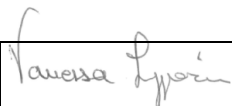
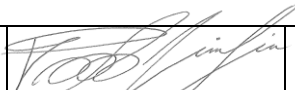



IECEX RULES FOR PRODUCT CERTIFICATION

04	16/06/2023	 Vanessa Lipparini	 Paolo Trisoglio	 Paolo Trisoglio
Revisione / Revision	Data / Date	Redazione / Redaction	Verifica / Check	Approvazione / Approval

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REVISION DESCRIPTION

Date	Revision	Points modified	Description of the modification
20-07-2013	00	--	Prima emissione
07-01-2014	01	vari	Aggiornamento logo aziendale. Variazione acronimo: da EuM1 a EuT.
30-04-2014	02	vari	Variazione ragione sociale da Eurofins-Modulo Uno S.p.A. a Eurofins TECH S.r.l.
11-12-2014	03	vari	Aggiornamento ragione sociale da Eurofins TECH Srl a Eurofins Product Testing Italy Srl Variazione acronimo da EuT in EPT Aggiornamento riferimenti normativi
16/06/2023	04	2 – 3.3 – 3.4 3.5 – 3.6 7.4 - 11 11.1 – 11.2 - 13	Update reference standard Inserted confidentiality and independence and impartiality Update reference to Rules of product certification Inserted clarifications

1. SCOPE OF THE SCHEME

The scope of the IECEX scheme is the certification₁ of conformity (CoC) of the equipment destined to be used in potentially explosive atmospheres according to the rules contained in the Document IECEX 02 and in those linked to or derived from it (from now on they will be referred to as IECEX Standards).

EPT not wish nor can assume any obligation to successful assessment of compliance and for the issue of the certificate.

The present regulations establish the procedures for obtaining and keeping the certification.

The present regulation has to be read together with the Rules for Certification Product. If in contrast with the present document, the present document is valid.

They are valid starting from the date of issue.

The conformity certification of the equipment issued by Eurofins Product Testing Italy S.r.l. (after indicated with the acronym EPT) states that the products comply with the applicable requirements specified in the IECEX Standards, provided they are used properly.

The certificate may attest the conformity of:

- a **single project** which applies to all matching products;
- a **basic project which applies to a uniform series of matching products**, but differing from each other through a limited set of characteristics (size, main dimensions, variants, etc.);
- a **single product** (unique specimen).

2. REFERENCE STANDARD

Standards and / or frameworks are considered applicable in the version published in the latest edition, subject to the transitional period defined. The documents with legal or regulatory reference for the certification of individual products are shown in certification schemes.

IECEX 02	IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEX System)
OD 009	Operational Document - Procedures for the Issuing of IECEX Certificates of Conformity, IECEX Test Reports and IECEX Quality Assessment Reports
OD 010-1	Guidance for the development, compilation, issuing and receipt of ExTRs Part 1: Development and posting of blank IECEX Test Report (ExTR) Documents
OD 010-2	Operational Document - Guidance for the development, compilation, issuing and receipt of ExTRs Part 2: Procedures and guidance
OD 011-1 e 2	Guidance on Use of the IECEX Internet based "On-Line" Certificate of Conformity System Part 2: Creating IECEX Equipment Certificates of Conformity CoCs
OD 025	Operational Document - Guidelines on the Management of Assessment and Surveillance programs for the assessment of Manufacturer's Quality Systems, in accordance with the IECEX Scheme
OD 033	Operations Manual – IECEX Unit Verification Certificates
Eurofins Product Testing Italy S.r.l.	Quality system manual
Eurofins Product Testing Italy S.r.l.	M1.SGQ.101 "Rules for the product certification"
UNI CEI EN ISO/IEC 17065	Conformity assessment -- Requirements for bodies certifying products, processes and services
UNI CEI EN ISO/IEC 17025	"General requirements for the competence of testing and calibration laboratories"
ISO IEC Guide 67	"Conformity assessment -- Fundamentals of product certification"

3. FIELD OF APPLICATION OF THE SCHEME

3.1 Products

All the products designed to be used in potentially explosive atmospheres can be certified.

