PROCEDURE 16.101.004

Regulations for the certification of Personal Protective Equipment
EXCLUDED EYE AND FACE

INDICE

Rev.	Issuing date.	Reason of the revision	Drawn up by RSGQ	Checked by Scheme Manager	Approved by DIRECTION
2	19/05/2026	Regulation update for high visibility extension	Zenarolla A.	Tamburlin L. Perotto N. ~~Morandin T.~~	Facco C.

1. PURPOSE AND FIELD OF APPLICATION

Purpose

This document is issued as Regulations, and is considered as a contractual document providing for a series of rules that govern the relationship between CERTOTTICA S.c.r.l. (hereinafter referred to as CERTOTTICA) and the Client.

These Regulations define the methods and terms that the Client must observe to obtain and maintain the Product EU Type-Examination Certificate issued by CERTOTTICA.

CERTOTTICA certification services are available for any Client who requires them, in observation of these Regulations.

The acceptance of these Regulations is formalized with the signing of the Application for EU type-examination (in case of issue of a new EU Type-Examination Certificate) or of the applications for tests or surveillance for modules C2 or D (in case of maintenance of certificates for III category products with surveillance). **These Regulations are considered fully understood and accepted by the Client after signing and returning to CERTOTTICA the above-mentioned documents.**

Procedures to assess conformity

With reference to article 19 of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE), conformity assessment procedures to be followed for each of the risk categories specified in Annex I of Regulation (EU) 2016/425, are the following:

a) category I: internal production control (module A) as per Annex IV of Regulation (EU) 2016/425;
b) category II: EU type-examination (module B) as per Annex V of Regulation (EU) 2016/425 followed by conformity to type based on internal production control (module C) as per Annex VI of Regulation (EU) 2016/425;
c) category III: EU type-examination (module B) as per Annex V of Regulation (EU) 2016/425 and one of the following:
    - conformity to type based on internal production control plus supervised product checks at random intervals (module C2) as per Annex VII of Regulation (EU) 2016/425;
    - conformity to type based on quality assurance of the production process (module D) as per Annex VIII of Regulation (EU) 2016/425.

    Note: a possible dispensation for PPE manufactured as single units to adapt to a single user and classified as III category, procedure under letter b) may be applied.

Field of application of these Regulations

Conformity assessment in compliance with provisions of Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March 2016 on personal protective equipment, repealing Council Directive 89/686/EEC, related to Personal Protective Equipment, limited to risk categories II and III as per Annex I of Regulation (EU) 2016/425, as per the following procedures:

- EU Type-Examination Certificate (module B) as per Annex V of Regulation (EU) 2016/425 (see chapters 5, 6, 7 e 8 of these Regulations);
- conformity to type based on internal production control plus supervised product checks at random intervals (module C2) as per Annex VII of Regulation (EU) 2016/425 (see chapter 9.1 of these Regulations);
- conformity to type based on quality assurance of the production process (module D) as per Annex VIII of Regulation (EU) 2016/425 (see chapter 9.2 of these Regulations).

This Regulation applies **ONLY AND EXCLUSIVELY** to the following Personal Protective Equipment (PPE):

1. Head and hearing protection devices
2. Protective equipment against falls from a height;

3. Buoyancy aids;
4. Anti-drowning devices;
5. Devices for the protection of chest and groin;
6. Devices for the protection of foot and leg;
7. Devices for general body protection (clothing);
8. Devices for the protection of hand and arm, including protection against chemicals;
9. Protective equipment against electrical risk;
10. Protective equipment against electromagnetic fields;
11. Protective equipment against substances and mixtures which are hazardous to health;
12. Protective equipment against cold (under -50 °C);
13. Protective equipment against heat (over +100 °C);
14. Protective equipment against bullet wounds or knife stabs;
15. Protective equipment against hand-held chain saws;
16. Protective equipment against chemical and biological agents;
17. Protective equipment against slipping;
18. Protective equipment against le vibrations;
19. Protective equipment against static compression;
20. Protective equipment against mechanical risks;
21. Devices for the protection of the respiratory system
22. High visibility protective equipment (limitedly to the standard EN 397:2025)

As regards eye and face PPE, regulation PQ 16.04 "Regulation for the EU certification of Personal Protective Equipment for the eyes and face" applies, available on the website https://certottica.it/certificazione/

2. REFERENCES

- CERTOTTICA Statute
- Ethical code
- Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March on personal protective equipment and repealing 89/686/CEE of the Council
- Accredia Regulation RG-01– Regulations for the accreditation of Certification and Inspection – General Part
- Accredia Regulation RG-01-03 – Regulations for the accreditation of Product Certification Bodies
- Accredia Regulation RG-09 "Regulation for the use of ACCREDIA marking"
- UNI CEI EN ISO/IEC 17000 "Conformity assessment – Vocabulary and general principles"
- UNI CEI EN ISO/IEC 17020 "Conformity assessment - Requirements for the operation of various types of bodies performing inspection"
- UNI CEI EN ISO/IEC 17021 "Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements"
- UNI CEI EN ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories"
- ISO/IEC 17065 "Conformity assessment — Requirements for bodies certifying products, processes and services"
- ISO/IEC 17067 "Conformity assessment – Fundamentals of product certification and guide for product certification schemes"

- ACCREDIA LS-02 “List of reference standards and documents for the accreditation of Certification Bodies”
- Guide EA-2/17 “EA guide on horizontal requirements for the accreditation of conformity assessment bodies for notification purposes”
- UNI EN ISO 19011 “Guidelines for auditing management systems and/or environmental management”
- Directive of the Ministry of Production “Documents to produce for the authorization of Bodies for CE certification”
- ISO/IEC GUIDE 28 “Conformity assessment - Guidance on a third-party certification system for products”
- Technical sheets for coordination – Horizontal recommendation for use sheets (RFUs)
- PPE Regulation (EU) 2016/425 Guidelines
- IAF MD 1 “IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization”
- IAF ID 3 “Informative Document For Management of Extraordinary Events or Circumstances Affecting ANs, CABs and Certified Organizations”
- IAF MD 4 “Mandatory Document For The Use of Information And Communication Technology (ICT) For Auditing/Assessment Purposes”
- IAF MD 5 “Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems”
- IAF ID 12 “Principles on Remote Assessment”

With revisions of the current ACCREDIA standards and documents as specified by the issuing bodies and on the website www.ACCREDIA.it.

3. DEFINITIONS

The definitions given below apply to some terms, recurrently used in the text.

Personal Protective Equipment (PPE):

a) devices designed and manufactured to be worn or held by a person to protect against one or more risks to his/her health or safety;
b) interchangeable components of the devices described under letter a), essential to their protective function;
c) connection systems for devices described under letter a), which are not worn or held by a person, designed to connect such devices to an external device or to a safe anchor point, not designed to be connected in a permanent way and which do not require fixing before being used.

ACCREDIA: Italian body for the accreditation of conformity assessment bodies for notification purposes;

Manufacturer: any natural or legal person that manufactures PPE or has it designed or manufactured, and markets it under its name or trademark.

N.B.: The manufacturer may be established in the European Union or not; the manufacturer may appoint a representative that is established in the European Union, to act in the manufacturer’s name for certain activities. The appointment and the functions whereby the representative acts on behalf of the manufacturer shall be established in a written contract.

Representative: any natural or legal person established in the EU authorized by the manufactured through a written contract to perform on its behalf for certain established activities.

Importer: any natural or legal person established in the EU which places on the market of the Union PPE originating from a non-EU country

Making available on the market: the supply of the PPE to be distributed or used on the EU market within the scope of a commercial activity, both for profit or for free.

Placement on the market: the first time a product is made available on the EU market.

Client: term used to refer to the manufacturer or its representative established in the European Union, who supplies a product or service and that assigns the conformity assessment service to CERTOTTICA.

Product: result of the activity of the Client, which must comply with set specifications, national or international standards or requirements set by the Client or to other specific documents.

In the specific case it is a PPE as defined by Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March 2016, in the first paragraph of article 3.

Note: In these Regulations, "Product" is used with the meaning of product or family of consistent products belonging to the Certification plan which is the object of the EU type-examination application and of the contract in the models and variant therein defined.

Tests: process through which, the conformity of the products with the requirements of the relevant harmonized standards or technical specifications is assessed.

Conformity assessment: demonstration that the specified requirements of a product, process, system, person or body are met or not; CERTOTTICA performs the evaluation of conformity regarding the product or process in compliance with the requirements proposed in Annexes V, VII and VIII del Regulation (EU) 2016/425.

EU certification plan: activities performed by CERTOTTICA aimed at assessing the conformity of the Product, the Certification Plan is based on the requirements defined in these regulations and on specific Product requirements.

Sampling visit: activity by which a delegation of qualified CERTOTTICA sampling staff visits a place agreed on with the Client (manufacturing plants, warehouses, etc.) in order to perform sampling activities according to the provisions of "Module C2" of Regulation (EU) 2016/425.

Check visit: activity by which a delegation of qualified CERTOTTICA auditors visits a place agreed on with the Client (manufacturing plants, warehouses, etc.) in order to perform the checks on products and/or production according to the provisions of "Module D" of Regulation (EU) 2016/425.

Manufacturing unit: place where the Client produces the product object of the EU Type-examination application or has it produced.

Technical Documentation: it is the group of documents as established in Annex III of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016, and, in particular, it must include at least the following elements:

a) a complete description of the PPE and of its intended use;
b) an assessment of the risks against which the PPE is intended to protect;
c) a list of the essential health and safety requirements that are applicable to the PPE;
d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
e) the descriptions and explanations necessary to understand the drawings and schemes referred to in point (d) and of the operation of the PPE;
f) the references to the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;

i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

EU Certification: certificate, that is the issue of a statement based on a decision which follows a re-examination and assessment by a third-party on products, processes, systems of people; CERTOTTICA can issue the following EU Certificates:

- an EU Type-Examination Certificate;
- an Annual Confirmation Report of the Certification (ACRC);
- a Compliance Certificate for Module D.

EU Type-Examination Certificate: document by which CERTOTTICA declares that, with reasonable reliability, a product meets the essential health and safety requirements in compliance with the provisions of Annex V of Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March 2016.

Annual Confirmation Report of the Certification (ACRC): document by which CERTOTTICA declares that, with reasonable reliability, a product meets the requirements of Annex VII (Module C2) of Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March 2016.

Compliance Certificate for Module D: document by which CERTOTTICA declares that, with reasonable reliability, a product meets the requirements of Annex VIII (Module D) of Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March 2016.

EU Type-Examination: activity by which CERTOTTICA declares (by issuing a EU Type-Examination certificate) that, with reasonable reliability, a certain Product is compliant with one or more standards.

Supervised product checks at random intervals: activity by which CERTOTTICA checks the maintenance of conformity of a PPE of III category, object of an EU Type-Examination, according to methods proposed in Annex VII of Regulation (EU) 2016/425 (Module C2).

Quality assurance of the production process: activity by which CERTOTTICA checks the maintenance of conformity of a PPE of III category, object of an EU Type-Examination, according to methods proposed in Annex VIII of Regulation (EU) 2016/425 (Module D).

EU Type-Examination Application: a document/contract in which the Client formally applies for the EU type-examination procedure be initiated, in compliance with these regulations.

Application for checks (Module C2): a document/contract in which the Client formally applies for the activation of the activity of conformity to type based on internal production control plus supervised product checks at random intervals in compliance with these Regulations

Application for surveillance (Module D): a document/contract in which the Client formally applies for the activation of the activity of conformity to type based on quality assurance of the production process in compliance with these Regulations.

EU Declaration of Conformity: a declaration issued by the Client under his/her exclusive responsibility, declaring that a given product conforms to a specific reference legislation document.

PTA (Primary Type Approval): with reference to an extended EU Type-Examination Certification, the manufacturer of the Personal Protective Equipment holder of the EU Type-Examination Certificate regarding the original product.

STA (Secondary Type Approval): with reference to an extended EU Type-Examination Certification, third party to which the holder of the EU Type-Examination Certificate regarding a given product (PTA) grants, based on a previous commercial agreement, the possibility to place the same product on the market under his/her own name.

Auditor: staff qualified to execute a systematic, independent and documented process to obtain evidence of the audit and to evaluate them with objectivity, in order to establish to what extent the audit criteria were satisfied.

Sampling employee: staff qualified to execute a systematic, independent and documented process during activities calling for a sampling by CERTOTTICA, for example in compliance with Module C2 Regulation (EU) 2016/425.

Person in charge of assessment (RVAL): technical staff with a suitable training to re-examine the application for EU Type-examination, the application for checks (Module C2) or the application for surveillance (Module D) and assess the technical documentation supplied by the Client and check the assessments of conformity and homogeneity regarding activities of check of product/production in compliance with Annex VII of Regulation (EU) 2016/425.

Technical Decision-Making Function (FTD): technical staff with a suitable training to re-examine the assessment and in charge of the final decision for the certification, FTD is a subject (or a group of subjects who make up a committee) not involved whatsoever in the assessment process.

Uncertainty of measurement: with reference to a measurement to be found in a Test Report, it is the result of the estimate which determines the width of the range within which the value of the ideal result which may be found with a perfect measurement should be found, generally with a certain probability

Conformity judgment (regarding the outcome of a Product test): outcome (PASS or FAIL) associated with the result of a certain test when compared with a limit (requirement) in the standard/technical specification to which the above-mentioned test refers to.

Decision-making rule: rule describing how the uncertainty of measurement is taken into account when the conformity judgment is performed compared to a specific requirement.

Suspension of the certificate: temporary invalidation of the certificate for the whole scope of the certificate or for part of the scope.

Withdrawal (revocation) of the certificate: annulment of the certificate.

Appeal: request, addressed to CERTOTTICA, by the supplier of the object of the conformity assessment for the reconsideration of a decision that CERTOTTICA has taken in relation to that object.

Complaint: expression of dissatisfaction, other than the above-mentioned appeal, expressed to CERTOTTICA by a person or an organisation and relating to the activities of CERTOTTICA, for which a response is awaited.

Extraordinary event or circumstance: circumstance outside the control of the organization, commonly referred to as “force majeure”; examples of such circumstances which may be caused by wars, strikes, riots political instabilities, geopolitical tensions terrorism, crime, pandemics, floods, earthquakes, harmful computer piracy, other natural or man caused disasters.

Management System: IT system for managing tests and the Notified Body.

