CP UKCA PPE 01 00

UKCA PPE CERTIFICATION RULES
Regolamento 2016/425

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Revisione	**Data**	**Redazione**	**Verifica**	**Approvazione**

INDICE / INDEX

DESCRIZIONE DELLE REVISIONI / DESCRIPTION OF THE REVISION

Data	Revisione Revision	Punti modificati Points changed	Descrizione modifica Description of the change
23/10/2021	00	--	Prima emissione / First emission

1) INTRODUCTION

This Regulation defines the modalities by which Eurofins E&E CML Limited (hereinafter Eurofins) evaluates the conformity of the personnel protective equipment (hereinafter PPE) to the essential requirements of the Regulations 2016/425.

With reference to the list of types of PPE of the Regulations 2016/425, Eurofins is recognized as an Approved Body for the following types of PPE:

- ear protector;
- respiratory protector.

Regulation 2016/425 lays down requirements for the design and manufacture of personal protective equipment (PPE) which is to be made available on the market, in order to ensure protection of the health and safety of users and establish rules on the free movement of PPE in the Union.
The "UKCA marking" means a marking by which the manufacturer* indicates that PPE is in conformity with the applicable requirements set out in Union legislation or technical specifications.
The Regulation lays down three PPE categories (according to Annex I of the Regulation) for which different conformity assessment procedures are applicable:

Category I: The manufacturer shall establish the technical documentation (according to Annex III of the Regulation), manufacturer´s information (according to Annex II, section 1.4 of the Regulation and the specifications on each applicable Standard), marking (according to each applicable Standard) and the affixing of the CE marking, according to the rules and conditions set out in Article 17 of the Regulation without the intervention of an Approved Body (Self-certification). Furthermore, the manufacturer shall draw up a written UK declaration of conformity for its PPE according to the requirements set out in Annex IX of the Regulation.

Category II: The manufacturer shall affix the UKCA marking after the UKCA type examination (Module B) according to Annex V followed by the assessment of the conformity to type based on internal production control (Module C) according to Annex VI, and including the technical documentation, manufacturer´s information, marking or labelling and the UK declaration of conformity (as in Category I) and issuing the UKCA type-examination certificate.

Category III: After the UKCA type-examination certification (Module B) is completed, an annual verification of the production is carried out by the Approved Body. The manufacturer shall choose the procedure for the annual verification of the production: sampling (module C2) or audit (module D) of the quality management system. Then the manufacturer affixes the UKCA marking followed by the number of the Notified Body that carried out the production control.

2) DEFINITIONS

Protective Personal Equipment (PPE): 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.
The interchangeable components for the equipment above referred to which are essential for its protective function. The connexion systems for equipment above referred to 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.

Manufacturer: Means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark;

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.

Importer: Any natural or legal person established at United Kingdom who places PPE from a third country.

Distributor: Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market.

Economic operators: means the manufacturer, the authorised representative, the importer and the distributor.

Conformity assessment: means the process demonstrating whether the essential health and safety requirements of this Regulation relating to PPE have been fulfilled.

3) STANDARD

The certification activities specified are carried out to assess the conformity of products with the requirements set out in Annex I of the Regulation 2016/425.
The conformity of products to the harmonized standards presupposes conformity to the requirements defined in the Regulation.
The list of reference standards is periodically updated within Eurofins and brought to the attention of all personnel involved in the assessment activities.
In the absence of specific harmonized standards, technical standards issued or being issued by international or national standardization bodies are assumed.

4) OBLIGATION OF THE PARTIES
4.1) Obligations of the certification body

4.1.1) Management of impartiality
Eurofins companies has taken all the necessary measures in order to guarantee and assure impartiality of the personnel (either internal or external) related to the activities of conformity assessment of the certification process, avoiding that the commercial, financial or other pressures can comprise their impartiality.
Eurofins works in order to identify, eliminate or minimise risks to its impartiality on an ongoing basis, including those risks arising from its activities, from its relationships or from the relationships of its personnel. Furthermore, there is the top management commitment to impartiality and a code of ethics
The Eurofins personnel involved in the certification of products and the entities under its organizational control shall not:

a) be the designer, manufacturer, installer, distributer or maintainer of the certified product.
b) be the designer, implementer, operator or maintainer of the certified product.
c) be the designer, implementer, provider or maintainer of the certified service.
d) offer or provide consultancy to its clients.
e) offer to provide management system consultancy or internal auditing to its clients where certification scheme requires the evaluation of the client´s management system.

