PPE CERTIFICATION REGULATION

EUROPEAN INSPECTION AND CERTIFICATION CLIENT S.A.

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PERSONAL PROTECTIVE EQUIPMENT CERTIFICATION REGULATION

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5, 12	02	Changes in par. 1.6 & 1.7 and ANNEX A	02-12-2020

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0. INTRODUCTION

0.1 EUROCERT EUROPEAN INSPECTIONS AND CERTIFICATIONS CLIENT S.A., is a private client that is activated in a National, European and International level.

0.2 Eurocert, its affiliates and subsidiaries and their respective officers, employees or agents shall not provide any consultancy services. Eurocert is a type "A" inspection body as defined by ISO/IEC17065.

0.3 All product information acquired for Eurocert to assess the compliance of the personal protective equipment is treated as strictly confidential.

0.4 EUROCERT's independence is assured by its Constitution, its organisational structure and the Certification Committee's operation.

0.5 EUROCERT treats all clients in an equal manner and co-operates with them under the exclusive subject of good interpretation and application of the Standards and this regulation.

USED APPREVIATIONS

I.T. **:** Inspection Team
C.C.C. **:** Catalogue of Certified Clients
R.C.C. **:** Register of Certified Clients
EU **:** European Union
ESHR **:** Essential Safety and Health Requirements

ARTICLE 1 : SCOPE

1.1 This Regulation complies with the requirements of ISO/IEC 17065. This Regulation defines the responsibilities of manufacturers or their authorized representatives in EU hereafter called "clients" as well EUROCERT's rules and guidelines for the procedures concerning the inspection of pressure Equipment. All certificates issued are listed and notified to the Hellenic Ministry of Development.

1.2 This Regulation describes Eurocert's conditions and certification processes for inspection of personal protective equipment.

1.3 The Regulation defines client and Eurocert obligations, additional to the ones referenced in offers or certification agreements.

1.4 The clients are those who are responsible for designing, manufacturing personal protective equipment in order to be placed in the EU market.

1.5 This Regulation has been approved by EUROCERT's Managing Director and each amendment ought to be approved by him. Interested parties, at any time, may receive the latest version of this Regulation upon request.

1.6 In order for the personal protective equipment to be certified, the clients shall comply with this Regulation, Eurocert's inspection and audit procedures, ESYD guiding documents, 2016/425 Regulation and applicable standards.

1.7 Eurocert shall provide management system audits and inspection services to PPE as a Notified Body with recognition number 1128 (referenced in NANDO, official EU website for Notified Bodies). Eurocert's accreditation scope which describes the

standards and modules Eurocert is accredited for is included in the relevant annex to accreditation certificate No.3 and No.21, issued by ESYD (Hellenic Accreditation System) as it is valid each time. The latest version can be provided at any time upon request. A non signed non stamped copy is also available at www.esyd.gr

ARTICLE 2 : REFERENCES

1.1. ISO/IEC 17065 "Conformity assessment – Requirements for bodies certifying products, processes and services"
1.2. IAF/ILAC A4 «Guidance on the Application of ISO/IEC 17020»
1.3. EA-2/17: 2009 - EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes
1.4. M.D. F23/11267/547/09.01.15 "Decision authorization / notification of the Body by the Ministry of Development and Competitiveness"
1.5. Regulation 2016/425 for placing Personal Protective Equipment into the market
1.6. PPE Regulation Guidelines – 1st Edition, April 2018
1.7. Horizontal Recommendation for use sheets (RfUs) of the European Coordination of Notified Bodies in the field of Personal Protective Equipment (PPE) – April 2019
1.8. ΔΠ13.1
1.9. ΔΠ13.114

ARTICLE 3 : DEFINITIONS

3.1. All terms used in this Regulation are in line with EN 45020.

ARTICLE 4 : GENERAL REQUIREMENTS

4.1 All clients regardless of size or scope may submit an application to EUROCERT regarding inspection against one or more conformity modules as per PPE Regulation.
4.2 All applications are evaluated in line with Eurocert quality procedure ΔΠ6.1 and the Eurocert's PPE quality procedure ΔΠ13.114 as they are both valid at the time of application or inspection.
4.3 EUROCERT's Management and personnel (permanent staff and external associates) treat all client related information as highly confidential and accept the terms of Eurocert's Code of Ethics.
4.4 Clients ought to be aware that all documents that are issued by EUROCERT are Eurocert's property. Hence any full or part duplication or reproduction and distribution to third parties is prohibited without Eurocert's written consent.
4.5 Eurocert inspection documents including certificates shall state compliance of the examined Personal Protection Equipment to Regulation 2016/425 ESHR.
4.6 The standards used by the clients shall be referenced in the certificates issued unless they are not included in Eurocert's accreditation scope. In such a case, the certificates shall reference only compliance to the Directive.