4. GENERAL CONDITIONS

4.1 Process for EU-Type examination or assessment of conformity of products with surveillance (III category)

In order to begin the process for the activity of EU type-examination or assessment or conformity of products with surveillance (III category) by CERTOTTICA the Client shall:

- meet the requirements of the Certification Plan for the product subject of the Application for EU type-examination, or the Application for checks (Module C2) or the Application for surveillance (Module D), depending on what is applicable,
- accept the conditions set out by these Regulations and by the Product Certification Contract, by signing the Application for EU type-examination, or the Application for checks (Module C2) or the Application for surveillance (Module D), depending on the applicable Certification Plan.

4.2 Application for EU type-examination, Application for checks (Module C2) and Application for surveillance (Module D)

The Application for EU type-examination, the Application for checks (Module C2) and the Application for surveillance (Module D) define:

- the applicable Certification Plan,
- the product(s) subject to EU type-examination

4.3 Payment

The issue of EU type-examination Certificate or of the conformity assessment certificates according to modules C2 and D of Regulation (EU) 2016/425 are subject to the payment of the corresponding fees.

5. PROCEDURE FOR EU TYPE-EXAMINATION

5.1 Foreword

The procedure for EU Type-Examination by CERTOTTICA, in compliance with the provisions of Regulation (EU) 2016/425, Module B, aiming at the first issue of the EU Type-Examination certificate for a specific Product, takes place according to the following main steps

- Sending of the Type-Examination Application, Technical Documentation of the Product and reference sample by the Client.
- Examination of the documents sent by the Client by CERTOTTICA.
- Issue of EU Type-Examination Certificate.

5.2 Request of quotation for EU Type-Examination

The Client shall request to CERTOTTICA sales department (hereinafter referred to as COM) for a quotation for the EU Type-Examination service, giving them all the necessary information.

Such information can be supplied by filling in the Data Collection Form (form M.108.2.002) by asking for it directly to CERTOTTICA sales department, or by using another method that CERTOTTICA considers suitable and exhaustive.

If the data supplied are considered not sufficient, COM asks to the client for further and more detailed information. In any case no quotation will be sent until CERTOTTICA deems it has sufficient information.

If the data supplied are considered sufficient, COM sends the Client a quotation together with the Application for EU type-examination (form M.16.03.001.1). Inside the quotation the Client will find the name of the people in charge of assessment (Person in charge of assessment, RVAL, and Technical Decision-Making Function, FTD) whom CERTOTTICA entrusts for the operational performance of the EU Type-Examination.

If the Client applying for the examination is a new (or fairly new) Client for CERTOTTICA, besides the Application for EU Type-Examination CERTOTTICA will send also the following documents:

- These Regulations for certification, PQ 16.101.104;

- The procedure to fill in the Application for EU Type-Examination, PQ 16.108.002;
- The procedure to fill in the Product technical documentation PQ 16.108.003.

All these documents, including the Application for EU Type-Examination (form M.16.03.001.1) can anyway be downloaded from CERTOTTICA website "www.CERTOTTICA.it - Certification area", in Italian and English.

The Client can accept or not accept the quotation sent by CERTOTTICA.

a) If the Client accepts the quotation, the conditions under paragraph 5.3 of these Regulations apply.
b) If the Client does not sign or consider the quotation, the commercial transaction is closed.
c) The Client can reject the names of the assessment functions specified in the quotation: in this case the Client shall motivate such rejection and, if CERTOTTICA believes the motivation is exhaustive it can change the names compatibly with the internal job descriptions. Furthermore, if CERTOTTICA does not deem that the motivations are exhaustive, the Client shall accept the names proposed by CERTOTTICA or can waive the agreement, thus ending the commercial transaction.

If at this stage the Client asks for a variation of the quotation (for example to add more models which require to quote further certificates) CERTOTTICA will implement the same measures described above by issuing a reviewed quotation based on the Client's needs.

5.3 Submission of the Application for EU Type-Examination and of the Product Technical Documentation

Following the acceptance of the quotation, the Client sends CERTOTTICA the Application for EU Type-Examination duly filled in and signed by the Legal Representative of the company or by his/her delegate; to fill in the application refer to the instructions to be found in CERTOTTICA Procedure PQ 16.108.002.

Together with the Application for EU Type-Examination, the Client shall submit the Product Technical Documentation in compliance with Annex III of EU Regulation 2016/425; to prepare the technical documentation refer to the instructions contained in CERTOTTICA procedure PQ 16.108.003.

Note: the Technical Documentation shall include a review index and/or an issue date, to enable identifying any subsequent reviews and/or updates.

The Client shall also supply one or more actual reference sample(s) which shall be representative of the range of products included in the Certification Plan which CERTOTTICA keeps as reference, as specified under chapter 21 of these Regulations.

Languages accepted by CERTOTTICA for the Application for EU Type-Examination and the Technical Documentation are Italian and/or English.

Documentations in a language different from the two officially accepted languages can be accepted at CERTOTTICA's discretion and shall anyway be agreed on with COM before the preparation of the quotation.

5.4 Starting the procedure to issue the EU Type-Examination Certificate

5.4.1 Re-examination of the Application for EU Type-Examination

Once the Application for EU Type-Examination and the Product Technical Documentation are received, CERTOTTICA assigns a number to the Application for EU Type-Examination, by recording it in a specific register. Usually, CERTOTTICA processes the Applications for EU Type-Examination following the corresponding registration. CERTOTTICA technical staff carries out a check (re-examination) of the Application for EU Type-Examination in order to assess that:

- the information collected about the Client and the Product are sufficient to carry out the certification process;
- the document has been correctly filled in for every point (e.g. identification of the Client, legal

representative, kind of Product, intended use of the Product etc.) and duly signed in all necessary parts;

- every possible misunderstanding between CERTOTTICA and the Client has been solved, including the detail of applicable standard or other applicable documents;
- the scope of the certification applied for has been defined;
- in CERTOTTICA there are the necessary means to carry out all the assessment activities.

If this preliminary re-examination stage of the application ends with a negative outcome, possible additions or changes (depending on the nature of the non-conformities found) will be asked to the Client, together with the request of sending amended and correct documents.

In case of positive outcome, the Application for EU Type-Examination is signed by CERTOTTICA Legal Representative: the signature of the Application for EU Type-Examination by CERTOTTICA Legal Representative following the final acceptance of the quotation and of the general conditions of service by the Client, marks the acceptance and formalization of the contract (the absence of the signature of the Application by CERTOTTICA Legal Representative implies that the contract is not recorded and is therefore non-binding for the Client).

The notification of the formalization of the certification contract is communicated to the Client by email or by any other suitable method: together with this communication, only to Clients with an Agreement will be sent the order confirmation for the certification, while for all Clients the official opening of the job order for the issue of the EU Type-Examination will be communicated and the they will be informed of the signature of the Application by CERTOTTICA Legal Representative (this document will then be included in the final Technical file which will be sent to the Client).

It is possible that, for some reasons CERTOTTICA wants to entrust assessment activities to (Person in charge of assessment, RVAL, and Technical Decision-Making Function, FTD) to people different from those initially mentioned in the quotation for EU Type-Examination (for example due to a change in CERTOTTICA job descriptions, temporary non availability of one of the staff in charge etc.); in this case the Client will be informed before the job order for EU Type-Examination is opened, by email or other suitable method: the Client can accept or reject the new staff proposed names as mentioned under chapter 5.2 of these Regulations.

5.4.2 Evaluation of the technical documentation

After the certification job order is opened, CERTOTTICA reviews more in depth (at technical level) the supplied documentation in order to:

- assess the completeness and suitability of the Product Technical Documentation object of the Application for EU Type-Examination;
- check that the contents of the Product Technical Documentation are consistent with the reference sample(s) supplied to be kept;
- check the completeness of the tests carried out on the Product (test reports) to assess its correspondence with the applicable essential health and safety requirements.

  Note: CERTOTTICA accepts test reports issued by other laboratories provided that they comply with the requirements of UNI CEI EN ISO/IEC 17025 for the tests and that, from the examination of such test reports, there are no evident discrepancies or any inconsistencies. Exceptions to this point can be made for specific or recently implemented tests where it is not easy to find a laboratory compliant with UNI CEI EN ISO/IEC 17025 or to questions of convenience or cost of the service: in these cases, CERTOTTICA implements the necessary measures to guarantee that the results proposed are reliable. When accepting test reports issued by other laboratories CERTOTTICA takes in to account the uncertainty of measurement for the conformity judgement as specified under paragraph 5.4.3.2 of these Regulations, regardless of how this has been considered by the laboratory which issued the test. Any discrepancies may lead to the repetition of the tests which had an ambiguous result under this point of view.

a) If the outcome of the check on the technical documentation is not suitable and/or incomplete, CERTOTTICA informs the Client, by written communication specifying the points which have been found non-compliant and asks for an update.

Note: It is also possible that from the documentation supplied by the Client some tests performed on the Product are found missing or insufficient (test report): for these cases the operating instructions are found under chapter 5.4.3 of these Regulations.

In such a case:

- the Client shall commit to solve the non-conformity found: the process (certification job order) is suspended for a maximum time limit of 365 (three hundred and sixty-five) days starting from the date in which the non-conformity has been communicated to the Client;
- the Client sends CERTOTTICA the Product Technical Documentation and, if necessary, a new a new version of the Application for EU Type-Examination, reviewed based on the non-conformities found, following the instructions under paragraph 5.3 of these Regulations and, if necessary, send the samples for the repetition/integration of the tests;
- CERTOTTICA checks through additional tests or with a document check that the non-conformities have been solved by the Client: to this end the procedures described under paragraph 5.4.2 and 5.4.3 (if necessary) of these Regulations will be applied. The costs connected with this new EU Examination are charged to the Client.

If the Client does not accept the evaluation made by CERTOTTICA, it can ask for further analysis by explaining the reasons of his/her non-acceptance following the procedure under point 18 of these Regulations.

b) On the contrary, if the outcome of the check on the documentation sent is suitable CERTOTTICA follows the procedure to issue the EU Type-Examination Certificate.

The responsibility of this evaluation activity is of the Person in charge of assessment (RVAL), whose name is mentioned in the quotation for certification. At the end of the evaluation, RVAL issues an evaluation report which will be enclosed in the technical file to be sent to the Client.

5.4.3 Execution of tests to complete the Technical Documentation

5.4.3.1 – Operational method

If, after the evaluation of the documentation as described under paragraph 5.4.2 of these Regulations, there is a lack of tests on the Product to demonstrate its complete compliance with applicable essential health and safety requirements, the Client shall integrate the tests on the Products within the set timeframe. The Client may ask for the execution of the tests by CERTOTTICA laboratory, if it can offer his service: in such case he/she shall ask CERTOTTICA sales department (hereinafter referred to as COM) a quotation for the testing service. COM sends a quotation to the client, including the number of necessary samples to perform the missing tests.

Once the samples to be tested are received, CERTOTTICA analyses them to:

a) Check that the number is correct compared to what asked for in the quotation;
b) Check that they are compatible with the contents of the Product Technical Documentation.

NOTE: samples shall be representative of the future production in case of tests on prototypes. For PPE produced in series where each item is adapted to fit an individual user, samples representative of the range of different users shall be supplied, while for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be supplied.

If CERTOTTICA detects non-conformities in this stage of the check it will:

a) ask the Client to send missing samples to integrate those required in the quotation if there is a lack in this sense;
b) ask the Client to re-send samples in case they are found to be different from what is mentioned in the Product Technical Documentation.

CERTOTTICA shall not begin any testing activities as long as it has received the necessary samples to perform the tests following the methods outlined in the quotation: the above-mentioned procedure will be repeated until the non-conformities detected are full solved.

Once the conformity of the samples received has been confirmed, CERTOTTICA carries out the tests based on the test list included in the quotation and it issues one or more test report(s).

Is the result of the tests is NON compliant with the requirements of the harmonised standard or the technical specification applicable to the Product, CERTOTTICA informs the Client about the non–conformities, clarifying the discrepancies found.

The Client shall assess the causes of such non-compliant result and can send new samples for the repetition of the whole test list or of part of it depending on the new test list which will be included in the new quotation sent by COM; the procedure will be exactly the same as specified above. Besides the new samples, depending on the nature on the non-conformity, the Client may have to send updated application for examination and/or technical documentation, with new application of the procedure described under chapters 5.3 and 5.4 of these Regulations.

The cost of sending the samples and performing the tests if fully changed by CERTOTTICA to the Client.

The above-mentioned missing tests shall also be ordered by the Client to a laboratory other than CERTOTTICA, provided that the minimum requirements specified in the note under paragraph 5.4.2 are met.

5.4.3.2 Issue of the test report and application of the uncertainty of measurement in establishing the judgement of conformity

The result of the missing tests is documented by CERTOTTICA Laboratory by issuing Test Reports; test reports are generally sent to the Client in electronic form (pdf), with the electronic signature of the person in charge. Test reports shall contain, in general terms, the results of the tests on the Product compared with the limits set by the reference standard or technical specification (judgement of conformity): they translate into a “PASS” result when the standard limit or requirement is respected or into a “FAIL” result in the opposite case.

If the result of a test is numerical (quantitative), it has an uncertainty of measurement associated with it, as defined in classical numerology: uncertainty of measurement will not always be present in the Test Reports sent to the Client but it is always and, in any case, associated to the result of the measurement, even if implicitly.

In establishing judgments of conformity regarding the results of a certain test, CERTOTTICA takes into account the uncertainty of measurement associated to that specific test. The decision-making rule that CERTOTTICA applies in establishing judgments of conformity may change depending on the following cases:

a) The decision-making rule is NOT to be found within the requirements of the specific standard/technical specification: in this case CERTOTTICA shall apply the decision-making rule of figure 1, considering w=U. Setting the value of w=U determines a risk of acceptance of false-positive results lower than 2.5%.

