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1 GENERAL

1.1 SCOPE AND APPLICABILITY

Centro Tessile Cotoniero e Abbigliamento S.p.A. (hereinafter referred to as Centrocot) as Notified body (Notified Body, hereinafter referred to as NB) it is authorized to issue **EU Type-examination certificate** for Personal Protective Equipment and for the activity of **Conformity to Type Assessment** for category III Personal Protective Equipment pursuant to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016.

The application field of notification includes the types of Protective Equipment listed below:

1) High visibility clothing;
2) Protective clothing, gloves and accessories against cold (down to minus fifty degrees centigrade);
3) Protective clothing, gloves and accessories for welding and similar activities;
4) Protective clothing to be used where there is a risk of entanglement on moving parts;
5) Protective clothing, gloves and accessories with antistatic properties;
6) Protective clothing, gloves and accessories for sports use;
7) Protective clothing, gloves and accessories against biological risks;
8) Protective clothing, gloves and accessories against chemical risks;
9) Protective clothing, gloves against mechanical risks;
10) Protective clothing, gloves for motorcycle riders;
11) Protective clothing, gloves for users of hand-held chain saws;
12) Protective clothing, gloves and accessories against heat and flame;
13) Protective clothing, gloves and accessories for fire fighters.

The application field of notification includes the following conformity assessment procedures:

1) EU type-examination (module B) set out in annex V of Regulation (EU) 2016/425
2) Conformity to Type based on internal production control plus supervised product checks at random intervals (Module C2) set out in annex VII of Regulation (EU) 2016/425
3) Conformity to Type based on quality assurance of the production process (Module D) set out in annex VIII of Regulation (EU) 2016/425

The purpose of the Regulation for EU Certification and Conformity to Type Assessment (hereafter called "Regulation") is to regulate activities conducted by Centrocot as Notified Body (NB), by applying specific and documented procedures to issue **EU Type-examination certificate** for Personal Protective Equipment and for the activity of **Conformity to Type assessment** for category III Personal Protective Equipment.
The Regulation defines the procedures to issue, suspend, extend and withdraw the EU Type-examination certificates and procedures for Conformity to Type Assessment regarding category III Personal Protective Equipment.

The Regulation defines, likewise, obligations and responsibilities for Centrocot and for Customer within the abovementioned procedures, according to the provisions of Regulation (EU) 2016/425

1.2 DEFINITIONS

For the purposes of this Regulation, the following definitions apply:

- **EU Type-examination certificate** – document issued by Centrocot as Notified body which certifies the conformity of PPE within the requirements established by the Regulation EU 2016/425
- **EU Type-examination certificate reviewed** - document issued by Centrocot as Notified body stating that the **EU Type-examination certificate** already issued has been object of a variation**.**
- **Competent authority** – Ministry for Economic Development
- **Customer** – Subject requesting certification, based on the activity carried out, as Manufacturer, Authorised Representative, Importer and Distributor of Personal Protective Equipment.

- **Declaration of Conformity EU**– document issued according to Annex IX from Regulation EU 2016/425, in which the Customer declares that the PPE is compliance with the Regulation requirements
- **Personal Protective Equipment (PPE) means:**
  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 point, that are not designed to be permanently fixed and that do not require fastening works before use;
- **Distributor** – means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market. An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that compliance with Regulation (EU) 2016/425 may be affected
- **Technical Documentation for PPE** – Technical Documentation drawn up by the Manufacturer according to contents of Annex III of Regulation EU 2016/425 specifying the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II
- **Application for EU type-examination or Application** – Document lodged by Customer's authorised representative requiring EU type-examination on one or more PPE models drawn up in accordance with Annex III point 3 requirements of the Regulation. Available on website www.centrocot.it
- **Extension Application** - Document lodged by Customer's authorised representative requiring extension of its own EU type-examination certificate to an importer or to a distributor who will market the product with his own trademark. Available on website www.centrocot.it
- **Application for Review of the EU Type-examination certificate for changes on the approved type** - Document lodged by Customer's authorised representative requiring the review of its own EU Type-examination certificate following a modification and/or variation on PPE object of certification. Available on website www.centrocot.it.
- **Application for Review of the EU Type-examination certificate for changes in the state of the art** - Document lodged by Customer's authorised representative requiring the review of its own EU Type-examination certificate following changes in the state of the art. Available on website www.centrocot.it.
- **Application for Review of the EU Type-examination certificate for expiry of the same** - Document lodged by Customer's authorised representative requiring the review of its own EU Type-examination certificate for expiry of the same. Available on website www.centrocot.it
- **Application for simplified Review of the EU Type-examination certificate** - Document lodged by Customer's authorised representative requiring the review of its own EU Type-examination certificate due to the expiry of it provided that no changes have been made on approved type and in the state of the art. Available on website www.centrocot.it
- **Application for Conformity to Type assessment -** Document lodged by Customer's authorised representative requiring a conformity assessment on one or more PPE models object of certification concerning one of the procedures (module C2 or module D) referred to in art. 19 letter c) of Regulation (EU) 2016/425. Available on website www.centrocot.it
- **Manufacturer** - means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark

