Relative to the provisions pursuant to Directives (UE) 2016/797 and (UE) 2016/798 ,the process of certification/assessment of the conformity indicated in the special system document CER_QAS 075 I is applied.
Relative to the provisions pursuant to Decree ANSF No. 4/2012 and ANSF Guidelines No. 06/2017, the process of certification/assessment of the conformity indicated in the special system document CER_QAS 093 I is applied (see § 2).

E.4.1.2 Presentation of the application for certification

The Manufacturer (manufacturer or his representative) who intends to obtain the certification/assessment of a family of containers must submit to IIS CERT an application for certification using the special form and specifying the module that he intends to use in the realization of the component/subsystem.
The certification/assessment process of the component/subsystem continues following the flow indicated in the special system document CER_QAS 075 I for audits/certifications of interoperability or in the document CER_QAS 093 I for VIS audits/certifications.

E.4.1.3 Declaration of EC Conformity

The declaration of conformity is the document with which the Manufacturer declares that the component/subsystem complies with the directive and the legislation applied.
The declaration of conformity is written by component/subsystem and must include the user and maintenance manuals.

E.4.1.4 IIS CERT tasks in the capacity of VIS

IIS CERT in the capacity of VIS

- Pursuant to Legislative Decree 162/2007 as amended, assesses the conformity of a vehicle, structural subsystem, generic application, generic product or component with the safety requirements defined by

the national technical standards applicable to them and their suitability for use and/or to institute the procedure for the authorization to commission and/or the authorization to use, by request of an applicant;

- Pursuant to Legislative Decree 57 of 14/05/19 as amended, institutes the EC assessment procedure of the structural subsystems when national standards apply (in the role of designated body);
- Pursuant to Regulation (EC) 352/2009, evaluates the correct application of the risk management procedure pursuant to Annex I of the aforementioned Regulation and the results of that application, as Assessment Body.

E.4.8 Registration documents

The registration documents listed in the system document CER_QAS 075 I (see § 2) are stored electronically.

E.4.9 Additional requirements by ERA

This paragraph takes into account the additional requirements, compared to those of ISO/IEC 17065, ISO/IEC 17020 and ISO/IEC 17021, indicated in the accreditation scheme prepared by the ERA (European Railway Agency) for the purposes of notification under the directive UE) 2016/797, hereinafter also referred to as IOD (document ERA"Sectorial scheme for the accreditation of notified bodies under Directive (UE) 2016/797 – "Part II: Harmonized Requirements for Accreditation of Notified Bodies").

The following table therefore shows the points of the above mentioned ERA documents (hereinafter the "ERA Scheme"), the reference to the points of the applicable accreditation standard and the related additions envisaged by the ERA Scheme, and therefore are additional requirements with respect to what is indicated in the previous paragraphs, to which IIS CERT complies.

In the table the following main acronyms are used:
QMS: quality management system
DIV: intermediate verification declaration
CB: certification body

§ ERA	rif. ISO/IEC	Integrazioni
7.1	17065, § 7.1	**(General)** Point 7.1.2: the following text shall be added at the end of the point. Requirements are defined by (not exhaustive): -essential requirements as defined in the IOD 2008 and IOD 2016 -requirements included in the decision for railway modules; -basic parameters included in the text of the TSIs; -standards quoted in the text of the TSIs NOTE 1: those standards are usually called mandatory standards. -Harmonised European Standards applied in full or in part, as defined by the applicant in order to meet the essential requirements as defined in the TSIs NOTE 2: those standards are usually called voluntary standards. -alternative solutions to Harmonised European Standards, such as other public standards, documentation and company standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs NOTE 3: those standards are usually called voluntary standards. -ERA technical opinions; -ERA technical documents. NOTE 1: this assessment scheme includes implicitly an "evidence phase" which is not defined in the ISO/IEC 17065, because it is not performed by the CAB seeking notification. The "evidence phase" includes products, installations and associated documentation; it produces fundamental inputs for the evaluation, review and certification decision performed by the CAB seeking notification. Fig 3 on this PART 2 "Annex E" provides a graphical representation: -Evidence phase (not included in the ISO/IEC 17065); it is performed by other organisation than the CAB seeking notification; - -Evaluation (included in the ISO/IEC 17065 - see point 7.4); it is performed by the CAB seeking notification; -Review (included in the ISO/IEC 17065 – see point 7.5); it is performed by the CAB seeking notification; -Certification decision (included in the ISO/IEC 17065 – see point 7.6); it is performed by the CAB seeking notification. NOTE 2: The client of the CAB may have produced the evidences by any organisation the client deems appropriate (in-house bodies, testing laboratories, in-house inspection bodies, outsourcing to external bodies, etc.). Restrictions may apply on conditions for producing evidences (e.g. possible needs for accredited lab).
7.2	17065, § 7.2	**(Application)** ***[The following text shall be added at the end of the section.*** The certification body shall have a written procedure to manage applications.