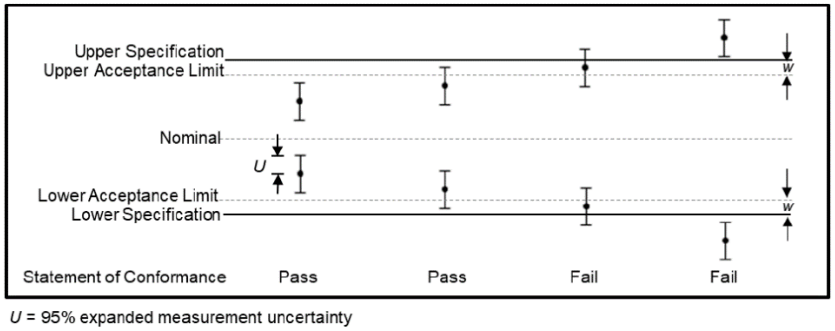

Figure 1

b) The decision-making rule is to be found directly inside the requirements of the specific standard/technical specification applied: in this case CERTOTTICA follows the rules of the standard.

5.4.3.3 Tests subcontracting

Due to excessive workload or to lack of suitable equipment, CERTOTTICA may subcontract tests to external qualified laboratories. The name of the appointed laboratory will be previously communicated to the client who will be asked to approve it. Anyway, the appointed laboratory is kept under control by CERTOTTICA; a preferential title of choice is the accreditation of the selected laboratory for the test which is subcontracted in compliance with standard UNI CEI EN ISO/IEC 17025

5.5 Decision for the certification and issue of the EU Type-Examination Certificate

5.5.1 Decision for the certification

CERTOTTICA Technical Decision-Making Function (FTD), whose name is mentioned in the certification quotation, has the task of re-examining the documentation supplied and organized by RVAL and has the responsibility of expressing an opinion on the certification (decision).

FTD gives an opinion on the outcomes of the evaluation made, which are to be found in the evaluation report prepared by RVAL.

a) If the outcome of the evaluation is NON compliant, the certification is rejected; the Client cannot submit again the Product object of the rejection to the EU Type-Examination and CERTOTTICA shall inform ACCREDIA, the notification authorities and other notified bodies which may be potentially interested in this.
b) If the outcome of the evaluation is compliant, FTD sends to the Scheme Manager (DOC) of CERTOTTICA his/her (positive) decision, mentioned on a decision report; this document is not usually included in the technical file which will be sent to the Client.

5.5.2 Issue of the EU Type-Examination Certificate

Based on the positive decision of FTD, the Scheme Manager (DOC) of CERTOTTICA, issues an EU Type-Examination Certificate. The EU Type-Examination Certificate has on first page the “number”, the issuing date (start of validity), the expiry date and the date of signature (of drafting).

The EU Type-Examination Certificate is the official CERTOTTICA document which declares that the Product in question meets with reasonable reliability the applicable requirements of health and safety.

Two copies of the EU Type-Examination Certificate are issued: one is sent to the Client and the other is kept by CERTOTTICA for a minimum period of (5) from the end of the validity of the Certificate. The Client shall retain his/her copy of the EU Type-Examination Certificate for a minimum of ten (10) years from the date of the last placing on the market of the Product. Each copy is signed and authenticated on every page with stamp and initials by the legal representative or by the Scheme Manager of the Notified Body is appointed to do so.

Note: the EU Type-Examination Certificate is property of CERTOTTICA.

The official languages for drawing up the EU Type-Examination Certificate are Italian and English.

It is possible for the Client to request the EU Examination Certificate to be issued in a language other than Italian or English: in this case, CERTOTTICA will implement the necessary measures to ensure that the translation is as faithful as possible to the original; in the event of doubts or inconsistencies that may emerge from reading the translated Certificate, the corresponding content included in the original version always prevails.

CERTOTTICA initially sends to the client a scanned copy of the EU Type-Examination Certificate. Later on, the Client will receive a hard copy of the following documents regarding the EU Type-Examination for the Product:

- Original copy of the EU Type-Examination Certificate,
- Evaluation report issued and signed by RVAL,

- Application for EU Type-Examination, signed by CERTOTTICA Legal Representative,
- Product Technical Documentation, including all test reports necessary to assess the compliance of the Products with the applicable essential health and safety: this part of the technical file may also not be sent to the client upon prior notice by the Client.

The above-mentioned collection of documents is available on request also in digital format (as organised by RVAL during the evaluation stage).

Following the issue of the EU Type-Examination Certificate, the Client is generally authorised to place the Product object of the certificate and applying the CE marking, after issuing the corresponding Declaration of Conformity as provided for by article 15 of the EU Regulation 2016/425. For III category devices which need a periodic evaluation as provided for by the procedures described in Annex VII or VIII of EU Regulation 2016/425, consider additionally the provision of chapter 9 of these Regulations.

6. MODIFICATION AND EXTENSION OF THE EU TYPE-EXAMINATION CERTIFICATE

6.1 Change (revision) of the EU Type-Examination Certificate

The change (revision) of the EU Type-Examination Certificate can generally take place due to the following reasons:

- Change to the Product object of the original certificate;
- Change of the state of the art for that specific Product, e.g. an update of the harmonised standard or technical specification, which may imply a change in the applicable essential health and safety requirements;
- Request of change of the EU Type-Examination Certificate on the Client's request

It is also possible for the customer to request the renewal of the certification (see Chapter 7) at the same time as the change; this request must be included in the application for examination and must be submitted no earlier than 12 months after expiry of the EU Type-Examination Certificate. In this case, the Customer has the option, directly within the application for EU Type Examination (see form M.16.108.2.001), of requesting that the EU Type-Examination Certificate be drawn up with a date prior to the natural expiry date but keeping the period of validity of the certificate intact or of requesting that the EU Type-Examination Certificate be drawn up by making the date of signature (of drawing up) coincide with the date of commencement of validity (in the latter case the EU Type-Examination Certificate will lose its life).

6.1.1 Change of the Product by the Client

If the Client intends to make any changes to a Product that has already been granted EU type-examination Certificate, or changes to the EU type-examination Certificate that has been issued, he/she sends a specific request to CERTOTTICA.

a) If the changes the Client intends to make are minimum, so that they don't alter substantially the protective and constructive characteristics the Product had been certified for (that is, modifications that don't influence the compliance of the product with the applicable essential health and safety requirements or to the conditions of validity of the Certificate), there is no need to review the EU type-examination Certificate. If required to do so, The Client sends CERTOTTICA a copy of the review of the Technical Documentation. If it deems it necessary, CERTOTTICA may request a number of samples in order to carry out tests to confirm that the original protective features of the product have been maintained: in this case the procedure described under paragraph 5.4.3 of these Regulations is followed. At the end of the checks, if the outcome is positive, CERTOTTICA, sends the Client a communication declaring that it has taken note of the request and authorizes

the changes. If the outcome of the controls is negative, CERTOTTICA sends the Client a communication stating that it does not authorise the production of the changed product.

b) If the changes the Client intends to make to the Product are substantial, to the point that they alter substantially the protective and constructive characteristics the Product had been certified for (that is modifications that influence the conformity of the product to the applicable essential health and safety requirements or to the conditions of validity of the Certificate), or intends to add some variants or to extend the field of application, the EU type-examination Certificate must be reviewed. The costs for the review of the EU type-examination Certificate and the tests are charged to the Client. The procedure to be followed in this case is exactly the same as the one proposed in chapter 5 where the Client will be asked by CERTOTTICA to integrate the Technical Documentation with the necessary tests to guarantee the update of the field of application of the EU Type-Examination Certificate based on the intended changes

   If the analysis gives a positive outcome, CERTOTTICA issues a review of the EU Type-Examination Certificate.

   If the review of the EU type-examination Certificate is successful, the original certificate number is maintained adding the code “Rev. X”, where “X” is the progressive review number that is issued, beginning from 1. Every later review automatically cancels and replaces the previous one from the date of issue (start of validity) of the revised certificate.

   If the outcome of the analysis is negative the rules specified under chapter 5 of these Regulations are applied: in this case CERTOTTICA will not issue a review of the certificate and the Client shall implement all necessary measures to solve the non-conformities found. The Client will not be allowed to place the modified product on the market.

c) If the changes made mean that the Product is completely different from the one previously examined, the EU type-examination Procedure must be repeated as if it were a new product. In this case the procedure to be followed is that under chapter Article 5 of these Regulations.

6.1.2 Change of the state of the Art of the certified product

CERTOTTICA follows the evolution of harmonised standard and technical specifications used for the evaluation of Product conformity.

In this case CERTOTTICA informs the Client, by a newsletter, an e-mail, or another suitable means that the state of the art of the Product object of the previous assessment has been subject to changes: it is generally an update of the harmonised standard or technical specifications which implies a change in the applicable essential health and safety requirements.

The Client shall then update the EU Type-Examination Certificate and maybe the Product itself in order to guarantee that it keeps meeting the new applicable essential health and safety requirements.

The cost of review of the EU Type-Examination Certificate and any additional Test is charged to the Client. The procedure to be followed in this case is exactly the same as the one proposed in chapter 5 where the Client will be asked by CERTOTTICA to integrate the Technical Documentation with the necessary tests to guarantee the extension of the field of application of the EU Type-Examination Certificate based on the intended changes.

If the outcome of the EU type-examination is successful, CERTOTTICA issues a review of the EU Type-Examination Certificate. The original certificate number is maintained adding the code “Rev. X”, where “X” is the progressive review number that is issued, beginning from 1. Every later review automatically cancels and replaces the previous one from the date of issue (start of validity) of the revised certificate.

If the outcome of the analysis is negative the rules specified under chapter 5 of these Regulations are applied: in this case CERTOTTICA will not issue a review of the certificate and the Client shall implement all necessary measures to solve the non-conformities found. The Client will not be allowed to place the modified product on the market until it is compliant with the new applicable essential

health and safety requirements and until the revised EU Type-Examination Certificate is issued by CERTOTTICA.

6.1.3 Change of the standard or technical specification not associable with a change in the state of the art of the certified Product

If there is an update of the standard or technical specifications which does not imply a substantial change in the essential health and safety requirements applicable to the Product (e.g. introduction of updates or corrections to the standard in force, change of essential requirements which are not applicable to the product, passage from projects of standard to official standard, etc.) it is generally the Client's choice to revise the EU Type-Examination Certificate.

If the Client wants to proceed with the review of the Certificate the cost of such process is charged to the Client. The procedure to be followed in this case it exactly the same outlined under chapter 5. If the outcome of the documents analysis is positive, CERTOTTICA issues a review of the EU Type-Examination Certificate. If the outcome of the documents analysis is negative, the procedure under chapter 5 of these Regulations shall be followed.

The review of the EU Type-Examination Certificate has the same number as the original certificate adding the code "Rev. X", where "X" is the progressive review number that is issued, beginning from 1. Every later review automatically cancels and replaces the previous one.

6.1.4 Change to the EU Type-Examination Certificate

If the Client needs a change to the information mentioned in the EU Type-Examination Certificate, he/she gives written communication to CERTOTTICA. CERTOTTICA sales department sends a quotation. If the Client accepts the quotation, CERTOTTICA updates the EU Type-Examination Certificate. The updated EU Type-Examination Certificate has the same number as the original certificate adding the code "Rev. X", where "X" is the progressive review number that is issued, beginning from 1. Every later review automatically cancels and replaces the previous one from the date of issue (start of validity) of the revised certificate.

CERTOTTICA may also deem non acceptable the change requested by the Client, and it sends the reasons on non-acceptance of the request in writing to the Client in this situation, the Client can follow two different ways:

- accepts the communication by CERTOTTICA and gives up the request for changes;
- does not accept the communication by CERTOTTICA and gives communication in writing by specifying the reasons of the disagreement. In this case the procedure outlined under chapter 18 of these Regulations is followed.

If the request of change of information mentioned in EU Type-Examination Certificate by the Client is due to a mistake by CERTOTTICA when issuing the EU Type-Examination Certificate and the mistake has been actually verified, CERTOTTICA issues a review of the EU Type-Examination Certificate. The review of the EU Type-Examination Certificate has the same number as the original certificate adding the code "Rev. X", where "X" is the progressive review number that is issued, beginning from 1. Every later review automatically cancels and replaces the previous one from the date of issue (start of validity) of the revised certificate.

6.2 Extension of the EU Type-Examination Certificate

The extension of the EU Type-Examination Certificate is the procedure by which a subject, the Client holding a valid EU Type-Examination Certificate for a specific product (hereinafter PTA – primary type approval), agrees to customise the product with an identification declaring another person as manufacturer (hereinafter STA – secondary type approval). STA will place the Product on the marked under its name while PTA will maintain the responsibility related to the conformity of the production of the Product object of the EU Type-Examination Certificate.

The extension of the EU Type-Examination Certificate in favour of STA can only be activated if PTA holds a valid EU Type-Examination Certificate issued by CERTOTTICA.

The request for the extension is generally submitted by PTA; the quotation issued by CERTOTTICA shall be accepted by PTA and STA. The Application for EU Type-Examination and the Technical Documentation shall be signed and sent by STA.

In order to activate the extension procedure, it is necessary to follow the steps detailed under chapter 5 of these Regulations except for the following points.

It is not necessary that the Technical Documentation supplied by STA includes all the elements provided for by Annex III of Regulation (EU) 2016/425 as some parts may be in common with the Technical Documentation supplied by PTA; anyway, the minimum contents for STA Technical Documentation are the following:

1. application for EU Type-Examination for STA's product;
2. STA's user information;
3. marking placed in the product by STA;
4. copy of PTA's EU Type-Examination Certificate;
5. document signed by PTA and STA as detailed below.

The document signed by PTA and STA shall include the elements listed below from 1 to 8 as specified in RFU n° PPE-R/00.047, which can be downloaded from the website of the European Commission https://ec.europa.eu.

1. Declaration that the Product object of the extension is physically identical to the product covered by the EU Type-Examination Certificate, whose number and issue date shall be quoted.
2. Being understood what is stated in the previous point, a declaration on the possible differences between what is stated in the original EU Type-Examination Certificate and what is required (e.g. reduction in the number of versions of the certified product).
3. Declaration by PTA that only the Product object of the original EU Type-Examination Certificate will be supplied to STA for the extension of the EU Type-Examination Certificate.
4. Declaration that PTA commits to inform STA and CERTOTTICA of any changes which may affect the validity of both the EU type-examination Certificate and, in case of class III PPE, of the monitoring procedures of product/production in accordance with "Module C 2" and/or "Module D" of the Regulation (EU) 2016/425.
5. Declaration that PTA commits to inform STA and CERTOTTICA of any changes he/she wants to make to the Product before proceeding to the change as provided for by chapter 6.1 of these Regulations.
6. Declaration that PTA and STA reciprocally exchange information about any incidents involving the Product subject of the agreement.
7. Declaration that the original Product Technical Documentation of PTA is put at CERTOTTICA disposal to support it in the performance of the conformity evaluation procedures.
8. In case of III category devices, a declaration that the procedure adopted by PTA in compliance with the provisions of Module C2 or D of Regulation (EU) 2016/425 is still valid and in line with the requirements proposed in Regulation (EU) 2016/425.

