

CESI-ATEX SCHEME

CERTIFICATE OF CONFORMITY OF PRODUCTS FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES DIRECTIVE 2014/34/UE

REGULATIONS

Document under surveillance by CESI Impartiality Steering Committee (ISC). It replaces Regulations C5013812.

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1 PURPOSE OF THE SCHEME

The purpose of the Scheme is the ATEX certification of conformity of products and/or production to the requirements for use in potentially explosive atmospheres according to 2014/34/EU Directive (from now on it is called "Directive") reissue of Directive 94/9/CE.

These Regulations set the methods to obtain and maintain the certification and are applied from the date of issue.

The certification of conformity is carried out by CESI¹ as a Product Certification Body, as part of the Accredia accreditation No. 00026 Products/Services/Processes of compliance with ISO/IEC 17065 and Accredia Regulations RG-01 and RG-01-03² in the version in force and as far as applicable.

In carrying out its certification activities, CESI avails itself of the control of the Impartiality Steering Committee (ISC), which was established as an impartiality safeguard Mechanism in accordance with ISO/IEC 17065.

With reference to the ISO/IEC 17067³ standard, this certification scheme is classified as type "5" and includes the cases in which both type tests and (where applicable) surveillance are performed which includes periodic assessments of the production process and audits of the Manufacturer's management system.

CESI does not carry out further activities under a potential conflict of interest regime and guarantees that all personnel involved in the activity offer the necessary guarantees of impartiality and confidentiality towards third parties.

The product conformity certification granted by CESI certifies that the products identified therein, if used in accordance with their intended use, meet the essential health and safety requirements specified in Annex II of the Directive.

The production conformity certification granted by CESI certifies that the production identified therein meets the requirements specified in the Directive in Annexes IV, V, VI and VII).

The Scheme also provides for the issue of the Receipts for filing the technical dossiers prescribed by the Directive, Article 13, paragraph 1 b ii).

The Certificate can attest to the conformity of:

- a single project applicable to all products corresponding to it;
- a basic project applicable to a homogeneous series of products corresponding to it, but different from each other for a limited set of characteristics (size, main dimension, variants, etc.);
- a single product (unique specimen).

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

² All Accredia Regulations can be found on the website www.accredia.it.

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

2 FIELD OF APPLICATION OF THE SCHEME

2.1 Products and production

All products or production of the same which are subject to the Directive may be certified, and in particular:

- protective appliances and systems designed to be used in potentially explosive atmospheres;
- safety, control and adjustment devices designed to be used outside of potentially explosive atmospheres, but necessary or useful for the safe operation of protective appliances and systems, regard to the risks of explosion;
- components, defined as essential parts for the safe operation of equipment and protection systems, but without an independent function.

The list of products included in ATEX Certification Scheme is listed in Annex of Accreditation Certificate Accredia No. 00026 *Products/Services/Processes*, published also in CESI website www.cesi.it.

2.2 Requirements

The Scheme certifies the conformity of products to:

- the requirements of the harmonised standards, the reference of which was published in the Official Gazette of the European Union for the purposes of the Directive, or of the national standards which assimilate a harmonised standard;
- the essential health and safety requirements contained in Annex II of the Directive.

The applicable harmonized reference standards are published periodically in the Official Journal of the European Community and can be consulted on the official website of the European Community, on the page dedicated to the Directive. The new rules are currently indicated by means of the publication of Decisions.

The CESI-ATEX Scheme provides for the issue of different types of Certifications, according to the applicable procedures for their granting and the choices made by the Manufacturer according to the Directive.

The Certificates are issued by CESI as a Notified Body for Product Certification and Quality Assurance Notification of the production process in force of the Ministerial Decree authorizing CE certification that is published on the site Ministero delle Imprese e del Made in Italy.

Starting from January 1st, 2012, the Accredia trademark is affixed to the Certificates covered by these Regulations.

All the Certificates listed below are issued in both Italian and English.

2.2.1 Type Conformity Certificates

EU Type Examination Certificate (Annex III – Module B of the Directive)

The Certificate attests the conformity of the project with all the essential health and safety requirements applicable to it indicated in Annex II of the Directive. Compliance with these requirements is ensured by using, if they exist, the harmonized standards published for the purposes of the Directive and applicable to the product.

EU-type Examination Certificates do not allow products to be placed on the market unless accompanied by a Certificate of production conformity.

