PROCEDURE 16.04

Rules for EU type-examination of Personal Protective Equipments

CONTENTS

0. INTRODUCTION

Since 1995, Certottica S.c.r.l., has been offering a service to assess conformity of optical sector products, such as personal protective equipment of II and III category for the protection of the eyes and the total or partial protection of the face.
Every manufacturer working in the design, manufacturing and marketing of personal protective equipment for the protection of the eyes and the total or partial protection of the face (hereinafter called Client) can have free access to EU type-examination services without any discrimination and without being subject to any unfair conditions.
Consultancy about design, production and marketing of personal protective equipment (herein referred to as PPE) for the eyes and face is not included among the services offered by CERTOTTICA; consequently, apart from providing information within the scope of these Rules, CERTOTTICA does not perform any consultancy activities.

1. PURPOSE AND FIELD OF APPLICATION

Purpose

This document is issued as Rules, it has contractual character and it contains a series of provisions that govern the relationship between CERTOTTICA and the Client throughout the duration of the EU type-examination contract.

These Regulations define the methods and terms that the Client shall observe to obtain and maintain the EU type-examination certificate issued by CERTOTTICA.

By sending the signed application for EU type-examination the Client declares s/he has completely understood and accepted these Rules.

CERTOTTICA services are available for any Client requesting them in compliance with these Rules.

The conformity of these Rules, and of any other Rules for EU Product Certification Plan with applicable normative documents is guaranteed by the Impartiality Committee (IC).

Full acceptance of these Rules is formalized by signing the EU type-examination Application.

Field of EU type-examination

EU type-examination, in compliance with the provisions of Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March 2016 regarding personal protective equipment, repealing Council Directive 89/686/EEC, related to Personal Protective Equipment.
Regarding the following products:

1. equipment providing eye protection
2. equipment providing partial and full face protection

In compliance with the provisions of the annexes of the above-mentioned law:

- V (EU type-examination)
- VII (Conformity to type based on internal production control plus supervised product checks at random intervals)

2. REFERENCES

- Standard UNI CEI 70006:2008 “General rules for a standard product certification method by an independent organisation”
- ACCREDIA Regulation RG-01 rev.04 – Regulation for the accreditation of Certification and Inspection Bodies – General Part
- ACCREDIA Regulation RG-01-03 rev.01 – Regulation for the accreditation of Product Certification Bodies
- UNI CEI EN ISO/IEC 17020:2012 “Conformity assessment—Requirements for the operation of various types of bodies performing inspection””
- UNI CEI EN ISO/IEC 17021:2015-1 “Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements”
- UNI CEI EN ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories”
- ACCREDIA LS-02 rev.14 “List of reference standards and documents for the accreditation of Certification Bodies”
- EA-2/17 “EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes”
- UNI EN ISO 19011:2012 “Guidelines for auditing quality management systems and/or environmental management”
- Directive of the Minister of Productive Activities on "documentation to be produced for the authorization of EC certification bodies" of 19 December 2002.
- ISO/IEC 17065:2012 “Conformity assessment — Requirements for bodies certifying products, processes and services”
- ISO/IEC 17067:2013 “Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes”
- UNI CEI 70017:2008 (ISO/IEC Guide 67:2004) “Conformity assessment - Fundamentals of product Certification”
- ISO/IEC GUIDE 28:2004 “Conformity assessment - Guidance on a third-party certification system for products”
- Accredia Rules RG-09 rev. 07 “Rules for the use of the ACCREDIA mark”
- Technical sheets for coordination – Horizontal recommendation for use sheets (RFUs);
- Regulation (EU) 2016/425 of the Parliament and of the Council of 9 March 2016 regarding personal protective equipment, repealing Directive 89/686/EEC of the Council.

3. DEFINITIONS

The definitions explained below apply to some terms, used within these Rules:

ACCREDIA: Italian accreditation body of Certifying bodies for notification purposes.

Personal Protective Equipment (PPE):

a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;
b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;
c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage.

EU type-examination certificate: document through which CERTOTTICA declares that, with reasonable reliability, a product meets the applicable essential requirements of health and safety in compliance with the provisions of Annex V of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016.

EU type-examination: activity through which CERTOTTICA declares (by issuing an EU type-examination certificate) that, with reasonable reliability, a given Product complies with to one or more normative documents.

Manufacturer: any natural or legal person who manufactures a product or has it designed or manufactured, and places it on the market under his name or trademark.

Representative: any natural or legal person established in the Union who has received a written appointment by a manufacturer authorizing him/her to act on his/her behalf regarding certain activities;

Authorised representative: means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

Client: term used to indicate the manufacturer or his/her authorised representative in the Union, who asks CERTOTTICA for a service within the scope of these Rules.
Note: the manufacturer may be established in the Union or not. The manufacturer may appoint an authorised representative who is established in the Union, to act in his/her name for certain activities The appointment and the functions whereby the authorised representative represents the manufacturer shall be established in writing in a contract.

Technical Documentation: technical documentation 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, in particular, it shall 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 for the understanding of the drawings and schemes referred to in point d) and of the operation of the PPE;
f) the references of 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.

Application for EU type-examination: document/contract through which the Client formally applies for the opening of the procedure of EU type-examination in compliance with these rules.

EU Declaration of Conformity: it is the declaration through which the Manufacturer, or his/her authorised representative in the Union, takes responsibility of the product conformity with one or more Union harmonisation legislation.

Product: result of the Client's activity, which must comply with pre-set specifications, national or international laws or with requirements developed by the Client or with other identified documents.
In the case in question, it refers to PPE for the eyes and PPE for the partial or total protection of the face, as defined by Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016, in the first paragraph of article 3.
In these Rules, the term "Product" has the meaning of product or homogenous family of products belonging to the Certification Plan which is the object of the application for EU type-examination and of the Contract, in the models and variants which are defined therein.