EPT can certify only against applicable standards falling within the scope of EPT as an “Ex certification Body” (ExCB) under IECEX recognition.

About the correct list of standard that EPT can do certification, the applicant has to see the IECEX web site.

3.2 Requirements

The scheme certifies the conformity of products that comply with the requirements of the IEC standards issued by Technical Committee TC for one or more types of protection.

The list of the applicable reference documents is issued in the IECEX Bulletin.

3.3 Certificates

The present scheme foresees different types of certificates, depending on the applicable procedures and the manufacturer's decisions.

The certificates are issued by EPT, which “Ex certification Body” (ExCB) by virtue of IECEX recognition.

a) IECEX Test report (ExTR)

According to the definition of standard UNI CEI EN ISO/IEC 17065 the "certification of conformity" is a document whereby an independent third party declares that, with reasonable reliability, a given product, process or service conforms to a specific Standard or other normative document.

This document details the evaluation of the conformity of a product's project to the reference standards and documents. These include the test reports, issued by the laboratory (EXTL), with the explanation of the examinations and tests carried out on the product and the information used for its identification.

The ExTR may also include the evaluation of the conformity to other national standards.

b) Quality Assessment Report (QAR)

The document presents the results of the verifications performed on the Quality Management System of the manufacturer in order to ascertain its conformity to the requirements of the IECEX Standards.

c) IECEX Certificate of Conformity (CoC)

This document certifies the conformity of a product (device or component) to all requirements of the applicable reference standards, based on the evaluations contained in the ExTR and in the QAR. It can certify the conformity to more than one standard, also with reference to several rated characteristics or intended uses of the apparatus.

3.4 Use of the ExTR and QAR for national certification

According to the IECEX regulations, EPT can use ExTR and QAR Evaluation Reports issued by other Certification Bodies recognised by IECEX in order to issue own certificates having national validity.

Likewise, another Certification Body complying with the IECEX Scheme shall accept the ExTR and QAR issued by EPT in order to issue their own certificate with national validity.

According to the UNI CEI EN ISO/IEC 17065 standard, the acceptance of such assessment report is subject to the following conditions:

- the differences between the national and IEC Standards should be complied with, as far as both the product (ExTR) and the quality assessment of the manufacturer(QAR) are concerned;
- the identity of the certifying object with respect to the ExTR is assured.

To this purpose the applicant of the certification must enclose to the request a copy of the assessment records issued by other certification bodies, and if it is requested by EPT, a sample of the product and any other documentation referred to the above said reports.

The applicant must also engage to accept the EPT rules ascertained, for example, for the surveillance and the payment of the established rates.

Where EPT found any errors in the ExTR and QAR issued by another certification body, it would notify it thereon. In case of disputes it would refer to the IECEx appeal committee.

3.5 Confidentiality

The protection of the confidentiality of information obtained or arising from the certification is guaranteed of the commitment signed at all levels of EPT structure, including committees and external bodies or persons that acting on its behalf.

All the personnel involved in certification, signs the by the confidentiality commitment that are an integral part of the contractual relationship.

The commitments of confidentiality expressly contemplate that the information collected during the certification activities are not disclosed to anyone other than the people involved in the certification activities unless written authorization.

If such informations are requested by legislative provisions and/or by the provisions of the accreditation bodies and competent authorities, where permitted by law, the concerned parts will be notified.

All information (letters, notices, etc.), except those made public by the Applicant, received in the activities of product certification are considered confidential and will be managed in accordance with the laws in force concerning the protection of privacy, except as provided for by legislative provisions and / or by the provisions / requests of the accreditation body, the competent authorities or the judicial authorities (in this last case, EPT will notify the client, unless otherwise provided by the judicial authorities).

The access to and consultation for the registration documents is only reserved to the functions involved in the certification and the to the Applicant in question as also indicated in the Quality Manual of EPT.

3.6 Impartiality and independence

EPT guarantees its impartiality and independence in the performance of conformity assessment activities.