2.2.2 Production Conformity Certificates

Notification of the Quality Assurance of the production process (Annex IV - Module D of the Directive)

The Notification attests that the Manufacturer has a production quality system that complies with the specifications of the Production Quality Assurance module described in Annex IV of the Directive. The quality system of the production Unit must guarantee the conformity of the products to the type for which an EU Type Examination Certificate has been granted.

The products listed in the Notification, provided with an EU declaration of conformity and, except for the components, bearing the EC mark, may circulate freely in the countries of the European Union starting from March 01, 1996.

Type Conformity Certificate based on product verification (Annex V - Module F of the Directive)

The Certificate attests that all the product specimens listed on the Certificate are in compliance with the type specified in the EU Type Examination Certificate.

The products for which a Product Conformity Certificate has been granted according to the procedure specified in Annex V of the Directive, bearing the EU Declaration of Conformity and, except for the components, the EC mark, may circulate freely in the countries of the European Union starting from March 01, 1996.

Type Conformity Report based on internal production control combined with supervised product testing (Annex VI - Module C1 of the Directive)

The report describes the verifications carried out by CESI to demonstrate that the tests concerning the technical aspects of protection against explosions are correctly executed for all the products by the Manufacturer or by Others on its behalf, and that the results of these tests satisfy the prescribed requirements.

The products for which a EU Type Examination Certificate has been granted and for which the procedure specified in the Annex VI has been applied, bearing the EC Declaration of Conformity and, except for the components, the EC mark, may circulate freely in the countries of the European Union starting from March 01, 1996.

Notification of product quality assurance (Annex VII – Module E of the Directive)

The Notification attests that the Manufacturer applies a quality system that complies with the Product Quality Assurance module described in Annex VII of the Directive.

The quality system of the production Unit must guarantee the conformity of the products to the type for which a EU Type Examination Certificate has been granted.

The products listed in the Notification, bearing the EC Declaration of Conformity and, except for the components, the EC mark, may circulate freely in the countries of the European Union starting from March 01, 1996.

In cases of *connected Notification*, that is applied to situations in which a subject (Reseller or other Manufacturer) **B** places a product on the market based on commercial agreements with the original Manufacturer (O.E.M). **A**, it is necessary that this agreement be formalized and made available.

Manufacturer **A** must provide **B** with the authorization to use its EU Type Examination Certificate and the documentation attached to the latter. **B** must request the Notified Body to issue an EU-Type Examination Certificate in the name of **B**, relating to the product(s) on the basis of **A**'s Certificate and after the issuance of the latter, request the Body Notified the issuance of the Notification according to the Quality Assurance form described in Annex IV or VII of the Directive, as appropriate.

The Notified Body that evaluates **B**'s Quality Assurance system will issue this Notice once it has ascertained that the requirements of the Annex to the Directive have been met. Since **B** does not physically produce the product, a full assessment against Annex IV or VII cannot be obtained unless compliance with **A**'s Quality Assurance System has been established, as the actual Manufacturer of the product that **B** places on the market. To this end, the following must be ensured:

- that the Quality Assurance line can be traced back to the original assessment of the EU-Type Examination Certificate issued and held by Manufacturer **A**;
- compliance with the requirements of Annex IV or VII is demonstrated through the combined Quality Assurance systems of **B** and the actual Manufacturer **A**;
- an adequate Quality Assurance System exists for the products identified in the EU-Type Examination Certificate, so that the Notified Body can issue its Notification to **B**.

Having obtained the Notification, **B** issues its EU Declaration of Conformity, affixes the EC mark with the identification number of the Notified Body from which it obtained the Notification and sells the equipment in its own name on the EU market. **B**, resulting in this case the original Manufacturer, has the obligation to report to **A** any complaint or indication relating to the safety of the product that reaches him from the market.

For the procedure described it is necessary to have:

- application for certification;
- letter of agreement between the Manufacturer and the Dealer;
- EU type examination certificate (s) issued in the name of the Reseller;
- plate drawings relating to the above Certificate(s).

2.2.3 Other Certificates

Conformity Certificate of a single product (Annex IX – Module G of the Directive)

The Certificate attests the conformity of a single product to all the essential health and safety requirements applicable to it indicated in Annex II of the Directive.

Compliance with these requirements is ensured by using, if any, the harmonized standards published for the purposes of the Directive and applicable to the product.

The products for which a Certificate of Conformity for a single product has been granted according to the procedure specified in Annex IX of the Directive, bearing the EU Declaration of Conformity and, except for the components, the EC mark, may circulate freely in the countries of the European Union starting from March 01, 1996.

