

CESI-IECEx SCHEME

CERTIFICATE OF CONFORMITY OF PRODUCTS USED IN POTENTIALLY EXPLOSIVE ATMOSPHERES DOCUMENT IECEx02

REGULATIONS

Document under surveillance by CESI Impartiality Steering Committee (ISC). It replaces Regulations B9003521.

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1 PURPOSE OF THE SCHEME

The purpose of the CESI-IECEx Scheme is the certification of conformity of the electrical apparatus 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).

These Regulations set the procedures to obtain and maintain the certification.

They are applied from the date of issue.

The conformity certification of the electrical apparatus, issued by CESI¹ as an independent Certification Body according to ISO/IEC 17065, states that the products comply with the applicable requirements specified in the IECEx Standards², provided they are used properly.

With reference to the Standard ISO/IEC 17067³, the present Certification Scheme is classified as type “5” and includes cases when both type tests and surveillance (through periodic assessment of production process and audit of Manufacturer’s Quality Management System) are performed.

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 FIELD OF APPLICATION OF THE SCHEME

2.1 Products

All the elements that are parts of an electrical system and any other item using electricity and designed to be used in potentially explosive atmospheres can be certified.

These include, among others: equipment for the generation, transmission, distribution, storage, measurement, regulation, conversion and utilization of electrical energy; telecommunication apparatus. Components, i.e. parts of electrical equipment, that are not to be used separately in potentially explosive atmospheres but need an additional certification can also be certified when they are parts of electrical equipment or systems used in potentially explosive atmospheres.

2.2 Requirements

The Scheme certifies the conformity of products that comply with the requirements of the IEC Standards issued by 31 TC for one or more types of protection.

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

2.3 Certificates issued by CESI

The present Scheme foresees different types of Certificates, depending on the applicable procedures and the Manufacturer’s decisions.

The Certificates are issued by CESI, as Ex Certification Body with IECEx accreditation.

¹ The activities are carried out within the KEMA Labs Business Unit of CESI.

² All IECEx Rules and Procedures can be found on the website <https://www.iecex.com/>

³ Or equivalent national version. The same applies to all other citations in the text.

They are issued in English language.

2.3.1 Report and Certificate

a) **IECEX Test Report (ExTR)**

This document details CESI's evaluation of the conformity of a product's project to the reference Standards and documents. These include the test reports, issued by the laboratory, 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.

2.4 Use of the ExTR and QAR for national certification

According to the IECEx regulations, CESI can use ExTR and QAR Evaluation Reports issued by other Certification Bodies recognised by IECEx to issue own Certificates having national validity.

Likewise, another Certification Body complying with the IECEx Scheme shall accept the ExTR and QAR issued by CESI to issue their own Certificate with national validity. According to the guidelines provided by the ISO/IEC 17065, 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 CESI, a sample of the product and any other documentation referred to the above said Reports.

The Applicant must also engage to accept CESI's rules ascertained, for example, for the surveillance and the payment of the established rates.

Where CESI 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 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 maintenance of Certificates are subject to the fulfillment of the contractual conditions defined by CESI, to the specific requirements and, when applicable, to the 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 the surveillance of the Manufacturer's quality assurance system is foreseen, the Applicant engages should consent to CESI access to his production premises to carry out periodical audits during normal working hours.

4 PERMITTED USE OF CERTIFICATES

The granting of a conformity certification by CESI allows the Holder, for the entire period of validity of the Certificate, to show or quote it for all legal, promotional and commercial purposes, which do not mislead the Receiver as to 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 Holder may, on its own responsibility, exhibit the Certificates in support of the single products put on the market only if the following conditions are satisfied:

- the products conform to the type indicated in the subject of the Certificate and conform to the descriptive documentation indicated therein.
- In the case of a Conformity Certificate of a single product, the object must be that indicated in the Certificate;
- the characteristics and methods of use assigned to the products correspond to the characteristics and methods of use indicated in the Certificate;
- the products meet all the requirements of the reference Standards, even if they are not subject to verification by CESI;
- the products have been built in the production Units notified to CESI and are part of the production on which CESI was able to carry out periodic verifications according to the applicable procedure.