Tests: process through which CERTOTTICA determines the product conformity with the applicable harmonized standards or relevant technical specifications, before issuing or extending the EU type-examination certificate.
In these Rules the Initial Tests are those necessary for the first issue of the EU type-examination certificate.

EU Certification plan: activities performed by CERTOTTICA aimed at assessing the conformity of the Product. The Certification Plan derives from the requirements established in these Rules and from product-specific requirements.

Tests on supervised product checks at random intervals: activity through which CERTOTTICA checks that the conformity of a category III PPE, object of an EU type-examination certificate is maintained.

Manufacturing unit: place where the Client manufactures the product object of the application for EU type-examination, or has it manufactured.

Auditor: staff qualified to carry out a systematic, independent and documented process to obtain the results of the audit and to evaluate them with objectivity, in order to establish to what extent the audit criteria have been met.

4. GENERAL CONDITIONS

4.1 EU type-examination procedure

To enable CERTOTTICA to begin the procedure for the EU type-examination, the Client must:

- Meet the requirements of the EU Certification plan for the product object of the application for EU type-examination,
- Accept the conditions set by these Rules and by the Contract for Product certification (hereinafter called “application for EU type-examination”),

such acceptance is formalized by the Client by signing the application for EU type-examination.

4.2 Application for EU type-examination

The application for EU type-examination defines:

- The applicable Certification plan,
- The product(s) object of the EU type-examination.

4.3 Payments

The issuing of the EU type-examination certificate and its retention is subject to the payment of the relevant amounts.

4.4 Free access to areas, information and documents

If the Client has started the procedure for supervised product checks at random intervals (annex VII of Regulation (EU) 2016/425) with CERTOTTICA, s/he shall grant that CERTOTTICA’s auditors, who may be accompanied by ACCREDIA personnel, the body accrediting the activities of CERTOTTICA (in its capacity as observer of the work of CERTOTTICA’s auditors), and personnel of the relevant authorities, have free access to the areas, information and documentation necessary to perform the sampling program, to identify and/or take samples.

If the Client does not grant free access to the areas, information and documentation which are necessary for the sampling by CERTOTTICA’s auditors and/or ACCREDIA’s personnel, the procedure of supervised product checks at random intervals will be interrupted, or the EU Type-Examination Certificate may be suspended/revoked if it has already been issued to the Client.

CERTOTTICA carries out the sampling at least once a year, at random intervals. Anyway the first sampling of the product takes place within one year from the date of issue of the EU type-examination certificate.

4.5 Safety

The Client shall guarantee that all the necessary precautions to ensure safety of work conditions, work places and installations are taken during the sampling program. Moreover, when necessary, the Client shall also inform CERTOTTICA’s auditors, ACCREDIA’s personnel and personnel of the relevant authorities of any known current and/or potential hazards and risks, which may be associated with sampling and test samples, including any risks due to radiation, toxic or harmful substances, explosive elements or materials, polluting or poisonous substances.

5. PROCEDURE FOR EU TYPE-EXAMINATION

5.1 Request of quotation for EU type-examination

The Client shall make a request to CERTOTTICA sales office (hereinafter referred to as COM) for a preliminary quotation for the EU type-examination service, by supplying all the necessary information. Such information can be supplied by filling in the EU type-examination data collection form (Module M.8.2.007), which can be downloaded from CERTOTTICA’s website www.certottica.it

or by asking for it to CERTOTTICA's sales office, or by using another method that CERTOTTICA considers suitable and complete.
If the information supplied is deemed sufficient, COM sends the Client a preliminary quotation together with the application for EU type-examination (Module M.8.2.005).

> Note: the preliminary quotation is not a final quotation for the EU type-examination service, but an approximate quotation that shall be confirmed or updated further to sending the application for EU type-examination, the Technical Documentation and the samples necessary to perform the initial tests, where applicable.

If the information supplied is not deemed sufficient, COM asks the Client further and more detailed information. In any case, no preliminary quotation shall be sent until CERTOTTICA believes it has sufficient information.
CERTOTTICA performs its activity taking into account the dimensions of the Client, the sector in which it operates, the degree of complexity of the technology of the PPE under examination and the serial or mass nature of the manufacturing process.
While doing this, however, CERTOTTICA respects the degree of rigor and the level of protection necessary to assess the conformity of the PPE to the requirements of Regulation (EU) 2016/425.

5.2 Acceptance of the quotation for EU type-examination

The countersigning of the application for EU type-examination by CERTOTTICA's Legal Representative, following the acceptance of the final quotation and of the general conditions by the Client, formalizes the acceptance and the formalization of the contract. In the absence of the countersigning by CERTOTTICA's Legal Representative, the contract will not be registered and therefore it will not be binding for the Client.

5.3 Submission of the application for EU type-examination

Following the acceptance of the preliminary quotation, the Client sends CERTOTTICA the duly filled in application for EU type-examination.

Together with the application for EU type-examination, the Client shall also send:

- The Product Technical Documentation in compliance with the provisions of Annex III of Regulation (EU) 2016/425
- The number of necessary samples for initial tests as indicated in the preliminary quotation;

The Client must also send whatever else is required to satisfy the requirements given in the Certification Plan for the type of product concerned.

The EU type-examination Application shall be filled in all its parts to be deemed valid. Non-applicable parts shall be crossed out.

Languages accepted by CERTOTTICA for the application for EU type-examination and the Technical Documentation are Italian and/or English.
Documents in a language other than the two officially accepted ones may be accepted at the CERTOTTICA's discretion, and anyway this shall be agreed upon by COM during the preparation of the preliminary quotation.

5.4 Opening of the EU type-examination procedure

When it receives the application for EU type-examination, CERTOTTICA examines it in order to:

- check it has been correctly completed in every relevant part (e.g. Client's identification, legal representative, type of Product, field of application of the Product, etc.),

- check the completeness and suitability of the Technical Documentation of the Product object of the application for EU type-examination.
  Note: if the Technical Documentation is made up of several parts, there shall be a general index that identifies the various parts in an unambiguous way.
  Note: the Technical Documentation shall include a review index and/or an issue date, to make it possible to identify any possible following reviews and/or updates.