ARTICLE 5: APPLICATION AND INSPECTION ACTIVITIES

5.1 Upon a Request for Quotation sent by a client, Eurocert will provide an offer with technical and financial terms. The signed and stamped by the client offer is a legal binding document in the place of an agreement. Upon acceptance of the offer, the client shall receive from Eurocert an application form to complete prior to any further assessment activities. The application form shall contain invoicing and identity information about the applicant and the manufacturer if the applicant is different as well as information about the product and the desired assessment module(s) subject to inspection.

5.2 The application ought to be dully filled in.

5.3 The conformity assessment procedure commences after receipt of the signed and stamped application form.

5.4 During the review of the application, EUROCERT's accreditation scope and notification status, where required, are considered. In case the applied standard is covered by notification but it is not mentioned in the official schedule issued by the accreditation body, then the standard is used as technical specification for checking the design of the product but not mentioned on the certificate.

5.5 After acceptance of the application form, the Inspection Team (IT) is appointed to handle the rest of the procedure steps. In the event the application is not accepted the interested client is informed in writing of the reasons it was rejected.

5.6 Eurocert has the overall responsibility to carry out the Notified Body services in accordance with this regulation given by the legal Hellenic authorities and by ESYD. This also includes the work carried out by the Local Eurocert Units.

5.7 Personnel engaged as auditors or technical experts shall fulfill the requirements as defined by Eurocert.

5.8 The manufacturer agrees to promptly supply to Eurocert, where duly justified, any relevant information, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

5.9 The manufacturer will further ensure that Eurocert and its employees and other acting on behalf of Eurocert will get all necessary work and access permits as well as access to relevant documents, required to perform their assessment tasks. The required days for audit will conform with Annex A.

5.10 The IT, consists of one, or more Inspectors, permanent or external associates that have been approved by EUROCERT's Board of Directors, based on the requirements defined in the International Standards and occasionally by technical expertise. The formation of the IT occurs in such a way that it is in a position to assess the special technical requirements or the personal protective equipment examined.

5.11 The technical experts may come from Public Organisations, Legal Parties of Public Right, Legal Parties of Private Right, Educational Institutions, Technological/ Research Centres, and Businesses etc.

5.12 When external associates are used, EUROCERT takes all proper measures to assure the objectivity, the integrity, and the confidentiality. In any case, the interested client has the right to ask for the replacement of a member of the IT.

5.13 The IT acts according to quality procedure ΔΠ13.114 (non disclosed document for use by EUROCERT IT and staff only).

5.14 In cases where sampling is required, the received samples are sealed and marked

and are forwarded to the appropriate laboratories on applicant's costs. In the case sampling is executed in an uninformed inspection mode, then the frequency of the sampling is annual and the required quantity is taken per product type selected from those ready to be dispatched.

5.15 In cases where testing is required, these are performed by accredited laboratories (members of ILAC) approved by EUROCERT and according to instructions designated by the relevant manufacturing standards for the acceptance criteria. The manufacturing standards designate the inspection method as well as the evaluation method of the findings.

5.16 The laboratories selected by the client must be evaluated by EUROCERT and shall be accredited. The client shall specify to the lab the requirements of the relevant standards. The number of test specimens is decided according to the test requirements of the applicable standard. The test specimens are chosen randomly from the production line.

5.17 When the audit report is prepared a closing, meeting takes place with the company's members and management where the lead auditor presents the audit report and the findings to the company. The participants during the closing meeting are also included in the audit report. The lifting of the findings may require onsite visit or extra testing, depending on their nature.

5.18 The relevant manager, on the basis of the inspection results and the outcomes of the laboratory tests and after verification of the corrective actions examines if the personal protective equipment conforms to the requirements of this Regulation, the corresponding reference standards and the relevant procedures and decides accordingly upon the issue or not of the certificate.

