

**REGULATION
FOR THE EVALUATION OF THE COMPLIANCE OF
PERSONAL PROTECTIVE EQUIPMENT
IN ACCORDANCE WITH REGULATION (EU)
2016/425**

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1 PREAMBLE

- 1.1** A.N.C.I Servizi S.R.L a socio unico, CIMAC Laboratories division (hereinafter CIMAC) is a Notified Body for the assessment of Module B conformity to type and for the assessment of Module C2 and D conformity to type under EU Regulation 2016/425 of the European Parliament and Council of 09.03.2016, and is accredited by Accredia according to UNI CEI EN/ISO/IEC 17065 and applicable parts of UNI CEI EN/ISO/IEC 17021 for the following types of Personal Protective Equipment (hereinafter PPE):
- 1.1.1 foot and leg protection equipment;
 - 1.1.2 hand and arm protection equipment;
 - 1.1.3 respiratory protective equipment (anti-dust half masks with filter);
 - 1.1.4 equipment providing general body protection (clothing).
- 1.2** CIMAC is authorized by the Ministry of Enterprises and Made in Italy and by the Ministry of Labour and Social Policies to act as a Notified Body for the evaluation of the compliance aimed at issuing a CE certification of PPE as per point 1.1 in connection with the provisions of EU Regulation 2016/425.
- 1.3** CIMAC has a third-party liability insurance policy for its activities as Notified Body pursuant to the Ministerial Directive of 13 December 2017 - Authorization and notification requests from conformity assessment bodies.

2 PURPOSE AND SCOPE OF APPLICATION

- 2.1** This Regulation define the terms and conditions for the issuance by CIMAC, after appropriate assessment, of the certification of conformity aimed at granting and maintaining the CE marking of the PPE referred to in 1.1, for which CIMAC is authorized at the inter-ministerial level (hereinafter referred to as the Service).
- 2.2** The purpose of this Regulation is to regulate the relationship between CIMAC and customers who intend to obtain and maintain the EC certification (hereinafter the "Customer(s)"), identifying their respective obligations, describing the general procedure governing the tasks of CIMAC as Notified Body, in connection with the provisions of EU Regulation 2016/425 and in accordance with the applicable Harmonised Standards for the following conformity assessments:
- 2.2.1 EU Module B type-examination for Categories II and III PPE (Ann. V - EU Regulation 2016/425).
 - 2.2.2 Module C2 Conformity to type based on internal production control plus supervised product checks at random intervals for Category III PPE (Ann. VII - Regulation EU 2016/425).
 - 2.2.3 Module D Conformity to type based on quality assurance of the production process for Category III PPE (Ann. VIII - EU Regulation 2016/425).
- 2.3** CIMAC operates in such a way as to avoid any discrimination against Customers. CIMAC does not carry out consultancy or design and/or manufacturing activities in the PPE sector or any other design, production or service activity that could compromise confidentiality, objectivity and impartiality in the procedure for the issuance of the certification of conformity aimed at awarding and maintaining the EC certification of PPE.

Independence and impartiality are ensured by the Committee for the Safeguarding of Impartiality and Independence, a technical and impartial body, i.e. representative of all parties involved in the certification process.

- 2.4** The Service is accessible to all Customers, manufacturers, representatives, importers, distributors who request it, in compliance with this Regulation, without discrimination based on their size, their membership of associations or groups and without any conditions.
- 2.5** It is CIMAC's aim to issue certifications that are the result of an evaluation process carried out in a transparent, competent and impartial manner.
- 2.6** CIMAC may entrust the performance of tests to external laboratories accredited according to the UNI CEI EN ISO / IEC 17025 standard or qualified by CIMAC itself, retaining full responsibility in relation to the Customer, communicating this in the relevant offer to provide Services (hereinafter referred to as "Offer and Quotation") or, when this is not possible, subsequently. It is the Customer's right to request the name of the external facility and to not accept it, by sending written notice. CIMAC does not use external facilities for the conformity assessment and issuance process of EU Type-Examination Certificates, test reports and conformity to type certificates based on quality assurance of the production process.
- 2.7** For conformity assessments, CIMAC applies the current price list, ensuring its fairness and uniformity of application.

3 TERMS AND DEFINITIONS

- 3.1** The following definitions apply in this Regulation
- 3.1.1 Personal protective equipment (PPE):**
- a) equipment designed and manufactured to be worn or held by a person, to protect himself or herself against one or more risks to his or her health or safety;
 - b) interchangeable components of the equipment referred to in point (a), which are essential for its protective function;
 - c) connection systems for the equipment referred to in point (a), which are not held or worn by a person, and which are designed to connect such equipment to an external device or a secure anchorage point, not designed to be permanently connected and which do not require attachment before use.
- 3.1.2 Personal Protective Equipment of Category I:** Category I includes exclusively the following minimal risks:
- a) superficial mechanical injury;
 - b) contact with cleaning materials of weak action or prolonged contact with water;
 - c) contact with hot surfaces not exceeding 50 °C;
 - d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);
 - e) atmospheric conditions that are not of an extreme nature.
- 3.1.3 Personal Protective Equipment of Category III:** Category III includes exclusively the risks that may