If CERTOTTICA feels that the outcome of the check on the documentation supplied is not suitable and/or incomplete, CERTOTTICA sends a written communication to the Client, specifying the non-compliant points and requesting an update.
In this case, the procedure is suspended until the Client has complied with the officially communicated requests by CERTOTTICA.

After CERTOTTICA has accepted the application for EU type-examination, COM sends a written confirmation of the acceptance of the application for EU type-examination to the Client, by confirming the preliminary quotation or by sending an updated quotation, further to analysing the Technical Documentation and the samples sent for the Initial Tests.

If the preliminary quotation is confirmed or if the updated quotation is accepted by the Client, CERTOTTICA begins the EU type-examination procedure, by countersigning the application for EU type-examination and registering it in the relevant register.

The beginning of the EU type-examination procedure is followed by CERTOTTICA's in-depth analysis of the documentation in the technical file, which consists of the Technical Documentation, any additional documentation and the application for EU type-examination.

5.5 Initial Tests

Together with the application for EU type-examination and the Technical Documentation, the Client shall send the number of Product samples, as indicated in the initial or updated quotation, if existing.

NOTE: The sample(s) shall be representative of the production. For PPE produced in series where each item is manufactured to fit an individual user, the samples supplied shall be representative of the range of different users, and for PPE produced as a single unit to meet the special needs of an individual user, a basic model shall be provided.

The Client shall correctly identify the samples sent to CERTOTTICA for the Initial Tests, as indicated in the quotation.

The Initial Tests necessary to assess Product conformity, will be carried out by CERTOTTICA at its laboratories.

If the outcome of the Initial Tests does not comply with the requirements provided for in the Technical Documentation, CERTOTTICA informs the Client about the non-conformities, by detailing the discrepancies which have been found.

The Client shall then evaluate the causes of the non-conforming outcome and, within the time limits agreed with CERTOTTICA, s/he may submit new samples to repeat all or part of the tests according to the indications to be found in the possible quotation sent by COM and/or the updated Technical Documentation and/or the application for EU type-examination.

If the non-conformity persists, or if the Client does not submit new samples to repeat the tests within the set time limits, CERTOTTICA may consider closed the EU type-examination procedure with a negative outcome.

The expenses to send the samples and perform the tests is fully charged by CERTOTTICA to the Client.

The outcome of the Initial Tests and of possible additional tests is recorded by CERTOTTICA's laboratories by issuing Test Reports.

5.6 Issue of the EU type-examination certificate

5.6.1 The documentation concerning the application for EU type-examination and the tests is checked by CERTOTTICA's Executive Technical Board.

After checking that all the requirements of the Certification Plan have been fully met, the Executive Technical Board sends his/her decisions to CERTOTTICA's Certification Services Manager, in a written decision report. CERTOTTICA's Certification Services Manager, by appointment of the Board of Directors, ratifies the decisions of the Executive Technical Board regarding the issuing of the EU type-examination certificate.

5.6.2 When the EU type-examination procedure ends with a positive outcome, CERTOTTICA's Certification Services Manager issues an EU type-examination certificate. The EU type-examination certificate has the "number" and issue date on every page.
The EU type-examination certificate is the official document through which CERTOTTICA declares, with reasonable reliability, that the product object of the certificate meets the applicable health and safety requirements.
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 ten (10) years since the last placing of the on the market of the Product. Each copy is signed, stamped and initialled on each page by the legal representative or the Certification Services Manager, if duly appointed to do so.
The Client keeps the copy of the EU type-examination certificate for a minimum period of ten (10) years since the last placing of on the market of the Product.
Note: the EU type-examination certificate is property of CERTOTTICA.
The official languages of the EU Type-Examination Certificate are Italian and English.

5.6.3 In case of negative outcome of the EU type-examination, CERTOTTICA notifies the Client in writing about the reasons of such decision, by detailing any discrepancies found as against the requirements of the applicable Certification Plan. The Client shall undertake to correct the discrepancies within the time limit set by CERTOTTICA, which anyway shall not exceed 540 (five hundred and forty) days.
After 540 (five hundred and forty) days, the Contract expires and the Client will have to begin the EU type-examination procedure from the beginning.

5.6.4 If the Client does not accept CERTOTTICA's decision, s/he may require an additional investigation, explaining the reasons of his/her disagreement, by following the method explained under point 17 of these Rules.

5.6.5 Once the EU type-examination certificate has been issued, the Certification Services Manager records the issue in the "EU type-examination certificates register" and communicates this information to the notifying authorities.
Note: The Commission, the Member States and other notified bodies can obtain, upon request, a copy of the EU type-examination certificates and/or their annexes. Upon justified request, the Commission and the Member States can obtain a copy of the Technical Documentation and of the results of the examinations carried out by CERTOTTICA.
In particular, CERTOTTICA will inform the notifying authority:

a) about any refusal, limitation, suspension or withdrawal of a certificate or an approval;
b) about any circumstances which may affect the scope or the condition of the notification;
c) about possible requests for information received by the market surveillance authority regarding conformity assessment activities;

d) on request, about conformity assessment activities carried out within their notification and about any other activities, including cross-border and sub-contracting ones;

Moreover, CERTOTTICA will supply the other conformity assessment bodies with information regarding questions concerning negative outcomes and, upon request, positive outcomes regarding conformity assessment.

5.6.6 Following the issue of the EU type-examination certificate the Client is authorized to place on the market the Product object of the EU type-examination certificate by applying the CE marking.
The EU type-examination certificate may have one or more annexes.

