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1. GENERAL

1.1 SCOPE AND APPLICABILITY

Centro Tessile Cotoniero e Abbigliamento S.p.A. (hereinafter referred to as Centrocot) is authorised since 1996, under art. 6 of Legislative Decree no. 475 of 4/12/1992 and subsequent amendments (transposition of the Directive 89/686/EEC and subsequent amendments), to issue EC-Type Examination Certificate for Personal Protective Equipment (garments and gloves); such authorisation has been integrated by the act of 23/06/2006 of the Ministry of Economic Development, with which Centrocot is authorised to the issue of Certificate of Compliance for the EC-Type Certification in the terms of art. 10 and control of the production in the terms of art. 11 part A and part B of the Directive 89/686/EEC relative to the Protective Equipment listed below:

1) High visibility clothing;
2) Protective clothing, gloves and accessorises against the cold (down to minus fifty centigrade);
3) Protective clothing, gloves and accessories for welding activities and the like;
4) Protective clothing to be used where there is a risk of catching on moving parts;
5) Protective clothing, gloves and accessories with antistatic characteristics;
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 motorcyclists;
11) Protective clothing, gloves for users of chain-saws;
12) Protective clothing, gloves and accessories against heat and flame;
13) Protective clothing, gloves and accessories for Fire Fighters.

Articles
10 (EC -Type)
11A ("EC" Quality Assurance System of the Finished Product)
11B ("EC" Quality Assurance System of the Production with Surveillance)

In the matter of alignment of the European regulations that has modified the notification rules (Regulation (CE) no. 765/2008) the authorization and notification references are as follows:

- Centrocot Accreditation of 24/05/2013 as Product Certification Body by the resolution of the Sectorial Accreditation Committee OONN of ACCREDIA according to standards UNI CEI EN 45011, UNI CEI EN ISO/IEC 17021 and UNI CEI EN ISO/IEC 17025.
- Authorization confirmation to Centrocot to operate as Notified Body declared by decree 2013 published in the Official Gazzette n°195 of 21/12/2013.
- Adaptation 2015 of the accreditation according to standards UNI CEI EN ISO/IEC 17065, UNI CEI EN ISO/IEC 17021 and UNI CEI EN ISO/IEC 17025 (Adaptation consequent to the withdrawal by the International Standardization Bodies of the standard UNI CEI EN 45011 replaced by standard UNI CEI EN ISO/IEC 17065)
- Adaptation 2016 of the accreditation upon resolution of the ACCREDIA "Sector Accreditation Committees OONN" with extension of the scheme established by the (EU) Regulation 2016/425 of European Parliament and Council of 9th March 2016 on PPE and that repealing the Directive 89/686/EEC concerning articles in force from 21th October 2016.

The scope of the Regulation of Certification and Surveillance EC (henceforth as "Regulation") is to control, applying specific documented procedures, the activities conducted by Centrocot as Notified Body (Certification Body, hereinafter referred to as CB) for the issue of the **EC-TYPE CERTIFICATES** for Personal Protective Equipment and for the **Surveillance** activity concerning Third Category Personal Protective Equipment. The Regulation defines, therefore, the procedures for issue, suspension, extension and revoking of EC-type certification and of Surveillance certification for Personal Protective Equipment of Third Category. The regulation defines obligations and liabilities of Centrocot and the Costumer in the area of the aforesaid procedures, according to the provisions of Directive 89/686/EEC (hereafter referred to as Directive) and to Legislative Decree no. 475/92 of national implementation and subsequent amendments.