In the event that there are personnel who may compromise impartiality of a certification process, such personnel shall be excluded from the evaluation, revision or decision-making activities for an established period of 4 years from the date of the consulting service provision.

Eurofins shall reject any application for certification if quality management system consulting, including internal audits, has been provided by a company belonging to the Eurofins Group.

For each application, the client is requested to provide information about consulting services in order to assess if there is any reason why the impartiality of the evaluation may be compromised.
Impartiality is monitored by the "Committee for Safeguarding Impartiality" that meet at regular intervals and in an extraordinary way when requested by Eurofins or the Committee itself.
Manufacturers, users, authorities and experts are represented in the "Committee for Safeguarding Impartiality"

Eurofins may decline those certification applications in which exists conflict of interest and the impartiality may be compromised, explaining the client the reasons why it is rejected.

4.1.2) Non-discriminatory conditions
Eurofins shall provide the certification and conformity assessment services, without distinction, to any client regardless of the size of the company, membership of any association or group or number of certifications already issued.
Eurofins confines its requirements, evaluation, decision and surveillance to those matters specifically related to the scope of certification.
However, Eurofins can decline to accept a certification application from a client when fundamental or demonstrated reasons exist (such as the client participating in illegal activities, negative financial statement …).

4.1.3) Confidentiality
Eurofins is responsible for the confidentiality of its activities and shall treat all the information related to the application for certification as confidential and shall not communicate such information to third parties without the applicant´s explicit consent.
Except for information that the client makes publicly available, or when agreed between Eurofins and the client (e.g. for the purpose of responding to complaints), all other information is considered confidential. Eurofins shall inform the client, in advance, of the information it intends to place in the public domain.
Information about the client obtained from sources other than the client (e.g. from the complainant or from regulators) shall be treated as confidential.
The confidentiality principle is not applicable when, according to legal requirements, the information about certified products shall be communicated to the authorities. Eurofins, as Approved body, is responsible for communicating to the relevant authorities a list of the certified products and their manufacturers or of the suspension or withdrawing of the certificates previously issued.

4.1.4) Public information
Eurofins makes available upon request the following information:

- Information about the certification scheme, including evaluation procedures.
- The rules and procedures for grating, maintaining, for extending or reducing the scope of a certification.
- The rules and procedures for suspending, for withdrawing or for refusing certification.
- A description of the means by which Eurofins obtains financial support and of the fees applicable to the certification processes.
- A description of the rights and duties of applicants, including requirements, restrictions or limitations on the use of the Eurofins certification mark and on the ways of referring to the EU certification.

- Information about procedures for handling complaints and appeals.

4.1.5) Code of Ethics of Eurofins and Anti-Bribery Policy

The activities of Eurofins are carried out according to the code of ethics of the Company "Eurofins Code of Ethics" and the anti-bribery policy "Eurofins Anti-Bribery Policy". Both documents have been approved by the Group Operating Council and are part of the Eurofins Core Compliance Documents
The Company has an irregularity reporting point "Eurofins Whistleblowing Point of Contact" to enable the reporting of breaches of the code of ethics or the anti-bribery policy.

4.1.6) Operational obligations of the Approved Body
Where an Approved Body finds that the essential health and safety requirements or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.
Where, in the course of the monitoring of conformity following the issue of a certificate or approval decision, a certification body finds that a PPE no longer complies; it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision if necessary.
Where corrective measures are not taken or do not have the required effect, the Certification body shall restrict, suspend or withdraw any certificates or approval decisions.
The Approved Body shall inform the clients about any change, modification or cessation of validity of the Standard(s) affecting their Certificate(s) issued by Eurofins based on each case, detailed information about the change(s) in a Standard(s) shall be send to the client, as well as how that/those change(s) affect their certificate(s) in order to adapt them so they are still compliant.