5.6.7 CERTOTTICA reserves the right to keep one or more samples of the tested Product in its archives.

5.7 Validity of the EU type-examination certificate

The validity period of a newly-issued certificate and, if applicable, of a renewed certificate is of no more than 5 (five) years
Any changes, updates, extensions or revisions of an EU type-examination certificate during the 5 (five) years' period from the issue date ot to the renewal date, does not change its expiry date. The expiry date is reported on the EU type-examination certificate.
The EU type-examination certificate will not be automatically renewed.
If the Client wishes to renew the EU type-examination certificate, a simplified re-examination procedure is applied. The manufacturer supplies CERTOTTICA with the following:

- his name and address and data identifying the EU type-examination certificate concerned;
- confirmation that there has been no modification to the approved type, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or other technical specifications applied;
- confirmation that there has been no change in the state of the art;
- where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer; and
- for category III products, where not already available to the notified body, information on the results of the supervised product checks at random intervals carried out in accordance;
- document signed by PTA and STA including the content of points 1 to 6 provided for by paragraph 6.2 in case of renewal of the extended EU type-examination certificate;

to this end it is possible to use module M.003.007 or M.003.008 supplied by CERTOTTICA.
If CERTOTTICA confirms that no changes have been made to the approved type and that no evolution of the state of the technique has taken place, the simplified re-examination procedure is applied, and no examinations nor tests are performed.
In such cases CERTOTTICA renews the EU type-examination certificate.
The Client is free to submit any additional documents to support the application for renewal, such as: independent Product certifications, independent quality system certifications, etc.
The submitted documents will be analysed within 2 (two) months from their reception.
If, after analysing the documents as explained above, CERTOTTICA finds any discrepancies, the Client will be asked to address such discrepancies before proceeding with the renewal of the EU type-examination certificate.
If CERTOTTICA deems it appropriate to check that the current Product is identical to the one which had been originally certified, it can ask further information, such as: detailed drawings, photographs etc. and, if deemed necessary, a sample of the Product in question.
If the harmonised standards, used to evaluate Product conformity, have been revised and published in the Official Journal of the European Union, CERTOTTICA will examine the changes as against

the current data. All requirements not satisfactorily met will be subject to Tests before the EU type-examination certificate is renewed. If a certificate is not based on a harmonized standard, the technical specification adopted shall be reviewed against Regulation (UE) 425/2016 to take into account the evolution of associated or applicable standards. In any case, the possible adjustment to the state of the art (adjustment to the reference Standard/Technical specification) shall be made before or at the latest at the moment of the renewal of the EU type-examination certificate (such adjustment will follow the operative methods to be found at chapter 6.1 of these Rules).
The application for renewal can be submitted 12 (twelve) months and not less than 6 (six) months before the EU type-examination certificate expires to guarantee continuity to the EU type-examination certificate.
If the harmonised standards and/or technical specifications used to assess Product conformity have been replaced/modified and published in the Official Journal of the European Union within 12 (twelve) months before the expiry date of the EU type-examination certificate, the validity of a EU type-examination certificate may be extended by a maximum of 12 (twelve) months to give the Client sufficient time to comply with the revised/modified version.
CERTOTTICA follows the evolution of harmonized standards used to assess conformity and, in case of changes and revision of the standards, it evaluates if the product object of the EU type-examination certificate is no longer compliant with the applicable essential health and safety requirements. CERTOTTICA decides whether such evolution requires further investigation and, if so, it informs the Client.
The Client shall grant that the PPE continues to meet the applicable essential health and safety requirements in the light of possible changes to harmonized standards. The Client asks CERTOTTICA to review the EU type-examination certificate in case of evolution in the state of harmonized standards. In case the EU type-examination certificate is modified, updated, extended or revised, due to changes in the applicable harmonized standards, during the 5 (five) years' period from its issue or renewal date, this does not change its expiry date.

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

6.1 Modification of the Product by the Client

If the Client wishes to make changes to a Product which already has an EU type-examination certificate, or to the EU type-examination certificate following possible modifications or revisions of the harmonized standards and/or of the technical specifications used to assess conformity, a specific request shall be sent to CERTOTTICA.

If the changes the Client wants to make are minimum, so not to alter substantially the protective and constructive characteristics the Product had been certified for, that is, modifications that do not affect the conformity 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 necessary, the Client sends CERTOTTICA a copy of the revised Technical Documentation. If CERTOTTICA deems it necessary, it may request a sufficient number of samples to carry out Tests to confirm that the original protective features of the Product have been maintained. The cost of the Tests is charged to the Client. The Client shall sign and send the quotation received from COM to CERTOTTICA, together with the number of requested samples. At the end of the checks, if the outcome is positive, CERTOTTICA sends the Client a communication in which it states that it has taken note of the request and authorizes the changes. At the end of the checks, if the outcome is negative, CERTOTTICA sends the Client a communication in which it states that does not authorize the manufacturing of the modified Product.

If the changes the Client wants to make are substantial, such as to alter the protective and constructive characteristics the Product had been certified for, that is, modifications that affect the conformity of the product with the applicable essential health and safety requirements or the conditions of validity of the certificate, or if s/he wants to add variants or if the field of application is widened, it is necessary to review the EU type-examination certificate. The cost of revision of the EU type-examination certificate and of the necessary Tests is charged to the Client. COM will send a quotation. If the Client believes the quotation is fair, s/he sends it signed to CERTOTTICA as acceptance together with the revisioned Technical Documentation, a new application for EU type-examination and the necessary number of samples for the Tests specified in the quotation. If the outcome of the document analysis and of the Tests is positive, CERTOTTICA issues a revision of the EU type-examination certificate. If the outcome of the document analysis and/or of the Tests is not positive, CERTOTTICA sends a written communication to the Client. Within the time limit agreed upon with CERTOTTICA, the Client may submit a new revision of the Technical Documentation and/or new samples to repeat all or part of the tests. CERTOTTICA documents the outcome of the Tests by issuing Test Reports.
In case of positive outcome, the revision of the issued EU type-examination keeps its original number with the addition of code “Rev.X”, where “X” indicates the progressive review number issued, beginning from 1.