EPT is responsible for guaranteeing the impartiality of its conformity assessment activities, not allowing commercial, financial or other types of pressure to compromise its impartiality in any way.

To this end, EPT has prepared and implements procedures to safeguard impartiality and continuously analyzes and updates the potential risks of conflict of interest that could affect impartiality, adopting appropriate actions to eliminate or monitor these risks.

Impartiality is also guaranteed thanks to the involvement of special control bodies of the service delivery methods. EPT also undertakes not to carry out, or not to carry out, conformity assessment activities with its inspectors and the members of the Resolution Committee, in all cases where there are situations that may conflict with the requirements of independence and impartiality. To this end, EPT requires all its inspectors and members of the Resolution Committee, both internal and external, to sign a declaration of responsibility for confidentiality, independence and impartiality.

EPT does not offer or provide services that may conflict with its independence of judgment, impartiality and integrity, relating to the conformity assessment activities for which it is designated or which may compromise confidence in its independence, impartiality or objectivity.

4. GRANTING AND MAINTAINING CONDITIONS OF CERTIFICATES

The certificates can be requested by the manufacturer, or by another subject on his behalf, provided that the manufacturer complies with the requisites and obligations foreseen by the IECEx Standards. The certificates are always issued with the manufacturer's name.

The granting and keeping of certificates are subject to compliance with the contractual conditions defined by EPT, with any specific prescriptions and, when applicable, to surveillance audits.

The verifications on the documentation and the type tests on a set of representative samples of the product should demonstrate they comply with all the applicable requisites foreseen by the reference Standards. The components integrated in the product must also conform to the requirements which apply to them.

When surveillance of the manufacturer's quality assurance system is foreseen, the applicant engages should consent to EPT access to his production premises, in order to carry out periodical verifications.

5. PERMITTED USE OF CERTIFICATES

The granting of a conformity certificate allows the applicant to exhibit or quote it, during the entire validity period of the certificate, for all lawful, promotional and commercial purposes, provided this does not entail any possible mistake as regards its actual meaning.

In particular, the applicant is not allowed to let others believe that the certificate attests the compliance of projects or products different from those intended, or with different Standards.

The applicant may, under his responsibility, exhibit certificates in support of the single marketed products, but only if the following conditions are satisfied:

- the products must conform to the type indicated in the subject matter of the certificate and must conform
- to all the descriptive documentation indicated therein.
- In the case of certificate for a single product, it must be the one indicated in the certificate;
- the characteristics and modality of use methods assigned to the products must correspond to the
- characteristics and modality of use indicated in the certificate;
- the products must satisfy all the prescriptions of the reference Standards;
- the products must have been constructed in the production units notified, and must be part of the production on which EPT was able to run periodic checks according to the IECEx requisites.

6. INSTRUCTIONS FOR THE CERTIFICATE APPLICATIONS

The applicant must present to EPT a copy of this document, signed for acceptance, and also an application for each certificate it intends to obtain, using the forms supplied.

Applications for the issuance of the **IECEX Certificate of Conformity (CoC)** (or **ExTR evaluation report** only) must contain the following:

- commercial name of the products to be certified;
- type of certificate requested;
- reference Standards for the certification;
- rated characteristics of the products and mode of protection;
- descriptive documentation of the project, manufacturing and operation of the products, including the necessary drawings and diagrams and a list of the components they contain;

- conformity certificates and reports concerning the calculations, tests and verifications required by the reference Standards and already performed on the products, materials and components used for the construction.

Applications for the **Quality Assessment Report (QAR)** only must contain the following:

- commercial name of the products;
- certification procedure used;
- copies of certificates already granted and which apply to the type referred to by the request;
- if possible, descriptive documentation of the project, manufacturing and operation of the products, including the necessary drawings and diagrams and a list of the components they contain;
- identification of the production plants by which the finished products will be supplied;
- a copy of any certificate from notified bodies concerning the quality system of the production units for the purposes of the Scheme, and a copy of the certificates stating the conformity to the EN ISO 9001;
- Standards, issued by certification bodies accredited both nationally and internationally;
- identification of the test laboratories where the tests prescribed for the certification procedure used will be carried out;
- a copy of any certificate accrediting the test laboratories in compliance with the ISO/IEC 17025 Standards, issued by national or international accrediting bodies.