<p>cause very serious consequences such as death or irreversible damage to health relating to the following:</p> <ul style="list-style-type: none"> a) substances and mixtures which are hazardous to health; b) atmospheres with oxygen deficiency; c) harmful biological agents; d) ionising radiation; e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C; f) low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less; g) falling from a height; h) electric shock and live working; i) drowning; j) cuts by hand-held chainsaws; k) high-pressure jets; l) bullet wounds or knife stabs; m) harmful noise. <p>3.1.4 Personal Protective Equipment of Category II: Category II includes risks other than those listed in Categories I and III.</p> <p>3.1.5 Making available on the market: the supply of PPE for distribution or use on the EU market as part of a commercial activity, whether in return for payment or free of charge.</p> <p>3.1.6 Placing on the market: the first making available of a PPE on the EU market.</p> <p>3.1.7 Manufacturer: any natural or legal person who manufactures a PPE or who has it designed or manufactured and markets it under its own name or trademark.</p> <p>3.1.8 Authorised representative: any natural or legal person established within the European Union who has received a written mandate from a manufacturer to act on its behalf in relation to specific activities.</p> <p>3.1.9 Importer: any natural or legal person established in the European Union who places PPE originating in a third country on the Union market.</p> <p>3.1.10 Distributor: any natural or legal person in the supply chain, other than the manufacturer or importer, who makes PPE available on the market.</p> <p>3.1.11 Economic operator: the manufacturer, the authorised representative, the importer and the distributor as defined above.</p> <p>3.1.12 Technical specification: a document that prescribes the technical requirements that the PPE must meet;</p> <p>3.1.13 Harmonised Standard: a standard according to §2, point 1, letter c) of EU Regulation 1025/2012. References to harmonised standards are periodically</p>	<p>published in the OJ in the framework of the application of the Regulation (EU) 2016/425.</p> <p>3.1.14 Accreditation: as defined in § 2, point 10 of Regulation (EC) No 765/2008; 31.3.2016 L 81/57 Official Journal of the European Union</p> <p>3.1.15 Notified Body: as defined in § 2 point 11 of Regulation (EC) No 765/2008.</p> <p>3.1.16 Conformity assessment: the process to demonstrate a PPE's conformity with the essential health and safety requirements.</p> <p>3.1.17 Conformity assessment body: a body that carries out conformity assessments, including calibration, testing, certifications and inspections.</p> <p>3.1.18 Consultancy: participation in the design, manufacture, maintenance or distribution of PPE that has been certified or that is to be subject to conformity assessment.</p> <p>3.1.19 Management system advice: participation in the design, implementation or maintenance of a management system. Examples: development or production of manuals or procedures and provision of specific advice, instructions or solutions for the development and implementation of a management system.</p> <p>3.1.20 Withdrawal: any measure aimed at preventing the making available on the market of PPE already present in the supply chain.</p> <p>3.1.21 CE marking: a marking by which the manufacturer declares that the product is in conformity with the safety requirements of the applicable Community directives or regulations and the applicable harmonised standards.</p> <p>3.1.22 EU Module B Type-Examination Certificate: document attesting to the conformity of a category II and III PPE to the health and safety requirements of the applicable harmonised standards published in the Official Journal of the European Union in accordance with Annex V of Regulation (EU) 2016/425.</p> <p>3.1.23 Module C2 Test report: document attesting to conformity to type of Category III PPE, based on internal production control plus supervised product checks at random intervals according to Annex VII to Regulation (EU) 2016/425.</p> <p>3.1.24 Module D Certificate: document attesting to the conformity to type of Category III PPE based on quality assurance of the production process under Annex VIII to Regulation (EU) 2016/425.</p> <p>3.1.25 "Inactive" certificate: status of an EU Module B Type Examination Certificate of a Category III PPE that does not allow the PPE to be placed or made available on the relevant market.</p> <p>3.1.26 Notifying authority: Ministry of Enterprises and Made in Italy and the Ministry of Labour and Social Policies.</p> <p>3.1.27 Technical file: documentation drawn up in accordance with the provisions of Annex III of Regulation (EU) 2016/425 which specifies the means used by the manufacturer to ensure the conformity of the PPE with</p>
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the applicable essential health and safety requirements.

3.1.28 **Decision Committee:** a body independent of the one that has carried out the documentary examination, testing or audit activity, which decides on the issuance of the EU Module B Type-Examination Certificate, the Module C2 Test Report and the Module D Certificate.

3.1.29 **Committee for safeguarding impartiality and independence:** a body appointed by CIMAC, composed of members appointed by bodies equitably representing the stakeholders (users, producers, oversight bodies), so as to ensure the impartiality of the conformity assessment body, without the predominance of individual interests.

3.1.30 **Non-conformity:** evidence gathered during the conformity assessment determined by the failure to meet the legislative and regulatory requirements (Module B) that generate significant doubts about the Customer's ability to provide type-compliant PPE and to ensure conformity to type of production (Module C2 and D).

3.1.31 **Remarks:** Evidence gathered during the conformity assessment, determined by the partial fulfilment of the regulatory and legislative requirements and which does not generate significant doubts about the Customer's ability to supply type-compliant PPE and to guarantee conformity to type of production (Module C2 and D).

3.1.32 **Manufacturer's instructions and information (user information):** a document containing all the information required by Annex II paragraph 1.4 of the Regulation (EU) 2016/425.

3.1.33 **Technical Sheet or Bill of Materials:** a document that contains all the information related to PPE materials, components and processes.

3.1.34 **Technical documentation:** documentation consisting of a technical file, Manufacturer's instructions and information (user information) and any attachments.

3.1.35 **Application form:** form filled in and signed by a representative of the Customer, which is required to initiate the conformity assessment process.

3.1.36 **Test Report:** document recording the analytical results of the tests - and the information necessary for the interpretation of the results - issued by CIMAC or provided by the Customer and accepted by CIMAC, at its sole discretion, if issued within 5 years prior to the application for certification, by laboratories accredited for the specific tests under the UNI CEI EN ISO /IEC 17025 standard.

4 CONFIDENTIALITY

Any information, material or documents exchanged between CIMAC and the Customer are considered strictly confidential, and in no case may they be disclosed to third parties unless expressly required by law, or otherwise provided for by law or by justified requests by the competent authorities and Accredia.

5 CONFORMITY ASSESSMENT PROCEDURE FOR THE PURPOSE OF ISSUING THE EU MODULE B TYPE-EXAMINATION CERTIFICATE

5.1 For the purpose of activating the Service, the Customer fills in the application form and send it to CIMAC.

5.2 CIMAC, after evaluating the information received and the possibility of providing the Service within the required deadlines, sends to the Client the Proposal and Quotation concerning the conformity assessment activity and, if necessary, the Proposal and Quotation relating to the testing activity with explicit sampling required to start the required activity. The acceptance of the Proposal and Quotation determines the activation of the Service.

5.3 By accepting the Offer and Quotation the Customer also declares to have read and accepted this Regulation, as transmitted to it and/or published on the website www.cimac.it.