		The necessary information to be contained within the application shall include at least the following: -name and address of the applicant and, if the application is lodged by the authorised representative, the name and address of the authorised representative; -contact details (e.g. office phone, mobile phone, e-mail etc.) of the physical person acting as contact point for the applicant or for the authorised representative; -all relevant information for the product including Type (i.e. product ID, product definition), and product (i.e. configuration, version, interfaces); -all the applicable TSIs, including any available or expected derogations; -the choice of the module or modules for assessment; -the scope of ISV (if the application refers to an ISV); -the declaration in writing containing the statement "that the same Application has not been lodged with any other Notified Body"; -any useful EC Certificate, Technical File, Technical Documentation; -in case of use of ISVs also ISV Certificates, ISV Technical Files, ISV Declarations of any preceding Modules or ISVs. If these are not available at time of application, the intended ISV scope and interfaces shall be precisely defined.
7.3	17065, § 7.3	**(Application review)** --
7.4	17065, § 7.4	**(Evaluation)** Point 7.4.1: The following text shall be added at the end of the point. The plan for evaluation shall be documented and it shall be the first document of the evaluation phase. The plan shall be updated if and as required during the project progress. Point 7.4.2: The following text shall be added at the end of the point. The assignment of the personnel to perform each evaluation task shall be in writing. Point 7.4.9: The following text shall be added at the end of the point. Per each product under evaluation, depending on the module chosen by the client of the CAB, the results of the evaluation phase shall be recorded by an inspection report and a QMS audit report. NOTE 1: according to the reading instructions, this point 7.4.9 is here misplaced. It is placed in this part of the document, after point 7.4.1, only to improve the readability of this document. Point 7.4.3: The following text shall be added at the end of the point. Depending of the appropriate module or modules chosen, the evaluation tasks shall contain at least one of the following: -testing, -inspection, and -quality Management System Approval.
--	17025	**(PROVE DI LABORATORIO)** Evaluation activities relating to laboratory tests follow the applicable requirements of ISO / IEC 17025 described here. IIS CERT has documented methods to ensure the aforementioned criteria according to the following possibilities: - accredited tests, - non-accredited tests.
7.4.TEST.A	17025	**(Accredited test)** The assessment provides the necessary confidence and trust in the test reports prepared under such assessment. The accredited test is the preferred means by CABs for demonstrating both acceptance criteria. NOTE 1: It is common practice that tests are contracted by manufacturers and/or applicants directly to accredited test laboratories. The assessment of the test body / laboratory shall be provided by a signatory of the multilateral agreement of EA or ILAC. NOTE 2: in EU these usually are the National accreditation bodies. An accredited test shall be accepted only if: - the test report includes a valid assessment mark and/or the assessment ID-number, and - if the CAB has received a copy of assessment certificate of the laboratory performing the test, including its annex. The performed test must have been performed within the scope and subject to the rules of this assessment. NOTE 3: the assessment certificate and its annex can be also provided electronically via website.
7.4.TEST.B	17025	**(Non Accredited test)** IIS CERT shall have a documented process for assessing the technical competence of the non-accredited testing laboratory before the performance of the tests. IIS CERT documented process shall ensure that: -IIS CERT staff who assesses the testing laboratories have the adequate competence; -IIS CERT keeps records to demonstrate the performed assessment towards the laboratory for compliance with requirements of ISO/IEC 17025 as below: Point 4.1 Organisation Point 4.5 Subcontracting of tests and calibrations Point 4.9 Control of nonconforming testing and/or calibration work Point 5.2 Personnel Point 5.3 Accommodation and environmental conditions Point 5.4 Test and calibration methods and method validation Point 5.5 Equipment Point 5.6 Measurement traceability Point 5.7 Sampling Point 5.8 Handling of test and calibration items Point 5.9 Assuring the quality of test and calibration results Point 5.10 Reporting the results -the testing laboratory presents all records of a specific test under request by the CAB;