4.1.7) Information obligation
Approved bodies shall inform the notifying authority of the following:

- Any refusal, restriction, suspension or withdrawal of a certificate or approval decision
- Any circumstances affecting the scope of or conditions for notification
- Any request for information which they have received from market surveillance authorities regarding conformity assessment activities.
- On request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
- Approved bodies shall provide the other bodies approved with relevant information on issues relating to negative and, on request, positive conformity assessment results.

4.2) OBLIGATION OF MANUFACTURERS

When placing a PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Regulation - 2016/425.
Manufacturers shall draw up the technical documentation referred to in Annex III of the PPE Regulation and carry out the applicable conformity assessment or have it carried out.
Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated, manufacturers shall draw up the UK declaration of conformity and affix the UKCA marking on each PPE.
Manufacturers shall keep the technical documentation and the UK declaration of conformity for 10 years after the PPE has been placed on the market.
Manufacturers shall ensure that procedures are in place for series production to remain in conformity with the Regulation. Changes in the design or characteristics of the PPE and

changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.
When deemed appropriate with regard to the risks presented by a PPE, manufacturers shall carry out sample testing of PPE made available on the market and shall keep a register of complaints of non-conforming PPE.
Manufacturers shall ensure that the PPE which they place on the market bears a batch or serial number or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.
Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in Annex II of the Regulation in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.
The manufacturer shall draw up and provide the UK declaration of conformity with the PPE, according to Annex IX of the Regulation, or shall include in the instructions and information set out in Annex II of the Regulation the internet address at which the UK declaration of conformity can be accessed.
Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with the Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it.
Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details of the non-conformity and of any corrective measures taken.
Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, in a language which can be easily understood by that authority, necessary to demonstrate the conformity of the PPE with this Regulation.

4.2.1) Certification agreement
Eurofins shall draw up a document and give it out to the clients who request a conformity assessment for both to sign it, giving conformity to the rules and commitments that both are obliged to fulfil according the Regulation and the Standard ISO/IEC 17065.
The Certification Agreement contemplates the certification general rules and processes as well as the legal aspects of confidentiality, impartiality, non-discrimination and use of the UKCA marking.

5) CONFORMITY ASSESSMENT

Ahead of any certification process, the Certification Agreement shall be signed both by the client and Eurofins.
The client shall lodge an application filled in (choosing the one corresponding to the Module needed and a quotation shall be issued according to the corresponding fees.

Eurofins then plans the verification activity by identifying the inspectors for the execution of the verification.
The evaluator are chosen from those listed in specific lists for the different areas in which Eurofins can operate, on the basis of the list of qualifications, the proximity to the location of the manufacturer's production site, their availability and having verified their independence with respect to the activity in question.
Only personnel who have been approved by Eurofins and are on the list of technicians shall be used.
The client is notified of the composition of the audit team (if not already communicated at the time of acceptance of the assignment) as well as the audit plan, with a request to send it back

for acceptance. In this document is asked among other things if the customer has justified reasons such as to refuse the staff of the audit team.

5.1) UKCA Type-Examination (Module B)

UKCA type-examination is the verification of the design and documentation of a "prototype" or initial example of a PPE in order to confirm that it meets the "Basic requirement of health and safety" according to the regulation applicable. This process is based on the claims made on the product and it is achieved through a technical documentation according to Annex III of Regulation 2016/425 that includes 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, subassemblies 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
g. standards, the documentation shall specify the parts which have been applied;
h. 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;
i. 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;
j. 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;
k. 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;
l. a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
m. 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;
n. 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
o. process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

The manufacturer´s instructions and information shall include the information set out in Annex II section 1.4 of Regulation 2016/425 as well as the information requested by the applicable harmonised standards.
Eurofins shall carry out a preliminary evaluation in order to determine if the information provided is sufficient to issue a proposal of services or, if otherwise, more details shall be requested.
Based on the documents received and examined, Eurofins shall issue a proposal and send it to the client who shall confirm it by signature.