5.4 Following acceptance of the Offer and Quotation, the Customer shall forward to CIMAC the requested duly marked samples, the technical documentation as provided for by Regulation (EU) 2016/425 and the applicable harmonised standards, and, if provided by the Customer, the test reports, within 6 months from the acceptance of the Offer and Quotation.

5.5 Upon receipt the technical documentation and/or the samples, CIMAC reserves the right to confirm or modify the Offer and Quotation and to request any additions to the Technical Documentation, based on the characteristics of the samples received, and will send to the Customer any revision of the Offer and Quotation for acceptance and consequent activation of the Service.

5.6 If the testing has been requested and/or is necessary, upon its completion the Customer will receive the Test Reports with the results of the tests performed.

5.7 If the testing is unsuccessful, CIMAC will require corrective actions, for which new samples shall be sent for testing. In this case, the Customer receives a new Offer and Quotation.

5.8 If the testing is successful, the conformity assessment may be carried out in accordance with the Offer and Quotation.

5.9 In the case of a new Customer, along with the Application Form and the Technical Documentation, the Customer shall also send to CIMAC the certificate issued by the competent Chamber of Commerce, Industry, Crafts and Agriculture (or similar authority in the case of a European customer not resident in Italy) stating that the company has been entered in the business registers and detailing the person who is the legal representative of the company, as well as the production/marketing/importing of the PPE, if not already included in the certificate issued by the Chamber of Commerce, Industry, Crafts and Agriculture, also sending a declaration stating, under its responsibility, that it is in the free exercise of its rights, not being in a state of liquidation, bankruptcy or arrangement with creditors.

5.10 For the purposes of the conformity assessment, CIMAC performs the documentary examination with the aim of assessing the Application, the Technical Documentation and

Test Reports, in order to meet the requirements of EU Regulation 2016/425.

- 5.11** If the documentary examination is negative, CIMAC informs the Customer of the Non-conformities. The Customer is required to reply within 60 working days of said communication. Beyond this deadline, the certification application is rejected and the Customer is not allowed to submit a new application for conformity assessment of the PPE in question. In the case of rejection, CIMAC communicates to the Customer the relevant reasons and informs the Notification Authorities, Accredia and the other Notified bodies, whose conformity assessment activities are similar and concern the same types of PPE.
- 5.12** After passing the documentary examination, the Technical Documentation and the related Test Reports are submitted to the Decision Committee for a decision.
- 5.13** If the review of the information and evaluation results and the certification decision (resolution) are positive, CIMAC issues the relevant EU type-examination certificate Module B, which is valid for no more than 5 years from the date of issuance.
- 5.14** If the review of the information and assessment results is negative, the procedure will be suspended while the issues are investigated. Once the issues are resolved, the application is submitted to the Decision Committee. If the certification decision (resolution) is negative, the certification application is rejected and the Customer can no longer submit a new conformity assessment application for the PPE subject to a negative decision. In the case of refusal, CIMAC communicates the reasons to the Customer and informs the Notification Authorities, Accredia and the other Notified Bodies, whose conformity assessment activities are similar and focus on the same types of PPE.
- 5.15** For PPE of Category II, following the issue of the EU type-examination certificate Module B, the Customer is authorised to place the PPE on the market after application of the procedure of conformity to type based on internal production control Module C (Annex VI of the Regulation (EU) 2016/425), affixing of the CE marking and issuing of the EU declaration of conformity.
- 5.16** For Category III PPE, the placing on the market is subject to one of the control activities provided for by art. 19 of Regulation (EU) 2016/425 and described in § 9 and § 10 of this Regulation. In the event of failure to apply the provisions of § 5.16, the EU Module B type examination certificate will remain valid for its five-year duration but will be registered as "Inactive" and, therefore, the Customer will not be able to make available and / or place the PPE on the market. The reactivation of the EU Module B type examination certificate can only take place following the application of the control activities described in § 9 and § 10 of this Regulation.
- 5.17** In the event of editorial errors and/or typos, the EU Module B Type-Examination Certificate will be reviewed and sent to the manufacturer as an attachment to an email with a delivery and read receipt notification. In the case of category III PPE for which a Module C2 or Module D assessment has already been performed, the Module C2 Test Report or the Module D Certificate will also be reviewed, and the EU Module B Type Examination Certificate will be updated accordingly. The review

of these documents does not alter the date of expiry indicated in the documents replaced.

6 EXTENSION OF THE EU MODULE B TYPE-EXAMINATION CERTIFICATE

- 6.1** When a holder of an EU Module B Type-Examination Certificate agrees to customise the PPE with an identification declaring another person as the Manufacturer, the EU Module B Type-Examination Certificate may be extended to another person (hereinafter the "Extension Service"). This new person, as a new Manufacturer, will place the PPE on the market under its own name and brand (OBL - own brand labelling - regime).
- 6.2** The extension service may be requested, subject to agreement between the Customer and the new Manufacturer if:
- the PPE has not been modified and its EU Module B Type-Examination Certificate is current.
 - the PPE has been modified and the test activity has been performed to verify its compliance.
- 6.3** The agreement between the Customer and the new Manufacturer shall include the following:
- without prejudice to the customisations agreed upon, a declaration that the PPE subject to extension is identical to the PPE already certified, including the number of the EU Module B Type-Examination Certificate and date of issuance;
 - declaration by the Customer that only the PPE that complies with the original Certificate will be supplied to the new Manufacturer, without prejudice to customisations;
 - declaration that the Customer undertakes to notify the new Manufacturer and CIMAC of any change that may affect the validity of the original Certificate;
 - declaration that the Customer undertakes to inform the new Manufacturer and CIMAC of any changes it intends to make to the PPE before proceeding with such change;
 - declaration that the Customer and the new Manufacturer will exchange information on any incidents involving the PPE covered by the agreement.
- 6.4** For the purpose of activating the Extension Service, the Customer and the new Manufacturer will fill in and sign the Application Form and send it to CIMAC.
- 6.5** CIMAC, after evaluating the information received and the possibility of providing the Extension Service within the required terms, sends an Offer and Quotation to the Customer (i.e. the new Manufacturer, who has become a Customer). The acceptance of the Offer and Quotation determines the activation of the Extension Service.
- 6.6** By accepting the Offer and Quotation the Customer also declares to have read and accepted this Regulation, as transmitted to it and/or published on the website www.cimac.it.
- 6.7** In the event from acceptance of the Offer and Quotation, the Customer forwards to CIMAC within 6 months from the acceptance of the Offer and Quotation:
- the technical documentation of the PPE;
 - a duly marked PPE sample as required by Regulation (EU) 2016/425 and the applicable harmonised standards.