1.2 DEFINITIONS

For the purposes of the regulation, the following definitions apply:

- **EC-type examination Certificate or Certificate -** A document attesting the compliance of a personal protective equipment with the Directive requirements issued by Centrocot as Notified Body.
- **Revised certificate**: document issued by Centrocot as Notified Body attesting that the originally issued EC-Type Examination Certificate has been revised.
- **Competent authority** – Ministry for Economic Development
- **Customer** – Subject requesting certification, in function of the activity carried out, as Manufacturer, Importer, and Distributor of Personal Protective Equipment.
- **Declaration of Conformity** – The procedure according to which the Customer declares that the Personal Protective Equipment conforms to the reference standards in compliance with provisions of the Directive
- **Personal Protective Equipment or PPE** any equipment intended to be worn and held by the worker for the purpose of protecting him against one or a number of risks that may threaten safety or health during work, as well as any complement or accessory intended for this purpose;
- **Distributor** natural or legal person other than Manufacturer or Importer, who makes a PPE available on the market (Decision N. 768/2008/EC)
- **Technical Documentation or Technical file –** Customer documentation including all the information and the systems used to obtain the conformity of PPE object of the EC-Type Certificate with the essential requirements of the Annex III^ of the Directive.
- **Certification Application or Application** - act signed by the Customer for the issue or variation of the EC-Type Certificate on one or a number of PPE models, specifying: type and description, trade name, product standard or risk type, category of classification of PPE. Available on website www.centrocot.it.
- **Extension Application** – act signed by the Customer to request the extension of its own EC-Type Certification to a Distributor who wants to commercialise the PPE object of the EC-Type Certificate with its own trademark. Available on website www.centrocot.it.
- **Surveillance Application –** act signed by the Customer to request a Surveillance Audit on category III PPE subjected to EC-Type-examination Certificate. Available on website www.centrocot.it.
- **EC-type examination** - (for PPE of II and III category): A procedure by means of which the Notified Body, through examinations of samples and tests foreseen in reference standards, ascertains the conformity of the PPE with the essential requirements of the Directive.
- **Manufacturer** - Natural or legal person that manufactures a product or makes it be designed or manufactured and that markets the product with his own name or trademark (Decision n.768/2008/EC).
- **Importer** - The importer is defined as any natural or legal person who places a product from a third country on the EU market. (Decision N. 768/2008/EC)
- **CE Marking** – Marking by means of which the manufacturer indicates that the PPE object of the EC Type Certificate conforms to applicable requirements laid down in community standards of harmonising that foresees the affixing of this.
- **Harmonised standard** - a standard adopted by one of the European normalisation bodies indicated in attachment 1 of directive 98/34/EC of the European Parliament and the Council, dated 22/06/1998 and which foresees a procedure of information in the sector of technical norms and rules and regulations in respect of the services of the information company on the basis of a request submitted by the Commission in compliance with article 6 of this directive;
- **Instruction for use** - Information supplied by the Customer in accordance with point 1.4 of annex II of the Directive. These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

- **Offer** - a contract by Centrocot that defines the economic conditions of the service required for the completion of activities for the release of EC-Type Certificate for PPE and for the Surveillance activity for category III PPE.
- **Certification Body (CB)** - Centrocot acting as Notified Body
- **Notified Body** - Body that assess conformity of third party notified by the Notification Body of a member state of the European Union to the Commission and other member States.
- **Renewal of EC-Type Certificate** - Issue of a new EC-Type Certificate for the expiration of the same or for any substantial amendment of the Directive 89/686/EEC and/or harmonized standards according to which the EC-Type Certificate was issued.
- **Production control systems** - **Control of finished product**. A procedure adopted by the notified body for ascertaining the homogeneity of the production of category III PPE subjected to EC-Type examination and the correspondence with the model subjected to EC-Type examination in accordance with art. 11 A of the Directive.
- **Production control systems** - **Control of the Quality System.** A procedure adopted by the notified body for ascertaining the homogeneity of the production of category III PPE subjected to EC-Type examination and the correspondence with the model subjected to EC-Type examination in accordance with art 11 B of the Directive.
- **PPE surveillance** - A procedure adopted by the notified body for ascertaining the homogeneity of the production of category III PPE subjected to EC type examination and compliance with the model subjected to EC-type examination in accordance with Art. 11 A and 11 B of the Directive.

If some terms and definitions are defined in normative documents, in the case of conflicts the normative documents shall prevail.