- **Importer** – means any natural or legal person established within the Union who places PPE from a third country on the Union market. An Importer shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that compliance with Regulation (EU) 2016/425 may be affected.
- **Placing on the market–** the first making available of PPE on the Union market
- **Manufacturer's instructions and information (instruction for use)** – Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II of the Regulation (EU) 2016/425 in a language which can be easily understood by consumers and other end-users (art. 8 point 7 of Regulation (EU) 2016/425)
- **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
- **CE marking** - means a marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing
- **Making available on the market –** means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge
- **Harmonised standard** - means a harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012
- **Union harmonisation legislation -** means any Union legislation harmonising the conditions for the marketing of products
- **Offer** – contract defining economic conditions of the required service from Customer
- **Economic operator -** means the manufacturer, the authorised representative, the importer and the distributor
- **Notified Body (NB)** – Centrocot acting as Notified Body. Conformity assessment body of third party by notifying authority of European Union member state to the commission and to other member states
- **National accreditation body**– means a national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No. 765/2008

- **Conformity assessment procedures:** procedures laid down in Article 19 of Regulation EU 2016/425 to be followed for each of the risk categories:
  a) Category I: internal production control (module A) set out in Annex IV of Regulation EU 2016/425;
  b) Category II: EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C) set out in Annex VI of Regulation EU 2016/425;
  c) Category III: EU type-examination (module B) set out in Annex V, and either of the following:
     - conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII of Regulation EU 2016/425
     - conformity to type based on quality assurance of the production process (module D) set out in Annex VIII of Regulation EU 2016/425.

- **Surveillance** – Operating procedure adopted by Centrocot (as Notified Body) to assess that the manufacturer meets all the obligations arising out of the approved quality system – module D of Regulation (EU) 2016/425
- **Technical specification –** means a document that prescribes technical requirements to be fulfilled by PPE
- **Conformity assessment** – means the process demonstrating whether the essential health and safety requirements of Regulation (EU) 2016/425 relating to PPE have been fulfilled
- **Conformity assessment body –** means a body that performs conformity assessment activities including calibration, testing, certification and inspection [herein referring to assessment activity carried out by Centrocot concerning PPE certification]
- **Recall –** means any measure aimed at achieving the return of PPE that has already been made available to the end-user;
- **Review of the EU type-examination certificate** – means the issue of a new EU Type-examination certificate due to changes on the approved type, changes in the state of the art, expiry of certificate.
- **Withdrawal –** means any measure aimed at preventing PPE in the supply chain from being made available on the market.

1.3 COMMITTEE FOR SAFEGUARDING IMPARTIALITY

1.3.1 Centrocot operates in a way to avoid any discrimination towards customers. Centrocot does not provides for any consulting activities nor design and/or manufacture activities in PPE area or any other design, production or service activity that might affect confidentiality, objectivity and impartiality concerning procedures for issue EU Type-examination certificates and in the activity of Conformity to type assessment for category III PPE.

1.3.2 Centrocot's independence, impartiality and competence (intended as adequacy of resources) are ensured by the Committee for Safeguarding Impartiality (CSI) which is a body appointed by Centrocot Board of Directors including members appointed by the different interested Bodies so as to be equally represented and so as to ensure that judgements are impartial without any individual interest predominating.

1.4 PERSONNEL

1.4.1 Centrocot warrants the suitability and professional qualifications of the personnel concerning procedures to issue EU Type-examination certificates and to the activity of Conformity to type assessment for category III PPE and keeps up-to-date information concerning the qualification, training, expertise and development of all involved parties to prove that the requirements established by standards UNI CEI EN ISO/IEC and UNI CEI EN ISO/IEC 17021 are satisfied.