5.1.1) Application
The manufacturer shall lodge an application for UKCA type-examination that shall include:

- The name and address of the manufacturer and the authorised representative (if applicable).
- A written declaration that the same application has not been lodged with any other Approved body.
- The technical documentation described in Annex III of the Regulation.
- The specimen(s) of the PPE representative of the production envisaged. The Approved body may request further specimens if needed for carrying out the test programme.
- Along with the application, the client shall provide test reports in order to guarantee the conformity with the applicable requirements, as long as they meet the following requirements:
- The test requester shall appear on the test report. If it does not match the EU type examination applicant, the test report owner shall issue an authorisation letter/document allowing its usage. If otherwise, Eurofins shall not accept the test report.
- The test report submitted shall be accepted only if the issuing date does not exceed two years regarding the certification requesting date.
- The test shall be carried out by a laboratory accredited under ISO/IEC 17025 at the time the test is performed. The accreditation entity shall be signatory to the mutual recognition arrangement ILAC.
- If the laboratory does not belong to a Approved Body, the test report shall be submitted along a declaration of impartiality where it is stated that the laboratory has not participated in the design, manufacturing, maintenance, distribution or placing on the market of the tested samples.
- Test reports shall include the uncertainty of measurement of the laboratory. If the uncertainty of measurement is not specified, the uncertainty values shall be.
- Test reports shall have been performed using the method specified in each product Standard.
- In order to accept the test reports submitted by the manufacturer to comply with the Standard requirements, risks applicable and health and safety requirements, the test shall have been performed in the same conditions that the pre-treatment specified in the marking of the garment that it is being evaluated (e.g. washing temperature, drying method, Standard). The report submitted shall be accepted if the number of cycles used during the test is superior to the number the manufacturer will specify in its garments, but never when the number is inferior.
- When a Certificate of Innocuousness is submitted (Oeko-tex, Reach), it shall only be accepted if it is submitted along with the test report and only when the issuing date does not exceed a year regarding the certification requesting date.
- Test reports presenting any deviation regarding the Standard shall not be accepted.
- If the client does not submit any test report or the ones submitted are not sufficient to comply with the requirements, Eurofins will inform the client of the possibility of subcontracting the tests to a collaborator laboratory.

5.1.2) Application review

Eurofins shall review the information submitted in the application and, if appropriate, shall request tests, samples or additional information in order to complete the documentation. The applicant shall provide the documents necessary to allow a correct identification and description of the products, product families and, if appropriate, materials.

The object of the application review is to verify the integrity of the documentation and does not imply in any way that the content complies with the applicable requirements.

Where it is find that the documentation does not comply with the requirements concerning the application, the applicant shall be informed so it can be modified.

In the event that additional tests are needed, the test shall be carried out by a laboratory of the Eurofins Group or shall be subcontracted to a collaborator laboratory accredited under ISO/IEC 17025. The additional tests shall be budgeted and approved by the applicant. The applicant can submit test reports in case of dismissing the quotation.

5.1.3) Evaluation process
If the application is considered admissible, the documentation shall be evaluated by the evaluation technician who shall issue a technical report including, if appropriate, the deviations of the aspects evaluated. This report shall be sent to the client to solve all the critical points.
The applicant shall have 6 months to provide the necessary clarifications and corrections.
If after 6 months the corrections have not been received, the certification process shall be cancelled and it shall be necessary to fill in a new application, including the certification fees.
When the applicant answers to the remarks made, the application shall go to the review and decision process.

5.1.4) Review process
The person qualified to carry out the certification review shall compile all the information obtained in the application and during the evaluation process in order to present it to the decision committee.
The person who carries out the review shall not have participated in the evaluation process and can take part in the decision process.

5.1.5) Decision process
According to the internal procedure of the Approved Body concerning the decision making, the decision committee shall evaluate the PPE compliance with the Regulation and applicable Standard and shall approve for EU type-examination certificate to be issued when all the compulsory requirements are met.
If it is not possible to demonstrate the PPE compliance with the health and safety requirements, the decision committee shall present a proposal to refuse the EU type examination certificate and shall inform the applicant, giving reasons for its refusal.

5.2) Supervised product checks at random intervals (Module C2)

5.2.1) Application
The manufacturer shall lodge an application for supervised product checks at random intervals that shall include:

- The name and address of the manufacturer and the authorised representative (if applicable).
- A written declaration that the same application has not been lodged with any
- other Approved body.
- The identification of the PPE concerned.
- Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:
- The technical documentation described in Annex III of the Regulation.
- A copy of the UKCA type-examination certificate.