1.3 COMMITTEE FOR SAFEGUARDING IMPARTIALITY

1.3.1 Centrocot acts in order to avoid any discrimination towards Customers. Centrocot does not provides for any consulting activities nor design and/or manufacture activities in PPE sector or any other design, production or service activity that might compromise confidentiality, objectivity and impartiality in the area of proceedings for issue of EC-Type Examination certificates and in the surveillance area of category III PPE.

1.3.2 The independence, impartiality and competence (intended as adequacy of resources) of Centrocot 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 interests predominating.

1.4 PERSONNEL

1.4.1 Centrocot warrants the suitability and professional qualifications of the personnel engaged in Surveillance activities and the issue of EC-Type Certificates and Surveillance for category III PPE and keeps up-to-date information concerning the qualification, training, experience and development of all parties involved for the purposes of documenting that the requirements foreseen in standards UNI CEI EN ISO/IEC and UNI CEI EN ISO/IEC 17021.

1.5 EQUIPMENT

1.5.1 Centrocot has laboratories and equipment suited to performing the tests foreseen from the Directive and/or the harmonised standard. The laboratory is accredited by ACCREDIA (accreditation no. 0033) according to the requirements of the standard UNI CEI EN ISO/IEC 17025. Accreditation attests 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 Centrocot has the faculty of entrusting test execution to external Bodies only when necessary equipment and competences are temporally not available. In such cases, the performed tests are to be considered as not accredited.

1.6.2 Centrocot may entrusts not accredited test execution to external Notified Bodies and/or to accredited Laboratories that have signed the Multi-Lateral Mutual Recognition Arrangements (EA, IAF, ILAC), subject to prior evaluation of their adequateness on the basis of provided documents or through audits 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 together with the offer or, if it would not be possible, later. The Customer has the right not to accept the proposed external body by means of written notification.

1.6.4 Centrocot, in any case, assumes and maintains towards the Customer the total responsibility concerning the 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 EC-type examination certificates.

1.7 CE MARKING

1.7.1 The Customer has the right to affix CE Marking on PPE object of EC-Type examination certificate, and, for category III PPE, the number of Notified Body appointed by the Customer to perform surveillance activities as set forth under art 11 (part A and part B) of the Directive. The graphics and minimum dimensions of the marking must be compliant with what is laid down in attachment IV of Directive and in Directive EEC 93/68.

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 of, 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 EC-Type Certificate with the sample subject to certification pertains exclusively to the Customer, as Centrocot assumes no liability and/or obligation in 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, EC-Type examination certificate and observations resulting from these.

1.8.3 The Customer takes due note and acknowledges that Centrocot is under no information obligations towards the Costumer concerning any amendments to current regulation.

1.9 LIABILITIES OF THE CUSTOMER 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 in 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 represents and warrants that all the information, texts, graphics, data, news, images and so on, are not contrary to legal 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, except for authorization in writing by Centrocot.

1.9.5 Without prejudice to the duties set forth under foregoing points, the Customer in all events relieves Centrocot from all liability, 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 indicated above, and is to meet any injury that might be done towards Centrocot.

1.9.6 It is responsibility of the Committee to maintain a copy of previous claims concerning the PPE object of the EC-Type Certification 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 definition of the contract.

1.10 CLAIMS AND RECOURSE (under the reference standard UNI EN CEI ISO/IEC 17065)

1.10.1 The Customer may make complaints in written form towards Centrocot in case he considers that the quality of the offered certification service and/or of the Surveillance for the Third Category PPE does not correspond to what stated in this Regulation. Centrocot shall inform the customer about the recourse receipt within 7 days, declaring the commitment to verify the problem and to give clear and exhaustive answers in written within 30 days.

1.10.2 In case Customer believes that Centrocot did not adequately replied to the claim can make appeals. Recourses must be submitted to the Director 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 fully or properly assessed.

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

1.10.4 Recourses are evaluated by the Director of Certification Body as third independent party. The Director of Certification Body in performing 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 CONCERN

1.12.1 This Regulation is subject to the laws of Italy.

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

2 EC TYPE CERTIFICATION

2.1 CERTIFICATION REQUEST

2.1.1 A Customer intending to obtain EC-type examination certificate must submit the Application or an Offer Request with the details of the PPE for which the certification is requested, the relative harmonised standards or the risk type.