		-competence and independence of the laboratory personnel are evaluated and recorded; -participation to inter-laboratory comparison or proficiency-testing programmes is recorded (if available); -IIS CERT assesses periodically, at least every 24 months, the laboratory to demonstrate that its competence is maintained, as far as required for the purpose of the certification. The above list can be amended by a TSI if the TSI permits certain testing by non-accredited test laboratories (e.g. by infrastructure manager's maintenance teams). In this case, the TSI may provide alternative requirements to those mentioned above in this section.
--	17020	**(INSPECTION)** The evaluation activities related to inspections shall follow the applicable requirements of ISO/IEC 17020 described in this point. The requirements for the resources for evaluation performing inspections are described in point 6.1 of this document CER_QAS 075 I.
7.4.ISP.A	17020, § 7.1	**Inspection methods, procedures and requirements** Point 7.1 including all the subsections of ISO/IEC 17020 applies together with requirements as described below. Point 7.1.1 of ISO/IEC 17020 the following text shall be added at the end. The specific methods, procedures and requirements for inspection shall be derived at least from the items of the followinglist. modules descriptions (e.g. Dec 713/2010, Annexes in TSIs, etc.); the text of the TSIs; standards quoted in the text of the TSIs; NOTE 1: those standards are usually called mandatory standards. Harmonised European Standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs; alternative solutions to Harmonised European Standards, such as other public standards, documentation and company standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs; NOTE 2: those standards mentioned in the two previous bullet points are usually called voluntary standards. ERA technical opinions; ERA technical documents; NB-Rail coordination group documents (e.g. RFUs, Q/Cs, and FAQs). The methods, procedures and requirements for inspection derived from the above listed items shall be applied simultaneously. The evaluation plan (see point 7.4.1 of this document) shall reference to these methods, procedures and requirements. NOTE 3: the methods, procedure and requirements are usually of generic nature; however there could be methods, procedures and requirements for a very specific technical solution. In this case the exact set of methods, procedures and requirements applied in a project can only be determined at the end of that project. Point 7.1.3 of ISO/IEC 17020 the following text shall be added at the end The inspection method shall include, for each product under inspection, a specific exhaustive check list. NOTE 1: The check list can be subdivided into several check lists having a matrix style format. The check list shall systematically include at least the following information: TSI parameters: structured list of all individual TSI parameters to be assessed; NOTE 2: it can happen that a TSI parameter needs to be subdivided into several sub-elements to support an efficient performance of the inspection. TSI mandatory requirements: references to applicable mandatory standards to the aforementioned TSI parameters, other mandatory references within TSIs (e.g. Chapter 6 of the TSIs, Annexes of TSIs) and where they are defined mandatory references to other TSIs or ERA Technical Documents; Other requirements (used to assess conformity with the essential requirements): exhaustive description of project specific choices of harmonised standards, voluntary standards and alternative solutions; Inspection items: references for one or several evidences used during the inspection of the aforementioned requirements. The inspection items shall refer to following point 7.4.ISP.B; Inspection results: professional judgment by the inspection body staff whether the inspection item complies with the aforementioned requirements, including reference to name of staff and date of statement. NOTE 3: it is good practice to have inspection results categorised by 3 kinds of results: Compliant, Non-compliant, not relevant (e.g. requirements for pantographs in a diesel locomotive project). Conditions for use: any conditions for use of the product under inspection as resulting from the assessment (e.g. a speed limit for rolling stock). NOTE 4: The following example can be considered as complying with the above stated minimum set of information in a matrix format. CABs may however decide to add additional columns to increase readability or may include further information. The completed check list may serve as collection of detailed information to support the report as defined in point 7.4.ISP.D of this document.
7.4.ISP.B	17025, § 7.2	**(Inspection items and samples)** Point 7.2 including all the subsections of ISO/IEC 17020 applies together with requirements as described below. Point 7.2.1 of ISO/IEC 17020 the following text shall be added at the beginning. Inspection items and inspection samples are defined as: items: are documents which demonstrate certain properties of a product; samples: are products, which can be a prototype, a first in series or product taken from a mass production. NOTE 1: all documents used by the CAB for the conformity assessment activity become items under inspection. IIS CERT shall receive from the applicant a set of items for inspection, specific for the product under assessment. The items for inspection shall include at least the following elements: functional description, including interfaces; technical description, including interfaces; design drawings;