1.5 EQUIPMENT

1.5.1 Centrocot owns laboratories and equipment suitable to perform tests in compliance with the Regulation (EU) 2016/425 and/or with the harmonised standards. The laboratory is accredited by ACCREDIA (accreditation no. 0033) according to the requirements of the standard UNI CEI EN ISO/IEC 17025. Accreditation states the technical competence of personnel, the use of adequate equipment and the impartiality of the personnel involved in testing.

1.6 EXTERNAL FACILITIES

1.6.1 In the case of lack of equipments and/or adequate expertise Centrocot may entrust the execution of accredited tests to external facilities. In such cases, the performed tests are to be considered as not accredited.

1.6.2 Centrocot may entrusts non-accredited test execution to external Notified Bodies and/or to accredited Laboratories which have signed the international agreements on mutual recognition (EA, IAF, ILAC), subject to prior evaluation of their adequateness on the basis of provided documents or through audits performed according to UNI CEI EN ISO/IEC 17025, particularly focusing on technical competence of personnel and the activities for quality assurance, objectively verified.

1.6.3 Centrocot informs the Customer about subcontracted tests in the offer or, were it not possible, later on. The Customer has the right to not accept the proposed external body by means of written notification.

1.6.4 Centrocot, in any case, assumes and maintains the total responsibility towards the Customer concerning tests performed by external facilities.

1.6.5 Centrocot, in any case, never avails itself of external bodies for the evaluation of the conformity and the issue of EU Type-examination certificates.

1.7 CE MARKING

1.7.1 The Customer has the right to affix CE Marking on PPE object of EU Type-examination certificate, and, for category III PPE, the number of Notified Body entrusted by the Customer to perform activity of conformity to type assessment as set forth under article 19 (Module C2 or D) of the Regulation (EU) 2016/425. The artwork and minimum dimensions of the marking must be compliant with what is laid down in annex II of the Regulation (EU) 765/2008.

1.7.2 If it is found that the CE Marking has been incorrectly or unlawfully affixed or has been made an improper use of it, Centrocot has the right to suspend or revoke the issued Certificates.

1.8 LIABILITIES OF CENTROCOT

1.8.1 The results of tests performed by Centrocot are considered as being valid only for samples subject to test: Ensuring the conformity of PPE and its components object of EU Type-examination certificate with the sample subject to certification pertains exclusively to the Customer, as Centrocot assumes no liability and/or obligation regarding this matter.

1.8.2 The Customer takes due note and acknowledges that Centrocot assumes no liability for any use that may be made by the customer concerning test results, EU-Type Examination Certificate and consequent observations.

1.8.3 The Customer takes due note and acknowledges that Centrocot has no obligations to provide information to the Customer concerning any amendments to current regulation.

1.9 CUSTOMER'S LIABILITIES, WARRANTIES AND RELIEF

1.9.1 The Customer undertakes to preserve the Technical Documentation referred to PPE object to EC-Type examination certificate and of any revised. Certificates according to law provisions for the entire period of PPE production and, in any case, for the following 10 years from the last placing on the market.

1.9.2 The Customer represents and warrants to have the right to use of the PPE object of the EC-Type examination certificate, if it is object of patent, trademarks and other representation, as well as their lawfulness, and is therefore the sole and exclusive responsible towards the Public Administration and third parties.

1.9.3 The Customer declares and warrants that the information, texts, graphics, data, news, images and so on, are in compliance with standards, regulations and/or other sources and do not infringe any copyright, distinctive sign, trademark, patent or other right of third parties, either absolute or relative.

1.9.4 The Customer cannot use Centrocot logo, unless written authorization by Centrocot

1.9.5 Without prejudice to the duties set forth under foregoing points, the Customer in all events relieves Centrocot from all liabilities, demand and claim even for indemnity, that might be made against Centrocot by third parties, including Public Authority and Authority of control in the event of breach by the Customer of the duties listed above, and has to meet any injury that might be done towards Centrocot.

1.9.6 It is responsibility of the Customer to maintain a copy of claims concerning the PPE object of EU type-examination certificate received by its own clients, as well as of the actions taken to correct the causes that have determined the actions. The documentation has to be maintained for at least four years from the date of the claim.

1.10 CLAIMS AND APPEALS (under standard reference EN ISO/IEC 17065)

1.10.1 The Customer may make claims in written towards Centrocot in case he deems that the quality of the certification service offered and/or of conformity assessment activity concerning Third Category PPE does not correspond to what stated in the Regulation. Centrocot shall inform the customer about the appeal receipt within 7 days, declaring the commitment to verify the problem and to provide clear and exhaustive answers in written within 30 days.