At the end of this procedure, if the evaluation has a positive outcome, issues a new EU Type-Examination Certificate in the name of STA. in case of negative outcome the measures provided for by chapter 5 of these Regulations are applied.

The expiration of the extended EU type-examination Certificate issued to STA will correspond to the expiration date of the original certificate issued to the PTA by CERTOTTICA and in any case it will be of no more than 5 years. It may be revoked in advance in the event the aforesaid conditions are no longer valid, in particular if the EU Type-Examination Certificate issued to PTA and from which the extension derives should lapse (paragraph 12.2). In short, extended certificates issued for STA are indissolubly linked to the primary original certificate of PTA from which they descend.

7. RENEWAL OF EU TYPE-EXAMINATION CERTIFICATE

The EU Type-Examination Certificate will not be renewed automatically.

EU Type-Examination Certificates are only renewed following a written request by the customer and against evidence submitted with the application; this request must be submitted using the renewal application (form M.16.108.2.005).

The application for renewal shall be submitted not before of 12 (twelve) months before the expiry date of the EU Type-Examination Certificate.

In order for CERTOTTICA to be able to fulfil its duties, the application for renewal, if possible, should be submitted no less than 6 (six) months prior to the expiry date of the EU Type-Examination Certificate to be renewed; if the application for renewal of certification is received by CERTOTTICA less than six months prior to the expiry date of the EU Type-Examination Certificate to be renewed, CERTOTTICA cannot guarantee that the renewed EU Type-Examination Certificate will be prepared and issued within the expiry date of the EU Type-Examination Certificate.

If CERTOTTICA confirms that no modifications have been made to the examined type and that no evolution on the state of the art has taken place, the simplified review procedure is applied and no tests and exams are performed; in that case, CERTOTTICA renews the EU Type-Examination Certificate.

7.1 Submitting the Renewal Application and Documentation

The commercial department of CERTOTTICA periodically checks the status of EU type examination certificates. If there are any EU Type-Examination Certificates expiring, if the Client has not applied for them or communicated the renunciation, CERTOTTICA's commercial department prepares form M.16.03.005 "Renewal offer" and attaches to it form M.16.108.2.005 "Application for renewal" to be filled in by the Client. Inside the offer the Client will find the names of the assessment functions (Person in charge of assessment, RVAL, and Technical Decision-Making Function, FTD) appointed by CERTOTTICA for the operational execution of the EU type examination procedure.

The application for renewal, form M.16.108.2.005, includes the following main parts:

- data concerning the Manufacturer, the Authorised Representative (if any), the scope of certification and the Product, including any variants, similar to what is present in classical EU Type-Examination applications, as well as the references of the EU Type-Examination Certificate to be renewed;
- request for a timeframe for the issuance of the renewed certificate;
- confirmation by the manufacturer that no changes have been made to the approved type, including materials, sub-components or sub-assemblies, or to the relevant harmonised standards or other technical specifications applied;
- confirmation by the manufacturer that no change in the state of the art has occurred;

As an attachment to the renewal application, the customer is requested to provide:

- copies of current drawings and images of the product, product markings and information made available by the manufacturer;
- for category III products, if not yet available to the notified body, information on the results of tests of the product under official control carried out at random intervals or the results on conformity to type based on quality assurance of the production process;
- document signed by PTA and STA including what is stated in points 1 to 8 of paragraph 6.2 of these Regulation in case of renewal of EU Type-Examination Certificate in extension, only in case of EU Type-Examination Certificates in extension and only if the contractual conditions between PTA and STA have changed for some reason with respect to the original certification.

If the Client accepts the renewal offer, it shall complete and initial forms M.16.03.005 and M.16.108.2.005 and forward them to CERTOTTICA together with the required documentation indicated in the application for renewal.

NOTE: The Client may also send the signed offer in advance and only afterwards the application for renewal together with the various required annexes; the offer for renewal must be countersigned by the Client no more than 12 (twelve) months and, if possible, no less than 6 (six) months prior to the expiry date of the EU Type Examination Certificate.

It is possible that for some reason CERTOTTICA intends to entrust the certification activities (Person in charge of assessment, RVAL, and Technical Decision-Making Function, FTD) to appointees other than those indicated in the renewal offer (e.g. due to modification of CERTOTTICA internal job description, temporary unavailability of one of the appointees, etc.); in this case the Client will be informed in advance of the renewal order opening, by e-mail or other suitable means: the Client shall be entitled to accept or reject the proposed new appointments in accordance with paragraph 5. 2 of this Regulation.

The languages accepted by CERTOTTICA for the application for renewal and documentation are Italian and English. Documentation written in a language other than the two officially accepted languages may be accepted at the discretion of CERTOTTICA.

The Client is free to submit any additional documents to support the application for renewal, e.g. independent product certifications, independent quality system certifications, etc.

7.2 File Instruction for the Granting of the Renewed EU Type-Examination Certificate

7.2.1 Review of the renewal application and evaluation of documentation

The Person in charge of assessment (RVAL) appointed by CERTOTTICA, upon receipt of the documentation from the Client, performs the review of the application for renewal of the EU Type-Examination Certificate and the evaluation of the documentation provided as an annex to the application in order to assess that:

- the application for renewal:
  - is filled out completely and adequately in the required parts,
  - there are no discrepancies with respect to the application for EU type-examination sent at the time of the original certification (previous certification), specifically in relation to the scope and field of application of the certification requested, to the Product subject of the original EU type-examination (including any product variants present) and to the data of the Manufacturer (including references of the production unit) and/or the Authorised Representative.
  - is duly countersigned by the client or person delegated by him
- the declarations included in the application for renewal are true and confirmed, also after a review of the documentation attached to the application for renewal.

At the same time, it also evaluates the renewal documentation provided by the customer and attached to the renewal application; the main analysis of the documentation involves verifying that it:

- is complete and exhaustive with respect to the requests,
- no typos or errors,
- does not include any parts that are contradictory to the Technical Documentation submitted during the original certification, even to the extent that the product is suspected of having been modified with respect to the previous certification.
- In the event that the renewal documentation includes substantially different parts from the technical documentation of the previous certification, RVAL performs the practice evaluation in accordance with Section 5.4.2.

NOTE 1: Examples of this type are, compared to the contents of the technical documentation submitted in the previous certification, the presence in the documentation of revised technical drawings, significantly different product markings and user manual, and a different document signed by the PTA and STA; in all these cases, an assessment by RVAL is required in order to verify whether these revised documents are still consistent with those included in the previous certification or lead to the forfeiture of

7.2.2 Management of non-conformities detected

In the event that the review and assessment activity conclude with a negative outcome, RVAL prepares the Assessment Report for renewal, which will have a negative outcome, and indicates in Section I the non-conformities found.

The review and evaluation activity may fail in the following cases:

1) changes to the product or to the original scope of certification not previously indicated by the customer emerge;
2) developments in the state of the art relating to the Product under consideration emerge (e.g. the technical standard used for the initial evaluation of the Product);
3) changes occur in the relevant harmonised standards or other technical specifications applied for the conformity assessment of the Product under consideration;
4) the documentation provided is not complete with respect to the minimum required parts;
5) the documentation provided includes parts that are erroneous, different or contradictory to the Technical Documentation submitted during the previous certification;
6) the original test reports and any new test reports provided are not acceptable according to the current parameters of CERTOTTICA;
7) for category III products, the information on the results of production checks against Form C2 or D of the Regulation is not complete and/or not exhaustive;

- In cases 1), 2) and 3), it will be necessary to proceed, together with the renewal, also with the revision of the EU Type-Examination Certificate and therefore to proceed as established in paragraphs 6.1 or 6.2 of this Regulation, as applicable: in this case, all the activity related to the certification renewal is concluded, without the need to go through the Deliberation Body (FTD), since a certification revision activity will have to be forced as established in paragraphs 6.1.1 or 6.1.2 of this Regulation, as applicable. CERTOTTICA sends the Evaluation Report for renewal to the Client and DOES NOT sign "Application for renewal" M.16.108.2.005 prepared by the Client.
- In cases 4) and 5) CERTOTTICA communicates to the Client the need for documentary supplementation and, if necessary, the sending by the Client of a sample for analysis. CERTOTTICA sends the Evaluation Report for renewal to the Client and does NOT sign the "Application for renewal" M.16.108.2.005 prepared by the Client.
- In case 6) CERTOTTICA requests the integration of the deficient evidence, as described in paragraph 5.4.3 of these Rules. RVAL sends the Evaluation Report for renewal stamped and countersigned by it to COM, which in turn will forward it to the Client and will NOT sign the "Application for renewal" M.16.108.2.005 prepared by the Client.
- In case 7) the certification process is concluded with a negative outcome as the file is lacking in one of its fundamental parts; CERTOTTICA requests the Client to carry out the certification tests in full, at least on the most recent products (latest production) and the complete re-certification of the product is requested.

If requested in the Evaluation Report for renewal, the Client will send updated documentation: CERTOTTICA will proceed to a second review with evaluation as indicated above and will assess whether the outcome is positive or negative; it will proceed in the same way until the outcome is positive.

7.3 Decision Making (Decision for Certification) and Issue of the EU Type-Examination Certificate

Technical Decision-Making Function (FTD) of CERTOTTICA, whose name is indicated in the preliminary offer for certification, has the task of reviewing the documentation provided and ordered by RVAL and is responsible for expressing an opinion on the certification (decision). The FTD

expresses its opinion on the certification by deciding on the renewal of the EU Type-Examination Certificate.

The Scheme Manager of CERTOTTICA (DOC), after a positive decision by the FTD, issues the renewed EU Type-Examination Certificate. The EU Type-Examination Certificate bears on the first page the "number", the date of first issue (coinciding with the date of issue of the first version of the Certificate), the date of issue (beginning of validity), the date of expiry and the date of signature (drafting).

The renewed EU Type-Examination Certificate has the same certification number as the original certificate with the addition of the code "Rev.X", where X indicates the revision number which will be the next of that of the original EU Type-Examination Certificate, a new issue date (or start of validity) with its expiry date extended by 5 years from the new issue date (or start of validity).

The EU Type-Examination Certificate is produced in duplicate, one copy is sent to the Client and one copy is retained by CERTOTTICA for a minimum period of five (5) years from the expiry date of validity of said certificate. The Client is required to keep his copy of the EU Type-Examination Certificate for a minimum of ten (10) years from the date the product was last placed on the market. Each copy is signed and stamped on each page by the legal representative or the Scheme Manager of the Notified Body if duly delegated.

Note: the EU Type-Examination Certificate is the property of CERTOTTICA.

The official languages in which the EU Type-Examination Certificate can be produced are Italian and English; it is possible for the Customer to request the EU Type-Examination Certificate to be issued in a language other than Italian or English: in this case, CERTOTTICA will implement the necessary measures to ensure that the translation is as faithful as possible to the original; in the event of doubts or inconsistencies that may emerge from reading the translated Certificate, the corresponding content included in the original version always prevails.

CERTOTTICA shall first send the Client a scanned copy of the renewed EU Type-Examination Certificate. Subsequently, the Client will be sent a hard copy of the following documents relating to the EU type examination for the Product:

- Renewed EU Type Examination Certificate;
- application for renewal M.16.108.2.005 completed and countersigned by RVAL;
- original documentation sent by the Customer as an annex to the application for renewal, reviewed and ordered by RVAL (this part may or may not be returned in hard copy to the Customer according to his wishes);
- Evaluation report for renewal completed and countersigned by RVAL.

The aforementioned collection of documents is also available in digital format on request (as ordered by RVAL during the evaluation phase).

8. VALIDITY OF THE CERTIFICATE

8.1 Conditions of validity of the EU Type-Examination Certificate

The validity of the EU Type-Examination Certificate is subject to the fact that the Client maintains the conditions which determined its issue.

Any change in the conditions which determined the issue of the EU Type-Examination Certificate shall be immediately communicated to CERTOTTICA, in compliance with the prescriptions of paragraph 10.3 of these Regulations.

After such communication CERTOTTICA reserves the right to decide any actions to be performed to assess and guarantee that the conditions which determined the issue of the certificate are maintained.

8.2 Duration of the EU Type-Examination Certificate

The period of validity of a newly issued EU Type-Examination Certificate and, if applicable, of a renewed certificate, is not more than 5 (five) years. The following cases may apply:

- EU Type-Examination Certificate modified because of a change in the Product (see paragraph 6.1.1): in this case the expiry date of the EU Type-Examination Certificate does NOT change and it will be shorter than 5 (five) years;
- EU Type-Examination Certificate modified because of a change in the state of the art (see paragraph 6.1.2): in this case the expiry date of the EU Type-Examination Certificate will be renewed and the duration restored to 5 (five) years;
- EU Type-Examination Certificate modified because of a request of change of the content by the Client (see paragraph 6.1.5): in this case the expiry date of the EU Type-Examination Certificate does NOT change and it will be shorter than 5 (five) years;
- EU Type-Examination Certificate modified because of a change in the reference standard or technical specification which does not constitute a change in the state of the art (see paragraph 6.1.4): in this case the expiry date of the EU Type-Examination Certificate does NOT change and it will be shorter than 5 (five) years;
- Renewed EU Type-Examination Certificate (see chapter 7): the expiry date is restored to 5 (five) years;
- extension of an EU Type-Examination Certificate in favour of STA (see paragraph 6.2): in this case the expiry date shall coincide with the original PTA's EU Type-Examination Certificate of di PTA and it will be shorter than 5 (five) years.

Once the expiry date (expiry date shown on the first page of the certificate) is reached, the EU Type-Examination Certificate is no longer valid; this implies that the Client cannot place his/her Product on the market after this deadline has been reached.

The expiry date is indicated on the EU Type-Examination Certificate and is related to the date of issue (or of commencement of validity) of the EU Type-Examination Certificate.

Each revision of an EU Type Examination Certificate automatically cancels and replaces the previously issued version as from the date of issue (start of validity) of the renewed certificate.