		manufacturing drawings; installation drawings; “as-built” drawings; simulations and calculations reports; verification and validation reports; testing programme; test reports; on-site measurement reports; manufacturer’s final inspection report; previous certificates where existing (e.g. ec certificates, isvs certificates etc.); previous technical file/technical documentation where existing; previous declaration by manufacturer where existing; condition of the product under assessment for: integration into railway system use maintenance commissioning where applicable: previous authorisation certificates for placing into service; listing of data required for interoperability registers (e.g. rinf, eratv, nvr, etc.). The above items and samples for inspection shall: be inspected using the methods and procedures described in point 7.4.ISP.A of this document; relate to the inspection of the design, manufacture, installation, final testing, operation and maintenance of the product under inspection. NOTE 2: It is normal industry practice that the client proposes to the CAB a system of product/variant/series identification and marking (including any hardware and software); the CAB shall agree on the suitability of such arrangements
7.4.ISP.C	17020, § 7.3.1	**(Inspection Records)** --
7.4.ISP.D	17020, §§ 7.4	**(Inspection Reports)** Following the inspection of each product under inspection, the CAB shall produce the following documentation: - an inspection report in which the main findings are identified and links are provided to the accompanying appropriate collection of detailed information, and - an accompanying appropriate collection of detailed information to support the report and to improve the understanding of the inspection report. The report shall make clear recommendation to the CAB to perform the certification phase, including clear statement whether the inspection has provided positive results or not, including proposals for conditions and validity period. NOTE 1: the accompanying collection of detailed information typically should be included in the technical file supporting the EC certificate at the end of the certification phase. Point 7.4.1. of ISO/IEC 17020 applies with the following elements. The term “inspection certificate” shall be removed from the text. Point 7.3.2. of ISO/IEC 17020 applies without additional elements. Point 7.4.2 of ISO/IEC 17020 applies with the following elements: - The term “inspection certificate” shall be removed from the text. - Points from a) to e) apply without modifications. - Point f) the following text shall be added at the end. The statements of conformity shall be provided individually for each TSI parameter in the check list under the heading inspection results as defined in 7.4.ISP.A of this document. Point g) shall be replaced by the following text. - g) the overall inspection findings shall summarise the statements of conformity for the individual TSI parameters. The inspection findings shall be reported within the inspection report as defined in clause 7.4.9 of this document. NOTE 1: the following elements should be included in the inspection reports: - Annex B of ISO/IEC 17020 bullet point from a) to g) - Annex B of ISO/IEC 17020 bullet point m) Other elements from Annex B of ISO/IEC 17020 may be applied as well. Point 7.4.4. of ISO/IEC 17020 applies without additional elements. NOTE 2: Point 7.4.3 of ISO/IEC 17020 shall not apply.
--	17021	**(QUALITY MANAGEMENT SYSTEM APPROVAL)** The evaluation activities related to quality management system shall follow the applicable requirements of ISO/IEC 17021 described in this point. The requirements for the resources for evaluation performing audits are described in point 6.2 of this document CER_QAS 075 I. In the context of the IOD and in this Scheme, the term “Management System Certification” of the ISO/IEC 17021 shall be read as “Quality Management System Approval in the framework of the IOD for a precisely defined product”
7.4.QMS.A	17021	**(Application)** Points from 9.1.1.a to 9.1.1d of ISO/IEC 17021 shall apply with amplified requirements described below. The application shall also at least include: -name and address of the manufacturer(s); -the project breakdown structure detailing the name and address of each involved entity for production, final inspection and serial testing. This shall include all project related sites, main sub- suppliers, and where this is not otherwise known to the CAB, the number of staff involved in the project at the sites;