1.10.2 In case the Customer believes that Centrocot did not adequately reply to the claim can make appeal submitting it to the General Manager of Certification Body no later than 30 days from notification of the decision and/or measure referred to. They must contain the reasons for dissent and indicate, if possible, the matters deemed not properly or fully assessed.

1.10.3 It is responsibility of the General Manager of Centrocot (as Director of Notified body) to examine the received recourse, to carry out appropriate checks and to provide a clear and exhaustive response in written within and not later than 90 days from claim receipt.

1.10.4 Claims are evaluated by Notified Body's General Manager as third independent party. The Notified Body's General Manager performing the evaluation of recourses is controlled by the Committee for Safeguarding Impartiality.

1.11 CONFIDENTIALITY

1.11.1 All information, material or document provided between the Customer and Centrocot are to be deemed strictly confidential and in any case shall not be notified to third parties, except for ACCREDIA, and the Competent Authority.

1.12 APPLICABLE LAW AND COURT OF JURISDICTION

1.12.1 This Regulation is subject to Italian laws.

1.12.2 In the case of any controversy concerning interpretation of this regulation and execution of its contracts, the Competent Court will be exclusively the one of Busto Arsizio.

2 EU TYPE EXAMINATION (MODULE B)

2.1 APPLICATION

2.1.1 A Customer intending to obtain EU type-examination certificate must submit the Application or a request for quotation with the details of the PPE for which the certification is requested, the related harmonised standards or the risk type.

2.1.2 Centrocot evaluates the Application or request for quotation with the right to, where necessary, require integrative information.

2.1.3 At the outcome, Centrocot shall send to the Customer the quotation based on the rates in force, containing types and number of samples that shall be sent for testing.

2.1.4 The charges applied for issue EU type-examination certificate and for test executions are listed in the "Laboratory tests and services Catalogue" approved by the Technical Manager and by the General Manager of Centrocot. The correct and impartial application of the tariffs is subject to the supervision of the Committee for Safeguarding Impartiality.

2.1.5 If the Customer appoints Centrocot as Notified body shall send the following documentation:

- Offer signed for acceptance;
- Application (if not yet sent);
- Technical documentation;
- Manufacturer's instructions and information;
- Number of samples as indicated in the Offer, including some additional samples for an eventual retesting (if applicable).

2.1.6 The Application shall indicate, the Customer details, the PPE description for which the certification is requested, the related harmonised standards or type of risk and PPE category.

2.1.7 In the Application, the Customer shall declare he has not sent an analogous Application to other Notified Bodies and that the technical documentation of PPE, for which the certification is required, has not been previously refused by other Notified Bodies.

2.1.8 The Technical documentation shall be drawn up according to annex III of Regulation (EU) 2016/425 and 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.

2.1.9 Manufacturer's instructions and information shall contain information of Annex II clause 1.4 of Regulation (EU) 2016/425 and information requested by the applied harmonised standards.

2.1.10 The non-submission or incomplete submission of documentation and products as set above will not allow Centrocot to carry out the procedure for the release of EU type-examination certificate.

2.1.11 The Documentation may be sent by e-mail.

2.1.12 Upon a positive outcome of the assessment concerning the documentation received in terms of appropriateness and adequacy, Centrocot will start the procedures to issue the EU type-examination certificate.

2.2 CERTIFICATION PROCEDURE

2.2.1 Centrocot evaluates the documentation listed in 2.1.5 verifying the conformity of this with harmonised standards or with the essential requirements of the Regulation (EU) 2016/425.

2.2.2 If the documentation outcome is positive, Centrocot will perform the laboratory tests on delivered samples. The outcome of the tests is communicated to the Customer, sending the related test reports.

2.2.3 Following positive outcome of laboratory tests performed on the samples delivered, Centrocot shall issue the EU Type-examination certificate. If tests have an unfavourable outcome, notification has to be given to the Customer who will implement the necessary modifications and resend the modified samples in order to restart with the process of certification. If the Customer does not implement the modifications, Centrocot will deem that there is no interest in continuing with the certification activity.

2.2.4 The decisions and the resolutions about issue EU Type-examination certificate have to be taken by the Technical and Resolving Function set up by Centrocot.