EPT checks that the application is complete and conforms to the IECEx prescriptions, begins the certification procedure, and notifies the applicant about that.

After the start of the evaluation/certification procedure, any modification to the documentation must be limited to the correction of non-conformity reported by EPT.

7. CERTIFICATION PROCEDURE

The certification procedure includes the steps indicated in the OD 009 document “Operational Document - Procedures for the Issuing of IECEx Certificates of Conformity, IECEx Test Reports and IECEx Quality Assessment Reports”.

We can reassume the main steps:

- verification of conformity of documentation;
- verification of type of products;
- verification on manufacturer SQ (when applicable);
- evaluation of the results and granting of the certificate;
- periodical verification (when applicable).

7.1 Verification of the documentation

EPT examines the descriptive documentation of the project presented by the applicant, checks if it is adequate for providing a complete, correct definition of safety against explosions and checks if all the aspects of the project conform to the applicable Standards for the correspondent type of protection.

7.2 Verification of type of products

7.2.1 Selection of samples for verification

As regards all products to be certified, the number of samples to be submitted for verification is determined by conformity to the prescriptions in the reference Standards.

This prescription can be lightened if the Standards permit to do so and if the certification refers to products corresponding to the same basic project. If the examinations of the project show that they are part of a uniform series, EPT has the right not to request type tests on the samples of all types and on the specified variants and to restrict the tests only to extreme types in the series (for each of the significant variables) and to some intermediate types in the properly way to allow - with sufficient confidence - interpolating the results to the complete series.

7.2.2 Verification that samples correspond to project documentation

EPT checks by means of visual and dimensional controls that the samples submitted for verifications and tests, including components they contain, were manufactured in conformity with the descriptive documentation.

7.2.3 Verification of conformity of samples

All samples are subjected to all the verifications and type tests, which are prescribed by the applicable documents for the correspondent type of protection, reserving the right not to run the tests results of which it considers to be certain.

If the project presented for certification corresponds to the development of a previous project already examined by EPT, the verifications must be repeated. However, the applicant may ask at EPT to use the results of the verifications carried out previously, and to consider the possibility of not to repeat verifications and tests which were successful. The verification results affected by another applicant can be used only under the approval by the original applicant or by his/her successors.

The verifications can also be performed on test reports produced by other laboratories than EPT. Even if EPT does not directly run the tests, we can accept the correctness responsibility of their results. To this end, EPT approves the selection of test laboratories used, ascertains their conformity to the requirements of Standards ISO/IEC 17025, and surveys the performance of the tests with its own inspectors.

7.3 Verification of the manufacturer's quality system

The verifications are carried out when a certificate with surveillance or a Quality Assessment Report (QAR) is requested.

The verifications consist in two stages:

1. the exam of the technical documentation concerning the products and the quality system of the productive unit which is indicated in the request.
The exam tends to verify that the employed test laboratories correspond to the qualifications of the Standards ISO/IEC 17025
2. ascertainment through audit near the manufacturer to check the compliance to the requisites which are specified in the IECEx document (OD005 and ISO/IEC 80079-34) and valued in compliance to the applicable Standards ISO 9001.

Check that the quality control procedures assure the satisfaction of the prescriptions concerning the execution of the exams and tests contained in the applicable rules to the products which are subject to the certification, shown in the relative conformity certificate of type.

If the productive units, which have a quality system, certified by a third part recognized organism will be submitted to a reduced verification according to the IECEx document OD025.

7.4 Evaluation of results and granting of certificate.

EPT examines the test (EXTR) and inspection reports (QAR).

If the results of all the verifications above described show conformity to the requirements, EPT issues the certificate of Conformity IECEX (CoC).

If all checks are in compliance with the standard it is possible to issue a certificate.