- 6.8** The Offer and Quotation details the sampling necessary and any additions to the Technical Documentation in order to start the requested activity.
- 6.9** In the event that the new Manufacturer is also a new Customer for CIMAC, along with the provisions of paragraph 6.7 letters a), b), c), it shall also forward the certificate issued by the competent Chamber of Commerce, Industry, Crafts and Agriculture (or similar authority in the case of a European customer not resident in Italy) and a declaration in which the same declares, under its responsibility, to be in the free exercise of its rights, not being in a state of liquidation, bankruptcy or arrangement with creditors, as indicated in paragraph 5.9.
- 6.10** For the purposes of the conformity assessment, CIMAC carries out the documentary examination with the aim of assessing the Application Form, the Technical Documentation and the Test Reports, in order to meet the requirements of EU Regulation 2016/425.
- 6.11** After passing the documentary examination, the Technical Documentation and the related Test Reports are submitted to the Decision Committee for a decision.
- 6.12** In the case of a negative result of the documentary examination, CIMAC informs the Customer of the Non-conformities for the purpose of passing the documentary examination. The Customer is required to respond within the next 60 working days. Beyond this deadline, the certification procedure is cancelled and the Customer is not allowed to submit a new application for conformity assessment for the PPE in question. In the case of rejection, CIMAC communicates to the Customer the relevant reasons and informs the Notification Authorities, Accredia and the other Notified bodies, whose conformity assessment activities are similar and concern the same types of PPE.
- 6.13** If the review of the information and evaluation results and the certification decision (resolution) are positive, CIMAC issues the relevant EU type-examination certificate Module B, which is valid for no more than 5 years from the date of issuance.
- 6.14** If the review of the information and evaluation results is negative, the process will be suspended while the issues are investigated. Once the issues are resolved, the application is submitted to the Decision Committee. If the certification decision (resolution) is negative, the certification extension request is refused and the Customer is not allowed to submit a new application for conformity assessment for the same PPE subject to the negative decision. In the case of refusal, CIMAC shall inform the Customer of the reasons and inform the Notification Authorities ACCREDIA and the other Notified Bodies, whose conformity assessment activities are similar and focus on the same types of PPE.
- 6.15** For the PPE of Category II, following the issuance of the EU type-examination certificate Module B, the subject acting as a new Manufacturer is authorised to place the PPE on the market after application of the procedure of conformity to type based on internal production control Module C (Annex VI of the Regulation (EU) 2016/425), affixing of the CE marking and issuing of the EU declaration of conformity. For PPE of Category III, the placing on the market is subject to one of the control activities provided for by art. 19 of Regulation (EU) 2016/425.
- 6.16** In the event of editorial errors and/or typos, the EU Module B Type-Examination Certificate will be reviewed and sent to the

manufacturer as an attachment to an email with a delivery and read receipt notification. In the case of category III PPE for which a Module C2 or Module D assessment has already been performed, the Module C2 Test Report or the Module D Certificate will also be reviewed, and the EU Module B Type Examination Certificate will be updated accordingly. The review of these documents does not alter the date of expiry indicated in the documents replaced.

7 REVISION OF THE EU MODULE B TYPE-EXAMINATION CERTIFICATE

- 7.1** The EU Module B Type-Examination Certificate must be reviewed if the Customer communicates changes to an already certified PPE (hereinafter the "Revision Service") and/or to the technical documentation that are relevant to the essential health and safety requirements or change in the legal, organizational or ownership status of the Manufacturer.
- 7.2** For foot and leg PPE, a revision cannot be requested if the changes affect the sole, as such a change results in a new PPE model. In this case, the PPE must be submitted to the conformity assessment procedure for the purpose of issuing the EU Module B Type-Examination Certificate, as indicated in Chapter 5.
- 7.3** For the purpose of activating the Revision Service, the Customer fills in the application form.
- 7.4** CIMAC, after evaluating the information received and the possibility of providing the service within the required terms, sends to the Customer the Offer and Quotation concerning the conformity assessment, and, where necessary, the testing. The Offer and Quotation details the sampling necessary.
- 7.5** By accepting the Offer and Quotation the Customer also declares to have read and accepted this Regulation, as transmitted to it and/or published on the website www.cimac.it.
- 7.6** Following acceptance of the Offer and Quotation, the Customer forwards to CIMAC the Technical Documentation of the PPE and the duly marked required samples within 6 months from acceptance of the Offer and Quotation.
- 7.7** Upon receipt of such samples, CIMAC reserves the right to confirm or modify the Offer and Quotation, based on the characteristics of the samples received, and shall send to the Customer any revision of the Offer and Quotation for acceptance and consequent activation of the Revision Service.
- 7.8** At the end of the testing, the Customer shall receive the Test Reports with the results of the tests performed.
- 7.9** If the testing is unsuccessful, CIMAC will require corrective actions, for which new samples shall be sent for testing. In this case, the Customer receives a new Offer and Quotation.
- 7.10** If the testing is successful, the conformity assessment may be carried out in accordance with the Offer and Quotation.
- 7.11** CIMAC performs a documentary examination with the aim of assessing the Application, the Technical Documentation and Test Reports, in order to meet the requirements of EU Regulation 2016/425.
- 7.12** In the case of a negative result of the documentary examination, CIMAC informs the Customer of the non-conformities for the purpose of passing the documentary examination. The Customer is required to respond within the

next 60 working days of communication. Beyond this deadline, the certification application is rejected and the Customer is not allowed to submit a new application for conformity assessment for the PPE in question. In the event of a negative result, CIMAC communicates the reasons to the Customer and informs the Notification Authorities, Accredia and the other Notified Bodies, whose conformity assessment activities are similar and concern the same types of PPE.