2.2.5 EU Type-examination certificates are to be signed by Centrocot General Manager as Director of Notified Body.

2.2.6 Certification activity may be carried out also in the presence of ACCREDIA inspectors and/or personnel of the competent authority.

2.3 CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (Module C)

2.3.1 Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer ensures and declares under his sole responsibility that the PPE in object is in conformity with the type described in the EU Type-examination certificate and satisfies the applicable requirements of Regulation (EU) 2016/425.

Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of Regulation (EU) 2016/425.

CE marking and EU declaration of conformity

The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of Regulation (EU) 2016/425.

The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

2.4 DECLARATION OF CONFORMITY

2.4.1 Once the EU type-examination certificate has been obtained, the Customer has to assess the conformity of the PPE subject to EU type-examination certificate and the provisions of the Regulation (EU) 2016/425, by means of the EU Declaration of Conformity as foreseen in Annex IX of the Regulation (EU) 2016/425. The Declaration of Conformity shall referred to EU Type-examination certificate issued.

2.5 DURATION AND VALIDITY CONDITIONS OF CERTIFICATION

2.5.1 The EU Type-examination certificate is valid for 5 years with effect from the date of issue. On expiry date it will be no longer valid.

2.5.2 The EU Type-examination certificate will be no longer valid also in the case of substantial modifications of the Regulation (EU) 2016/425 and/or harmonised standards on which the released EU type-examination certificate was based.

2.5.3 In both cases, the Customer is entitled to present to Centrocot an Application for issue the renewal. In case of renewal for expiry, in order to carry out the tasks entrusted to Centrocot, the customer shall submit the application not later than twelve months and not before than six months of EU type-examination Certificate expiration date.

2.5.4 The EU type-examination certificate is personal and can be used exclusively by the customer whose name is on the EU type-examination certificate itself. The EU type-examination certificate cannot be transferred to a third party for any reason. In case of Customer's company dissolution and if the Customer is subject to bankruptcy procedures, the EU Type-examination certificate loses effectiveness, as well as any EU Type-examination certificates subject to extension for reasons of the following point 2.7.

2.5.5 The EU Type-examination certificate is no longer valid if the Customer makes variations of the PPE subject to the EU Type-examination certificate without having previously sent an application to Centrocot following the criteria indicated in the subsequent paragraph 2.6.

2.6 REVIEW OF THE EU TYPE-EXAMINATION CERTIFICATE

2.6.1 EU Type-examination certificate is referred to the PPE subject of the application form and exclusively to this.

2.6.2 If the Customer shall make changes on the PPE subject to EU Type-examination certificate, he has to send to Centrocot the Application specifying the type of the variations.

2.6.3 Centrocot performs an appropriate assessment, and at the outcome informs the Customer whether variations of the PPE object of the EU Type-examination certificate can be made and can be object of revised EU Type-examination certificate or if the modified PPE shall be object of a new EU Type-examination certificate.

2.6.4 The revised EU Type-examination certificate maintains the duration and validity of the original EU Type-examination certificate and shows the date in which the revision was performed.

2.7 EXTENSIONS

2.7.1 If the Customer wants to extend the EU type-examination certificate to another subject who acts as Distributor/Importer and that has the necessity to put on market an (OBL) Own Brand Labelling PPE, he shall request an extension to Centrocot, sending the Extension Application subscribed by both Customer and Distributor/Importer. The application form concerning the extension shall follow all the points settled down in the Recommendation CNB/P/00.130 of the Horizontal Committee. After the issue of EU Type-examination certificate extension, the Distributor/Importer can place on market the PPE subject to manufacturer's EU Type-examination certificate using his own company name and logo.

2.7.2 The EU Type-examination certificate extension can be issued by Centrocot only with reference to EU Type-examination certificates issued by Centrocot.

2.7.3 The EU Type-examination certificates extension have a whole new number but the same expiration date of Eu type- examination Certificate they refer to.

2.7.4 In case the EU Type-examination certificate extension is issued, the Customer has to:

- Keep the EU Type-examination certificate in validity status and give evidence to Conformity to Type assessment according to module C2 or D of Regulation (EU) 2016/425 in case of category III PPE;
- Provide the distributor PPE identical and totally compliant with the one object of EU Type-examination certificate;

- Inform the Distributor of all the facts and circumstances that can affect the validity of the EU Type-examination certificate or, for category III PPE, Conformity to Type assessment according to module C2 or D Regulation (EU) 2016/425.
- Send to Centrocot and Distributor any proposal for amendment of the PPE.
- Inform the Distributor of any problem related to PPE subject to EU Type-examination certificate.