5.19 The client shall a) keep a record of all complaints made known to the supplier relating to a product's compliance with requirements of the relevant standard and to make these records available to EUROCERT when requested, b) take appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification, c) document the actions taken.

5.20 EUROCERT reserves the right to reissue a revised inspection report or certificate where mistakes have been spotted after the report or certificate has already been issued and sent to the client for further submission to the competent authority.

5.21 Certification shall be refused if the product or the quality system is found not to comply with PPE Regulation.

5.22 Eurocert shall communicate refusal of certification to the applicant in writing. Information regarding the appeal procedures shall be provided upon request.

5.23 Eurocert shall make relevant information regarding the certification's refusal available to other PPE Notified bodies and the appropriate national authorities.

5.24 EUROCERT shall not disclose, to any third party, any documents and information related to inspection cases without a written consent by the client. All informations are treated as confidential. In the event that a competent authority requests information, the client is informed prior to any information is disclosed. ESYD within the frame of the accreditation of EUROCERT, like any other competent body of accreditation and only in this case, as governed by a code of ethics for the protection

of client's privacy, may have access to client case files. No other information other than those listed above is permitted to be treated as information with shared access.

5.25 Eurocert will publish all certificates listing product scope and relevant manufacturers on the Eurocert's website www.eurocert.gr (CQC - Certification Quick Check)

ARTICLE 6: MAINTAINING THE CERTIFICATE

6.1. The manufacturer must at all times ensure that the requirements of the standards under the certification scope are complied with and undergo all Eurocert's scheduled assessment activities and visits. Corrective actions to identified findings must be implemented within the set time limits.

6.2. Eurocert is authorized by the manufacturer to pay unannounced visits to manufacturer's premises when foreseen by the directive or due to reasonably substantiated doubts regarding the compliance of the product or the appropriate function of the approved quality system. The fees as stipulated in the accepted offer must be paid following the conditions for payment stated therein.

6.3. The manufacturer is also obliged to keep a record of all complaints concerning the products under the certification scope with regard to the standard requirements. Eurocert will verify that the manufacturer has taken relevant corrective actions for these complaints in conjunction with the surveillance visits.

6.4. Eurocert shall assess the products subject to certification to the valid versions of the standards under the certification scope. The manufacturer is therefore obliged to keep the standards updated.

6.5. Clients shall report to Eurocert, within a reasonable time and preferably before execution of such change, all changes in the product design and/or production (hereunder changes in the organization, ownership, new products, modifications to the factory and services, location etc.), which may reasonably be considered to have an effect of the Certificate(s).

6.6. The manufacturer is required to have informed Eurocert of any changes to the products and/or modifications to the quality system under which the products are fabricated if relevant. Failure to do so, deems the issued certificate non valid and special assessment shall have to take place prior to a valid certificate is issued again.

ARTICLE 7 : RE-INSPECTION AND RENEWAL OF CERTIFICATE

7.1 The frequency of the re-inspections is stated on the certificate.

7.2 The re-inspection requires an onsite visit. The re-inspection requirements are defined in Eurocert's quality procedure ΔΠ13.114.

7.3 The steps included in article 5 of this Regulation are repeated.

ARTICLE 8: EXTENSION/ SUSPENSION/ WITHDRAWAL/ REDUCTION OF SCOPE OF CERTIFICATION

8.1 **Extension to Scope**

The client must submit a new application or a letter for extension to scope and

revised relevant documentation

The relevant Manager, shall appoint the IT to assess the client request. The extension to scope may take place at the time the client is prepared for or be combined with the annual surveillance inspection or recertification inspection, providing this will is agreed by the client.

Following steps of Article 5 of this Regulation with an additional offer sent (if required), a revised certificate is eventually issued.

8.2 **Suspension/ Withdrawal/ Reduction of Scope**

Eurocert reserves the right to withdraw or suspend the certificate if at the time when the certificate was issued:

- The client is systematically unable to follow the requirements of the design standard and this regulation
- The client denies the conduction of the inspection for the interval which is determined by EUROCERT
- The client has asked for the interruption of the Certification. The manufacturer may cancel the certificate at any time, provided that Eurocert receives a written notice at least 30 days before the desired cancellation date authorizing Eurocert to invoice all activities up to that date.
- Eurocert shall make relevant information regarding the certification it has withdrawn available to the other NB's and the appropriate national authorities
- The requirements as set out in the Directive on which the conformity assessment procedure has been based and which form the basis for issuing the certificate or the appendix were not fulfilled, or
- The product was incorrectly defined as personal protective equipment according to the Regulation.
- The product which has been subject to the conformity assessment procedure has been modified without prior notification to Eurocert, or
- The requirements for the quality system or the personal protective equipment are no longer fulfilled, or
- The product is no longer covered by the Regulation, or
- The personal protective equipment is no longer in compliance with the Regulation, and the shortcomings observed are not corrected by the manufacturer within an appropriate time period as defined by Eurocert under consideration of the sereneness and potential impacts of these shortcomings.