		-for H-type modules name and address of the designer(s), testing body(ies) and verification and validation body(ies). NOTE 1: several sites processing the identical product are possible; these may apply the same QMS or different QMS. - QMS related documentation relevant for the product under assessment and as required by the CAB to define the scope of work. In case of several QMS being related to the product, documentation related to all of them; - language(s) requested for the audit and for the audit report; NOTE 2: Language of the Audit Report shall be aligned with language of the Technical File. - any other information as required by the module description in decision 2010/713/EU. NOTE 3: Point 9.1.1.e shall be considered optional.
7.4.QMS.B	17021, § 9.1.2	**(Application review)** QMS application review shall apply point 7.3 of this document in combination with Point 9.1.2 of ISO/IEC 17021
7.4.QMS.C	17021, § 9.1.3	**(audit Programme)** ***[Point 9.1.3.1 of ISO/IEC 17021 shall apply with amplified requirements described below.*** The audit programme is a part of the "plan for the evaluation activities" as defined in ISO/IEC 17065 7.4.1. If the plan for the evaluation activities addresses all the requirements for the audit programme, it shall not be required to prepare a separate audit programme. The audit programme shall cover only the aspects of the requirements of the management system related to the product under certification. Point 9.1.3.2 of ISO/IEC 17021 shall apply with amplified requirements described below. The audit programme shall explain the full certification cycle. For the initial certification shall include a two-stage initial audit, the initial certification decision and following periodic audits for surveillance and/ or re-certification at intervals as defined in each individual TSI. The possibility for unexpected visits shall be mentioned. Each periodic time interval begins with the last day of the related preceding audit. The determination of the audit programme and any subsequent adjustments shall consider the size of the client, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits. NOTE 1: differences in periodic intervals of certification are due to the different durations between the certification of the ISO/IEC 17021 (nominally three years) and the QMS approval provided by the Decision on Railway modules. Point 9.1.3.4 of ISO/IEC 17021 shall apply with amplified requirements described below. The CAB shall have a documented procedure on how certification(s) already granted to the applicant for the site(s) and scope of activities and product(s) in question by another CAB, is "taken into account". The Audit Programme shall determine the 'Audit-Objectives, Scope and Criteria' as defined in point 7.4.QMS.G of this document
7.4.QMS.D	17021, § 9.1.4	**Determining audit time** ***Point 9.1.4 including all the subsections of ISO/IEC 17021 shall apply with amplified requirements described below.*** The audit time shall be adjusted to focus on the QMS related to the product to be certified. NOTE 1: IAF MD 5 shall apply taking into account only the number of staff related to the product to be certified and not the full number of staff of the company. Point 9.1.4.4 shall apply with amplified requirements described below. As defined in Annex C of this document, the QMS Lead Auditor / QMS Auditor can be accompanied by technical experts to fulfil the competency requirements. In this case both the time accounted by the Technical Expert(s) as well as the time accounted by the Lead Auditor/ Auditor(s) supported by them shall be accounted only with 50% of their time of participation in the audit activities. If overlapping activities for several products are audited at the same time and site, the total duration may be reduced accordingly..
7.4.QMS.E	17021, § 9.1.5	**multi site Sampling** Point 9.1.5 ISO/IEC 17021 shall apply with amplified requirements described below. Audits are required to include an assessment visit to the premises of the relevant entities concerned. NOTE 1: It is good practice to prepare a separate Audit Plan for each specific Site if the audit involves more than one site.
7.4.QMS.F	17021, § 9.1.6	**(Multiple management systems)** --
7.4.QMS.G	17021, § 9.2.1	**(Determining audit objectives, scope, criteria and topics)** I Point 9.2.1 including all the subsections of ISO/IEC 17021 applies with amplified requirements described below. Point 9.2.1.2b of ISO/IEC 17021 applies with amplified requirements described below. The terms 'statutory and regulatory' requirements shall be read as "IOD and applicable TSIs". (AUDIT OBJECTIVES) To verify that the QMS is capable of maintaining the continuous compliance of the product against all the applicable requirements of the applicable TSIs. The QMS approval shall provide confidence that the manufacturer has demonstrated the ability to re-produce TSI-compliant products which are in all their relevant aspects identical to that TSI compliant design prototype on which they are based. The QMS approval refers to the precise type of product to be certified and its specific design and/or production processes. AUDIT SCOPE The QMS approval shall have a scope for the product itself (object of the EC certification) and the overall design, manufacturing processes and final inspection as required by the applied module. If the manufacturing process is located on several sites, the audit scope shall be defined in order to verify all the sites. AUDIT CRITERIA The audit criteria are specific to this scheme. Throughout all the process' stages the QMS shall satisfy the combination of all audit criteria requirements for the production process including the final inspection and, for H-type Modules, also for the design and type testing as resulting from the following audit criteria sources:

		-AC source 1: Modules descriptions (e.g. Dec 713/2010, Annexes in TSIs, etc). - AC source 2: The text of the TSIs. - AC source 3: Standards quoted in the text of the TSIs. NOTE 1: the standards identified in AC source 3 are usually known as mandatory standards. - AC source 4: Harmonised European Standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs. - AC source 5: Alternative Solutions to Harmonised European Standards such as other public standards, documentation and company standards applied in full or in part, as defined by the applicant in relation to meet the essential requirements as defined in the TSIs. NOTE 2: the standards identified in AC source 4 and AC source 5 are usually known as voluntary standards. -AC source 6: ERA technical opinions. -AC source 7: ERA technical documents. -AC source 8: NB-Rail coordination group documents (e.g. RFUs, Q/Cs, FAQs). AUDIT TOPICS In order to establish a generic structure for QMS auditing activities, the CAB shall establish a documented approach (e.g. a checklist) identifying the following audit topics for guiding the audit team and for the general information of the auditees. NOTE 1: these Audit Topics have been derived from the generic audit criteria included in AC sources from 1 to 4. The CAB shall developed in more depth and detail the provided headings of the audit topics according to the audit criteria specific to the product to be certified. NOTE 2: in complex project situations, the application of additional sub-headings is recommended. Audit Topics: 1. General Aspects QMS, QMS Documentation, Document Management 2. Management Responsibility 3. Human Resources 4. Infrastructural Resources 5. Design - Planning, Inputs, Outputs 6. Design - Evaluation, Verification&Validation 7. Control of Design Changes 8. Production/ Service provision - Performance, Evaluation, Verification& Validation, Release of Products, Control of non-conforming products 9. Control of Monitoring and Measurement Equipment 10. Procurement and Control of purchased goods/ services 11. Continuous Monitoring, Measurement, Analysis 12. Continuous Improvement – Corrective Actions, Preventive Actions (incl. project SMS) NOTE 3: for information and further guidance, in Annex F of this document are provided references from these audit topics to 2010/713/EU, to ISO 9001:2008 and ISO 9001:2015. As long as all Audit Criteria are satisfied, this scheme is not mandating the auditee to operate a QMS based on ISO 9001. If the QMS is evaluated according to: -such H-type Modules where the product must be based on an “existing design” or -any D-type Module, the CAB may have a documented procedure to exclude the audit criteria related as following: 5.Design - Planning, Inputs, Outputs, 6.Design - Evaluation, Verification& Validation. In addition for D-type Modules, the following Audit Topic may be excluded: 7.Control of Design Changes. If the applicant operates a quality management system which is already certified by an accredited body, the CAB shall limit the detailed QMS assessment to the product to be certified only. The CAB shall not assess again the entire QMS. NOTE 4: Annex F of this document provides information about the audit topics which shall not be re-assessed in case of a manufacturer’s QMS certified to ISO 9001:2008 or ISO 9001:2015.
7.4.QMS.H	17021, § 9.2.2	**Audit team selection and assignments** **(**Point 9.2.2 including all the subsections of ISO/IEC 17021 applies with amplified requirements described below. The competence criteria of the audit team leader shall be as described in point 6.2 of ISO/IEC 17065 as “QMS LEAD AUDITOR”.”.
7.4.QMS.I	17021, § 9.2.3	(audit Plan) Point 9.2.3 including all the subsections of ISO/IEC 17021 applies with amplified requirements described below. An audit plan shall define the specific application of the audit programme to each individual audit contained in the overarching audit programme. The Audit Plan shall refer to the Audit Programme.
7.4.QMS.L	17021, § 9.3	(Initial certification audit)
7.4.QMS.M	17021, § 9.4	(Conducting audits) [Point 9.4 including all the subsections of ISO/IEC 17021 applies with amplified requirements described below. The findings referred to in ISO/IEC 17021 9.4.8.2.k shall be reported separately for each audit criterion listed in point 7.4.QMS.G of this document. NOTE 1: It is good practice, to perform audit stage1 as remote audit
7.4.QMS.N	17021, § 9.5	(Approval Decision) [Point 9.5 including all the subsections of ISO/IEC 17021 applies with amplified requirements described below. IIS CERT shall have a documented procedure for granting QMS approval in case of amendments of the TSIs against which the QMS has been already approved