Receipt of the technical dossier / Manufacturing Internal Control (Annex VIII Module A of the Directive)

The receipt attests that the technical documentation relating to the design of an apparatus has been sent to CESI.

The products indicated in Art. 13 sub-paragraph 1 b ii) of the Directive, for which a receipt for the deposit of the technical dossier has been issued and the manufacturing internal control procedure was implemented (Annex VIII- Module A of the Directive), bearing the EU Declaration of Conformity and, with the exception of components, the EC mark, may circulate freely in the countries of the European Union starting from March 01, 1996.

2.3 Certificates issued by CESI in compliance with the Ministerial Decree

Type Examination Certificates

In the spirit of the Directive, CESI also issues Type Examination Certificates, requested voluntarily by Manufacturers, for category 3 electrical or non-electrical equipment and for category 2 non-electrical equipment.

These certifications are not covered by accreditation by Accredia.

3 GENERAL INFORMATION

3.1 CESI personnel

CESI entrusts certification activities to employees or collaborators who have been previously qualified according to specific procedures based on their specific skills, in accordance with the applicable accreditation provisions.

3.2 Confidentiality

CESI, as a Certification Body, guarantees confidentiality during all conformity assessment activities and has a process in place for analysing, assessing and managing confidentiality risks.

CESI ensures that all information acquired during its activities, including the protection of customers' property rights and information acquired from various sources (e.g. complaints, authorities, etc.), is treated as strictly confidential, unless otherwise required by:

- legal provisions (in such exceptional cases, the customer is informed about the information disclosed to third parties);
- provisions of accreditation bodies.

In order to guarantee the aforementioned confidentiality, CESI personnel involved in certification sign a formal confidentiality agreement and are subject to continuous internal monitoring.

3.3 Impartiality

CESI, as a Certification Body, is required to guarantee its impartiality during all conformity assessment activities and has a process in place for analysing, assessing and managing risks to impartiality.

CESI is not, and undertakes not to be, related to any party directly involved in the design, manufacture, supply, installation, acquisition, marketing, possession, use and maintenance of products that are verified or similar to those verified and competitive with them.

3.4 CESI Ethical Code and Legislative Decree No. 231 of 8 June 2001

CESI has adopted an Ethical Code and a Model pursuant to Legislative Decree No. 231 of 8 June 2001 on the liability of legal persons, companies and associations, including those without legal personality, which is available on the website <https://www.cesi.it/about-us/overview/#code-ethics>.

Therefore, Customers who commission CESI to carry out activities referred to in these regulations are required to read them and behave in accordance with the highest ethical standards, undertaking to comply with the CESI Ethical Code and to fulfil their contractual obligations in such a way as to avoid behaviour that is relevant under Legislative Decree 231/01.

3.5 CESI accreditations

3.5.1 Obligations relating to accreditation

In its certification activities, CESI generally operates under accreditation and is therefore required to apply the requirements imposed by the accreditation bodies. Within the schemes and sectors in which accreditation is issued by ACCREDIA (Italian Accreditation Body), in accordance with the international standard ISO/IEC 17065, CESI must operate in compliance with this standard and with the specific regulations and provisions issued by ACCREDIA and expressly referred to in this document.

ACCREDIA also has the right to carry out audits not only at CESI's premises but also at CESI's clients' premises, in order to verify CESI's work within the accredited certification schemes⁴.

The use of the ACCREDIA mark or reference to accreditation in documents issued by CESI as an accredited certification body is subject to compliance with the provisions of ACCREDIA document RG-09, in its current revision, and in particular, the use of the ACCREDIA mark is prohibited to the Customer: it is reserved for Certification Bodies and cannot be used by the Customer who has received a certification service.

3.5.2 Suspension, withdrawal or revocation of CESI accreditation

If the CESI's accreditation and/or notification, necessary to operate, is suspended or revoked, or in the event of withdrawal, CESI will inform the Customer and assist them in transferring to another Notified Body.

CESI shall not be liable in any way for any damage caused to the Customer by the suspension, waiver, limitation of the scope or revocation of accreditation and/or notification, except in cases of proven wilful misconduct or gross negligence.

3.5.3 Subcontracting

If necessary, after informing the Customer, CESI reserves the right to subcontract part of the requested activities to third parties, where this is not excluded by applicable legislation. CESI assumes full responsibility for any activity outsourced and guarantees that the subcontractor is competent and complies with the applicable regulations and is not involved in the design and manufacture of the product, so as not to compromise the impartiality referred to in paragraph 3.3.