2.1.2 Centrocot examines the Application or offer request with the right of, where necessary, demand integrative information.

2.1.3 At the outcome, Centrocot sends the Offer based on the current tariffs to the Customer, in which they indicates types and number of samples that have to be sent for testing.

2.1.4 The tariffs applied for the issue of the EC-type Certificates and for test executions are indicated 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 tariffs is subject to the supervision of the Committee for Safeguarding Impartiality.

2.1.5 Where the Customer intends entrust Centrocot shall send the following documentation:

- Offer signed for acceptance;
- Application for certification (if it has not been sent yet);
- Technical file;
- Instruction for use;
- Number of samples as indicated in the Offer, including other samples for an eventual retesting (if applicable).

2.1.6 In the Application there has to be indicated, among other, the Customer details, the PPE description for which the certification is requested, the relative harmonised standards or type of risk and PPE category

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

2.1.8 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 the EC-Type Certificate.

2.1.9 The Documentation may be sent by e-mail.

2.1.10 Upon a positive outcome of the assessment concerning the documentation received in terms of appropriateness and adequacy, Centrocot will set in motion the procedures for the issue of EC-type examination certificate.

2.2 CERTIFICATION PROCEDURE

2.2.1 Centrocot examines the documentation listed in 2.1.5 verifying the conformity of this with harmonised standards or with the essential requirements of the Directive.

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 Costumer, sending the related test reports.

2.2.3 Following positive outcome of laboratory tests performed on the samples delivered, Centrocot shall issue the EC-type examination certificate. If the tests have an unfavourable outcome, notification is to be given to the Customer who will implement the necessary modifications and send again 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 the prosecution of the certification activity.

2.2.4 The decisions and the resolutions in the matter of issue of the EC-type examination certificate are to be taken by the Technical and Resolving Function set up by Centrocot.

2.2.5 EC-Type examination certificates are to be signed by Centrocot General Manager as Director of Certification 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 DECLARATION OF CONFORMITY

2.3.1 Once the EC-type examination certificate has been obtained, it rests upon the Customer to attest the conformity of the PPE subjected to EC-Type examination Certification and the provisions of the Directive, by means of the EC Declaration of Conformity as foreseen in Annex VI of the Directive. The Declaration of Conformity shall referred to EC-type examination certificate issued.

2.4 DURATION AND CONDITIONS OF CERTIFICATION VALIDITY

2.4.1 The EC-Type Examination Certificate is valid for 5 years with effect from the date of issue. At expiry date will be no longer valid.

2.4.2 The EC-Type Examination Certificate will be no longer valid also in the case of substantial modifications of the Directive and/or harmonised standards on which the released EC- Type Certificate was based.

2.4.3 In both cases, the Customer is entitled to present to Centrocot an Application for issue the renewal.

2.4.4 The EC-Type Examination Certificate is nominative and can be utilized exclusively by the customer whose nominative results on the EC-Type Certification itself. The EC-Type Certification cannot be subjected to transfer to third parties for any reason. In the case of cessation of business activity of the Customer and if the Customer is subject to bankruptcy procedures, the EC-Type Certificate loses effectiveness, as well as any EC-Type Certificates subjected to extension for reasons of the following point 2.6.

2.4.5 The EC-Type Certificate is no longer valid if the Costumer makes variations of the PPE subjected to the EC-Type certificate without having previously sent an application to Centrocot following the criteria indicated in the subsequent paragraph 2.5.

2.5 VARIATIONS

2.5.1 The Customer declares and acknowledges that every EC-type examination certificate is referred only to the PPE subject of the application form and exclusively to this.

2.5.2 If the Customer wants to make changes to the PPE subjected to EC-Type Certificate, it has to send to Centrocot the Application indicating the nature of the variations.

2.5.3 Centrocot performs an appropriate evaluation, and at the outcome communicated to the Costumer if the variations of the PPE object of the EC-Type Certificate are admissible and can be object of revised EC-Type Certificate or if the modified PPE shall be object of a new EC-Type Certificate.