7.4.QMS.O	17021, § 9.6	**(Maintaining approval)** ***[i §§ da 9.7 a 9.9 non applicable]***
7.5	17065, § 7.5	**(Review)** ***[testo da considerare aggiuntivo al § 7.5.1]*** Point 7.5.1: The following text shall be added at the end of the point. The assignment of the personnel to perform revision task shall be in writing. The board, group of persons or person assigned to have the overall authority and responsibility of reviewing as point 5.1.3 bullet point g) is called "Technical Reviewer". The technical reviewer shall have the competence as described in Annex C.
7.6	17065, § 7.6	**(Certification Decision)** Point 7.6.2: The following text shall be added at the end of the point. The assignment of the personnel to perform certification decision tasks shall be in writing. The board, group of persons or person assigned to make decisions on certification as point 5.1.3 bullet point h) decision is called "Decision maker". The decision maker shall have the competence as described in Annex C. NOTE 1: it is a good practice to have in single document the matrix of assignments for evaluation, revision and certification decision tasks. This document may have several names in the CAB (e.g. Project Plan, Project Quality Plan, Project assignments…) NOTE 2: As provided by point 7.6.2, the decision maker shall never be involved in any phase of the evaluation of the product under certification. This implies that the decision maker, if having the adequate competence, can act also as: -technical reviewer; -other board, group of persons or person described in this document, such as (e.g.) technical manager, etc.
7.7	17065, § 7.7	**Certification documentation**
7.8	17065, § 7.8	**Directory of certified products**
7.9	17065, § 7.9	**Surveillance**
7.10	17065, § 7.10	**Changes affecting certification**
7.11	17065, § 7.11	**Termination, reduction, suspension or withdrawal of certification**
7.12	17065, § 7.12	**Records**
7.13	17065, § 7.13	**Complaints and appeals**
8.1	17065, § 8.1	**Options**
8.2	17065, § 8.2	**General management system documentation (Option A)**
8.3	17065, § 8.3	**Control of documents (Option A)**
8.4	17065, § 8.4	**Control of records (Option A)**
8.5	17065, § 8.5	**Management review (Option A)**
8.6	17065, § 8.6	**Internal audits (Option A)**
8.7	17065, § 8.7	**Corrective actions (Option A)**
8.8	17065, § 8.8	**Preventive actions (Option A)**
Annex A	17065, Annex A	**Principles for product certification bodies and their certification activities**
Annex B	17065, Annex B	**(Application of ISO / IEC 17065 for processes and services)** --
Annex C	--	**(Competence descriptions)** The requirements of Annex C (normative) of the ERA scheme are considered in the system document CER_QAS 075 I.
Annex D	--	**(List of technical topics per scope of assessment)** The requirements of Annex D (normative) of the ERA scheme are considered in the system document CER_QAS 075 I.
Annex E	--	**(Graphic representation of the activities of a certification body))** The requirements of Annex E (normative) of the ERA scheme are considered in the system document CER_QAS 075 I.
Annex F	--	**(Audit Topics – correlations with ISO 9001)** This Annex does not exist in the ISO/IEC 17065. This annex has an informative value, not a normative value. The decision on railway modules states that the NoBo "shall presume conformity with those requirements in respect of the