9. OFFICIAL CONTROL ON THE PRODUCT AND/OR ON THE PRODUCTION PROCESS FOR CLIENTS HOLDING EU TYPE-EXAMINATION CERTIFICATES

9.1 Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)

9.1.1 Premises

The Client holding an EU Type-Examination Certificate for a category III PPE (products subject to the application of Annex VII of Regulation (EU) 2016/425 – Module C2 – "Conformity to type based on internal production control plus supervised product checks at random intervals"), shall adopt all the necessary measures to guarantee that the production process and its control, including the intermediate and final controls, guarantee uniformity of production and conformity with the provisions mentioned in the Product Technical Documentation and with applicable essential health and safety requirements. The aforementioned intermediate and final controls relating to the production process must be subject to registration.

If necessary, and if it is appointed to do so CERTOTTICA implements the procedure of production control through supervised product checks at random intervals (Module C2) for Clients holding an EU Type-Examination Certificate for III Category Products in order to assess uniformity of production

and conformity of the Products with the whole production and with applicable essential health and safety requirements. The procedure of production control through supervised product checks at random intervals takes place through a suitable statistical sampling of the manufactured Product, followed by suitable tests in compliance with the applicable technical harmonized standards and/or equivalent tests specified in other technical specifications in order to check the conformity of the PPE with the type described in the EU type-examination Certificate and with the applicable essential health and safety requirements.

9.1.2 Submitting the application for checks (Module C2)

Before placing on the market a III category PPE, the client shall submit an application for supervised product checks at random intervals to CERTOTTICA or to another notified body of his/her choice.

If the notified body chosen is CERTOTTICA, the Client shall send the Application for checks Module C2 (form M.16.108.2.004) duly filled in. It is possible to send the Application for checks Module C2 together with the application for EU Type-Examination, i.e. when asking for a quotation for the issuing of the EU Type-Examination Certificate for a certain Product, if the Client already intends to assign this activity to CERTOTTICA).

If CERTOTTICA is not the notified body that has performed the EU type-examination procedure (Module B), this Application for checks Module C2 shall include:

- Technical Documentation of the Product;
- Copy of the EU Type-Examination Certificate.

In this specific case, CERTOTTICA can ask the Client for a reference sample to be kept in its records, in compliance with the method described under chapter.

Note: CERTOTTICA may contact the notified body that issued the EU type-examination Certificate in case of difficulty related to the evaluation of conformity for the Product

The application for supervised product checks at random intervals shall be filled in in every part to be considered valid. Non-applicable parts shall be barred.

Languages accepted by CERTOTTICA for the application for supervised product checks at random intervals are Italian and English.

Upon receiving the Application for checks Module C2, if necessary, together with the EU Type-Examination Certificate and the Product technical documentation, CERTOTTICA technical staff carries out a general and preliminary check of the documents received to assess that:

- information collected about the client and the product are sufficient to carry out the activities connected with Module C2 of Regulation (EU) 2016/425;
- the Application for checks Module C2 has been correctly filled in for each applicable point (e.g. identification of the Client, legal representative, type of Product, intended use, etc.) and duly signed in all necessary points;
- every possible misunderstanding between CERTOTTICA and the Client has been solved, including the detail of applicable standard or other applicable documents;
- the scope of the assessment activities applied for has been defined;
- in CERTOTTICA there are the necessary means to carry out all the assessment activities.

If this preliminary re-examination stage ends with positive outcome, the Application for checks Module C2 is signed by CERTOTTICA's Legal Representative: the signature of the Application for checks Module C2 by CERTOTTICA's Legal Representative marks the acceptance and formalization of the contract (the absence of the signature by CERTOTTICA's Legal Representative implies that the contract is not recorded and is therefore non-binding for the Client).

In case of negative outcome, possible additions or changes (depending on the nature of the non-conformities found) will be asked to the Client, together with the request of sending amended and correct documentation.

The original hard copy of the Application for checks Module C2 signed by CERTOTTICA Legal Representative is sent to the Client while CERTOTTICA keeps a copy.

9.1.3 Sampling and evaluation of conformity

The sampling phase is normally notified to the Client by CERTOTTICA, generally with 15 (fifteen) calendar day' notice, by sending a quote which includes the travel costs for the auditors, the cost for the tests on the sampled products and the costs of the activity of evaluation and decision-making; the quote will include also the names of CERTOTTICA's sampling staff besides the names of people in charge of evaluation and decision-making.

The Client shall return the signed quote to CERTOTTICA by the date scheduled for the sampling. If the Client does not accept the sampling before the scheduled date, s/he must immediately send a written communication with the reasons for refusal (e.g. interruption of production or Product check carried out by another notified body). In the event that no written statement is received within two months after COM sent the quote, CERTOTTICA will initiate the procedure of suspension as provided for in paragraph 12.1 and it will inform, if necessary, the notified body which holds the EU Type-Examination Certificate for that Product.

The Client can reject the names of the sampling staff and assessment and decision-making functions specified in the quotation: in this case the Client shall motivate such rejection and, if CERTOTTICA believes the motivation is exhaustive, it can change the names compatibly with the internal job descriptions. Furthermore, if CERTOTTICA does not deem that the motivations are exhaustive, the Client shall accept the names proposed by CERTOTTICA.

Once the Client sends the signed quotation, CERTOTTICA activates the check procedure, as provided for by the Certification plan.

CERTOTTICA carries out the selection of the samples to be analysed: the sampling of the Products is carried out by CERTOTTICA's sampling staff who may be accompanied by ACCREDIA'S staff. The sampling activity is carried out on available stock of the manufacturer, so that it is representative of the Product under examination. The sampling takes place at a place previously agreed on with the Client (for example warehouse of the manufacturer, manufacturing plants, distributors/points of sale, etc.).

In order to assess the homogeneity of production CERTOTTICA shall select samples on a maximum of four different batches in a year. If the manufacturer has available less than four batched produced in a year, CERTOTTICA shall select products from all manufactured batches, if the manufacturer has available more than four batched produced in a year, CERTOTTICA shall select products from four batches, by sampling products from the first and the last batches and from 2 intermediate batches.

CERTOTTICA will perform, or, if necessary, shall have performed, tests on the samples products and will issue one or more test reports on the tests performed.

On the selected products CERTOTTICA will assess:

- homogeneity of production: all sampled batches shall have the same features (there shall not be differences in shape, construction, etc. between batches and within the same batch) and they shall be compliant with the requirements of the reference standard(s);
- homogeneity with the content of the Product Technical Documentation: by comparing the sampled products with the content of their technical documentation (or by comparing them with the reference sample in CERTOTTICA'S records) there shall be no differences of any kind;
- conformity with applicable essential health and safety requirements; all tests performed by CERTOTTICA shall have positive outcome, not only regarding the minimum requirements of the standard but also, if applicable, regarding the minimum performances expected for each model (for example loads shown on the marking of a mountaineering connector shall be respected even if the y are higher than the standard minimum limits).

The responsibility of this evaluation activity is of the Person in charge of assessment (RVAL) whose name is included in the initial quotation for the performance of this activity. At the end of the assessment activity, an evaluation report is issued and sent to the body in charge of decisions on conformity. Such evaluation report can only have positive or negative outcome.

If the outcome of the evaluation is compliant, an evaluation report with positive outcome is issue.

If CERTOTTICA finds non-homogeneity in the sample or if the product is not compliant with the applicable essential requirements, it informs the Client in writing, highlighting the non-conformities found; there are two different ways to be followed in case the negative outcome of the evaluation is due to "non-homogeneity" or "nonconformity":

a) in case of "non-conformity" with applicable essential requirements, an evaluation report with negative outcome is issued right away;
b) in case of "non-homogeneity" of the product:
    1. the Client shall investigate the causes of the non-homogeneity found;
    2. the Client informs CERTOTTICA of the result of their analysis of the non-conformities and the solutions they have adopted to solve the issue;
    3. CERTOTTICA decides which and how many tests are required to evaluate the Product conformity;
    4. CERTOTTICA carries out a second sampling of the Product and carries out tests and evaluations on the Product;
    5. If tests and evaluations give positive outcome, a positive evaluation report is issued;
    6. If tests and evaluations give negative outcome yet again, there is a further opportunity to follow procedure outlined in points from 1 to 4 (third sampling);
    7. If also the results of the third sampling give a result on non-conformity the procedure describe under point "a" is followed "a".
c) It is also possible that, further to tests performed, the Product shows performances lower than those declared in the Product technical documentation and marking, yet guaranteeing compliance to minimum standard requirements; in this case the evaluation report for C2 Module will be issued only after the Client has adjusted the EU Type-Examination Certificate to the new performance levels. It is therefore necessary to modify the EU Type-Examination Certificate by keeping into account the new performance levels (the identification of the model shall be different from the original one, as provided for by RFU PPE-R/00.002).
    - In case the EU Type-Examination Certificate for the product was issued by CERTOTTICA, procedures under points 6.1.5 of these Regulations apply;
    - in case the EU Type-Examination Certificate for the product was not issued by CERTOTTICA, the Client shall contact the notified body which issued the EU Type-Examination Certificate and ask for its modification.

Any additional activity explained above are charged to the Client.

If the client does not accept the evaluation performed by CERTOTTICA, it can ask for further analysis by explaining the reasons of his/her refusal according to the methods under point 18 of these Regulations.

9.1.4 Decision-making for the evaluation activity in compliance with Module C2

CERTOTTICA'S Technical Decision-Making Function (FTD) whose name is included in the initial quotation sent for the performance of these activities, has the task of re-examining the documentation supplied and organized by RVAL and has the responsibility to express an opinion on compliance (decision).

FTD expresses an opinion on the outcomes of the evaluation performed which can be found in the evaluation report.

a) Following an evaluation with negative outcome, the issue or renewal of the Annual Confirmation Report of the Certification (ACRC), depending on the fact it is the first or a subsequent surveillance, is denied: the Client will no longer be allowed to market the product which is being produced. If it was CERTOTTICA which issued the EU Type-Examination Certificate for the Product, CERTOTTICA communicated to the notified body which issued the EU Type-Examination Certificate the negative outcome of the surveillance: the Client is forbidden to use

CERTOTTICA identification number on the product marking next to the CE mark. In any case CERTOTTICA shall inform ACCREDIA and notifying authorities.

b) Following an evaluation with positive outcome, FTD sends to the Scheme Manager of CERTOTTICA (DOC) its (positive) decision on a decision-making report.

9.1.5 Issue of the Annual Confirmation Report of the Certification (ACRC)

The Scheme Manager of CERTOTTICA, following a decision with positive outcome by FTD, issues an Annual Confirmation Report of the Certification (ACRC). The Annual Confirmation Report of the Certification (ACRC) is a document of one (1) page stating the date of first issue, the date of renewal (if applicable) and the expiry date, besides references to the Product object of the evaluation, to the manufacturer and to the l EU Type-Examination Certificate of the Product.

This document testifies to the Products conformity with the requirements Annex VII of Regulation (EU) 2016/ and it will be sent to the Client in hard copy to be kept for ten (10) years from the placing of the PPE on the market. The document is signed and stamped by CERTOTTICA'S Legal Representative or by the Scheme Manager of the Notified Body, if appointed to do so.

The Annual Confirmation Report of the Certification (ACRC) issued by CERTOTTICA shall expire on 31st December of the year after the evaluation of conformity according to Module C2 has taken place (for example, if the evaluation activity has been carried out in 2020 the ACRC expiry date will be 31/Dec/2021).

The Annual Confirmation Report of the Certification (ACRC) is no longer valid once the deadline has been reached; for the Client this implies that, once this date has been reached, it is no longer possible to place the Product on the market (at least not with CERTOTTICA identification number next to the CE marking, this happens if the Client has decided to entrust the surveillance activity to another Notified Body), unless the certificate is updated within the set deadline.

The issuing of a new Annual Confirmation Report of the Certification (ACRC) for the renewal of the EU Certificate automatically cancels and replaces the previously issued version for the same product.

The official languages in which the Annual Confirmation Report of the Certification (ACRC) can be drawn up are Italian and English.

It is possible for the Customer to request the Annual Confirmation Report of the Certification (ACRC) to be issued in a language other than Italian or English: in this case, CERTOTTICA will implement the necessary measures to ensure that the translation is as faithful as possible to the original; in the event of doubts or inconsistencies that may emerge from reading the translated Certificate, the corresponding content included in the original version always prevails.

CERTOTTICA sends a preliminary scanned copy of the Annual Confirmation Report of the Certification (ACRC). Later on, the Client will receive the hard copy of the following documents:

- "Annual Confirmation Report of the Certification (ACRC) Module C2" issued by DOC;
- evaluation report for Module C2 issued by RVAL.

Following the release (first issue) of the Annual Confirmation Report of the Certification (ACRC), the Customer is generally authorised to place on the market the Product covered by the same, bearing the CERTOTTICA identification number alongside the CE marking, following the issue of the relevant Declaration of Conformity, as provided for in Article 15 of Regulation (EU) 2016/425.

After the renewal of the Annual Confirmation Report of the Certification (ACRC), the Client is generally authorised to keep placing the Product (object of the report) on the market with CERTOTTICA identification number next to the CE marking.

9.1.6 Lead-time and special cases

The first evaluation of the product compared with the requirements proposed in Module C2 of Regulation (EU) 2016/425 shall be performed before placing on the market the product subject to the conformity assessment: if CERTOTTICA is the notified body which issued the EU Type-

Examination Certificate, it will organise the surveillance activity in compliance with Module C2 as soon as possible consistent with the planned placing on the market of the product.

The following surveillance activities in compliance with Module C2 shall be performed at least once a year randomly: in this case the sampling of the necessary samples for the check at the Client's premises will take place at random intervals established by CERTOTTICA.

The following special cases may take place:

- Suspended production: CERTOTTICA will not perform the sampling if the samples set out in the test list are not available because of limited or non-existing production of the Product; in this case the client shall supply a specific declaration in which the suspension of the production is clearly stated: the manufacturer commits to inform CERTOTTICA before resuming the production or when the necessary samples will be in stock. In this case CERTOTTICA shall perform a preliminary sampling of the product.
- The manufacturer produces the PPE in two or more manufacturing units: in this case the above-mentioned instructions apply to all manufacturing units.
- In case of changes to the harmonised reference standard(s) applying to the Product object of the EU Type-Examination Certificate, CERTOTTICA shall perform the tests on the product in compliance with the harmonised standard(s) mentioned in the EU Type-Examination Certificate.