If the changes made mean that the Product is completely different from the previously examined one, the EU type-examination Procedure shall be repeated as if it were a new Product. In this case the method provided for by Article 5 of these Rules is applied.

It is hereby specified that, if a Client requires to make some changes to the EU type-examination certificate due to change of the corporate name and/or headquarters address, it is necessary to perform a revision of the certificate.

6.2 Extension of the EU type-examination certificate

The extension of the EU type-examination certificate is the procedure by which a party, the Client, holder of a valid EU type-examination certificate for a particular product (hereinafter PTA - primary type approval), agrees to customize the product with an identification declaring another party is the manufacturer (hereinafter STA - secondary type approval). STA will place the product on the market under its own name and PTA will maintain de facto responsibility for manufacturing conformity of the Product object of the EU type-examination certificate.

Extension of the EU type-examination certificate can only be activated if PTA is the holder of a valid EU-type examination certificate issued by CERTOTTICA.

The extension application is signed by PTA; the general conditions of the quotation made by CERTOTTICA shall be accepted both by PTA and STA. The application for EU type-examination and the Technical Documentation shall be submitted and signed by STA.

In order to start the extension procedure, it is necessary to apply the procedure provided for by paragraph 5 of these Rules, excluding the initial tests, and the points below shall be followed:

- Use of Module M.8.2.008 Data collection form for extension of the EU type-examination certificate instead of Module M.8.2.007 Data collection form for EU type-examination certificate (paragraph 5.1);
- Preparation of a document signed by PTA and STA including the provisions of points 1 to 6 listed below, as specified in FAQ RFU no. PPE-R/00.047 rev.01. This document shall be enclosed with the application for EU type-examination (paragraph 5.3).

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. the provisions of the previous point being understood, a declaration on the possible differences between what is stated in the original EU type-examination certificate and what is applied for (e.g. reduction in the number of variants of the Product);
3. declaration by PTA that only the Product conforming with the original EU type-examination certificate will be given to STA, for which the extension of the EU type-examination certificate is applied for;
4. declaration that PTA undertakes to inform STA and CERTOTTICA of any changes which may affect the validity both of EU type-examination certificate and, in case of class III PPE, of the procedure of supervised product checks at random intervals (module C2).
5. declaration that PTA undertakes to inform STA and CERTOTTICA of any changes s/he intends to make to the Product before implementing the change, as provided for by paragraph 6 of these Rules.
6. declaration that PTA and STA reciprocally exchange information about any accidents involving the Products object of the agreement.

Barring specific agreements between PTA and STA, CERTOTTICA will perform - if applicable – any supervised product checks at random intervals on production at PTA's. Anyway, if deemed necessary to guarantee product conformity, CERTOTTICA reserves the right to perform supervised product checks at random intervals on production at STA's, also independently from possible agreements between PTA and STA.

At the end of this procedure, CERTOTTICA issues a new EU type-examination certificate to the name of STA.

The expiry date of the extended certificate issued to STA will correspond to the expiry date of the original certificate issued to PTA by CERTOTTICA and it in any case it will not exceed 5 years. It may be revoked in advance in the event the above-mentioned conditions do no longer apply, in particular if the EU type-examination certificate issued to PTA and from which the extension derives should be suspended (paragraph 11). In short, secondary certificates issued to STA are indissolubly linked to the original PTA's certificate from which they descend (see paragraphs 11, 12 and 13).

As for production control procedure (supervised product checks at random intervals), the following cases may apply:

1. PTA has entrusted CERTOTTICA with supervised product checks at random intervals: in this case CERTOTTICA may deem not necessary to perform further checks on STA;
2. Both PTA and STA have entrusted a body other than CERTOTTICA with supervised product checks at random intervals: in this case CERTOTTICA's action is limited to issuing the EU type-examination certificate to STA;
3. PTA has entrusted a body other than CERTOTTICA with supervised product checks at random intervals and STA wants to entrust CERTOTTICA with the checks: in this case CERTOTTICA will perform the check on production on STA, through supervised product checks at random intervals.

7. VALIDITY OF THE CERTIFICATION

7.1 Conditions for the validity of the EU type-examination certificate

The validity of the EU type-examination certificate is subject to the Client maintaining the conditions which determined its issue.

Any changes to the conditions whereby the EU type-examination certificate was issued shall be promptly communicated to CERTOTTICA, in compliance with the provisions by paragraph 8.3 of these Rules.

Following the above-mentioned communication, CERTOTTICA reserves the right to decide possible actions to be taken to assess and guarantee that the conditions determining the issue of the EU type-examination certificate are maintained.

8. RIGHTS AND DUTIES OF CLIENTS HOLDING EU TYPE-EXAMINATION CERTIFICATES

8.1 Publicity of the EU type-examination certificate

The Client has the right to publicise the EU type-examination certificate in the ways s/he considers most suitable, as long as s/he always makes correct reference to the field of application and the limitations of the issued EU type-examination certificate and/or to the certificate number.

In the information for the user, the Client shall refrain from giving information which may mislead the user into thinking that performances not included by the applicable and/or applied Certification Plan are covered by the EU type-examination certificate. The instructions and information accompanying the Product (manual and/or instruction for use, etc.) and referring to a specific Certification Plan, shall be approved by CERTOTTICA, when this is provided for by the Certification Plan.

8.2 Client's duties

The Client holding an EU type-examination certificate shall undertake to:

- keep all the conditions which made it possible to issue the EU type-examination certificate unchanged,
- manufacture the Product in compliance with the requirements established by the standards, these Rules, the provisions of the Technical Documentation and the normative documents used for the manufacturing of the sample(s) approved by CERTOTTICA,
- grant access to CERTOTTICA's auditors and ACCREDIA's personell, under the circumstances provided for by these Rules,
- perform an investigation on the complaints received,
- keep a record of all complaints received s/he is aware of, relating to conformity with certification requirements and to make these records available to CERTOTTICA upon request, and:
  1. take suitable actions with respect to such complaints, and to any fault found in products which affect conformity with certification requirements,
  2. document the actions taken.
- not use the EU type-examination certificate issued by CERTOTTICA in such a way as to discredit CERTOTTICA and not make any declarations regarding the issued certificate which CERTOTTICA may consider misleading or unauthorized (see paragraph 10);

- The client undertakes to submit a certification application for the device object of the EU type-examination certificate only to CERTOTTICA and not to other Notified Bodies.