The Customer, who will be informed of the details of the subcontracted activities and, if requested, of the subcontractor's references, has the right to refuse, for justified reasons, such outsourcing to third parties within five (5) working days from the date of notification.

3.6 Obligations of the Applicant

3.6.1 Applicant's obligations

The Applicant undertakes to:

- ensure that it has not submitted a similar application for certification to another Certification Body in accordance with the requirements of the Directive;

⁴ Note: Updated information on CESI's accreditation status is available on the websites <https://www.cesi.it/about-us/accreditations-certifications/> and, for accreditations issued by ACCREDIA, www.accredia.it.

- guarantee CESI personnel responsible for certification, where applicable, access to the design, manufacturing, installation, inspection and testing sites, as well as provide the necessary means and assistance to enable CESI to perform the requested Service;
- with reference to § 3.5.1, guarantee ACCREDIA inspectors, the Italian Accreditation Body, access to the aforementioned locations, accompanied by CESI personnel. Such visits, the purpose of which is to monitor the work of CESI personnel and not that of the Applicant, shall be communicated in advance with adequate notice;
- in the event of rejection of the certifier assigned by CESI for the activities, to communicate this within five (5) working days of the date of notification, providing justification.

3.6.2 Safety at work – Mandatory disclosure

The Applicant, in accordance with current legislation on safety and accident prevention in the workplace, undertakes to provide CESI personnel and any accompanying persons with comprehensive and detailed information on the specific risks existing in the working place in which they are to operate. Furthermore, through its representatives, the Applicant undertakes to promote cooperation and coordination for the implementation of measures to protect against and prevent risks at work that may affect the work of CESI inspectors and any accompanying persons.

The Applicant, based on any specific risks that may exist, shall provide CESI personnel and any accompanying persons with the appropriate personal protective equipment (PPE) and shall implement all necessary safeguards to ensure that the activity is carried out in complete safety.

4 GRANTING AND MAINTAINING CONDITIONS OF CERTIFICATES AND RECEIPTS

The following definitions are applicable to the Subjects referred to in this document:

- **Applicant:** Subject who submits a request to CESI for a certification or an extension to an existing Certificate, or a Subject who makes an appeal.
- **Holder:** a Subject who holds a Certificate or a Receipt issued by CESI (coincides with the "Manufacturer" or who takes its place, pursuant to Directive 2014/34/EU).

The granting and maintenance of Certificates and Receipts are subject to the fulfilment of the contractual conditions defined by CESI, to the specific requirements and, when applicable, to the surveillance audits indicated in the following paragraphs.

With reference to the EU Type Examination Conformity Certificate or Conformity Certificates of a single product, the verifications of the documentation and the type verifications of a set of representative samples of the products subject to the certification must demonstrate that they comply with all the requirements prescribed by the reference standards or by Annex II of the Directive.

The components integrated in the product must also comply with the requirements applicable to them and to their intended use.

The conditions for granting the Production Conformity Certificate depend on the certification procedure adopted by the Applicant, among those applicable to the products subject to the certification, according to the requirements of the Directive.

5 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 to its actual meaning.

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 are conforming to the type indicated in the subject of the Certificate and compliant 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.

The Holder of a Certificate can make full copies of the document only. It is not allowed to extract and use in any other way the CESI logo and the associated Accredia mark.

6 SETUP OF THE CERTIFICATION REQUEST

A Certificate can simultaneously attest the compliance with several standards, also with reference to more nominal characteristics or uses envisaged for the product.

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 certification applications for the EU Type Examination must be accompanied by the Applicant's declaration certifying that, for the same products, no other applications have been submitted to other Notified Bodies in the European Union.

The application for Type and Single Product Certificates 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.

The applications for Production Conformity Certificates must contain the following:

- commercial name of the products to be certified;
- adopted certification procedure;
- copy of already granted EU Type Examination 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 in compliance with the requirements and that:

- the certification procedure indicated by the Applicant complies with the requirements of art. 13 of Directive 2014/34/EU, depending on the intended use and the characteristics of the products;
- the EU Type Examination Certificates presented by the Applicant comply with the requirements of the Directive and the projects described in them correspond to those adopted for the manufacturing of the products for which the Production Conformity Certificate is required;
- all the received documents are issued in English or Italian language.

In the positive case, CESI starts the production conformity assessment procedure, notifying the Applicant of this.

7 CERTIFICATION PROCEDURE FOR CERTIFICATES OF EU TYPE EXAMINATION AND OF A SINGLE PRODUCT

The certification procedure includes the following phases:

- verification of documentation compliance;
- verification of product type;
- evaluation of the results and granting of the Certificate.