5.2.2) Application review
Eurofins shall review the information submitted in the application and, if appropriate, shall request additional information in order to complete the documentation. The applicant shall provide the documents necessary to allow a correct identification and description of the products, product families, materials and the size of the production batches.
The object of the application review is to verify the integrity of the documentation and does not imply in any way that the content complies with the applicable requirements.
During the application review, the Approved Body technician in charge of the evaluation shall select the sample size to carry out the control at the production site and the tests according to the health and safety requirements. The Approved Body shall send a quotation for the sampling

and tests to be performed which shall be carry out either inside the Eurofins Group or shall be subcontracted to a laboratory accredited under ISO/IEC 17025.
If the client modifies or cancels the inspection dates, once the transportation has been booked, cancellation fees shall be charged.
The Approved Body shall send the final quotation for the inspections and tests, which shall be approved by the client.

5.2.3) Product checks process
Product checks shall be carried out at least once a year at random intervals set by the Approved Body. The first product checks shall be carried out no more than one year after the date of issue of the UKCA type- examination certificate.
The Approved Body technician shall designate an inspector who shall carry out the sampling and shall agree with the client on the date(s) and site for the visit. All the items of PPE of the sample shall be examined and appropriate tests set out in the approved testing plan shall be carried out.

5.2.4) Evaluation process
The Approved Body shall issue a test report with the results of the product checks and related tests (which have been subcontracted to a laboratory accredited under ISO/IEC 17025) and shall be sent to the review and decision process.

5.2.5) Review process
The person qualified to carry out the certification review shall compile all the information obtained in the application and during the evaluation process in order to present it to the decision committee.
The person who carries out the review shall not have participated in the product checks or in the evaluation process and can take part in the decision process.

5.2.6) Decision process
According to the internal procedure of the Approved Body concerning the decision making, the decision committee shall evaluate the compliance with the requirements and shall notify its decision to the manufacturer when all the applicable requirements are met.
The Approved Body shall issue a test report to the manufacturer with the results of the product checks and related tests (which have been subcontracted to a laboratory accredited under ISO/IEC 17025). The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.
The manufacturer shall affix the Approved body´s identification number beside the UKCA marking on the label and on the manufacturer´s information of each item of PPE during the production.
If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the UKCA type-examination certificate or with the applicable essential health and safety requirements, the Approved body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.

5.3) quality assurance of the production process (Module D)
Conformity to type based on quality assurance of the production process (Module D) having a quality management system shall not exempt the client from the assessment, although the audit team may take it into consideration in order to focus the evaluation on the requirements concerning the PPE compliance with the Regulation requirements.
The quality systems shall be re-assessed at a recommended frequency of every third year.
Surveillance audits shall be carried out one per 12 months.
The additional requirements to ISO 9001 are specified in the document RfUs PPE-R 00.018 ver.2.

5.3.1) Application
The manufacturer shall lodge an application for assessment of his quality system with a

single Approved body of his choice. The application shall include:

- Name and address of the manufacturer and the authorised representative (if applicable).
- The address of the manufacturer's premises where the audits can be carried out.
- A written declaration that the same application has not been lodged with any other Approved body.
- The documentation concerning the quality system.
- Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:
- The technical documentation of the PPE described in Annex III of the Regulation.
- A copy of the EU type-examination certificate.

5.3.2) Documentation of the quality management system

The quality system documentation shall contain an adequate description of:

- The quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality.
- The corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used.
- The examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out.
- The quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.
- The means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3.3) Application review and audit planning

The Approved Body technician shall send an audit quotation which shall be approved by the client.
The Approved Body technician shall appoint the audit team which shall be formally communicated to the client.
The client can reject the audit team within a week of the communication. In the designation of the audit team shall be given all the necessary information to carry out the rejection.
If no communication is received within a week, the audit team shall be considered approved.
In the event of rejection, Eurofins shall propose a new audit team.
Once the audit team has been approved, the chief auditor shall send the audit plan to the client after the audit dates have been set.
The audit planning shall define the audit scope and the planning for executing it.
If the client modifies or cancels the audit dates, once the transportation has been booked, cancellation fees shall be charged.