5 SETUP OF THE CERTIFICATION REQUEST

The Applicant must present to CESI a copy of the present Regulations signed for acceptance and an application for each certification it intends to obtain, using the forms provided by CESI.

The applications for Certificates (or ExTR evaluation 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 methods of protection;
- descriptive documentation of the project, the manufacturing and the functioning of the products, including the necessary drawings and diagrams and the list of the components incorporated in them;
- Conformity Certificates and Reports concerning the calculations, tests and verifications required by the reference Standards and already carried out on the products, materials and components used in the construction.

Th applications for the production evaluation with QAR only must contain the following:

- commercial name of the products;
- adopted certification procedure;
- copies of already granted Certificates applicable to the type object of the request;

- if possible, the descriptive documentation of the project, the manufacturing and the functioning of the products, including the necessary drawings and diagrams and the list of the components incorporated in them;
- identification of the production sites from which the finished products are released;
- copy of any Certificates of Notified Bodies relating to the quality system of the production Units for the purposes of the Directive, and a copy of the Conformity Certificates to the Standards ISO 9000 issued by Certification Bodies accredited at national or international level;
- identification of the test laboratories where the tests prescribed for the adopted certification procedure will be carried out;
- copy of any Certificates of accreditation of the test laboratories in accordance with Standard ISO/IEC 17025 issued by national or international Accreditation Bodies.

CESI verifies that the application is complete and conforms to the IECEx prescriptions, starts 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 CESI.

6 CERTIFICATION PROCEDURE

The certification procedure includes the following stages:

- verification of documentation compliance;
- verification of product type;
- verification on Manufacturer QS (when applicable);
- evaluation of the results and granting of the Certificate;
- periodic verifications.

6.1 Verification of documentation compliance

CESI examines the descriptive documentation of the project presented by the Applicant, verifies that is adequate to give a complete and correct definition of explosion safety and verifies that all the aspects of the project comply with the applicable Standards for the correspondent type of protection.

6.2 Verification of product type

6.2.1 Selection of samples for verification

For each product to be certified, the number of samples to be subjected to type verification is determined in accordance with the requirements contained in the reference Standards.

This requirement can be mitigated if the normative allows it and the certification refers to products corresponding to the same basic project.

If the examinations of the project show that they constitute a homogeneous series, CESI has the faculty not to request the type tests on samples of all the foreseen types and variants and to limit the tests only to the extreme types of the series (for each of the significant variants) and to some intermediate types to the extent deemed adequate to allow, with sufficient confidence, to interpolate the results to the complete series.

6.2.2 Verification of the correspondence of the samples to the project documentation

CESI verifies with dimensional controls that the samples subjected to verifications and tests, including the components incorporated in them, have been manufactured in compliance with the descriptive documentation.

6.2.3 Verification of conformity of the samples

CESI ensures that the 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 carry out the tests of which it certainly considers the positive results.

If the project presented for the certification corresponds to an evolution of a previous project already examined by CESI, the verifications must normally be repeated. The Applicant can however ask CESI to use the results of the verifications already carried out and to evaluate the possibility of not repeating verifications and tests already carried out with a positive outcome.

The results of verifications carried out on behalf of another Applicant may be used only under the approval of the original Applicant or its Successors.

The verifications can also be carried out based on Test Reports produced by laboratories other than CESI. Even if the tests are not carried out directly, CESI takes responsibility for the correctness of their results. To this end, CESI approves the choice of the test laboratories used, verifies their compliance with the requirements of the ISO/IEC 17025 Standard and surveys the execution of the tests with its own Inspectors, according to OD 024.

6.3 Verification on Manufacturer Quality System (when applicable)

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

The verifications consist in the exam of the documentation, concerning the quality system of the productive Unit which is indicated in the request and in the ascertainment, through supervisory visit, of its compliance to the requirements which are specified in the IECEx document, valued in compliance to the Standards ISO 9001 Series and ISO/IEC 80079-34.

Besides, the exam tends to verify that the employed test laboratories are compliant to the requirements of the Standards ISO/IEC 17025 and that the quality control procedures assure the compliance of the prescriptions concerning the carrying out of the exams and tests contained in the Standards applicable to the products which are subject to certification, as shown in the relative Type Conformity Certificate.