		elements of the QMS that comply with the corresponding specifications of the […] harmonised standard". The most relevant generic harmonized standard in this regard is the EN ISO 9001 in both 2008 and 2015 revision. Each element of the following list contains the correlation with 2010/713/EU and in brackets the references to the related clauses in ISO 9001:2008 and ISO 9001:2015. NOTE 1: The following list is co-ordinated with point 7.4.QMS.G of this document. If the applicant operates a quality management system certified by an accredited body, the audit topic shall include only the reference highlighted in bold and underlined. The remaining references, not bold and not highlighted, are meant to be already covered during the evaluation for ISO9001:2008 or 9001:2015 for certification by the accredited body.1. General Aspects of QMS, QMS Documentation, Document Management (ISO 9001:2008 - 4.1; 4.2) + (ISO 9001:2015 – 4.1÷4.4; 7.4; 7.5) 2. Management Responsibility (ISO 9001:2008 - **5.1a**; 5.1b,c,d; 5.2÷5.6) + (ISO 9001:2015 - **5.1.2a,b**; 5.1÷5.3, 6.1; 6.2; 6.3) 3. Human Resources (ISO 9001:2008 - **6.1a**; 6.1b; **6.2**) + (ISO 9001:2015 - **7.1.1; 7.1.1; 7.1.4; 7.1.6; 7.2; 7.3**) 4. Infrastructural Resources (ISO 9001:2008 - **6.1; 6.3; 6.4**) + (ISO 9001:2015 - **7.1.1; 7.1.3; 7.1.4**) 5. Design - Planning, Inputs, Outputs (ISO 9001:2008 - **7.1; 7.2**; 7.2.3a,b; **7.3.1; 7.3.2; 7.3.3**) + (ISO 9001:2015 **8.1; 8.2; 8.3.1÷8.3.3; 8.3.5**) 6. Design - Evaluation, Verification & Validation (ISO 9001:2008 - **7.3.4; 7.3.5; 7.3.6**) + (ISO 9001:2015 - **8.3.4**) 7. Control of Design Changes (ISO 9001:2008 - **7.3.7**) + (ISO 9001:2015 - **8.2.4; 8.3.6; 8.5.6**) 8. Production/Service provision - Performance, Evaluation, Verification& Validation, Release of Products, Control of non-conforming products (ISO 9001:2008 - **7.1; 7.2**; 7.2.3a,b; **7.5.1 ; 7.5.2; 7.5.3; 7.5.4; 7.5.5; 8.2; 8.3**) + (ISO 9001:2015 - **8.5.1; 8.5.2**; 8.5.3; **8.5.4**; 8.5.5; **8.6; 8.7; 9.1; 10.2**) 9. Control of Monitoring and Measurement Equipment (ISO 9001:2008 - **7.6**) + (ISO 9001:2015 - **7.1.5; 8.5.1b**) 10. Procurement and Control of purchased goods/services (ISO 9001:2008 - **7.4**) + (ISO 9001:2015 - **8.4**) 11. Continuous Monitoring, Measurement, Analysis (ISO 9001:2008 - **8.1**; 8.2.1; 8.2.2; **8.2.3 8.2.4**; 8.4) + (ISO 9001:2015 - 9.1; 9.2; 9.3) 12. Continuous Improvement – Corrective Actions, Preventive Actions (incl. project SMS) (ISO 9001:2008 - **8.5**) + (ISO 9001:2015 - **10.1; 10.2**; 10.3)