5.3.4) Audit

The audit team shall be comprised by auditors qualified in quality management systems and shall have at least one member with experience of evaluation in the field of PPE and technology concerned, and knowledge of the applicable essential health and safety requirements.
The audit shall include an assessment visit to the manufacturer's premises. The audit team shall review the technical documentation of the PPE referred to verify the manufacturer's ability to identify the applicable essential health and safety requirements.
The manufacturer shall, for assessment purposes, allow the Approved body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- The quality management system documentation
- The quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.

- The audits shall be periodic, at least once a year and may be unexpected.

5.3.5) Evaluation process
The Approved Body shall draw up an audit report in which the deviations detected are classified as Major Nonconformity and Minor Nonconformity.
The manufacturer shall have one month to solve the Major Non-conformities and two months to solve the Minor Non-conformities, sending evidence of their rectification to the Approved Body.
The technician in charge of the evaluation shall draw up an audit report along with the actions taken in order to solve the deviations before the review and decision process.

5.3.6) Review process
The personnel taking part in the review process shall not have taken part in the audit or assessment process but may take part in the decision process.
If the audit conclusion is satisfactory, the non-conformities have been solved within the stipulated time, the evaluation technicians shall indicate it in the document "Review and decision making" thus the person who carries out the review process is able to know the final audit conclusion.
If the audit conclusion is unsatisfactory, the non-conformities have not been solved within the stipulated time, the evaluation technicians shall indicate it in the document "Review and decision making" thus the person who carries out the review process is able to know the reasons why the audit has not been satisfactory.
The personnel carrying out the review shall present all the information in the document "Review and decision making" to the decision committee.

5.3.7) Decision process
According to the internal procedure of the Approved Body concerning the decision making the decision committee shall evaluate the compliance with the requirements and shall notify its decision to the manufacturer when all the applicable requirements are met.
The notification shall contain the conclusions of the audit and the reasoned assessment decision.

The Approved body shall authorise the manufacturer to affix the Approved body's identification number to each individual item of PPE that is in conformity with the type described in the UKCA type-examination certificate and satisfies the applicable requirements of this Regulation.
The manufacturer shall affix the UKCA marking and, under the responsibility of the Approved body, the latter's identification number to each individual item of PPE that is in conformity with the type described in the UKCA type-examination certificate and satisfies the applicable requirements of this Regulation.
The manufacturer shall draw up a written UK declaration of conformity for each 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 UK declaration of conformity shall identify the PPE model for which it has been drawn up. The documentation mentioned in section 4.2.1 shall also be kept for 10 years.

6) UKCA MARKING

In most cases, the UKCA marking should be applied to the product itself or to the packaging. In some cases, it may be placed on the manuals or on other supporting literature. This will vary depending on the specific regulations that apply to the product.

The following general rules apply:
• UKCA markings must only be placed on a product by the manufacturer or authorised representative (where allowed for in the relevant legislation)
• The UKCA mark signifies conformity with the relevant UK legislation

• No marking or sign that may misconstrue the meaning or form of the UKCA mark should be used
• The UKCA mark cannot be placed on products unless there is a specific requirement to do so in the legislation Rules for using the UKCA image

You must make sure that:
• if you reduce or enlarge the size of your marking, the letters forming the UKCA marking must be in proportion to the version set out below
• the UKCA marking is at least 5mm in height – unless a different minimum dimension is specified in the relevant legislation
• the UKCA marking is easily visible, legible and from 1st January 2023 it must be permanently attached

7) REFUSALS AND COMPLAINTS
Certification is refused if the product or the quality system does not comply with the requirements of the directive. This refusal will be communicated in writing to the customer, with due justification and information.
If the Decision does not consider it possible to issue the certification, or to confirm the existing one, it will inform the customer.
The customer has the right to lodge appeals or written complaints.