2.7.5 If EU Type-examination certificate extension has been issued, the Distributor/Importer has to:

- Subscribe a Declaration of Conformity according to Annex IX of the Regulation (EU) 2016/425 before placing the PPE on the market;
- Place on the market a PPE identical to those subject to the EU Type-examination certificate for which the extension is requested;
- Not to make unauthorised modifications of the PPE;
- To inform the Manufacturer of any eventual problem related to PPE object of the EU Type-examination certificate.

2.7.6 All the documents referring to the original Technical Documentation have to be submitted together with the application for Extension (marking and the manufacturer's instructions and information); such documents shall be available for the Distributor and its constitute the basis to confirm the compliance of the PPE subject to the EU Type-examination certificate with the requirements of the Regulation (EU) 2016/425. Such documents shall be preserved by the Distributor for the following 10 years from the date of the last placing on the market of the PPE subject to the EU Type-examination certificate.

2.7.7 For the category III PPE subject to the EU Type-examination certificate, the Notified Body appointed by the Customer for the Conformity to Type Assessment according to Annex VII and VIII of the Regulation (EU) 2016/425 is entitled to carry out a Conformity to Type Assessment also at the distributor's premises.

2.7.8 The EU Type-examination certificate extension identifies the Distributor as Customer and reports the PPE identification as the one used by the Distributor. The EU Type-examination certificate extension shall contain the words "THE VALIDITY OF THIS CERTIFICATE IS SUBJECT TO THE VALIDITY OF THE CERTIFICATE (follows number of the Original Certificate) THIS IS THE EXTENSION OF", meaning that the EU Type-examination certificate extension will lose its validity and effectiveness if, for any reason, the EU Type-examination certificate which it refers to becomes invalid or ineffective.

2.7.9 The extension refers only to OBL and not to cases where the Distributor/Importer place on market products with manufacturer trademark.

2.8 SUSPENSION AND WITHDRAWAL OF EU TYPE-EXAMINATION CERTIFICATE

2.8.1 The use of EU Type-examination certificate is considered improper whenever it is used or advertised:

- in a way that might mislead the recipients of the information
  although not yet formally granted
- although revoked or suspended
- beyond scope of applicability
- after the Customer has made changes on PPE subject to EU Type-examination certificate which are not in compliance with instructions set out by Centrocot.

2.8.2 Centrocot may suspend the validity of the EU Type-examination certificate in case of:

- improper use by the Customer, in accordance with the provisions of point 2.8.1.
- negative outcome of conformity to type assessment
- unpaid invoices related to tests, certification or surveillance activities.

If even one of the previous circumstances shall occur, Centrocot shall inform the Customer in writing by registered letter with return receipt or by certified e-mail (PEC) (centrocot@certimprese.it), to arrange for suspension to be ended, and review certification.

The manufacturer has to act according to the before mentioned actions and, if applicable, review the compliance of PPE in stock and marketed.

The certification review with any reduction of application field, can be obtained only after Centrocot approval.

2.8.3 Centrocot may revoke the EU Type-examination certificate if the validity of effectiveness of EU Type-examination certificate has been suspended and the Customer has not removed the causes of suspension within the agreed time. In such case, Centrocot shall inform the Customer in writing with registered letter with return receipt or by certified e-mail (PEC) (centrocot@certimprese.it) about the revocation of EU Type-examination certificate validity, specifying the reasons of the provision. In the event of revocation of the EU Type-examination certificate, the Customer cannot keep on using the Certificate.

2.8.4 Centrocot shall inform about the aforementioned suspension/revocation: ACCREDIA, the Competent Authorities and the other Notified Bodies carrying out similar conformity assessment activities covering the same kinds of PPE.

3 CONFORMITY TO TYPE ASSESSMENT FOR CATEGORY III PPE

3.1 CONFORMITY TO TYPE ASSESSMENT REQUEST

3.1.1 The Customer is compelled to submit the PPE subject to the EU Type-examination certificate of Third Category, at his own choice to one of the production control according to article 19 (Module C2 conformity to type based on internal production control plus supervised product and Module D conformity to type based on quality assurance of the production process) of Regulation (EU) 2016/425

3.1.2 The Notified Body for control activities is chosen by the Customer and can be different from the Notified Body that has released the EU Type-examination certificate.