7.1 Verification of documentation compliance

CESI examines the descriptive documentation of the project presented by the Applicant, verifies that it is adequate to give a complete and correct definition of explosion safety and verifies that all aspects of the project comply with the applicable standards or the requirements of the Directive.

7.2 Verification of product type

7.2.1 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 base 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.

7.2.2 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.

7.2.3 Verification of conformity of the samples

CESI ensures that the samples are subjected to all the type verifications and tests necessary to verify whether the solutions adopted by the Manufacturer satisfy the applicable standards or the requirements of the Directive. CESI has the right to omit the tests of which it certainly considers the positive result.

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 on the basis of 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.

7.3 Evaluation of the results and granting of the Certificate

CESI examines the Test and Inspection Reports: if the results of all the verifications described in par. 7.1 and 7.2 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 and granting a deadline for taking the necessary corrective action. If this deadline passes without the non-compliance issues being resolved, the certification application shall be rejected and CESI shall notify the other Notified Bodies and the Ministry of Enterprise and Made in Italy (MIMIT).

8 CERTIFICATION PROCEDURE FOR PRODUCTION CONFORMITY CERTIFICATES

The production conformity certification procedure includes the following phases:

- preliminary verification;
- assessment of the results of the verification and granting of the Certificate;
- periodic verifications.

8.1 Preliminary verification

The preliminary verification, which also includes the inspections at the production sites, is applied, in different ways, to the procedures of Production quality assurance (Annex IV), Product verification (Annex V), Type conformity (Annex VI), and Product quality assurance (Annex VII).

8.1.1 Production quality assurance (Annex IV) and Product quality assurance (Annex VII)

The verification consists of examining the documentation relating to the quality system of the production Unit indicated in the application and of ascertaining, by means of an inspection, its compliance with the requirements specified in Annexes IV and VII of the Directive, assessed according to the applicable criteria of the ISO/IEC 80079-34 standard.

The examination also tends to ascertain that the used test laboratories comply with the requirements of the ISO/IEC 17025 standard and that the quality control procedures ensure the fulfilment of the requirements relating to the execution of the examinations and tests contained in the standards applicable to the products in question of the certification, indicated in the relevant Type Conformity Certificate.

8.1.2 Product verification (Annex V)

CESI verifies the conformity of the appliance to the type covered by the EU Type Examination Certificate, by controlling and testing each individual product.

8.1.3 Type conformity (Annex VI)

The verification consists in examining the compliance of the Applicant's test laboratory with the requirements of the ISO/IEC 17025 standard. The examination also aims to ascertain the competence of the laboratory with reference to the execution of the individual verifications and tests prescribed in the standards applicable to the products subject of the certification, indicated in the relevant EU-Type Examination Certificate.

The laboratories accredited by a recognized third-party Body will undergo a reduced verification.

Furthermore, the manufacturing and control plans are evaluated, according to the criteria of the ISO 10005 standard.

8.2 Assessment of the results of the verification and granting of the Certificate

CESI examines the Test and Inspection Reports and, if the results of all the verifications prove compliance with the requirements indicated in par. 8.1, 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 shall inform the Applicant, indicating the reasons for non-compliance and granting the Applicant a deadline to take the necessary corrective actions. If the deadline passes without the non-compliances being resolved, the certification application shall be rejected and CESI shall notify the other Notified Bodies and the Ministry of Enterprise and Made in Italy (MIMIT) through official channels.

8.3 Periodic verifications

CESI carries out periodic annual surveillance audit on the maintenance of the conditions that led to the issue of the Certificate to the Applicant, as referred to in § 8.1.1. and § 8.1.3.

During the surveillance audits, an assessment is made of the resolution of the observations and comments that emerged in previous audits, as well as an assessment of the implementation and effectiveness of the resulting corrective actions.

In the event of non-compliance, the Applicant must send CESI a proposal for the corrections and corrective actions established (following analysis and formalisation of the causes that generated them), with a timetable for implementation within the agreed deadline. CESI shall evaluate the proposed corrections and corrective actions and notify the Applicant in writing.

If the Applicant is unable to demonstrate resolution in accordance with the timelines and assessment methods established by CESI (through verification at the Applicant's premises or, where possible, through documentary evidence), certification will be suspended or, in the most serious cases, revoked (ref. § 15).

Surveillance is always carried out at the locations where the activities subject to certification are carried out, therefore: the production areas, warehouses and laboratories of the Applicant and any Suppliers must be open to CESI Inspectors.