- 7.13** After passing the documentary examination with positive results, the Technical Documentation and the related Test Reports are submitted to the Decision Committee for a decision.
- 7.14** If the review of the information and evaluation results and the certification decision (resolution) are positive, CIMAC issues the relevant EU Module B Type-Examination Certificate, which retains its numbering and the wording "Rev. 01" in the case of the first revision, with updating of the number in the case of subsequent revisions. The Certificate maintains the expiry date of the original one and bears the date on which the revision was decided.
- 7.15** If the review of the information and evaluation results is negative, the process will be suspended while the issues are investigated. If the certification decision (resolution) is negative, the certification revision request is refused and the Customer is not allowed to submit a new application for conformity assessment for the PPE in question. In the case of refusal, CIMAC shall inform the Customer of the reasons and inform the Notification Authorities, Accredia and the other Notified Bodies whose conformity assessment activities are similar and focus on the same types of PPE.
- 7.16** For PPE of Category II, following the issuance of the revised EU type-examination certificate Module B, the Customer is authorised to place the PPE on the market after application of the procedure of conformity to type based on internal production control Module C (Annex VI of the Regulation (EU) 2016/425), affixing of the CE marking and issuing of the EU declaration of conformity.
For PPE of Category III, the placing on the market is subject to one of the control activities provided for by art. 19 of Regulation (EU) 2016/425. The issuance of the EU type-examination certificate Module B in revision status involves the cancellation of the previous EU type-examination certificate Module B. CIMAC shall make available to the notifying authorities the list of such certificates.
- 7.17** In the event of editorial errors and/or typos, the EU Module B Type-Examination Certificate will be reviewed and sent to the manufacturer as an attachment to an email with a delivery and read receipt notification. In the case of category III PPE for which a Module C2 or Module D assessment has already been performed, the Module C2 Test Report or the Module D Certificate will also be reviewed, and the EU Module B Type Examination Certificate will be updated accordingly. The review of these documents does not alter the date of expiry indicated in the documents replaced.

8 SIMPLIFIED REVIEW PROCEDURE

The simplified review procedure for the transfer of certificates from Directive 89/686/EEC to Regulation (EU) 2016/425 is not

implemented since 21 April 2023, as required by Art. 47 of Regulation (EU) 2016/425.

9 CONFORMITY ASSESSMENT PROCEDURE FOR THE PURPOSE OF ISSUING THE MODULE C2 TEST CERTIFICATE

- 9.1** Category III PPE may be placed on the market or made available on the market only after they have undergone conformity assessment procedures for the purpose of issuing the Module C2 Test Report (hereinafter referred to as the "Module C2 Service") or the Module D Certificate.
- 9.2** The first check, in order to place the PPE on the market, must not be carried out more than one year after the date of issue of the EU Module Type B examination certificate. Otherwise, this certificate will be considered "Inactive", as provided for in § 5.16 above. The Manufacturer must provide CIMAC with a written communication in which he declares that the PPE has not been placed on the market.
Subsequent checks will be carried out at least once a year starting from the date of the previous check. The Customer must keep PPE from different batches to represent the history of production in the last year which will be sampled and collected. The Audit and Sampling methods, as well as the sampling that must be made available by the Customer, are indicated and described in the Proposal and Quotation as well as in the Audit and Sampling plan sent to the Customer for the purpose of activating the Service. Otherwise, the EU Module B Type Examination Certificate will be considered "Inactive", as provided for in § 5.16 above.
- 9.3** The Module C2 Test Report provides evidence that the Customer's manufacturing process and its control guarantee the conformity and homogeneity of the production and the conformity of the PPE manufactured to the type described in the EU Type B examination certificate and the requirements applicable of EU Regulation 2016/425.
- 9.4** The Module C2 Test Report can only be requested by the Customer if the PPE has already obtained the EU Module B Type-Examination Certificate, and such Certificate is current.
- 9.5** For the purpose of activating the Module C2 Service, the Customer fills in the Application Form. In the event that a void of validity should arise between a Module C2 certificate and the other, the Customer must provide CIMAC with a written communication in which the same declares that in that period the PPE was not made available on the market and undertakes not to make it available on the market before issuing the Module C2 certificate.
- 9.6** CIMAC, after evaluating the information received and the possibility of providing the Module C2 service within the required terms, sends to the Customer the Offer and Quotation concerning the audit and sampling and the subsequent testing on the samples that will be taken for assessing conformity.
- 9.7** The acceptance of the Offer and Quotation determines the activation of the Module C2 Service.
- 9.8** By accepting the Offer and Quotation the Customer also declares to have read and accepted this Regulation, as transmitted to it and/or published on the website www.cimac.it.
- 9.9** If it is a new Customer or the EU type-examination certificate Module B has not been issued by CIMAC, following acceptance

of the Offer and Quotation, the Customer shall forward to CIMAC, within 6 months from acceptance of the Offer and Quotation:

1. the Technical Documentation of the PPE;
2. copy of the EU type-examination certificate Module B
3. copy of the test reports;
4. in the event of a new Customer, the copy of the certificate issued by the relevant Chamber of Commerce, Industry, Crafts and Agriculture, as provided for in paragraph 5.9.

9.10 Following the acceptance of the Offer and Quotation CIMAC sends to the Customer the Audit and Sampling Plan which contains information on the date and place of sampling, the methods for collecting samples from production lots, the name of the inspector in charge and the list of documents subject to audit. The Customer shall allow CIMAC's inspectors and ACCREDIA and/or Notification Bodies' inspectors free access at the agreed location for the audit and sampling of PPE so that they can carry out the necessary activities and gather sufficient information and objective evidence on the compliance of the Service. The Customer, in accordance with current legislation, undertakes to provide CIMAC's inspectors and ACCREDIA and/or Notification Bodies' inspectors with the necessary information regarding any risks existing in the work environment in which they are to operate and shall ensure that all possible precautions are taken to protect the inspectors' health.

9.11 During the Audit and Sampling, the inspector in charge verifies the provisions adopted by the Customer to ensure that the PPE manufacturing process and its control guarantee the homogeneity of production and the conformity of the manufactured PPE to the type described in the EU Module B Type-Examination Certificate.

9.12 At the end of the Audit and Sampling, CIMAC issues to the Customer the Audit and Sampling Report, which contains the identification of the sample taken and any Non-conformities and Remarks.