8.3 Modification of the conditions of issue of the EU type-examination certificate

If a Client wishes to change the conditions which led to the issue of the EU type-examination certificate, s/he shall submit a request to CERTOTTICA, which opens a procedure for the necessary actions, as provided for by points 13.1 and 13.2 of these Rules.

8.4 Free access to the Client's premises

The Client holding an EU type-examination certificate for III category personal protective equipment undertakes to assist CERTOTTICA's auditors, ACCREDIA's personell and personnel of the relevant authorities during the sampling necessary to perform supervised product checks at random intervals, to grant access to his/her premises at any time during working hours, when applicable, and to implement possible corrective actions following any found discrepancies.

8.5 Forbidden use of the EU type-examination certificate

The Client undertakes not to use the EU type-examination certificate in case it is suspended, revoked or if it has expired.

8.6 Liability

The EU type-examination Certificate does not release the Client from its contractual obligations and responsibilities towards his/her Clients and the legal obligations arising from the supplied products. CERTOTTICA is liable for damage towards third parties only if it can be unambiguously demonstrated that such damage is connected with the EU type-examination activities it performs.

9. SUPERVISED PRODUCT CHECKS FOR CLIENTS HOLDING EU TYPE-EXAMINATION CERTIFICATES

The Client holding an EU type-examination Certificate for a category III products (products falling within the field of application of Annex VII of Regulation (EU) 2016/425 (Module C 2) – "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 checks, including intermediate and final checks, guarantee uniformity of production and conformity with the provisions of the EU type-examination certificate.

If relevant and if it is appointed to do so, CERTOTTICA performs supervised product checks at random intervals for Clients holding EU type-examination certificates for category III Products, in order to check the homogeneity of production and the conformity of the Product compared with the whole production since the last check performed. Product checks at random intervals take place through suitable statistical sampling of the manufactured equipment, followed by suitable tests in compliance with the relevant harmonized standards and/or equivalent tests established by 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.

The sampling of the Product performed by CERTOTTICA's auditor(s), who may be accompanied by ACCREDIA's staff, is carried out at a place agreed on with the Client, randomly, on the Manufacturer's available stocks, in order to be representative of the Product.

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

If the chosen notified body is CERTOTTICA, the Client shall submit the application for supervised product checks at random intervals (Module M.8.2.006) duly filled in.

If CERTOTTICA is not the notified body that has performed the EU type-examination procedure, the application shall include:

- the Product Technical Documentation;
- a copy of the EU type-examination certificate.

Note: CERTOTTICA may contact the notified body which issued the EU type-examination certificate in case of difficulties related to the evaluation of the Product conformity.

Every part of the application for supervised product checks at random intervals shall be filled in to be considered valid. Non-applicable par ts shall be crossed out.

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

The sampling stage is normally notified by COM with at least 15 (fifteen) calendar days' notice, by sending a quotation including the auditor(s)'s travel expenses and the tests to be performed on the sampled products. The Client shall return the signed quotation to COM before the date scheduled for the sampling. If the Client does not agree to the sampling on the scheduled date, s/he shall send a written communication giving detailed reasons for the decision (e.g. interruption of production or Product check carried out by another notified body). If no written statement is received within two months from the sending of the quotation by COM, CERTOTTICA will begin the suspension procedure as provided for by paragraph 11.

Following the sending of the signed quotation by the Client, COM starts the sampling procedure, as provided for by the EU Certification Plan.

CERTOTTICA performs the sampling checking the uniformity of the sample compared with the whole production of the Product since the last check performed.

If, following (scheduled or unscheduled) supervised product checks at random intervals, it is found that the manufacturing process does not guarantee uniformity of production or the examined Product samples are not compliant with the type described in the EU type-examination certificate, with harmonised standards and/or applied specifications, CERTOTTICA informs the Client in writing, and invites him/her to analyse and eliminate the detected discrepancies within a set time limit. Following the analysis by the Client the following stages take place:

- The Client informs CERTOTTICA about the outcome of the non-conformity analysis and of the solutions adopted to solve them;
- CERTOTTICA decides how many and what Tests are necessary to assess the Product conformity;
- CERTOTTICA performs another sampling of the Product and carries out the Tests;
- If the Tests have a positive outcome the procedure of supervised product checks at random intervals is closed;
- If the tests have a negative outcome, the above-mentioned procedure may be repeated with further analysis of the causes of the non-conformity by the Client, and further sampling and the execution of the necessary Tests by CERTOTTICA;
- If also the second additional series of sampling has a non-compliant outcome, the procedure of supervised product checks at random intervals is considered closed and the provisions of Article 11 of these Rules will be implemented.

All the above-mentioned additional activities are charged to the Client.

Following every sampling at the Client's premises and at the end of the procedure of supervised product checks at random intervals, CERTOTTICA draws up a test report summarising the results

of all the activities which have been carried out and their outcome. The test report will be sent to the Client who shall keep it for a period of ten (10) years from the placing of the PPE on the market. During the manufacturing process, the manufacturer shall place identification number 0530, under CERTOTTICA's responsibility

10. INCORRECT USE OF THE EU TYPE-EXAMINATION CERTIFICATE

The use of the EU type-examination certificate is deemed incorrect when it can mislead the addressees of the technical, commercial and advertising information.