9.1.6.1 Off-site sampling

An extraordinary event or circumstance may temporarily prevent DOLOMITICER sampling employees from performing the scheduled sampling activities at the sampling sited agreed upon with the Client. When such a situation occurs, an alternative "off-site" sampling is possible and it shall be reasonably scheduled and previously agreed with the Client.

CERTOTTICA asks the Client for a preliminary current and future analysis connected with the extraordinary event, requiring specific information by sending module M.16.105.100 "Off-site audit or sampling request"; in this way CERTOTTICA can determine possible risks compared to the usual "on-site" and decide for a possible off-site sampling. If the classic sampling activity at the Client's is confirmed to be actually not possible, the alternative off-site sampling activity is activated.

The operational methods regarding the sampling are the same as those described under chapter 9.1.3 of these Regulations, with the following differences.

- The Client will preliminarily be sent a specific sampling plan, module M.16.111.1.008 "Sampling plan off-site Module C2", containing the operational instructions which shall be followed during the off-site sampling; inside this sampling plan there will be a part which shall be filled in by the Client before the off-site visit takes place.
- The Client shall appoint a sampling employee who will have to perform the sampling on behalf of CERTOTTICA sampling employee, following the methods summarised in the specific sampling plan which will be sent by CERTOTTICA.
- All sampling stages are organised and managed CERTOTTICA's sampling employee off-site, by means of a video conference with the Client following the method which the sampling employee deems to be the most suitable. The video conference platform shall be previously agreed on between CERTOTTICA's sampling employee and the Client.
- The selection of samples at the Client's warehouse or plant shall be performed by the sampling employee appointed by the Client during the video conference with CERTOTTICA's sampling employee, who shall guarantee the compliance of the sampling activity by the sampling employee of the Client; the latter shall mark the selected samples by placing his/her signature and the date of selection directly on the product or on the packaging.
- The sampling employee appointed by the Client shall fill in and sign the "Sampling report off-site" M.16.105.007. The report will then be scanned and sent by FAX or email, or by any other means deemed suitable; CERTOTTICA's sampling employee shall check the contents of the document supplied by the Client and will sign it for acknowledgement. The original

document will be later on sent to the Client, while CERTOTTICA will keep a copy in its records.

- The Client will have to ship the samples selected to be tested.
- When samples are received, CERTOTTICA's sampling employee shall check that the samples are actually the ones selected by the Client on the day of the off-site, that they have the labels applied by the sampling employee appointed by the Client and that they are the same quantity and nature necessary to perform the tests. If they aren't, the Client may be requested to integrate the samples or repeat the procedure.

The activities of testing, evaluation, decision-making and issuing of the Annual Confirmation Report of the Certification (ACRC) are the same as those described in the previous paragraphs 9.1.3, 9.1.4 e 9.1.5.

9.1.6.2 Issue of the Annual Confirmation Report of the Certification (ACRC) in case of Products of extended certificates

If a Client holding an extension of an EU Type-Examination Certificate for a Product (STA – secondary type approval) of Category III wants to entrust CERTOTTICA with the activity of conformity evaluation in compliance with Annex VII of Regulation (EU) 2016/425, the procedure described under paragraphs 9.1.2, 9.1.3, 9.1.4 and 9.1.5 of these Regulations is applied, but taking into account the following aspects.

a) The holder of the original certificate (PTA) shall have a valid EU Type-Examination Certificate issued according to Module B and a valid approval issued according to Module C2.
b) The holder of the secondary certificate (STA) shall have a valid EU Type-Examination Certificate issued according to Module B.
c) The agreement signed by PTA and STA, as per the instructions under paragraph 6.2 of these Regulations, shall still be valid; otherwise, for example if the Notified Body which issued the EU Type-Examination Certificate for PTA and STA's Products was not CERTOTTICA which, such agreement shall be previously supplied to CERTOTTICA when submitting the Application for checks for Module C2.
d) If the sampling takes place at PTA's warehouse or manufacturing plant,
   - It can envisage the sampling of both PTA and STA's products: in this case both family of products shall undergo tests and homogeneity assessment;
   - It can envisage the sampling only of PTA's or STA's products (generally PTA's) to perform the tests, but at least one sample shall be supplied to assess marking and user information.
e) STA's Annual Confirmation Report of the Certification (ACRC) is valid only if the corresponding PTA's is valid.
f) Apart from cases described under point d), the evaluation of conformity of STA's products can be limited only to the analysis of the Product marking and user information (other evaluations shall be performed on PTA's product and will automatically be deemed applicable to the corresponding STA's product).

9.2 Conformity to type based on quality assurance of the production process (Module D)

9.2.1 Premises

The Client holding an EU Type-Examination Certificate for products of III Category (Products falling within the application scope of Annex VIII of Regulation (EU) 2016/425 – Module D – "Conformity to type based on quality assurance of the production process"), adopts an approved quality system for manufacturing, inspections of the finished product and the test of PPE and is subject to surveillance by CERTOTTICA, as described below.

If appointed to do so and if suitable CERTOTTICA enforces the procedure of production control through quality assurance of the production process (Module D) for the Client who holds an EU Type-Examination Certificate for products of III Category in order to check if the quality system set up by the Client meets the requirements specified under point 3.2 of Annex VIII of Regulation (EU) 2016/425. It assumes the compliance with such requirements by the elements of the quality system compliant with the applicable specification of the corresponding harmonised standards.

Below there is a summary of the main steps necessary to comply with the minimum requirements proposed by Regulation (EU) 2016/425, Annex VIII:

- submission of the Application for surveillance (Module D) by the Client;
- initial check of the manufacturer's quality system divided in to two separate activities (stage 1 and stage 2);
- issue of the Certificate of Compliance Module D, with corresponding renewal;
- periodic surveillance activity.

In order to perform the surveillance activity, besides referring to its own internal procedures, CERTOTTICA refers to the following documents issued by IAF:

- IAF MD 1 "Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization".
- IAF MD 5 "Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems".

9.2.2 Submission of the Application for surveillance (Module D)

The Client who wants to entrust CERTOTTICA with this surveillance activity shall send the Application for surveillance Module D (module M.16.108.2.003) duly filled in. Together with the Application for surveillance (Module D) the Client shall also send a copy of the documentation of its own quality system as specified under paragraph 9.2.3 of these Regulations.

If CERTOTTICA is not the body which performed the EU type examination (Module B), the Client shall also send:

- the Product technical documentation;
- copy of the EU Type-Examination Certificate.

In this specific case, CERTOTTICA can ask the Client for a reference sample to be kept in its records, in compliance with the method described under chapter 21.

Note: CERTOTTICA may contact the notified body that issued the EU type-examination Certificate in case of difficulty related to the evaluation of conformity for the Product.

The application for surveillance (Module D) shall be filled in in every part to be considered valid. Non-applicable parts shall be barred.

Languages accepted by CERTOTTICA for application for surveillance (Module D) are Italian and English.

The application for surveillance (Module D) contains:

- the name and address of the manufacturer and, if the application is submitted by the mandatory, his name and address as well;
- manufacturer's address and plants where the audits can be carried out;
- a written declaration that the same application has not been submitted to any other notified body;
- all information for the category of the PPE, including, if necessary, the documentation on the approved model;
- the documentation concerning the quality system;
- an undertaking to respect the obligations arising from the quality-control system and to maintain its adequacy and efficiency;

- an undertaking to keep CERTOTTICA informed about any modifications that the manufacturer is planning to make to the quality system.

When application for surveillance (Module D) is received, if necessary, together with EU Type-Examination Certificate and the Product technical documentation, CERTOTTICA' RVAL carries out a preliminary and general check of the documentation sent in order to assess that:

- information collected about the client and the product are sufficient to carry out the activities connected with Module D of Regulation (EU) 2016/425;
- the Application for surveillance (Module D) has been correctly filled in for each applicable point (e.g. identification of the Client, legal representative, type of Product, intended use, etc.) and duly signed in all necessary points;
- every possible misunderstanding between CERTOTTICA and the Client has been solved, including the detail of applicable standard or other applicable documents;
- the scope of the assessment activities applied for has been defined;
- in CERTOTTICA there are the necessary means to carry out all the assessment activities.

If this preliminary re-examination stage ends with positive outcome, the Application for surveillance (Module D) is signed by CERTOTTICA's Legal Representative: the signature of the Application for surveillance (Module D) by CERTOTTICA's Legal Representative marks the acceptance and formalization of the contract (the absence of the signature by CERTOTTICA's Legal Representative implies that the contract is not recorded and is therefore non-binding for the Client).

The formalization of the contract is notified to the Client by email or other suitable means: this communication will inform the Client of the signing of the Application for surveillance (Module D) by CERTOTTICA's Legal Representative (the original hard copy of the document will be sent to the Clients as soon as possible).

9.2.3 Initial Assessment of the System for quality management of the production

Together with the Application for surveillance (Module D), if necessary, accompanied by the Product Technical Documentation and the EU Type-Examination Certificate, the Client supplies the documents regarding its quality system to CERTOTTICA; in particular the documents shall include a suitable description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned;
- the means of monitoring the achievement of the required product quality and showing the effective operation of the quality system;
- description of the means employed by the manufacturer to grant the continuous conformity and homogeneity of the products in time.

With reference to the quality system assurance, the manufacturer shall include tests on the products, to check the conformity of the PPE with the essential health and safety requirements of the Regulation.

CERTOTTICA assesses the manufacturer's quality system to determine whether it complies with the requirements of the previous paragraph and if it is effective.

CERTOTTICA carries out the tests and, after examining the documentation and then by performing a specific audit at the Client's premises, it verifies the specific elements of the quality system, by

specifically checking if the system ensures the compliance of the PPE manufactured with the approved model.

The initial assessment of the Quality management system has two or three specific stages, depending on the cases:

- Stage 1 – Analysis of the documents and assessment of the set-up of the quality assurance system of the production process;
- Stage 2 – Audit on the quality assurance system of the production process.
- If necessary, additional check at the Client's.

During the preparation of the preliminary assessment activity, CERTOTTICA prepares the audit plan, by specifying the duration of stage 1, stage 2 and the surveillance activity which will be performed periodically by CERTOTTICA to maintain the Compliance Certificate Module D (see more specifically paragraph 9.2.7 of these Regulations); a quotation will also be included containing expected costs for the surveillance activities. Such planning is included in a specific module and the duration of such activities is estimated by CERTOTTICA based on documents IAF Mandatory Document IAF MD 5 in force. Such information is communicated to the Client by CERTOTTICA's Sales department.

In the preliminary quotation the Client shall find the names of auditors and people in charge of decision-making which CERTOTTICA appoints to the operational activity of the surveillance.

Stage 1 – Analysis of the documents and assessment of the set-up of quality assurance system of the production process

Stage 1 of the analysis of documentation is realized in the form of document review, which can be performed on-site or off-site. The activity of checking the set-up of the management system is always carried out at the headquarters of the organization.

a) The documentary analysis includes the study of the documents / information listed below compliance with the requirements of specific standards.
   - Manual of the quality system of the manufacturer;
   - Organization structure and related responsibilities;
   - Procedures and instructions that define the production process;
   - Procedures and instructions that define the controls to be performed on the product in the various phases of the production process (beginning, during process, final, …);
   - Procedures that grant the supplying of components and raw materials in compliance with the approved type, as described in the technical file;
   - Procedures that grant the metrological conformity of the measurement instruments used as control of the production process in the control activities of the product along the phases of the production process;
   - Procedures that describe the modalities adopted to check the documents and their revisions;
   - The procedure for the management of non-compliant products (corrective and preventive actions);
   - The procedure for the management of training;
   - The procedure for the planning and the performance of internal audits with related records
b) The audit carried out at the Client's manufacturing plant has the aim to verify mandatory elements such as: (list not-exhaustive):
   - the field of application and the degree of the system operation;
   - the level of preparation of the Client's staff, and the level of the Client's understandings regarding the requirements of the reference standards.
   - the planning of internal audits and their execution and reviewing by management
   - the level of implementation of the management system which shall provide evidence that the organization is ready for the audit of Stage 2

Outcomes and conclusions of the initial check (stage 1) are included into an audit report. The Audit report with the results is given to the Client. It highlights issues that, in the Stage 2 audit may be classified as (major/minor) non-conformities.

Stage 2 – Audit on the quality assurance system of the production process

The assessment (production process assessment) shall be carried out in compliance with the scheme checklist (checklist developed in compliance with requirements of standard UNI EN ISO 9001:2008, specific checklists developed according to product technical standards) which shall contain objective tests.

Non-conformities (NC) management methods to be followed by clients can be found in paragraph 9.2.4.

The Client is informed if the solution of non-conformities calls for document review or an additional audit.

Additional assessment

The additional assessment takes place in one single stage to be carried out at the plant.

The assessment (production process assessment) shall be carried out in compliance with the scheme checklist (checklist developed in compliance with requirements of standard UNI EN ISO 9001, specific checklists developed according to product technical standards) which shall contain objective tests.

In particular the additional assessment aims at checking the effective solution of the major NCs detected during the initial audit (stage 2).

The appointed staff (auditor) issues an audit report containing the outcomes of the check (stage 1, stage 2 and additional assessment, if applicable), listing all evidence regarding the solution of the major NCs previously detected and /or any further non- conformities and/or remarks; the audit report is shared and signed by the Client for acceptance. The audit report is then sent to FTD who will give an opinion about the EU Certificate.

If the Client does not accept the evaluation made by CERTOTTICA, it can ask for further analysis by explaining the reasons of his/her non-acceptance following the procedure under point 18 of these Regulations.

9.2.4 Classification of findings

Subsequent to the audit the following kinds of findings can be noticed, recorded and communicated to the Client (through the audit report): major non-conformities (impedimental to the certification of the quality system to ensure production quality), minor non-conformities (non-impedimental to the certification of the quality system to ensure production quality, which must nonetheless be taken into account by the Client) and remarks (non-impedimental to the certification, only suggestion for improvement).

- In case of “major non-conformities”:

  the Client must analyse their causes and tell CERTOTTICA how they mean to solve the non-conformity within one week (the actions planned by the client to solve a major non-conformity must be accepted by CERTOTTICA’s appointed staff). Further to the Client’s written communication of the closing of analysis of causes and of the solution of the non-conformities found, COM sends the Client a written quotation for an additional visit, in order to ascertain the effective solution of the non-conformity.