The productive Units, which have a quality system certified by a third part recognized Organism will be submitted to a reduced verification.

6.4 Evaluation of results and granting of the Certificate

CESI examines the Test and Inspection Reports: if the results of all the verifications described in par. 6.1, par. 6.2 and par. 0 demonstrate the compliance with the requirements indicated in par. 2.2, CESI issues the Certificate.

If the results of the verifications on the product and on the related documentation do not comply with the requirements, CESI informs the Applicant thereof, indicating the reasons for non-compliance and concludes the certification procedure.

The Applicant may present recourse against CESI's decision, according to the *Certification –Recourses, Claims and Disputes* procedure in force.

A copy of the Certificate is sent to the Ex Management Committee Secretary.

6.4.1 IECEX mark

The Manufacturer, which has obtained an IECEX Certificate from CESI, 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", correspond 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 issued by CESI.

6.5 Periodic verifications

For the Certificates and Quality Assessment Report (QAR), CESI makes verifications on the quality system of the Manufacturer by annual inspections at the production sites 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 requirements of the Standards ISO 9001 Series, considering the possible certifications of the quality system issued by Notified Bodies. Besides the manufacturing and control plans are re-examined, according to the criterions of the Standard ISO 10005, considering the possible modifications adopted by the Manufacturer.

CESI reserves for himself the right to make withdrawals of components and equipment to be submitted to tests at its laboratories or external laboratories, in confirmation of the results of the tests carried out by the Manufacturer.

7 EXTENSION OF THE CERTIFICATE

The Manufacturer, which intends to produce constructive modifications to the certified product, may request to CESI to examine that the modified product is kept in accordance with the reference documents. Besides, the Manufacturer may submit an application of extension of the Certificate to attest the conformity of the project to next revisions of the document or to new documents.

The Applicant has the obligation to request to CESI the extension for:

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

The application for extension with the relative documentation must be presented to CESI, which carries out the foreseen verifications for the concession of the Certificate

Following the favourable result of such verifications, the CESI issues, according to the rules established by the document IECEX, an extension to the Certificate which authorizes the modifications.

Extension requests relating to:

- Certificates of a different kind than the original one;
- new Applicants with respect to the one 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 period of the Certificates, except for the 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 CESI (the first one at 6 months from the first release of the Certificate and subsequently with annual cadence). The annual inspection verification preceding the expiry of the Certificate has the value

of the entire revaluation of the Manufacturer's quality system and is therefore carried out with the criteria and the completeness of the initial audit. The intermediate verifications are aimed at randomly controlling some aspects of the quality system and the related documents and records.

- Certificates of conformity of a single product: they have unlimited validity.

9 KEEPING OF SAMPLES AND DOCUMENTATION

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

Storage at CESI or at the Manufacturer of samples already subjected to verifications is not required.

A copy of the Certificates and of the significant dossiers of the technical documentation listed in the Certificates are kept by CESI for ten years after the expiry of the Certificate's validity.

CESI guarantees the keeping of the technical dossiers for a period of 10 years after the communication by the Manufacturers of the cessation of the production to which they refer or the failure by the Manufacturers to confirm their interest in their keeping.

10 INCORRECT USE OF CERTIFICATES

CESI examines any claims concerning the use that the Holder makes of the Certificates and, if such use violates the prescriptions of par. 4, CESI will advise the Holder to stop it; in case of recurrence, CESI adopts a revocation order.

If necessary, CESI may make visits without prior notice to ascertain whether the claims are justified.

11 SUSPENSION, REVOCATION AND RENUNCIATION OF CERTIFICATES

11.1 Suspension

The Certificates may be suspended, upon deliberation by the ICS when CESI ascertains one of the following conditions:

- the Certificate should not have been issued;
- the Holder ceases to fulfill the commitments made for the issue of the Certificate based on these Regulations and the other contractual documents with CESI;
- the conditions under which the Certificate was issued have ceased;
- failure to pay the sums due;
- serious or repeated non-conformities relating to the Dealer's quality system or to the certified product itself.