2.5.4 The revised EC-Type Certificate maintains the duration and validity of the original EC-Type Certificate and indicates the date in which the revision was performed.

2.6 EXTENSIONS

2.6.1 If the Customer wants to extend the EC-Type 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 will have to request an extension to Centrocot, sending the Extension Application subscribed by both the Customer and the 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 the EC-Type Certificate for extension, the Distributor/Importer can introduce on market the PPE subjected to the EC-Type examination Certificate of the Customer using his own company name and logo.

2.6.2 The EC-Type Certificate for extension can be issued by Centrocot only with reference to EC-Type Certificates issued by Centrocot.

2.6.3 The EC-Type Certificates for extension are identified by a new number vis-à-vis the other EC-Type Certificated to which they are referred to but they maintain the same expiry date.

2.6.4 If the EC-Type Certificate for extension is issued, the Customer has to:

- Maintain the EC-Type Certificate in validity and give evidence to the Surveillance according to art. 11A or 11B Directive 89/686/EEC in case of category III PPE;
- Provide the distributor PPE physically identical and totally conform to that object of the EC-Type Certificate;
- Inform the Distributor of all the facts and circumstances that can affect the validity of the EC-Type Certificate or, for the category III PPE, the control of Surveillance according to art. 11A or 11B Directive 89/686/EEC

- Send to Centrocot and the Distributor any proposal for amendment of the PPE.
- Inform the Distributor of any problem related to the PPE subjected to the EC-Type examination Certificate.

2.6.5 If it has been issued the EC-Type Certificate for extension, the Distributor/Importer has to:
- Subscribe a Declaration of Conformity according to the Annex VI of the Directive 89/686/EEC before placing the PPE in the market;
- Place in the market a PPE identical to those subjected to the EC-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 the PPE object of the EC-Type examination Certificate.

2.6.6 Along with the application for Extension all the documents referring to the original Technical Documentation have to be presented (marking and instructions for use); such documents have to be available for the Distributor and they constitute the basis to confirm the compliance of the PPE subjected to the EC-Type examination Certificate with the requirements of the Directive. Such documents have to be preserved by the Distributor for the following 10 years from the date of the last placing in the market of the PPE subjected to the EC-Type examination Certificate.

2.6.7 For the category III PPE subjected to the EC-Type examination Certificate, the Notified Body charged by the Costumer for the Surveillance according to the Art. 11 of the Directive 89/686/EEC is entitled to carry out a Surveillance also at the headquarter of the Distributor.

2.6.8 The EC-Type Certificate for extension identifies the Distributor as the Customer and reports the PPE identification as the one used by the Distributor. The EC-Type Certificate for extension is labelled as "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 EC-Type Certificate for extension will lose its validity and effectiveness if, for any reason, the EC-Type Certificate to which it refers becomes invalid or ineffective.

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

2.7 SUSPENSION AND REVOKING OF THE CERTIFICATION

2.7.1 The use of the EC-Type Certificate is considered improper whenever it is used or advertised:
- in a way that might lead to mislead the recipients of the information
  although not yet formally granted
- although revoked or suspended
- beyond its scope of applicability
- after the Customer has made variations to the PPE subjected to the EC-Type examination Certificate without respecting the prescriptions issued by Centrocot.

2.7.2 Centrocot may suspend the validity of the EC-Type examination certificate in case of:
- improper use by the Customer, in accordance with the provisions of the previous point 2.7.1.
- negative outcome of the Surveillance activity
- non-payment of invoices connected to tests, certification or surveillance activities.

If even one of the previous circumstances shall occur, Centrocot will invite the Customer in writing by registered letter with acknowledgement of receipt or by certified e-mail (PEC) (centrocot@certimprese.it), to remedy the irregularities detected, and restore the certification.

The manufacturer has to implement the communicated actions and, if applicable, restore the compliance of PPE in stock and marketed.

The restore of certification, with the eventual reduction of application field, can be obtained only after Centrocot approval.