In order to carry out the necessary surveillance audit, CESI has the right to request the verification of certain samples of the product present in the Applicant's warehouses at the time of the visit, compatibly with its production programme. In certain cases, CESI may also request the collection of samples. The Applicant undertakes to enable CESI to carry out the verification or take these samples.

8.3.1 Production quality assurance (Annex IV) and Product quality assurance (Annex VII)

The procedure involves the monitoring of the quality system and the approval of any changes adopted by the Applicant by means of annual inspections at the production sites indicated in the Production Conformity Certificate.

They are intended to ensure that the quality system remains adequate and effective, so as to meet the requirements specified in Annexes IV and VII of the Directive, assessed according to the applicable criteria of the ISO/IEC 80079-34 standard.

8.3.2 Type conformity (Annex VI)

The procedure provides for the monitoring of the tests performed by the Applicant on the products covered by the Production Conformity Certificate through periodic inspections at the laboratories used by the Applicant.

They are intended to ascertain that the laboratories remain competent for the execution of the prescribed tests, so as to satisfy the requirements of the ISO/IEC 17025 standard and the reference standards indicated in the Certificate or the essential requirements of the Directive.

Furthermore, the manufacturing and control plans can be reviewed, according to the criteria of the ISO 10005 standard.

As expressly required by Directive 2014/34/EU (Annex III - Par. 7), CESI shall take care to follow the evolution of generally recognized technological progress, in particular by monitoring the status of updating of the Certificates with respect to the evolution of the reference standards and requesting to the Manufacturer, if necessary, the adjustment of the Certificates to the most recent editions of these standards.

This activity will be carried out during the periodic verifications.

9 REMOTE INSPECTIONS

In circumstances of necessity (such as natural disasters, unforeseen unavailability, etc.) CESI may use, with the Client's consent, remote audit techniques in order to reduce possible problems caused by interruptions in tests or unacceptable delays.

The ways in which remote inspections are carried out are regulated by an internal procedure that CESI will ask to share at the appropriate time.

10 EXTENSION OF CERTIFICATES

The Holder can submit an application for extension of the EU type examination certificate (Annex III) or of the filing of the technical dossier (Annex VIII) to certify the conformity of the same project to subsequent editions of the standard or to new standards.

The Holder is obliged to request CESI the extension of the Certificates of products whose project has undergone changes that may affect the compliance with the essential requirements or whose designation and intended use have been modified with respect to what is indicated in the Certificate.

The documentation must be submitted to CESI which carries out all the verifications required for the granting of the Certificate. If the results of the checks confirm that also the new variants comply with the requirements of the reference standards, CESI grants an extension to the existing Conformity Certificate. The Holder is also required to communicate to CESI the intention to put into production new-concept products or products with modifications, with respect to those certified, which may require the extension of the products or production quality assurance Notifications and is required to prepare new or modified production plans.

When the Production Conformity Certificate is based on the surveillance procedures set out in Annex IV or VII, the Holder is obliged to notify CESI of any planned changes to the quality system of the production sites before adopting them.

When the Certificate is based on the surveillance procedure set out in Annex VI, the Holder is obliged to notify CESI of any planned changes to the quality system of the laboratories used for carrying out the tests before adopting them.

The documentation with changes and the production plans, new or modified, must be submitted to CESI who verifies them, decides on the possible need for a new audit and notifies the Manufacturer of this. If, on the other hand, the outcome of the verifications certifies that also the changes to the quality system and the production plans are in compliance with the requirements of the reference standards, CESI grants an extension to the existing Production Conformity Certificate.

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;
- Production Conformity Certificate for a different procedure than the original one;

are treated as new certification applications:

Requests for extension relating to Conformity Certificates based on the verification of the Unit (Annex IX - Module G of the Directive), or referring to a single product, are permitted only for minor modifications of the certified object, typically relating to accessories or other details however referred to the single serial number covered by the base Certificate; otherwise, they will be treated as new certification applications.

10.1 Extension of Certificates issued pursuant to Directive 94/9/EC

In accordance with the European Commission document "GUIDANCE DOCUMENT ON THE ATEX DIRECTIVE TRANSITION FROM 94/9/EC TO 2014/34/EU", the Certificates issued pursuant to Directive 94/9/EC are not automatically revoked.

Furthermore, in line with Art. 41 of the Directive itself, it is possible that the Holder of an EC Type Examination issued according to Directive 94/9/EC may submit an application to obtain an extension concerning the issue of a Certificate according to Directive 2014/34/EU, that is an additional certification to the previous Certificate, maintaining the number.