9.13 In case of Non-conformities, objective evidence of their resolution is required within 60 working days of the date of Audit and Sampling.

9.14 In the event that objective evidence of the resolution of Non-conformities is not received within the period of 60 working days indicated above, the process is cancelled. The EU Module B certificate will be considered "Inactive", as set forth under § 5.16. Any stocks in the PPE warehouse cannot be made available on the market.

9.15 The samples taken shall be subjected to laboratory tests.

9.16 In the case of tests with negative results, CIMAC communicates such results and informs the Notification Authorities, Accredia and the other Notifying Bodies, whose conformity assessment activities are similar and focus on the same types of PPE. The process is suspended until, within a maximum of 60 working days from such communication, the Customer resolves the causes that gave rise to the negative outcome of the tests, verified through further sampling and tests. During this period, the Customer may not place and/or make available the PPE on the market.

9.17 Once the tests have been successfully passed, the file is submitted to the Decision Committee for a decision.

9.18 If the review of the information and evaluation results and the certification decision (resolution) are positive CIMAC issues the

Module C2 Test Report, which is valid for 1 year from the date of first issue, unless the applicable harmonised standard is revised and, in any case, the expiry date of the last check cannot exceed the expiry date of the EU Module B Type-Examination Certificate.

9.19 The Customer, after obtaining the test report Module C2, shall affix the number 0465 next to the CE marking, this being the identification number of CIMAC as Notified Body, and may place or make available the PPE on the market, after issuing the EU declaration of conformity.

9.20 If the review of the information and assessment results is negative, the process will be suspended while the issues are investigated. If the certification decision (resolution) is negative, the Form C2 certification process is cancelled. The EU Module B Type-Examination Certificate will be considered "Inactive", as provided in § 5.16 above, until the Customer requests a new audit and sampling. Any stocks in the PPE warehouse cannot be made available on the market.

9.21 In the event of editorial errors and/or typos in the EU Module C2 Test Report, the document will be reviewed and sent to the manufacturer as an attachment to an email with a delivery and read receipt notification.

10 PROCEDURE FOR ASSESSING CONFORMITY TO TYPE FOR THE PURPOSE OF ISSUING THE MODULE D CERTIFICATE

10.1 Category III PPE may be placed on the market or made available on the market only after it has undergone a conformity assessment procedure for the purpose of issuing the Module C2 Test Report or the Module D Certificate (hereinafter the "Module D Service").

10.2 The Module D Certificate provides evidence that the Customer's quality management system guarantees the conformity to type based on quality assurance of the production process of the Category III PPE, and its conformity to EU Regulation 2016/425.

10.3 The Module D Certificate can only be requested by the Customer if the PPE has already obtained the EU Module B Type-Examination Certificate and such Certificate is current.

10.4 For the purpose of activating the Module D Service, the Customer fills in the Application Form, listing the PPE that needs to be covered by the quality system.

10.5 CIMAC, after evaluating the information received and the possibility of providing the Module D Service within the required terms, sends an Offer and Quotation to the Customer relating to the inspection activity. The acceptance of the Offer and Quotation determines the activation of the Module D Service.

10.6 By accepting the Offer and Quotation the Customer also declares to have read and accepted this Regulation, as transmitted to it and/or published on the website www.cimac.it

10.7 If it is a new Customer or the EU type-examination certificate Module B has not been issued by CIMAC, following acceptance of the Offer and Quotation, the Customer shall forward to CIMAC, within 6 months from acceptance of the Offer and Quotation:

1. the Technical Documentation of the PPE;
2. copy of the EU type-examination certificate Module B and its test reports;
3. in the event of a new Customer, the copy of the certificate issued by the relevant Chamber of Commerce, Industry,

Crafts and Agriculture and a declaration in which it affirms, under its own responsibility, that it is in the free exercise of its rights, not being in a state of liquidation, bankruptcy or arrangement with creditors as provided for in § 5.9.

- 10.8** The main phases of the procedure, for the purpose of issuing the Module D Certificate, include: an initial certification audit in two stages (Phase 1 and Phase 2), two subsequent monitoring audits conducted annually, a renewal audit in the third year, before the expiry of the Certificate. In the following three-year periods, the renewal audit and the two annual monitoring audits are repeated cyclically. The Customer is given an audit report at the end of each audit. The procedures for carrying out the audits are fully described in the Offer and Quotation, as well as in the Audit Plan sent to the Customer.
- 10.9** Following acceptance of the Offer and Quotation, the Customer forwards to CIMAC the documentation relating to the quality management system, including:
1. an adequate description of the quality objectives and the organisational structure, the responsibilities and powers of management with regard to product quality;
 2. an adequate description of the manufacturing, quality control and quality assurance techniques, processes and systematic interventions that are implemented;
 3. an adequate description of the examinations and tests carried out before, during and after manufacture and the frequency with which they are carried out;
 4. an adequate description of the means of monitoring the achievement of the required quality and the effective operation of the quality system;
 5. any further supporting documentation for quality assurance purposes, such as inspection reports, test and calibration data, and reports on the qualifications of the personnel involved;
 6. the list of PPE guaranteed by the quality system.
- 10.10** Following the acceptance of the Offer and Quotation, CIMAC sends to the Customer the Initial Audit Plan which contains information about the date and place of the initial audit, divided into Phase 1 and Phase 2, the name of the inspector in charge, the production sites, the elements of the system, the activities and processes to be audited, the expected audit timeframe. The duration of the audits is calculated according to IAF Mandatory Document For Duration of QMS and EMS audits Issue 1 (IAF MD5).
- 10.11** The Customer shall give CIMAC's inspectors and ACCREDIA and/or Notification Bodies' inspectors free access to the agreed audit site to allow them to carry out the planned activities necessary to gather sufficient information and objective evidence on the compliance of the quality system. The Customer, in accordance with current legislation, undertakes to provide CIMAC's inspectors and ACCREDIA and/or Notification Bodies' inspectors with the necessary information on any risks existing in the working environment in which they are to operate and shall

ensure that all possible precautions are taken to protect the inspectors' health.