2.7.3 Centrocot may revoke the EC-Type examination certificate if the validity of effect of the EC-Type examination certificate has been suspended and the Customer has not dealt with eliminating the causes that have given rise to the order of suspension within the agreed time. In such case, Centrocot is to advise the Customer in writing with registered letter with acknowledgement of receipt about the revocation of the validity of the EC-Type examination certificate, specifying the grounds for the order. In the event of revocation of the EC-Type examination certificate, the Customer is not allowed to continue using the Certificate.

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

3 SURVEILLANCE OF CATEGORY III PPE

3.1 SURVEILLANCE APPLICATION

3.1.1 The Customer is compelled to submit the PPE subjected to the EC-Type examination Certificate of Third Category, at his choice, to one of the systems of control foreseen under art. 11 (part A for the control of finished product and part B for the control of the Quality System) of Directive 89/686/EEC.

3.1.2 The Notified Body for the control activities is identified by the Customer and can be different from the Notified Body that has released the EC-Type Certificate.

3.1.3 Therefore, it can choose to appoint the surveillance to Centrocot:

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

3.1.4 The Customer who requires the EC-Type Certificate for the category III PPE to Centrocot, has to specify along with the Application if he wants to assign the Surveillance to Centrocot.

3.1.5 In order to plan the Surveillance activities, the Customer, after the issue of the EC-Type Certificate, agrees to communicate to Centrocot the date of beginning of production and, in case, of ending or temporary suspension of it.

3.1.6 The Customer, who has obtained the EC-Type Certificate from another Notified Body and wants to appoint Centrocot for the Surveillance activity, has to apply with a Surveillance Application enclosing a copy of EC-Type Certificate and related documentation.

3.1.7 Centrocot is entitled to request to the Notified Body that has issued the EC-Type examination Certificate the information and clarifications required for the Surveillance activity of Category III Personal Protective Equipment: technical file, instruction for use, EC-Type Certificate, number of samples.

3.1.8 The entrustment for the Surveillance activity concerning Category III of Personal Protective Equipment is referred to the whole period of validity of the EC-Type Certificate. Centrocot or the Customer are entitled to recede giving not less than 3 months notice to be communicated by registered letter with acknowledgement of receipt or by certified e-mail (PEC) (centrocot@certimprese.it).

3.2 SURVEILLANCE ACTIVITY FOR CATEGORY THIRD PERSONAL PROTECTIVE EQUIPMENT

3.2.1 Following the receipt of the Application by the Customer, Centrocot sends to the Customer its Offer issued on the basis of the Tariffs in force. The applied tariffs for the surveillance activities as stated by Article 11 of Directive 89/686/EEC 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 tariffs is subject to the control of the Committee for Safeguarding Impartiality.

3.2.2 Simultaneously to the offer, Centrocot sends to the Customer a Visit Plan containing the plan for Surveillance.

3.2.3 Activities of PPE surveillance may be performed by Centrocot inspectors also accompanied by inspectors from ACCREDIA and/or Personnel from the Competent Authority. The Customer must allow access at all times to inspectors at their premises.

3.2.4 If the Costumer does not agree to the access, Centrocot will communicate it to the Competent Authority for the proceedings of the case.

3.2.5 The Surveillance activities for Category III Personal Protective Equipment are done periodically and annually giving at least 10 working days notice. Centrocot is entitled to make inspection visits without notice in cases deems it necessary.

3.3 CONTROL OF THE FINISHED PRODUCT

3.3.1 The control activity of the finished product contemplated in the art. 11 part A of the Directive 89/686/EEC includes two phases: the first one consists of an inspection at the site of final assembly or storage of the Customer as contemplated in the AUDIT PLAN OF THE FINISHED PRODUCT; the second one consists of the tests execution on taken samples as foreseen in the OFFER.

3.3.2 During the inspection shall be verified the availability and the completeness of the documentation; the contents coherence with what declared during the certification phase; a number of samples sufficient and representative shall be taken to verify the correspondence between the PPE withdrawn and the PPE object of the EC-Type Certificate. In such circumstance the Inspector in charge shall issue to the Customer the AUDIT REPORT SURVEILLANCE FOR FINISHED PRODUCT.