Eurocert shall communicate withdrawal of certification to the applicant in writing. Information regarding the appeal procedures are available upon request.

In this case, a time interval of not than more six months is given to the client to comply with the requirements of the reference standard and this Regulation.

If at least one of the above still holds and the client is unable to resolve the problem, then EUROCERT may ask for the withdrawal of the client's certificate or the reduction of its certification scope.

For all the above the Client must be informed in writing as well as the relevant Directories of the Ministry of Development.

ARTICLE 9: COMPLAINS - APPEALS

9.1 The client may raise a complaint or appeal against decisions of EUROCERT, writing within thirty days from the notification to it.

9.2 COMPLAINS

9.2.1 All complaints raised by the client with regard to the Eurocert certification activities shall be handled according to Eurocert's internal procedures. An acknowledgement of received complaint will be sent without delay.

9.2.2 Any of Eurocert's staff may receive a complaint of any kind or nature, from a client or other interested party. It is required that the form ΔΠ18.1/Ε01 is completed, attaching the related letter or FAX of the client and forwards them to the Quality Manager.

9.2.3 The Quality Manager, together with the relevant Director, reviews the complaint and determines, if required to do so, the corrective actions. Eurocert's quality procedure ΔΠ19.3 is applicable.

9.2.4 The person(s) to whom the complaint is raised shall not take part in the evaluation of the complaint.

9.2.5 If the complaint, after the investigation process, is decided to be justifiable, a copy of the form ΔΠ18.1/ Ε01 is also forwarded to the Managing Director. The Quality Manager also informs the department Director involved in the matter. Eurocert executes all necessary actions at its own cost in order to make any corrections and satisfy the complainant.

9.2.6 If the complaint, after the investigation process, is decided to be not justifiable, then the client is informed by the Quality Manager accordingly in the form of a letter or email. In this case and if the complainant is not satisfied with the response, he has the ability to appeal the decision of the Body in accordance with the provisions of paragraph 9.3 hereof.

9.3 APPEALS

9.3.1 When there is an appeal against decisions of EUROCERT, Managing Director complete the form ΔΠ18.1 / Ε01, attaching and the relevant FAX or letter of the client in any written form has been filed (paper or electronic).

9.3.2 In order the CB to be received and examined, the application must have submitted within one month of notification of the decision to the person concerned.

9.3.3 Managing Director after consultation with the Director related to the issue, will examine and accept or reject the appeal.

9.3.4 If the appeal is accepted, the client amends its decision and inform the client in writing. At the same time Managing Director informs the Board and directly apply

corrective action to remedy the problem and the non reappearance of this, based on procedure ΔΠ19.3. The effectiveness of the corrective action verified by the Managing Director himself. In this case all corrective actions to be taken will be charged financially the Certification Body.

9.3.5 If the appeal is rejected, the applicant shall be notified and the decision is .fully justified

9.3.6 The decision on the acceptance or not of the appeal must be issued within three months of its submission, unless the applicable Community or national legislation or the competent authority imposes different.

9.3.7 The applicant and EUROCERT have the right to appeal if not satisfied in a Court of Arbitration in accordance with the provisions of the Civil Procedure Code..

ARTICLE 10 : FINANCIAL TERMS

10.1 Before the certificate is send to the client, the client ought to have paid the entire fee as agreed on the accepted offer.

10.2 Failure of the client to respect and follow the financial terms accepted at the stage of the offer may deem the certificate non valid.

For the acceptance of the rules & guidelines please sign below:

Date of acceptance: _____

For the company (name, signature & stamp):

ANNEX A

The required audit man-days are calculated by taking into account the PPE Regulation Guidelines and the Horizontal Recommendation for use sheets (RfUs) of the European Coordination of Notified Bodies in the field of Personal Protective Equipment (PPE).