- 10.12** The Phase 1 Initial Certification Audit is carried out partly at CIMAC's premises and partly at the Customer's premises and has the purpose of:
1. verifying the completeness and consistency of the Customer's quality management system documentation;
 2. assessing the location and specific conditions of the Customer's site and undertaking an exchange of information with the Customer's staff in order to establish the degree of preparation for the Phase 2 Certification Audit;
 3. reviewing the status and understanding of the Customer with reference to EU Regulation 2016/425, with particular regard to the identification of key performance or aspects, processes, objectives and effectiveness of the quality management system;
 4. assessing whether the internal audits and reviews by the Customer's management have been planned and executed and whether the level of implementation of the quality management system provides evidence that the Customer is ready for the Phase 2 Certification Audit;
 5. agreeing with the Customer the details of the Phase 2 Certification Audit.
- 10.13** The results of the Phase 1 audit are communicated to the Customer through an Audit Report. In the case of Non-Conformity, objective evidence of the solution is required before planning and confirming the initial Phase 2 certification audit; in the event of Remarks, an adjustment plan is required and will be audited during the initial Phase 2 certification audit.
- 10.14** The Phase 2 Initial Certification Audit is carried out where the production of PPE takes place and has the purpose of auditing the effective and efficient application of the quality management system in accordance with EU Regulation 2016/425. If the customer wants to certify PPE from several production sites, the Phase 2 audit shall take place at all the customer's production sites. During the Phase 2 Initial Certification Audit, CIMAC, where deemed appropriate, may take certain samples of PPE to be subjected to laboratory tests, in order to verify their homogeneity and conformity to the type described in the EU Module B Type-Examination Certificate. In such circumstance, CIMAC will send to the Customer the Offer and Quotation relating to the test activity.
- 10.15** The results of the Phase 2 Initial Certification Audit are communicated to the Customer by means of the Audit Report which contains any Non-conformities and Remarks, as well as the identification of any samples taken.
- 10.16** In case of Non-conformities or remarks, objective evidence of their resolving is required within 60 working days from the date of the Phase 2 Initial Certification Audit. If Remarks are made, an adjustment plan is required, which will be audited at the next periodic audit. In the case of tests with negative results, CIMAC communicates these results to the customer and the process is suspended until, within the maximum period of 60 working days from the communication, the customer does not resolve the causes that led to the negative outcome of the tests, by means of further sampling and testing.
- 10.17** In the event that the non-conformities are not resolved by the deadline or the laboratory tests have not been passed, the

certification application is rejected if the Customer does not request an additional audit. If the certification application is refused, the Customer is not allowed to submit a new application for conformity Module D assessment for the PPE in question. In the case of rejection, CIMAC informs the Customer of the reasons for the rejection or limitation of the relevant PPE and informs the Notifying authorities, ACCREDIA and the other Notified Bodies, whose conformity assessment activities are similar and have the same types of PPE as their object.

- 10.18** If the review of the information and evaluation results and the certification decision (resolution) are positive, CIMAC issues the Module D Certificate, which is valid for 3 years from the date of issue - subject to two subsequent monitoring audits carried out annually - and contains the list of the PPE covered by the Customer's quality management system.
- 10.19** If the review of the information and assessment results is negative, the process will be suspended while the issues are investigated. If the certification decision (resolution) is negative, the Form D certification process is cancelled. The EU Module B Type-Examination Certificate will be considered "Inactive", as provided in § 5.16 above, until the Customer requests a new audit and sampling. Any stocks in the PPE warehouse cannot be made available on the market.
- 10.20** The Customer, after obtaining the certificate Module D, shall affix the number 0465 next to the CE marking, this being the identification number of CIMAC as Notified Body, and may place or make available the PPE on the market, after issuing the EU declaration of conformity.
- 10.21** The purpose of the two monitoring audits carried out on an annual basis, using the modalities of Phase 2 audit, is to ensure that the customer complies with all the obligations of the quality management system approved by CIMAC. Monitoring Audits are performed where the production of PPE takes place. If the customer declares to have more than one PPE production site, the monitoring audit shall take place at all production sites. The planning of the activity in the three-year period may include, on a rotational basis, the evaluation of all business processes applied to the production of the PPE.
- 10.22** Every monitoring audit related to the Customer's quality system includes the audit of the following aspects:
- Internal audits and management review;
 - the management of the quality system with reference to its ability to meet the requirements of Regulation (EU) 2016/425 and ensure the conformity of PPE production to the type described in the EU Type-Certificate and the homogeneity of production;
 - the progress of planned PPE oversight activities;
 - ongoing operational control of all phases of PPE production;
 - the CE marking of the PPE.
- 10.23** CIMAC may carry out audits without prior notice as provided for in Annex VIII of EU Regulation 2016/425, point 4.4
- 10.24** The Customer undertakes to fulfil the obligations arising from the quality management system approved by CIMAC and to ensure that such system remains suitable and effective.
- 10.25** The Customer undertakes to keep CIMAC informed of any changes it intends to make to the approved quality management system. CIMAC reserves the right to evaluate the proposed amendments, including, if necessary, by carrying out an

additional audit. Changes to the documents of the Management System subject to certification can be made operational by the Customer only after approval by CIMAC.