  The costs of the visits and the scheduled date are clearly communicated in the quotation. When the Client accept the quotation, the procedure for the additional assessment activity described under paragraph 9.2.3 of these Regulations is followed.

  If, following the visit, CERTOTTICA’s auditing team detects major non-conformities which have not been solved effectively, the procedure explained in this point must be resumed with a second additional surveillance visit.

- In the case of "minor non-conformity": the customer must analyse the causes and communicate to CERTOTTICA how it intends to resolve the non-conformity. The corrective actions to be implemented to resolve the identified Minor non-conformities must be implemented within 6 months by sending the proposed analysis of the causes, treatment and actions to be undertaken, submitted to the Auditor for evaluation within 1 week. The evaluation of the actual implementation and adequacy of the minor corrective actions implemented by the Organization will be conducted during the subsequent surveillance visit to confirm the effectiveness of the actions taken.
- in the case of "observations/ideas for improvement": they constitute situations of possible improvement or situations of potential weakness that could potentially determine a situation of non-compliance if not corrected in advance. The customer must evaluate their usefulness by providing documented feedback during the subsequent verification.

9.2.5 Decision for the initial surveillance activity according to Module D

CERTOTTICA's Technical Decision-Making Function (FTD), whose name can be found in the initial quotation sent for the performance of these activities, has the task of re-examining the documentation supplied by the auditing team and the responsibility to give an opinion about conformity (decision).

FTD gives an opinion about the outcomes of the performed assessment:

a) If the outcome of the assessment shows "major non-conformities" detected and not solved within the set time frame, the Compliance Certificate Module D is not issued, as described under paragraph 9.2.6 of these Regulations, if the EU Type Examination Certificate(s) for the Product(s) has/have not been issued by CERTOTTICA, the latter informs the Notified Body which issued the certificate(s) about the negative outcome of the surveillance activity. In any case, CERTOTTICA shall inform ACCREDIA and notifying authority.

b) If the outcome of the assessment is compliant, FTD sends to the Scheme Manager (DOC) of CERTOTTICA his/her (positive) decision, mentioned on a decision report.

9.2.6 Issue of Compliance Certificate Module D

The Scheme Manager of CERTOTTICA, following the decision by FTD, issues a Compliance Certificate Module D. The Compliance Certificate Module D is a one-page document containing the issue and expiry date of the document, with an annex showing the Products object of the Certificate itself.

This document shall be sent to the Client in original hard copy; the Client shall keep it available for (10) years from the placing of the PPE on the market.

The Compliance Certificate Module D issued by CERTOTTICA has a validity of three years from the date of first issue and can be renewed following the procedure under paragraph 9.2.8 of these Regulations.

The Compliance Certificate Module D is no longer valid after its expiry date (expiry date on the document); this means that after the expiry date the Client cannot keep placing the Product on the market (at least not with CERTOTTICA identification number next to the CE marking, this happens, for example, if the Client has decided to entrust the surveillance activity to another Notified Body), unless the certificate is updated within the set deadline.

CERTOTTICA notifies its decision to the Client (listing the groups of products included in the scope of the manufacturer's quality system) and the notice includes the final remarks on the performed check and the justified assessment decision.

Thus, the Client is authorized to place the Product on the market by placing CERTOTTICA number (2008) next to the CE marking after performing the EU Type examination, unless already performed, and issuing the Declaration of conformity as provided for by article 15 of Regulation (EU) 2016/425.

9.2.7 Assessment activity of periodic surveillance of the Quality assurance system of the production process

The purpose of the periodic activity performed by CERTOTTICA is ensuring that the Manufacturer fulfils correctly the obligations deriving from the approved quality system.

CERTOTTICA carries out periodical checks, at least once a year from the issue of the Compliance Certificate Module D to ensure that the Client keeps and applies the quality systems and, at the end of the assessment, it issues a detailed audit report. CERTOTTICA reserves the right to perform unscheduled visits at the Client's.

9.2.7.1 – Surveillance assessment

The surveillance assessment takes place in one single stage to be performed at the plant.

The assessment (production process assessment) shall be carried out in compliance with the scheme checklist (checklist developed in compliance with requirements of standard UNI EN ISO 9001, specific checklists developed according to product technical standards) which shall contain objective tests. Non-conformities (NC) management methods to be followed by clients can be found in paragraph 9.2.4.

The Client will be informed about the outcome of the surveillance audit, in particular in case of non-conformities if document review or an additional audit are necessary.

9.2.7.2 – Additional assessment

The additional assessment takes place in one single stage to be carried out at the plant

The assessment (production process assessment) shall be carried out in compliance with the scheme checklist (checklist developed in compliance with requirements of standard UNI EN ISO 9001, specific checklists developed according to product technical standards) which shall contain objective tests.

In particular the additional assessment aims at checking the effective solution of the major NCs detected during the initial audit (stage 2).

The appointed staff (auditor) issues an audit report containing the outcomes of the check (stage 1, stage 2 and additional assessment, if applicable), listing all evidence regarding the solution of the major NCs previously detected and /or any further non- conformities and/or remarks; the audit report is shared and signed by the Client for acceptance. The audit report is then sent to FTD who will give an opinion about the EU Certificate.

If the Client does not accept the evaluation made by CERTOTTICA, it can ask for further analysis by explaining the reasons of his/her non-acceptance following the procedure under point 18 of these Regulations.

9.2.7.3 – Decision for the periodic surveillance activity according to Module D

CERTOTTICA's Technical Decision-Making Function (FTD), whose name can be found in the initial quotation sent for the performance of these activities, has the task of re-examining the documentation supplied by the auditing team and the responsibility to give an opinion about conformity (decision).

FTD gives an opinion about the outcomes of the performed assessment:

a) If the outcome of the assessment shows "major non-conformities" detected and not solved within the set time frame, the Compliance Certificate Module D is withdrawn, as described under paragraph 12.2 of these Regulations, If the EU Type Examination Certificate(s) for the Product(s) has/have not been issued by CERTOTTICA, the latter informs the Notified Body which issued the certificate(s) about the negative outcome of the surveillance activity. The Client is forbidden to use CERTOTTICA's identification number next to the Product CE marking.

   In any case, CERTOTTICA shall inform ACCREDIA and notifying authority. All additional activities described above will be charged to the Client.

b) If the outcome of the evaluation is compliant, FTD sends to the Scheme Manager (DOC) of CERTOTTICA his/her (positive) decision, mentioned on a decision report. The reports by

CERTOTTICA's auditors, containing positive outcomes of the surveillance assessment and, if the case, the additional assessment, shall be sent to the Client for his/her filing.

9.2.8 Renewal of the Compliance Certificate Module D

The Compliance Certificate Module D has a duration of three years; when it expires, if the Client wants to continue this activity with CERTOTTICA, it is necessary to renew the certificate. A general assessment of the Client's quality system shall be performed through an audit at the Client's which shall be scheduled before the certificate expiry date. If the audit for the renewal gives a positive result, CERTOTTICA renews the Compliance Certificate Module D by updating the duration for another three years; in case any non-conformities are detected, the instructions described in the previous paragraphs are applied: the certificate will be renewed only when non-conformities detected during the audit for renewal are solved.

9.2.9 Lead-time and special cases

The first evaluation of conformity of the product with the requirements proposed in Module D del Regulation (EU) 2016/425 (initial assessment of the client's quality system) shall be performed before placing on the market the Products object of the certification with the number of CERTOTTICA.

The assessment activity of Periodic surveillance of the Quality assurance system of the production process in compliance with Module D shall be performed at least once a year.

The Client shall keep the following available for national Authorities for ten years from the date of the placing of the Product ion the market:

a) the application for surveillance (Module D), together with the Product technical documentation and the EU certificates of the Products object of the EU certification;
b) the information regarding the change of the quality system, as approved;
c) the decisions and reports sent by CERTOTTICA.

If the manufacturer produces the PPE on one or more manufacturing units, the above-mentioned procedures apply to all manufacturing units involved.

9.3 Client's duties and responsibilities

9.3.1 Free access to areas, information and documents

The Client who has activated the process for internal production control plus supervised product checks at random intervals (annex VII of Regulation (EU) 2016/425, Module C2) or based on quality assurance of the production process (annex VIII of Regulation (EU) 2016/425, Module D) with CERTOTTICA for III Category Products, shall grant free access to areas, information and documents necessary to perform the sampling, identifying and/or sampling products or to perform technical audits to CERTOTTICA's auditors or sampling staff during the sampling or assessment visit. CERTOTTICA's staff may be accompanied ACCREDIA's staff, the body which accredits CERTOTTICA's activity (as observer of the activity of CERTOTTICA's auditors and sampling staff) and by staff of the Authorities.

If significant parts of the production take place at the seat of a supplier of the manufacturer, also such seats may be included in the sampling or auditing activities.

Pursuant to current laws on safety and accident prevention on the workplace, the Client undertakes to give CERTOTTICA's auditors or sampling staff all the necessary information about possible risks at the workplace where they are also going to work, and s/he guarantees that all possible precautions to protect the auditors or sampling staff's health have been taken.

The Client undertakes to let observers appointed by Control/Accreditation Bodies enter the plants to carry out their tasks of control and monitoring of the activities carried out by CERTOTTICA as Certification and Control Body.

Such observers will be accompanied by CERTOTTICA staff at all times. The communication of these observers' presence might be given with a short notice (less than 3 days), and the Client cannot claim this as a reason for not accepting their presence.

If the Client does not give its approval to free access to areas, information and documents necessary to perform the assessment visit or the sampling by CERTOTTICA's auditors or sampling staff and/or ACCREDIA's staff, the process for internal production control plus supervised product checks at random intervals (annex VII of Regulation (EU) 2016/425, Module C2) or based on quality assurance of the production process (annex VIII of Regulation (EU) 2016/425, Module D) shall be interrupted, or the EU Type-Examination Certificate will be suspended or withdrawn, if it had already been issued to the Client.

9.3.2 Client's responsibilities

By entrusting CERTOTTICA with the procedure of control of the production and/or of the production process, the Client takes on the responsibility to:

a) place to CERTOTTICA's disposal all necessary information to check if the product meets the applicable essential health and safety requirements;
b) respect the conditions according to which the EU Type-Examination Certificate, the Annual Confirmation Report of the Certification (ACRC) and/or the Compliance Certificate Module D have been issued;
c) inform CERTOTTICA in good time about any changes to the product, the Technical Documentation, the Quality System or, if the case, in the manual or procedures for quality control;
d) declare that s/he respects CERTOTTICA's procedures and regulations for the performance of conformity assessment activities.

Specifically, for the performance of assessment of the production process according to Module D, the Client takes on the responsibility to:

a) ensure that the approved production quality system is kept active and effective in order to guarantee the compliance of the manufactured PPE with the approved type;
b) inform CERTOTTICA about any significant change in manufacturing procedures on in check and assessment methods which may affect the homogeneity of production. This point includes the change of the PPE manufacturing plant;
c) commit to respect obligation deriving from the quality system and keep it compliant and effective;
d) inform in advance CERTOTTICA of any change to the quality system, CERTOTTICA reserves the right to check the proposal of change and decide if the quality system is still compliant (CERTOTTICA shall communicate its decision to the Client).

9.3.3 Safety

The Client shall guarantee that it has taken all necessary measures for the safety of working conditions, places and installations during the sampling and/or auditing program. Moreover, if necessary, it shall inform CERTOTTICA's auditors or sampling staff, ACCREDIA's and the Authorities' staff about any known current and/or potential danger or risk which may be associated with the visit and the test samples, there included the presence of risks due to radiations, toxicity or harmfulness or explosive, polluting or poisonous elements or materials.

10. RIGHTS AND DUTIES OF CLIENTS HOLDING AN EU CERTIFICATE

10.1 Publicising the EU Certificate

The Client has the right to publicise its EU Certificate issued by CERTOTTICA in the manner it considers most suitable, as long as it correctly refers to the field of application and the limits of the Certificate and/or to the Certificate number.

In the user information, the Client shall refrain from giving any information that could mislead the users into considering that any product performances that are not provided in the applicable and/or applied Certification Plan are covered by the EU Certificate. The instructions and other information accompanying the product (manual and/or user instructions, etc.) and which refer to a specific Certification Plan, shall be approved by CERTOTTICA if so required in the aforesaid Certification Plan.

10.2 Client's obligations

The client holding an EU Certification issued by CERTOTTICA shall commit to:

a) to maintain unchanged all the conditions that made it possible to issue the EU type-examination Certificate,

b) manufacture the Product in compliance with the requirements established by the standards, these Regulations, the provisions of the Technical Documentation and other legislative documents used for the production of the sample(s) approved CERTOTTICA;

c) allow access to CERTOTTICA's auditors and/or sampling staff and to ACCREDIA's staff, in the circumstances provided for by these Regulations;

d) perform investigation on any received complaints;

e) keep a record of all complaints made that it is aware of, relating to compliance with certification requirements and make those records available to CERTOTTICA when requested, and:
   1. take appropriate actions with respect to such complaints and any defects found in production which affect compliance with the certification requirements;
   2. record the actions taken;

f) not use its EU Certificate issued by CERTOTTICA in such a way as to bring CERTOTTICA into disrepute and not to make any statement regarding its product certification that CERTOTTICA may consider misleading or unauthorized,

g) apply for EU certification for the device, only to CERTOTTICA and not to other Notified Bodies.

10.3 Changes to the issue conditions of the EU Certificate

If a Client wishes to change the conditions that led to the issue of the EU Certificate, a request shall be made to CERTOTTICA which begins the necessary process, as explained under chapter 14 of these Regulations.

10.4 Free access to the Client's premises

The Client holding an EU Certificate issued by CERTOTTICA undertakes to assist CERTOTTICA's auditors or sampling staff, ACCREDIA's and the Authorities' staff during auditing visits and to grant at any moment access to its premises during working hours, if necessary, and to implement any corrective actions following the detection of NCs.

10.5 Forbidden use of the EU Certificate

The Client undertakes not to use the EU Certificate issued by CERTOTTICA if it is suspended, limited, withdrawn or expired.

10.6 Liability

The EU Certificate issued by CERTOTTICA does not release the Client from its contractual obligations and responsibilities towards its Clients and the law regarding the supplied products. CERTOTTICA is only responsible for third party liability if it can be clearly demonstrated that said damage is derived from the EU type-examination activities.