In particular, such use is deemed incorrect in the following cases, given here just as a partial example:

- The EU type-examination certificate has not yet been issued or has been suspended, revoked or limited;
- the Client makes a change to the Product which has not been communicated and accepted by CERTOTTICA,
- the Client fails to implement a change to the conditions of issue of the EU type-examination certificate made by CERTOTTICA,
- there are circumstances which may affect the conditions which made it possible to issue the EU type-examination Certificate,
- the Client has waived the EU type-examination.

11. SUSPENSION OR WITHDRAWAL OF THE EU CERTIFICATE

11.1 Suspension

Suspension of the EU type-examination certificate issued by CERTOTTICA.

CERTOTTICA may decide to suspend the EU type-examination certificate due to non-observance of the requirements of the EU Certification Plan, revealed by supervised product checks at random intervals or which CERTOTTICA has learned about in any other way, or due to non-observance of these Rules.

CERTOTTICA communicates the suspension to the Client by recorded-delivery letter, stating the conditions under which it can be revoked.

Suspension prevents the Client from using the EU type-examination certificate issued by CERTOTTICA in any way, and from placing products with CE marking, which are stocked in the warehouse or which are being produced, on the market.

Suspension is revoked only when CERTOTTICA has ascertained the restoration of conformity with the requirements of EU type-examination or of the observance of these Rules.

If suspension cannot be revoked within 180 (one hundred and eighty) days, CERTOTTICA will revoke the EU type-examination certificate and it will communicate it to the relevant Authorities, which will act according to their own procedures, to its notifying authority and to other notified bodies.

Expenses met by CERTOTTICA to perform investigations and/or checks due to suspension procedures are charged to the Client.

Suspension of CERTOTTICA identification code

CERTOTTICA may decide to suspend its identification number placed on the marking of a category III equipment, due to non-observance of the requirements of the EU Certification Plan, revealed by supervised product checks at random intervals it has been entrusted with, or due to non-observance of these Rules[M1].

CERTOTTICA communicates suspension to the Client and to the conformity assessment body which has issued the EU type-examination certificate in case it is not CERTOTTICA, by recorded-delivery letter, stating the conditions under which it may be revoked.

Suspension prevents the Client from using, in any way, CERTOTTICA identification code placed on the device marking.

Suspension is revoked only when CERTOTTICA has ascertained the restoration of conformity with the requirements of EU type-examination or of the observance of these Rules.

CERTOTTICA will communicate revocation of the suspension to the previously involved Notified Body.

If suspension cannot be revoked within 180 (one hundred and eighty) days, CERTOTTICA will communicate it to the relevant Notified Body, which will act according to its own procedures, to revoke the EU type-examination certificate.

Expenses met by CERTOTTICA to perform investigations and/or checks, due to suspension procedures are charged to the Client.

11.2 Withdrawal

CERTOTTICA may decide to withdraw the EU type-examination certificate due to:

- Serious non-observance of the requirements provided for by points 7, 8, 9 and 10 of these Rules,
- Non-restoration of the conditions which may have caused a suspension after the deadline of 180 (one hundred and eighty) days provided for by point 11.1 of these Rules,
- Repeated non-observance of the commitments taken with CERTOTTICA to solve the discrepancies from the requirements which have been detected and pointed out during Surveillance activities,
- Other serious breaches of the Contract,
- Communication of revocation by another Notified Body appointed to perform supervised product checks at random intervals,
- Bankruptcy or liquidation of the Client,
- Non acceptance by CERTOTTICA of changes as per points 13.2 and 13.3 of these Rules.

The decision to withdraw the certificate is communicated by CERTOTTICA via recorded-delivery letter:

- to the Client, ACCREDIA and the Relevant Authority and other Notified Bodies in case of EU type-examination certificate issued by CERTOTTICA;
- to the Client, ACCREDIA and the relevant Notified Body in other cases.

Following the communication of withdrawal, the Client shall:

- communicate the plan of withdrawal from the market of the products object of the revocation specifying the number of items and the schedule the withdrawal will follow. Such plan will be communicated to the relevant Authority which will check the application of the plan itself;
- return the original EU type-examination certificate to CERTOTTICA or to the relevant Notified Body;
- not use any copies or reproductions of the EU type-examination certificate;
- eliminate every EU type-examination references or symbols from technical documentation, advertising and products;
- not market nor place on the EU or extra-EU market products with CE marking and/or CERTOTTICA's identification code, existing in warehouses and/or which are being manufactured, which the EU type-examination certificate object of the withdrawal refers to.

CERTOTTICA, in its capacity as reference Notified Body will cancel the EU type-examination certificate issued to the Client from the Register as provided for by point 5.5.5 of these Rules, and it will publicise the matter in the ways it thinks suitable and which have been agreed upon in writing with Client.

If another Notified Body has been involved in the withdrawal process the above-mentioned procedure will be carried out by that body according to the methods and procedures of the body itself.

The 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 s/he has implemented all the measures which CERTOTTICA deems necessary to prevent the recurrence of the non-conformities that had generated the withdrawal.

12. WAIVING EU CERTIFICATION

A Client may waive the EU type-examination certificate s/he holds:

- If the manufacturing of the certified Product(s) does no longer take place in the Manufacturing Unit(s) declared in the EU type-examination application as provided for by point 5.1 of these Rules.
- due to non-acceptance of changes as per points 13.2 and 13.3 of these Rules.

In the latter case the waiver becomes effective 90 (ninety) days after the date of reception of the non-acceptance communication sent by the Client. Such communication shall be sent by the Client within 30 (thirty) days from the date of reception of CERTOTTICA's notification regarding changes to the conditions of issue of the EU type-examination certificate or of the notification of the proposed changes to the Client.

In case of ceased production, the waiver becomes immediately effective as from the date in which the Client has given written communication by recorded-delivery letter or equivalent official communication.

The waiver binds the Client to perform all the actions provided for by point 11.2 of these Rules.

Following the waiver by the Client, CERTOTTICA may decide to perform actions regarding the Product object of the EU type-examination certificate, similar to those provided for by point 11.2 of these Rules.