3.1.3 Therefore, it can choose to appoint the conformity to type assessment to Centrocot:

a. The Customer who requires the EU Type-examination certificate to Centrocot
b. The Customer who has obtained the EU Type-examination certificate from another Notified Body.

3.1.4 The Customer who requires the EU Type-examination certificate for category III PPE to Centrocot, has to specify in the Application if he wants to appoint the conformity to type assessment to Centrocot.

3.1.5 In order to plan conformity to type assessment activities, the Customer, after the EU Type-examination certificate being issued, shall inform Centrocot, by means of the conformity to type assessment application, about the date of beginning of production and, in case, of end or temporary suspension of it.

3.1.6 The Customer, who has obtained the EU Type-examination certificate from another Notified Body and wants to appoint Centrocot for the conformity to type assessment activity, has to apply with a conformity to type assessment Application enclosing a copy of EU Type-examination certificate and the related documentation.

3.1.7 Centrocot is entitled to request to the Notified Body that has issued the EU Type-examination certificate the information and clarifications required for the conformity to type assessment activity of Category III Personal Protective Equipment: technical file, manufacturer's instructions and information, EU Type-examination certificate, test reports.

3.1.8 The entrustment for the conformity to type assessment activity concerning Category III of Personal Protective Equipment is referred to the period of validity of the EU Type-examination certificate. Centrocot or the Customer is entitled to withdraw giving notice not before than 3 months by registered letter with return receipt or by certified e-mail (PEC) (centrocot@certimprese.it).

3.2 ASSESSMENT OF CONFORMITY TO TYPE ACTIVITY FOR III CATEGORY PPE

3.2.1 After receipt of the Application, Centrocot sends to the Customer the Offer issued on the basis of the fares in force. The applied fares for Conformity to Type assessment as stated by Article 19 of Regulation (EU) 2016/425 are included in the “Laboratory tests and services Catalogue” approved by the Technical Director and by the General Manager of Centrocot. The correct and impartial application of the fares is subjected to the control of the Committee for Safeguarding Impartiality.

3.2.2 Together with the offer, Centrocot sends to the Customer a Visit Plan containing the Conformity to Type assessment plan.

3.2.3 Activities of PPE Conformity to Type assessment may be performed by Centrocot auditing team also accompanied by auditors from ACCREDIA and/or Personnel from the Competent Authority. The Customer must allow access to auditing team at his premises.

3.2.4 If the Customer denies access, Centrocot shall inform the Competent Authority in order to act consequently.

3.2.5 The activities of Conformity to Type assessment for Category III Personal Protective Equipment are performed periodically and yearly giving at least 10 working days notice. Centrocot is entitled to make audits without notice if necessary.

3.3 CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

3.3.1 Conformity to type based on internal production control plus supervised product checks at random intervals stated in ANNEX VII of the Regulation (EU) 2016/425 includes two phases: the first one consists of an audit at the premises agreed by the parties as laid down in the "CONFORMITY TO TYPE ASSESSMENT AUDIT PLAN"; the second one consists of the tests execution on collected samples as per OFFER.

3.3.2 During the audit shall be verified the documentation availability and completeness; the consistency with what declared during the certification phase; enough and representative samples shall be collected to verify the correspondence between the PPE collected and the PPE object of the EU Type-examination certificate. In such circumstance the auditor in charge shall issue to the Customer the "CONFORMITY TO TYPE ASSESSMENT AUDIT REPORT" (MODULE C2).

3.3.3 After the tests performed on collected samples, Centrocot shall issue to the Customer the "CONFORMITY TO TYPE ASSESSMENT REPORT" that specifies the conclusive outcome of the assessment procedures.

3.3.4 For the outcome assessment, the below mentioned criteria are followed:

- Critical nonconformity**:** nonconformity that shows a failure to satisfy the compulsory requirements and jeopardizes the level and the scope of protection assured by the PPE (for example: products having characteristics that do not satisfy the requirements of the Regulation EU 2016/425 or product standards; the unrecorded of the requested documentation; non-authorized amendments concerning materials and PPE design; changes non consistent with information stated in the technical file).
- Non critical nonconformity: nonconformity that points out a partial fulfilment of requirements but that does not jeopardize the level and scope of protection assured by the PPE (for example: worsening of characteristics compared with what ascertained during the issuing of EU Type-examination certificate even satisfying the applicable requirements; difficulties in documentation traceability: use of non significant checks.