11. INCORRECT USE OF EU CERTIFICATION

It is incorrect to use the EU Certificate issued by CERTOTTICA if it could mislead the users of the technical, commercial and advertising information.

In particular, the use is incorrect in the following cases, which are just an example and not a complete list:

- If EU Certificate has not been granted or has been suspended, revoked limited or expired.
- If the Client makes a change to the Product without it being notified to and accepted by CERTOTTICA.
- If the Client fails to take in a change to the conditions for the issue of the EU Certificate communicated by CERTOTTICA.
- If there are circumstances that could negatively affect the conditions that made the issue of the EU Certificate possible.
- If the Client has waived the EU Certificate.

12. EU CERTIFICATE SUSPENSION OR WITHDRAWAL

CERTOTTICA informs its notification authority regarding EU Certificates which have been rejected, suspended, withdrawn or otherwise limited.

Note: the Commission, Member States and other notified bodies can obtain, upon request, a copy of the EU examination certificates and/or their annexes. Upon justified request, the Commission and Member States can obtain a copy of the Technical Documentation and the results of tests performed by CERTOTTICA.

In particular, CERTOTTICA shall inform the notifying authority about:

a) any rejection, limitation, suspension or withdrawal of an EU Certificate or approval;
b) any circumstance which may affect the scope or the condition of the notification;
c) any requests for information received by the market surveillance authorities regarding conformity assessment activities;
d) upon request, conformity assessment activities performed within their notification and any other activity, including cross-border and sub-contracting ones.

Moreover, CERTOTTICA shall supply other notified bodies relevant information on negative results and, upon request, positive results of the conformity assessment.

12.1 Suspension

The suspension of the EU Certificate is decided by CERTOTTICA due to failure to observe the requirements of the Certification Plan, which are detected during product and/or production assessment activities or which CERTOTTICA has learned about in any other way, or due to failure to observe these Regulations.

CERTOTTICA informs the Client about the suspension by recorded delivered letter or any other suitable means (certified e-mail for example), stating the conditions according to which suspension can be revoked; the following shall be communicated to the Client:

- actions to be taken to end the suspension and restore the certification for the product in compliance with the Certification plan;

- any other action required by the Certification plan.

Suspension means that the Client cannot use the EU Certificate issued by CERTOTTICA in any form, and cannot market products with CE marking under production.

Suspension is withdrawn only when CERTOTTICA has ascertained that compliance with the requirements which were deemed non -compliant has been re-established. A new compliance evaluation can be applied for, following instructions under chapters 5, 6, 7 and 9 of these Regulations.

For EU Certificates relating to Module C2 or D of Regulation (EU) 2016/425 for III category products, the suspension of EU Certificate entails the suspension of CERTOTTICA identification number placed on the marking of the III category product: such suspension forbids the Client to use, in any way, CERTOTTICA identification number placed on the marking of the device.

If suspension cannot be withdrawn within 180 (one hundred and eighty) days, CERTOTTICA shall revoke the EU Certificate and it will communicate suspension to the competent Body, which will act according to its own procedures, to its own notifying authority and to other notified bodies.

Expenses met by CERTOTTICA for preliminary analysis and/or checks, due to suspension procedures are charged to the Client.

12.2 Withdrawal

The withdrawal (or revocation) of the EU Certificate is decided by CERTOTTICA because of:

- serious failure to observe the requirements regarding the application of points 8, 9, 10 and 11 of these Regulations;
- failure to reinstate the conditions that caused suspension within 180 (one hundred and eighty) days, as established in article 12.1 of these Regulations;
- repeated failure to observe the commitments undertaken with CERTOTTICA to solve any discrepancies detected and notified during Surveillance activities;
- communication of revocation by another Notified Body responsible for procedure of product/production control in accordance with Module C2 and/or Module D of Regulation (EU) 2016/425;
- bankruptcy or winding up of the Client;
- refusal to accept changes described under points 14.1 and 14.3 del these Regulations, of these Regulations;
- other breaches of Contract.

CERTOTTICA notifies the decision to revoke the EU certification by means of a registered letter or any other suitable means (certified e-mail for example):

- to the Client, ACCREDIA, the Relevant Notifying Authority and other notified bodies in case of EU examination Certificates issued by CERTOTTICA;
- the Client, ACCREDIA and the relevant Notified Body in other cases.

Following the withdrawal, the Client shall:

- communicate the withdrawal plan from the market of the product subject to revocation specifying the number of items and the timetable which the withdrawal will follow. Such Plan will be communicated to the relevant body which will supervise the application of the plan itself;
- return the original EU Type-Examination Certificate to CERTOTTICA or the relevant Notified Body;
- not use any copies or duplicates of the EU type-examination Certificate;
- eliminate all references or symbols regarding EU type-examination Certificate from all the technical and advertising documentation and from the products;
- not market nor place into the EU or extra-EU market products with CE marking and/or with CERTOTTICA identification code (which are being manufactured) referring to the EU Type-Examination Certificate which has been revoked.

If another Notified Body has been involved in the withdrawal process, it must be responsible for the above-mentioned procedure, according to its own methods and procedures.

A Client whose certification has been withdrawn by CERTOTTICA or by another Notified Body may submit a new EU type-examination Application for the same Product after demonstrating that, in the meantime, all the measures that CERTOTTICA deems necessary to avoid the repetition of the non-conformities that generated the withdrawal.

13. WAIVING THE CERTIFICATION

A Client may waive the EU Certificate that it is holding:

- if the certified product(s) is/are no longer produced in the manufacturing unit(s) mentioned in the EU type-examination Application;
- due to failure to accept modifications under points 14.1 and 14.3 del these Regulations;

  In this case the waiver becomes effective 90 (ninety) days after the date the Client's refusal to accept has been received. Such communication shall be sent by the Client within 30 (thirty) days from the date of reception of CERTOTTICA's notification regarding the changes to the conditions for the issue EU type-examination Certificate or of the notification to the Client of the proposed changes.
- if it is planning to entrust the check of product/production control in accordance with Module C2 and/or Module D of Regulation (EU) 2016/425 for III category products to another notified body if an agreement is already in place with CERTOTTICA.

  In this case the waiver has immediate effect on the date in which the Client has given written communication by means of a registered letter or equivalent official communication; the Client can no longer use CERTOTTICA identification number (2008) next to the CE marking for products placed on the market after the date of request for waiver. CERTOTTICA may ask the Client for evidence of the first conformity assessment performed with another Body.

Following the waiver by the Client, CERTOTTICA may decide actions to take regarding the Product object of the EU Certificate, similar to those provided for in chapter 12 of these Regulations.

14. CHANGES TO EU CERTIFICATE VALIDITY TERMS

14.1 Changes made by CERTOTTICA

If CERTOTTICA makes any amendments to the terms for issuing and/or maintaining the EU type-examination Certificate further to changes to these Regulations.

CERTOTTICA sends the reviewed Regulations to the Committee for Impartiality of CERTOTTICA (that is the body appointed to check that CERTOTTICA's activity are performed with fairness) which shall express its opinion and to ACCREDIA.

The same revised Regulations are then sent to all Clients registered in the Record of Clients holding EU Certificates issued by CERTOTTICA, by using a method suitable to have proof of correct transmission. Clients SHALL adapt to the new provisions within the deadline which is set and is considered the most appropriate by CERTOTTICA based on the extent of the changes made.

If Clients do not accept the change(s), they may waive their EU type-examination certificate as long as they notify CERTOTTICA in compliance with the method stated under chapter 13 of these Regulations. After 30 (thirty) days with no communication from the Client, the new version of the Regulations is considered accepted by tacit consent.

CERTOTTICA reserves the right to verify the conformity of the adequacy of the certified Product to the new provisions, by repeating the type testing on new product samples or by requesting additions to the documentation.

Expenses for any additional assessment actions are charged to the Client. Clients will be officially notified also other changes is regulations, standards and technical documents.

14.2 Changes made by the Client

A Client who intends to make changes which may affect the conformity of the Product with the applicable Certification Plan, shall immediately notify CERTOTTICA.

CERTOTTICA:

- notifies the Client in writing within 30 (thirty) days from receipt of the notification, and, if it is the case, of the need to repeat all or part of the checks as per points 5.2 and 5.3 of these Regulations;
- notifies the Client if the changes are not accepted.

If the Client does not accept CERTOTTICA's decisions it may waive its EU Certificate as long as it notifies CERTOTTICA according to the methods set out under chapter 13 of these Regulations.

The expenses for the new checks are charged to the Client.

Operating methods are described under chapter 6.1.1 of these Regulations.

14.3 Changes in the state of the art

If changes are to the issue and/or maintenance conditions of the EU Type-Examination Certificate are necessary due to changes in:

- the Product reference standard,
- the generally recognised evolution of the technical state of the art.

CERTOTTICA informs the Clients affected by this change. The Client shall adjust the Product or the supporting documentation following methods described under chapter 6.1.2 of these Regulations.

Expenses connected to checks performed by CERTOTTICA are charged to the Client.

14.4 Other changes

Changes to the Client's organisation and/or company name or ownership make it possible to keep the EU type-examination Certificate, as long as:

- CERTOTTICA is immediately notified in writing;
- CERTOTTICA has checked that the changes comply with the applicable Certification Plan.

The costs regarding the checks carried out by CERTOTTICA are charged to the Client.

15. CONFIDENTIALITY

All paperwork (documents, letters, notifications, etc.) and information regarding certification activities, from the moment when the Application for EU type-examination is submitted, are considered confidential and access to them is governed by a specific procedure.

The information that CERTOTTICA commits to communicate to all those who require it, by specific written request to be sent by fax and/or by using the email address listed on CERTOTTICA's website, are those contained in the issued certificate (without need of any authorization by the Client).

CERTOTTICA's staff is bound by to professional secrecy for all information they gather while performing activities referred to in Annex V, VII and VIII of Regulation (EU) 2016/425 of 9 March 2016, or any other provisions of national law that could affect it, but not towards the relevant Authorities of the Member State where it performs its activity. Property rights are protected.

CERTOTTICA staff at all levels of its organisation, and external staff involved in the surveillance, tests and EU examination who, while performing their activities, may gain knowledge of the information contained in these documents and other information regarding the Clients with whom CERTOTTICA has EU type-examination agreements with, are all subjected to professional secrecy.

If the law establishes that certain information shall be disclosed to relevant Control Authorities which request it, CERTOTTICA will inform the Client of the information they have disclosed.

If asked by the Client to do so, CERTOTTICA is irrevocably authorised to transmit the reports, test reports, the EU type-examination Certificate and any other information to a third party in compliance with the current privacy law.

16. ECONOMIC TERMS

16.1 Rates

Rates for CERTOTTICA's services are specifically defined for each EU Certification Plan (according to the product type).

Every request to modify the EU Type-Examination Certificate (see paragraph 6.1.5 of these Regulations), entails the payment of an additional fee, as defined in the Price list.

16.2 Terms of payment

Rates regarding activities of EU Type-Examination shall be paid to CERTOTTICA according to the methods and within the time limits described in the quotation.

17. USE OF CERTOTTICA LOGO

The use of CERTOTTICA logo must be authorized by CERTOTTICA, upon request by the Client.

The Client shall send a draft of how the logo will be used and details of the documents it will be used on.

The logo shall respect the original proportions and colours, or be monochrome.

The logo can only be used once express authorisation has been received from CERTOTTICA.

All EU Certificates, issued by DOMITICERT, within the scope of accreditation, will bear the mark ACCREDIA following the rules defined in ACCREDIA Regulation RG-09.

18. APPEALS

The Client may appeal against a decision taken by CERTOTTICA by sending an e-mail at the PEC address certottica@pec.certottica.org, or by sending written communication by fax or recorded delivery letter. In order to be receivable, the appeal shall:

- contain a description of the decision which is appealed against;
- contain a clear and detailed statement of reasons supporting the appeal;
- be sent to CERTOTTICA within 45 days from the date of the communication which is object of the appeal.

Within 7 (seven) days from receipt of the appeal, CERTOTTICA gives formal communication to the Client if the appeal has been judged receivable or not and, in case of acceptability, the date within which a decision will be taken (maximum 30 days from the receipt of the appeal).

Decisions taken about the appeal are communicated to the Client by fax and/or recorded delivery letter and/or by sending an e-mail at the PEC address certottica@pec.certottica.org.

Appeals will be evaluated by CERTOTTICA staff not directly involved in the analysis of the certification documents.

19. COMPLAINTS

The Client can file a complaint to CERTOTTICA for activities carried out within the scope of these Regulations by sending an email to the PEC address certottica@pec.certottica.org or by written communication, to be sent by fax or registered mail.

CERTOTTICA formally manages every complaint received in writing (letter, fax or email); complaints made verbally are handled in a documented way if considered appropriate.

The management of the complaint implies:

- written reply (by letter, fax or e-mail) within 7 (seven) days from reception of the complaint, with the analysis of the complaint and possible actions envisaged for its management and relevant timing;
- written reply (by letter, fax or PEC certottica@pec.certottica.org) upon completion of the envisaged actions.

Complaints will be evaluated by CERTOTTICA staff not directly involved in the certification documents.

20. DISPUTES

Any disputes that may arise between the parties, which that are directly or indirectly related to the application or interpretation of these Regulations, which cannot be amicably settled between the parties, shall be referred to the exclusive jurisdiction of the Court of Belluno (Italy), as defined in the Contract included in the Application for EU type-examination, in the Application for checks (Module C2) or in the Application for Surveillance (Module D).

21. KEEPING OF REFERENCE SAMPLES

CERTOTTICA ensures, if possible, that at least one sample of the Product subject to EU type-examination is kept in its warehouse. In general, CERTOTTICA, shall not ask the Client to keep one reference sample for activities of assessment of conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or assessment of conformity to type based on quality assurance of the production process (module D), unless it was not CERTOTTICA which issued the EU Type-Examination Certificate (in this case the reference sample may be asked to the Client).

The counter-sample must reflect in all respects the contents of the Manufacturer's Technical Documentation and must reflect the Product that will then be marketed; the only exception permitted is the marking included on the counter-sample, which may differ from that envisaged for the productions or be absent: in these cases, reference will be made to the example included in the Manufacturer's Technical Documentation for the correct marking that will be affixed to the Product being marketed.