8) CHANGES AFFECTING THE CERTIFICATION VALIDITY AND COMMUNICATION OF CHANGES
The manufacturer shall keep the Approved Body informed of any change that could jeopardise the conformity of the product with the health and safety requirements.
The Approved Body shall take additional actions and evaluate the compliance with the applicable risks, according to any of the evaluation modules:

1. The Approved Body has the right to, at any time and with immediate effect, restrict the initial certification scope, suspend its validity, declare it invalid or withdraw it if:
   a) The product placed on the market is no longer conformity with the approved type and/or poses a risk to the consumer or other end-user.

b) If any fault of the product or the system which subsequently arises as a result from the periodic inspections, market test or from other sources, is not amended by the certificate holder within a reasonable period of time.
c) The certificate holder cannot confirm that the products are being manufactured in accordance with the evaluated and or/ certificated items.
d) The certification is expired or has been cancelled.
e) The certificate holder does not allow the periodic supervision in accordance to the law, the regulations of accreditation or the European directives or regulations; or prevents or restricts its adequate execution.
f) The certificate holder refuses to carry out additional tests when there are modifications to the testing specifications and/or certification requirements.
g) The certificate or its copies have been changed and, thus, forged.
h) When Non-authorised or misleading advertising is being carried out employing the evaluation reports, certificates or prototypes marking.

2. The certificate expires when:
a) The period of validity specified on the certificate is expired.
b) The certificate holder rescinds the certification agreement, informing the Certification body by written notification.
c) The certificate holder files for bankruptcy or refuses an application for insolvency against him due to the lack of assets.

3. The certificate holder automatically loses the right to affix the UKCA marking and the number of the Approved Body that issued the certificate to any product affected by the restriction or withdrawal or that, as a result of the certification agreement completion, expires at a certain date or that has recently been declared invalid. If the certificate is declared invalid of expires, the original shall be returned to the Certification body.

4. The certification body shall publish the restrictions, suspensions, invalidations and withdrawal of certified products. In particular, when a non-conformity concerning the legislation, the name and address of the client as well as the non-conformity nature and the reason why the certificate has been declared invalid along with the product information shall be submitted to the competent authorities.

5. The client shall inform EUROFINS of any modifications of the design or of the technical documentation that may affect the conformity of the PPE at the earliest. When a certification is about to expire, the client shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date.

6. The client shall inform EUROFINS of any modifications of the Quality Management System that may affect the conformity of the PPE at the latest 3 months prior to the following audit.

7. Eurofins shall contact the manufacturer if there is any modification affecting the applicable legislation or standards in order that the client can take the appropriate actions to update the certification in order to ensure the conformity of the PPE with the new requirements.

9) SUSPENSION AND/OR REVOCATION OF CERTIFICATION

In the event of significant non-compliance, Eurofins has the authority to temporarily suspend a product certification.
Examples of such failures include the following:

- failure to implement appropriate corrective action for any non-conformities within the required timeframe;
- placing on the market of products that do not comply with the requirements covered by the certification;

- improper use of the mark and/or certificate of conformity;
- failure to inform Eurofins about substantial facts that may affect the requirements of the certified product.

In the event of suspension, Eurofins shall send official notification of suspension by registered letter or equivalent, also indicating the timeframe available for revoking the suspension.
In the event that a non-compliant product is found to have been placed on the market, the Customer shall be responsible for any corrective action resulting from this fact (withdrawal or adjustment of defective products already placed on the market, replacement of defective products with compliant ones) and any consequences that may arise (e.g. accidents due to their use).
When Eurofins verifies that the Customer has resolved the anomalies that motivated the suspension, the suspension shall be revoked and the Customer shall be approved of such revocation.
If the conditions that led to its suspension are not corrected within the term indicated in the suspension notification, Eurofins shall withdraw the certificate. The certificate may also be withdrawn without prior suspension in the event of serious irregularities.
The certificate is also withdrawn if the Client expresses in writing the intention not to maintain the certification.
The withdrawal of the certificate is officially approved to the client.

10) APPEAL AGAINST DECISIONS OF THE CERTIFICATION BODY

If the Manufacturer has cause to complain or appeal about the certification service received from the Company, they should write to the Managing Director at the Company's operating address. Details of the applicable complaint procedure, its resolution and escalation will be provided on receipt of any written complaint.
For all the appeals an acknowledgement of receipt shall be sent in order to inform if it has been allowed or not and a communication of the appeal resolution when it has been allowed and resolved.
In the event of the NON-concession of a certification, the client shall lodge an appeal within 30 days of the communication of the NON-concession.
Any appeal shall be treated by personnel in authority and who has not taken part in the evaluation, review and decisions made processes.