The certificate is registered online on the IECEX website according to OD 011-1 rules.

If the results of the verifications on the product and the relevant documentation do not conform to the requirements, EPT informs the holder about it, indicating the reasons for non-conformity and or closes the certification activities or waits for the corrective action.

The modality of the resolution of the non-conformity can be only on paper (check of new documents) or needs of a new audit near the applicant/manufacture.

If the applicant doesn't want to solve the non-conformity or doesn't agree with the decision of EPT, may present recourse against EPT's decision, according to the document M1.SGQ.101 "Rules for the product certification" to which it refers.

7.5 IECEX mark

The manufacturer, which has obtained an IECEX certificate from EPT, has the responsibility to assure that the products, which have applied the IECEX conformity mark on, so like the products, which are declared «certified IECEX», are corresponding to the project of the certified product .

The violations on this respect or the illegal use of the mark can involve the suspension or the retirement of the IECEX certificate left.

7.6 Periodic verification

For the IECEX Certificate of Conformity (CoC) and Quality Assessment Report (QAR), EPT makes verifications on the quality system of the manufacturer by periodical inspections at the productive places indicated on the certificate.

Their purpose is to ascertain that the quality system is kept adequate and effective, in order to satisfy the requisites specified by the document IECEX, evaluated according to the applicable criteria of the Standards ISO 9001, considering the possible certifications of the quality system issued by notified bodies.

Besides, the manufacture and control plans are re-examined considering the possible modifications adopted by the manufacturer.

EPT reserves for himself the right to make withdrawals of components and equipments to be submitted to tests at its laboratories or outside laboratories, in confirmation of the results of the tests developed by the manufacturer.

7.7 Extension of the certificate

The manufacturer, which intends to produce constructive modifications to the certified product, can request to examine that the modified product is kept in accordance with the reference documents.

Besides the manufacturer can apply a request of extension of the certificate to attest the conformity of the same project to next editions of the document or to new documents.

The applicant has the obligation to request the extent for:

- attributing new commercial designations to the products corresponding to it;
- assigning new nominal characteristics;

- including new applications.

The request for extension with the relative documentation must be exposed to EPT, which carries out the foreseen verifications for the concession of the certificate. Against the favourable result of such verifications the EPT issues, according to the rules established by the document IECEX, an extension to the certificate, which authorizes the modifications.

The extension requests for:

- certificates of a different kind with respect to the original certificate;
- new applicants with respect to the applicant indicated in the original certificate;
- conformity of a different single product or project which are different from that certified.

are treated as new certification applications.

8. VALIDITY TERM OF CERTIFICATES

The validity duration of the certificates, except for various dispositions of law of the single countries, is the following :

- Certificates with surveillance and Quality Assessment Report (QAR): they have triennial validity, subordinate to the positive result of the verifications of periodic surveillance carried out by EPT. The annual verification preceding the expiry of the certificate has value of whole reevaluation of the quality system of the manufacturer and therefore is carried out with the criteria and the completeness of the initial visit.
The intermediate verifications have the purpose to check to sample a few appearances of the quality system and the relative documents and recordings.
- Certificates of Conformity (CoC) of a single product: they have unlimited validity if the reference standard or design change.

9. KEEPING OF SAMPLES AND DOCUMENTATION

EPT ensures that samples will be correctly managed during the verifications.

The keeping at EPT's premises or at the manufacturer's premises of samples already submitted for verification is not prescribed. A copy of the certificates and of the significant dossiers of the technical documentation listed in the certificates is kept by EPT for ten years after the expiry of the certificate's validity.

10. INCORRECT USE OF CERTIFICATES

EPT examines any claims concerning the applicant's use of the certificates, and, if such use breaches the prescriptions under par INSTRUCTIONS FOR THE CERTIFICATE APPLICATIONS.

EPT will advise the applicant to stop that use; if the applicant continues such breaches, EPT shall apply a revocation measures. If necessary, EPT may make visits without prior notice to ascertain whether the claims are justified.