This document (EU examination of type "*Supplement*") can be issued only by Notified Bodies pursuant to Directive 2014/34/EU.

10.2 Extension of Certificates issued pursuant to Directive 2014/34/EU

In accordance with the European Commission document "GUIDANCE DOCUMENT ON THE ATEX DIRECTIVE 2014/34/EU", and in the only cases listed in the previous par. 10, it is possible that the Holder of an EU Type Examination issued according to Directive 2014/34/EU may submit an application to obtain an extension, that is an additional certification to the previous Certificate, maintaining its number. This document (EU examination of type "*Supplement*") can be issued only by Notified Bodies pursuant to Directive 2014/34/EU.

11 RECEIPT FOR DEPOSIT OF THE TECHNICAL DOSSIER

The Applicant must submit to CESI a duly signed application for each Receipt that it intends to obtain together with a Declaration of acceptance of these Regulations.

The application must clearly indicate the identification of the products to which the dossier refers, to allow the registration and availability in the archive.

Upon receipt of the dossier, which must be sealed by the Applicant, CESI issues the Receipt, records and archives the dossier for a minimum guaranteed period of ten years, renewable upon expiry. Please note that the dossier must remain deposited for at least ten years from the date of the product's last placing on the market.

CESI does not carry out any checks on the completeness and correctness of the documents that constitute the technical dossier.

Near the end of the period, CESI asks the Holder to confirm his interest in keeping the file on deposit for the following decade.

12 VALIDITY TERM OF CERTIFICATES

The validity period of the Product Certificates is determined by the provisions of the law.

The Type Conformity Certification (Annex VI) provide for a three-year agreement, within which period CESI will remain available for the inspection activities requested by the Manufacturer, for the surveillance of production. The Conformity Certifications (Notifications) of the quality assurance of production (Annex IV) and products (Annex VII) are valid for three years, subject to the positive outcome of the periodic surveillance checks carried out by CESI (annually).

The annual inspection prior to the expiry of the Certification has the value of an entire re-evaluation of the Manufacturer's quality system and is therefore conducted with the criteria and completeness of the initial visit.

The intermediate checks are aimed at randomly checking some aspects of the quality system and related documents and records.

13 KEEPING OF SAMPLES AND DOCUMENTATION

CESI ensures the correct management of the samples 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 conservation of the technical dossiers for a period of 10 years after the notice by the Manufacturers of the cessation of production to which they refer or of the lack of confirmation by the Manufacturers of interest in their conservation.

14 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. 5, 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.

15 METHOD OF REFERENCE TO CERTIFICATION

In compliance with the requirements of Directive 2014/34/EU, with regard to certificates relating to CE product marking, the Applicant must indicate on each device produced, in a legible and clearly identifiable manner, the identification number of the Notified Body that issued the certification alongside the CE symbol; example for CE marking issued by CESI:

CE0722

Specific instructions for affixing the CE marking can be found in the EU Directives and on the European Union website: [CE marking - obtaining the certificate, EU requirements - Your Europe](#).

Once certification has been obtained, and for the entire period of its validity, the Applicant may refer to it in their technical and advertising publications in the manner defined by the various regulations.

This is on the sole condition that all references are made correctly and in such a way as to avoid misinterpretation; in particular, it must be clear that the certificate relates exclusively to the certified 'product'; this means the specific product expressly indicated on the certificate itself and no other, and not even certificates of conformity of production (e.g. the quality system or other types of system).

The correct use of the certificate and, in general, the correctness of references to certification are elements that are monitored during surveillance and renewal audits. The CESI inspector may therefore detect non-conformities in this area, and incorrect use of the certificate may result in its suspension.

In the event of suspension or withdrawal of the certificate, the customer must cease its use and any other form of reference to the certification, including the use of the CESI identification number as the Notified Body for surveillance. Otherwise, CESI reserves the right to take legal action.

Partial copies of the certificate are not permitted; enlargements or reductions of the certificate are permitted, provided that the structure is not distorted and the certificate remains uniform and legible.

16 SUSPENSION, REVOCATION AND RENUNCIATION OF CERTIFICATES

16.1 Suspension

The Certificates may be suspended when CESI ascertains one of the following conditions:

- the Certificate should not have been issued;
- the Holder ceases to fulfil 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 Holder's quality system or to the certified product itself.
- the Owner says they don't plan to do any surveillance audit;

- when CESI changes the rules of the certification scheme and the Applicant can't or won't meet the new requirements.