3.4 CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (MODULE D)

3.4.1 Conformity to type activity based on quality assurance of the production process laid down in ANNEX VIII of Regulation (EU) 2016/425 which includes the assessment of manufacturer quality system audited by Centrocot to ascertain that the quality system is adequate and effective to ensure that the PPE concerned is in conformity with the type described in the EU type-examination certificate
The activity involves the following procedure:

- An initial audit for quality system approval
- Two further surveillance audits carried out on yearly basis
- A renewal audit and two further surveillance audits carried out on yearly basis

The renewal audit and surveillance audits shall be repeated within every three years.
Without any evidence related to compliance and adequacy of third category PPE object of EU Type-examination certificate, during the audit, Centrocot may take samples and perform tests together with The Quality System assessment.

3.4.2 The activity plan includes the assessment of all business processes during initial audit and during the renewal phase; in the surveillance audit it is possible to analyse only part of the business processes depending on critical issues and importance, granting that for every three-year complete procedure of Quality System control, there shall be a sampling of all products or group of products object of surveillance.

3.4.3 The Customer, during audits, shall put at disposal of the auditor the following documentation:

- information concerning PPE objects of the EU Type-examination certificate, including, if necessary, the related documentation;
- documentation concerning Quality System:
  - Management procedures and operating instructions;
  - Aims of the Quality System, Organisational charts, documents stating authorities and responsibilities at least for first level employees;
  - Control plans and related tests on PPE object of EU Type-examination certificate produced and on raw materials and semi-finished products used to produce them;
  - Data related to test and calibration
  - Report containing qualifications of personnel involved.
  - monitoring indicators of Quality System effectiveness and efficiency;
- Declaration to keep the Quality System adequate and effective.

3.4.4 At the end of every audit, the auditor releases the CONFORMITY TO TYPE ASSESSMENT REPORT – MODULE D, which specifies the outcome of the surveillance activity.

3.4.5 For the outcome assessment, the below mentioned criteria are followed:

- **Critical nonconformity:** Nonconformity due to critical lacks in the Quality System considering it unable to keep under control the compliance of the PPE to the applicable compulsory requirements and that jeopardizes the level and the scope of protection assured by the PPE itself (for example: control plans of processes and products unsuitable with regard to frequency and type of controls; lack of purchase and sales documents that defines in a clear and complete way the specifications; lack of management of technical documentation, non conformities and complaints; lack of internal audits).
- **Non critical nonconformity**: nonconformity that has not as a consequence the inability of the adopted practices to assure the maintenance of the level and of the protection scope required for PPE (for example: non detailed definition of causes concerning claims and nonconformities; insufficient autonomy of personnel entrusted to perform the internal audits; low attention to the correct system documentation management to ensure that the related documents are at disposal of personnel entrusted; use of substantially appropriate practices but not fully satisfying instructions and procedures).

3.5 CLOSURE OF CONFORMITY TO TYPE ASSESSMENT

3.5.1 At the end of assessment activities either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D):

- In the event of a positive outcome, Centrocot issues the approval document and the PRODUCTION PROCESS CERTIFICATE which is sent to the Customer who can continue to markets and/or sells the PPE object of the audit;
- In the event of a negative outcome, Centrocot may decide, at its sole discretion, to carry out a further documental verification, tests execution on further samples or a supplementary Surveillance.
  In case of positive outcome, Centrocot shall issue the approval document and the PRODUCTION PROCESS CERTIFICATE.
  In case of negative outcome, if Centrocot has issued the EU type-examination certificate on which the Conformity to Type assessment was carried out, such certificate shall be suspended/revoked, as in point 2.8; if another Notified Body has issued the EU type-examination certificate on which was carried out the Conformity to Type assessment, Centrocot would communicate to such body the outcome of the Conformity to Type assessment.

3.6 VALIDITY STATUS OF REGULATION

3.6.1 Centrocot shall ensure the conformity of this regulation concerning legal requirements and operative aspects related to the certification activity, extension and surveillance, and if necessary, shall provide for the revision.
All revisions of the regulation are available on the website www.centrocot.it to ensure the correlation between the regulation revision status and date of application, extension and surveillance forms.
It is responsibilities of the customer to read and approve the regulation in validity status signing the following documents before certification and conformity to Type activities:

- Application for EU Type Examination
- Application for EU Type-Examination Certificate Extension
- Application for Conformity to Type Assessment category III PPE