3.3.3 After the test execution on the taken samples, Centrocot shall issue to the Costumer the FINISHED PRODUCT SURVEILLANCE REPORT that specifies the conclusive outcome of the surveillance.

3.3.4 For the evaluation of the outcome, we refer to the following:

- **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 does not satisfy the requirements of the Directive or product standards; the non-maintenance of the requested documentation; non-authorized amendments concerning materials and design of PPE; amendment non consistent with what stated in the technical file in general).
- **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 EC-type Examination Certificate even satisfying the applicable requirements; difficulties in documentation traceability: use of non significant controls.

3.4 CONTROL OF QUALITY SYSTEM

3.4.1 The evaluation activity concerning quality assurance system of production process under art.11 part B of Directive 89/686/EEC includes the assessment of manufacturer quality system conducted by Centrocot to ascertain the adequacy and effectiveness in order to ensure that the PPE subjected to inspection are in compliance with the type described on the related EC Certificates.
The activity provided for the following procedure:

- An initial audit for approval of quality system
- Two following surveillance audits carried out on annual basis
- A renewal audit and two following surveillance audits carried out on annual basis

For the next three years shall cyclically repeated the renewal audit and two following surveillance audits on annual basis.
Without any evidence related to compliance and adequacy of third category PPE object of EC-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 in function of 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 product lines object of surveillance.

3.4.3 The Customer, during visits, shall made available to the Inspector the following documentation:

- information concerning PPE objects of the EC-Type Certificate, including, if necessary, the relative documentation;
- documentation concerning Quality System:
  - Management procedures and implementation guidelines;
  - Aims of the Quality System, Organisation charts, documents attesting authorities and responsibilities at least for first level employees;
  - Control plans and tests foreseen on PPE objects of the EC-Type Certificate produced and on raw materials and semi-finished products utilised to produce them;
  - Data related to test and calibration
  - Report containing qualifications of personnel involved.
  - Indicators of controls as to the effectiveness and efficiency of the Quality System;
- Undertaking to keeping the Quality System adequate and effective.

3.4.4 At the end of the audit, the Inspector releases the AUDIT REPORT QUALITY SYSTEM SURVEILLANCE, which specifies the outcome of the surveillance activity.

3.4.5 For the evaluation of the result, the following criteria shall be taken into account:

- **Critical nonconformity:** Nonconformity due to critical lacks in the Quality System thus 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 in terms of 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 does not have as a consequence the inability of the adopted practices to assure the maintenance of the level and of the protection scope required to the PPE (for example: superficial definition of causes concerning claims and nonconformities; insufficient independence of personnel entrusted to perform the internal audits; little attention paid to the correct management of system documentation to ensure that the related documents shall be at disposal of personnel entrusted; use of substantially appropriate practices but not fully satisfying instructions and procedures).

3.5 CLOSURE OF SURVEILLANCE

3.5.1 At the end of inspections of both finished product and Quality System:

- In the event of a positive outcome, Centrocot issues the Resolution and the SURVEILLANCE CERTIFICATE which is transmitted to the Costumer who can continues the marketing and/or sales of 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 evaluations, Centrocot shall issues the Resolution and the SURVEILLANCE CERTIFICATE.
  In case of negative evaluation, if Centrocot issued the EC Type Examination Certificate on which the Surveillance was carried, it would suspends/revokes such certificate, as in point 2.7; if another Notified Body has issued the EC Type Certificate on which Surveillance was carried, Centrocot would communicate to such body the outcome of Surveillance.

3.6 VALIDITY STATUS OF REGULATION

3.6.1 Centrocot shall ensure the conformity of this regulation towards legal requirements and operative aspects connected to certification activity, extension and surveillance, and if necessary, shall provide for its 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 form, extension and surveillance.
It is responsibilities of the customer to read and approve the regulation in validity status at the time of signature of application form, extension and surveillance.