Moreover, the Client's waiver implies the cancellation of the issued EU type-examination certificate from the Register provided for by point 5.5.5 of these Rules, and the ensuing actions.

13. MODIFICATIONS OF THE CONDITIONS OF THE EU TYPE-EXAMINATION CERTIFICATE VALIDITY

13.1 Modifications made by CERTOTTICA

If CERTOTTICA makes changes to the conditions of issue and/or maintenance of the EU type-examination certificate following variations in:

- The Product reference standard,
- These Rules,
- The evolution of the generally recognized state of the art;

CERTOTTICA sends the updated rules to the Impartiality Committee which shall then express its opinion and to ACCREDIA.

The reviewed Rules are then sent to all Clients recorded in the Register of Clients holding an EU type-examination certificate or who have submitted an EU type-examination application, by using suitable means to prove the correct sending. Clients shall adapt to the new rules within the deadline decided and deemed the most suitable by CERTOTTICA, depending 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 provided for by point 12 of these Rules. After 30 (thirty) days with no communication from the Client, the new review of the Rules is considered accepted by tacit consent.

CERTOTTICA reserves the right to assess conformity of the suitability of the Product to the new provisions, by repeating type examinations on new samples or by requesting additional documentation.

The expenses of any assessment action are charged to the Client.

13.2 Modifications made by the Client

If the Client wishes to make changes:

- To the manufacturing process,
- To the product characteristics,

which may affect the conformity of the Product with the applicable EU Certification Plan, s/he shall immediately communicate them to CERTOTTICA.

CERTOTTICA will:

- communicate to the Client, in writing, within 30 (thirty) days from reception of the notification it made, the possible need to repeat some or all the assessments provided for by points 5.2, 5.3 and 5.4 of these Rules.
- notify the non-acceptance of such changes.

If the Client does not accept CERTOTTICA's decisions, s/he may waive the EU type-examination certificate as long as s/he notifies this, in compliance with the method provided for by point 12 of these Rules.

The expenses of new assessments are charged to the Client.

13.3 Other modifications

Organizational and/or company name modifications or changes in ownership of the Client allow to maintain the EU type-examination certificate as long as:

- CERTOTTICA is promptly informed in writing,
- CERTOTTICA has checked that the changes comply with the applicable EU Certification Plan.

The costs of the checks performed by CERTOTTICA are charged to the Client.

14. CONFIDENTIALITY

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

The only information that CERTOTTICA undertakes to communicate to all those who ask for it, through a specific written request to be sent by fax and/or e-mail to the address which can be found on CERTOTTICA's website, is that contained in the issued certificate (without any need of authorization by the Client).

CERTOTTICA staff is subject to professional secrecy for all the information they may get to know while performing the activities provided for by Annex V and VII of Regulation (EU) 2016/425 of 9 March 2016, or in compliance with any other provisions of national law which implements it, but not towards the relevant Authorities of the Member State where they perform their activity.

Property rights are protected.

CERTOTTICA's staff at all levels of its organization, and external staff involved in surveillance, testing and EU type-examination activities who, while performing their tasks, may gain knowledge of the content of these documents and of any other information regarding the Clients with whom CERTOTTICA has EU type-examination agreements, are all subject to professional secrecy.

If the law establishes that some information shall be communicated to Relevant Surveillance Authorities upon request, CERTOTTICA will inform the Client about the information it has supplied.

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

15. ECONOMIC TERMS

15.1 Rates

CERTOTTICA's services rates are set through specific fees for every EU Certification Plan.

Any request for re-issuing of an EU type-examination certificate entails the payment of an additional rate, in compliance with the methods defined is the Price List.

15.2 Terms of payment

Rates referring to EU type-examination procedure shall be paid to CERTOTTICA according to the methods and schedule set in the quotation.

16. USE OF CERTOTTICA LOGO

The use of CERTOTTICA logo shall be authorized by CERTOTTICA on the Client's request.
The client shall send the draft of the use of the logo and declare on what documents it shall be applied.
The logo shall respect the original proportions and the original colours or be monochrome. The logo can be used only subject to CERTOTTICA's express permission.

All EU type-examination certificates issued by CERTOTTICA within the accreditation procedure shall bear the ACCREDIA mark, in compliance with the criteria defined in ACCREDIA's regulation RG-09.

17. APPEALS

The Client may appeal against a decision taken by CERTOTTICA by sending a written communication to be transmitted by fax or recorded delivery letter. In order to be acceptable, the appeal shall

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

Within 7 (seven) days from receipt of the appeal, CERTOTTICA formally communicates to the Client whether the appeal has been judged admissible or not and, in case it has, the date within which a decision will be taken (maximum 30 days from receipt of the appeal).
Decisions taken about the appeal are communicated to the client by fax and/or recorded-delivery letter.
Appeals will be evaluated and managed by CERTOTTICA's staff who have not been directly involved in the documents analysis.

18. COMPLAINTS

The client can make a complaint to CERTOTTICA for the activities it performs within the scope of these Rules.
CERTOTTICA formally manages every complaint received in writing (letter, fax or email); complaints made verbally will be managed in a documented way if considered appropriate. The management of the claim implies:

- written reply (by letter, fax or e-mail) within 7 (seven) days from receipt of the complaint, with the analysis of the complaint and possible actions envisaged for its management, and relevant time schedule;
- written reply (by letter, fax or email) when the envisaged actions have been completed.

Complaints will be evaluated and managed by CERTOTTICA's staff who have not been directly involved in the documents analysis.

19. JURISDICTION

Any disputes that may arise directly or indirectly between the parties related to the application or interpretation of these Rules, which cannot be amicably settled between the parties, shall be referred to the exclusive jurisdiction of the Court of Belluno, as defined in the Agreement included in the EU type-examination application.

20. CONSERVATION OF THE REFERENCE SAMPLES

CERTOTTICA ensures, when possible, that at least one intact sample of the tested Product is kept in its warehouse.