The suspension period is aimed to allow the Holder to solve the above-mentioned cases of non-conformity and non-fulfillment.

When the Certificate is suspended, it is forbidden to use it associated with the products and to mention it in the catalogues and commercial documentation. It involves also the prohibition to affix the IECEx mark on the products manufactured from the communication date of the suspension.

The suspension can be canceled, upon deliberation of the ICS, when the resolution of the non-conformities and of the non-compliances that determined it has been verified.

Otherwise, the ICS can decide to revoke the Certificate.

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

11.2 Revocation

The Certificates may be revoked on deliberation of the ICS:

- when the time limits for the validity of the Certificate have expired;
- in the event of termination of the conditions for maintaining the certification;
- failure to resolve the non-conformities and non-fulfillments that lead to the suspension as mentioned in the previous;
- if the due sums continue to be unpaid by the Manufacturer.

The revocation of the Certificate has the following effects:

- the prohibition of the use of the Certificate in association with products built from the date of notification of the revocation;
- the prohibition to affix the IECEx mark on the products manufactured from the date of notification of the revocation;
- the elimination, by the Holder, of any reference to the Certificate in the catalogues and in the commercial documentation;
- the cancellation of the product from the CESI list of certified products and the publication of the revocation notice on its website 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:

- the prohibition of the use of the Certificate in association with the products built from the date of communication of the renouncement;
- the prohibition to affix the IECEx mark on the products manufactured from the date of communication of the renunciation;
- the elimination, by the Holder, of any reference to the Certificate in the catalogues and in the commercial documentation;
- the cancellation of the product from the CESI list of certified products and the publication of the renunciation notice on its website and/or other informative publications.
- the communication of the renunciation to the Secretary of the Ex Committee Management.

12 RECOURSES, CLAIMS AND DISPUTES

12.1 Recourses

During the certification process, the Applicant has the possibility to appeal to obtain a modified non-conformity decision by CESI.

Within 30 days from the date on which he became aware of the non-compliance decision, the Applicant may present the appeal directly to CESI.

The recourses are submitted by CESI to the ICS's examination normally at the first meeting following the appeal request, and in any case within ninety days of the proposal itself; the proceeding allows the Appellant to explain its reasons.

Any expense relating to the appeal remains with the Applicant, unless it is determined that CESI is in error.

12.2 Claims

The Applicant (or a third party) has the possibility to submit claims about the behavior of CESI during the certification process.

CESI is also required to examine any complaints regarding the use that the Holder makes of the Certificate issued to it. If it considers that the use was incorrect, it reports to the ICS for the relevant deliberations.

12.3 Disputes

Should any dispute arise concerning these Regulations, or otherwise connected to them, the Parties will first try to resolve them amicably.

If, following the negotiation, the Parties did not reach an agreement, the dispute will be referred to arbitration:

- a) if the Party is an Italian Client, the arbitrator will be chosen by mutual agreement among the accredited professionals in the sector and he will judge “ex bono et aequo” without having to follow any procedural rules. The venue of arbitration is Milan;
- b) if the Party is a Foreign Client, the decision of an arbitration panel, consisting of three arbitrators, will be used in accordance with the Conciliation and Arbitration Rules of the International Chamber of Commerce of Paris. The venue of arbitration is Paris.

13 CHANGES TO THE REGULATIONS

The present Regulations and all their modifications are approved by ICS.

In case of changes while the inspection activities are in progress, the Applicant is promptly informed by CESI and retains the right to accept or not the new version of the Regulations if the changes are not due to mandatory aspects.

A constantly updated copy of the regulations can be consulted on the website www.cesi.it.

The Applicant

Stamp and signature _____

Date _____

The Applicant declares explicitly of having read carefully and approved, with respect and to the effects of items 1341 and 1342 of the Italian Civil Code, all the sections of the present Regulations and in particular the following: 5 (Setup of the Certification Request), 6 (Certification Procedures), 7 (Validity Term of Certificates), 10 (Suspension, Revocation and Renunciation of Certificates), 11 (Recourses, Claims and Disputes).

The Applicant

Stamp and signature _____

Date _____