11. SUSPENSION, REVOCATION AND RENUNCIATION OF CERTIFICATES

Are applied the indication of the document M1.SGQ.101 "Rules for the product certification" to which it refers.

11.1 Suspension

In the event of significant non-compliance and in all cases in which EPT has reason to believe that the product being certified no longer meets the regulatory, legislative and/or normative requirements, EPT has the right to temporarily suspend the certification; in particular, when EPT ascertains one of the following conditions:

- the certificate should not have been issued;
- the holder ceases to fulfil the obligations taken on for the issue of the certificate according to these regulations and to the other contractual documents with EPT;
- the conditions on which the certificate was issued are lacking;
- due sums unpaid;
- serious or repeated non-conformity concerning the grantee's quality system or the certified product.

When the certificate is suspended, it is forbidden to use it associated with the products, mention it in the catalogues and commercial documentation and the holder must suspend the placing on the market of the products for which the suspension procedure has been activated. It involves also the prohibition to affix the IECEX mark on the products manufactured to leave from the date of communication of the suspension.

When EPT verifies that the holder has solved the anomalies that have led to the suspension (ie, by means of further examination), such suspension can be cancelled (expenditure relating to any additional verifications resulting from warning or suspension shall be borne by the holder).

If the causes that led to the suspension are not removed, EPT proceed to revoke the certification.

The information concerning the suspension provisions are also communicated to the secretary of the Ex Management Committee.

11.2 Revocation

Certificates may be revoked on deliberation of the CTC:

If the conditions that led to the suspension of the certificate are not remedied, EPT shall withdraw the certificate.

The certificate may be withdrawn without prior suspension in the event of serious irregularities and in all cases where the product itself does not ensure compliance with the minimum requirements of the reference standard or of the present Rules.

Furthermore, EPT notifies the revocation of the certification in all cases ordered by the competent authorities or in which it finds objective evidence of the following deviations/violations - non-exhaustive list - detected during surveillance inspections or through any other means:

- when the validity time limits of certificate have expired;
- if conditions for maintaining the certificate cease;
- if the cases of non-conformity and non-fulfillment leading to suspension as mentioned in the previous point are not solved;
- if the due sums continue to be unpaid by the manufacturer;

Revocation of the certificate has the following effects;

- prohibition to use the certificate in association with the manufactured products commencing from the date of notification of the revocation;
- the prohibition to affix the IECEX mark on the products manufactured to leave from the date of communication of the revocation;
- the holder must eliminate all reference to the certificate in the commercial catalogues and documentation;

- the holder must interrupt the production and placing on the market of the product covered by the revoked certificate
- cancellation of the product from EPT's list of certified products and publication of the revocation notice on its Internet site and/or on other informative publications;
- the communication of the revocation to the secretary of the Ex Management Committee.

11.3 Renunciation

Renunciation of the Certificate by the manufacturer entails:

- prohibition to use the certificate in association with manufactured products commencing from the date of advice of the renunciation;
- the prohibition to affix the IECEX mark on the products manufactured to leave from the date of communication of the renunciation;
- the holder must eliminate all reference to the certificate in the commercial catalogues and documentation;
- cancellation of the product from EPT's list of certified products and publication of the renunciation notice on its Internet site and/or on other informative publications;
- the communication of the renunciation to the secretary of the Ex Committee Management.

12. COMPLAINTS TO THE CERTIFICATE OWNERS

The holders of the certificates have the obligation to register the possible claims reported to the conformity of their products to the requisites established by the rules of reference (document of reference) and make them available at the request of EPT.

13. COMPLAINTS, APPEALS AND LITIGATIONS

EPT must examine any complaint referring to the use made of the certificate by the holder.

The holder may appeal in the event of disagreement with decisions taken against him by EPT.

On the EPT website there is a special form "Claim Form / Report" which the customer can use to formulate and notify EPT of the complaint.

EPT ensures that decisions relating to complaints or appeals are reviewed and approved by persons not directly involved in the complaint or appeal.

For details on the handling of complaints, appeals and litigations, please refer to the document M1.SGQ.101 "Rules for the product certification".