The suspension period is intended to allow the Holder to resolve the above non-conformities and non-compliances.

The suspension of the Certificate implies the prohibition of its use in association with the products.

The suspension can be cancelled when the resolution of the non-conformities and non-compliances that determined it has been verified.

Otherwise, that is when the non-conformities and non-compliances are not resolved within the foreseen period of time, CESI can deliberate the revocation of the Certificate.

16.2 Revocation

The Certificates may be revoked:

- when the time limits for the validity of the Certificate have expired;
- for Production Conformity Certificates in the event of termination of the Holder's activities;
- in the event of termination of the conditions for maintaining the certification;
- for failure to resolve the non-conformities and non-fulfilments that led to the suspension as mentioned in the previous point;
- in the event of persistence in non-payment of the sums due.
- the Owner formally requests it from CESI.

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 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;
- communication by CESI to the Ministry of Enterprise and Made in Italy (MIMIT) and, through official channels, to other Notified Bodies.

16.3 Renunciation

The Holder may renounce the Certificate:

- upon expiration of the Certificate, with at least two months' notice;
- due to changes in the reference normative documents, if it does not intend to adapt to the new technical requirements set by them;
- for substantial changes to these Regulations, if he does not accept the new conditions set by them.

The renunciation of the Certificate and the License involves:

- the prohibition of the use of the Certificate in association with the products built from the date of communication of the renouncement;
- 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;
- communication by CESI to the Ministry of Enterprise and Made in Italy (MIMIT) and, through official channels, to other Notified Bodies.

17 RECOURSES, CLAIMS AND DISPUTES

17.1 Appeals

During the certification process, the Applicant has the possibility to lodge appeals to obtain that a non-conformity decision taken by CESI is modified.

Within thirty calendar days from the date on which he becomes aware of the decision of non-conformity, the Applicant can present the appeal directly to CESI.

The Applicant is informed by CESI of the receipt of the appeal within three calendar days.

The appeal is managed by CESI in accordance with its applicable procedures designed to ensure independence of judgment and the resolution proposal is typically communicated to the Applicant within twenty-one calendar days.

Appeals are also submitted by CESI for examination by the ISC at the first meeting following the appeal request and, if the procedure is still open or in progress, the Applicant is allowed to intervene to explain his reasons.

Any expenses relating to the appeal remain the responsibility of the Applicant, unless it is determined that CESI is in error.

17.2 Claims

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

The Applicant is informed by CESI of the receipt of the claim within three calendar days.

The claim is managed by CESI in accordance with its applicable procedures designed to ensure independence of judgment and the resolution proposal is typically communicated to the Applicant within twenty-one calendar days.

Claims are also submitted by CESI for examination by the ISC at the first meeting following the appeal request and, if the procedure is still open or in progress, the Applicant is allowed to intervene to explain his reasons.

Any expense related to the claim remains the responsibility of the Applicant, unless it is determined that CESI is in error.

It is specified that CESI is also required to examine claims relating to the use that the Holder makes of the Certificate issued to him.

17.3 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.

Appeals or claims can be sent to CESI by sending an email to the legal email address atex.cesi@unapec.it, accessible directly from the website info@cesi.it, - ([TESTING & CERTIFICATION](#)).

In any case, in whatever form they are received, or appeals or claims are submitted by CESI for examination by the ISC, usually at the first meeting following the event that occurred.

The ISC examines the reasons for the dissent and any decisions already taken by CESI and deliberates on the matter. The resolutions of the ISC are binding for CESI.

18 CHANGES TO THE REGULATIONS

This Regulation and all its amendments are subject to verification by the ISC.

In the event of substantial changes to these Regulations or changes due to mandatory aspects while the certification activities are in progress, the Applicant is promptly informed by CESI and retains the right to accept or reject the new version of the Regulation.

In the case of valid conformity certifications with reference to Annexes IV, VI and VII, if the changes are substantial changes or mandatory aspects, the applicant will be required to comply, and the conditions signed at the time of stipulation will remain in place.

An updated copy of the Regulations can be requested by consulting the website www.cesi.it.

The Applicant

Stamp and signature _____

Date _____

Under the provisions of articles 1341 and 1342 of the Civil Code, the Applicant expressly declares that s/he has read and approved all the paragraph of these Regulations, the following in particular: 6 (Setup of the Certification Request), 7 and 8 (Certification Procedures), 12 (Validity Term of Certificates), 16(Suspension, Revocation and Renunciation of certificates, 17 (Recourses, Claims and Disputes).

The Applicant

Stamp and signature _____

Date _____