- 10.26** In the event that, during monitoring or renewal inspections Non-Conformities (of system or following laboratory testing with negative outcome) and if objective evidence of their solution is not received within 60 working days, the Module D certification process is cancelled. The EU Module B Type-Examination Certificate will be considered "Inactive", as provided in § 5.16 of the PPE in question and informs the Notification Authorities, ACCREDIA and the other Notified Bodies whose conformity assessment activities are similar and concern the same types of PPE.
- 10.27** If the Customer requests an extension of the Quality System to other PPE in possession of the EU Module B Type-Examination Certificate, CIMAC, after evaluating the information received and the possibility of providing the Service under the required terms, sends the Offer and Quotation to the Customer and, in case of acceptance, carries out an additional audit to verify the quality system and quality documentation applied to the new PPE. The extension of the Quality System to other PPE in possession of the EU Type-Certificate can also be implemented at the same time as the periodic monitoring audits.
- 10.28** The purpose of the audit of Module D Certificate renewal is to confirm the continued compliance and effectiveness of the quality system with the requirements of Regulation (EU) 2016/425. The renewal audit is implemented through a Phase 2 audit, which establishes:
- The effectiveness of the Quality System as a whole and its continued relevance and applicability to Regulation (EU) 2016/425 and to the PPE subject to the EU Module B Type-Examination Certificate;
 - The commitment shown to maintain the effectiveness and improvement of the Quality System in order to guarantee the homogeneity of production.
- When the renewal of the Module D Certificate is successfully completed before the expiry date of the Certification, CIMAC decides the renewal of the Quality System Certification, and the Module D Certificate provides evidence that the Customer's quality system guarantees the conformity and homogeneity of the production to type of the certified PPE.
- 10.29** If CIMAC cannot complete the renewal audit or is unable to verify the implementation of the Non-conformities by the expiry date of the certification due to customer unavailability, the Module D certification process is cancelled. The EU type-examination certificate Module B will be considered "Inactive", as provided for in § 5.16 above, until the Customer requests a Phase 2 audit. Any PPE inventory in the warehouse cannot be made available on the market.
- 10.30** When the renewal activity of the Module D certificate is successfully completed before the expiry date of the certification, CIMAC approves the renewal of the Quality System certification and the Module D certificate provides evidence that the customer's Quality System guarantees compliance and the homogeneity of production to the type of certified PPE.
- 10.31** If the resolution has a negative outcome, the Form D certification process is cancelled. the EU Module B Type-Examination Certificate will be considered "inactive", as provided for in § 5.16

above, until the customer requests an additional audit. Any stocks in the PPE warehouse cannot be made available on the market

- 10.32** In the event of editorial errors and/or typos in the Module D Certificate, the document will be reviewed and sent to the manufacturer as an attachment to an email with a delivery and read receipt notification.

11 SUSPENSION AND WITHDRAWAL OF CERTIFICATION

- 11.1** The use of the EU Module B Type-Examination Certificate will be considered improper if it is used or advertised:
- a) so as to mislead the recipients of the information;
 - b) if it has not yet been formally granted;
 - c) if it has been revoked or suspended;
 - d) outside its scope of application;
 - e) after the Customer has made changes to the PPE covered by the EU Module B Type-Examination Certificate and/or to the technical documentation without complying with the requirements issued by CIMAC.
- 11.2** CIMAC may suspend the validity of the EU Module B Type-Examination Certificate in the following cases:
- a) misuse by the Customer;
 - b) improper use of the CE marking;
 - c) negative outcome of Module C2 and Module D conformity assessments;
 - d) if for Module C2 the Customer refuses to carry out monitoring audits and sampling;
 - e) if for Module D the Customer factory refuses to carry out surveillance audits;
 - f) if the manufacturer does not notify CIMAC of significant changes to its Quality System and/or organisation;
 - g) when the type conformity assessment detects the failure to complete corrective actions to address Non-Conformities within the set time frame;
 - h) non-payment of invoices related to testing and conformity assessments;
 - i) for any other serious reason for CIMAC (e.g., substantiated serious complaints and reports, or actions by the Public Authority);
 - j) when the Customer does not inform CIMAC of any judicial and/or administrative proceedings initiated against it.

Where even only one of the above-mentioned circumstances apply, CIMAC shall communicate to the Customer in writing, by registered letter with acknowledgement of receipt or by certified email (cimac@pec.it), the necessary actions to end the suspension and restore the validity of the certification.

The Customer shall implement the actions communicated and, where applicable, restore the conformity of its PPE.

The restoration of the validity of the certification is only feasible after a positive opinion of CIMAC.

- 11.3** The Customer must implement the actions communicated within a maximum of 60 working days from the communication, and where applicable, restore the conformity of their PPE. During this period, the customer cannot place and/or make the PPE available on the market. The Customer can request CIMAC, justifying the reasons, to suspend the Certification for a period

not exceeding six months and, in any case, no later than the expiry date of the Certificate.

The restoration of the validity of the certification can only be implemented following a positive opinion from CIMAC and is subject to the elimination of the deficiencies that led to the suspension.

- 11.4** CIMAC has the right to revoke the Certification in the following cases:

- 11.4.1 if the Customer has not removed the causes that gave rise to the suspension order within the permitted period of 60 working days;
- 11.4.2 if particularly serious Non-Conformities are found;
- 11.4.3 non-compliance, resulting from gross negligence, with the provisions of this Regulation;
- 11.4.4 frequent non-compliance, even if only minor, with the obligations assumed;
- 11.4.5 bankruptcy or liquidation of the Customer;
- 11.4.6 refusal or obstruction of audits;
- 11.4.7 non-acceptance of changes to this Regulation;
- 11.4.8 non-acceptance of changes in the price list;
- 11.4.9 any other serious reason in the opinion of CIMAC.

In this case, CIMAC shall notify the Customer, Accredia, the Notifying Authority and the Notified Bodies that have as their purpose the Certification of the same PPE.

In the event of revocation, the Customer shall not continue to use the EC Certification, produce and market the PPE and shall remove all references to the Certification from their letterhead and all technical and advertising documentation. The Customer who after revocation intends to access the Certification again must follow the procedures set out in this Regulation.

12 RENEWAL

- 12.1** The application for renewal of the EU type-examination certificate Module B must be sent to CIMAC no more than twelve months and not less than six months before the expiry date of the EU type-examination certificate. If the application form is submitted less than six months before the expiry date of the EU type-examination certificate, CIMAC will be able to accept the application or not following the feasibility assessment of the renewal.
- 12.2** The application for renewal of the certificate Module D must be sent to CIMAC within two months of the expiry of the certificate. If the application form will be submitted less than two months before the expiration date of the certificate Module D, CIMAC will be able to accept or not the application following the feasibility assessment of the renewal within the expiration date of the certificate Module D.
- 12.3** In case of non-renewal of the EU Module B Type-Examination Certificate, the Customer shall cease to make the PPE available on the market.
- 12.4** In case of non-renewal of the Module D Certificate by the expiry date, the Customer shall cease to make the PPE available on the market.
- 12.5** If CIMAC confirms, through the verification of the Technical Documentation, that no changes have been made to the type approved Module B and that there has been no evolution of the state of the art (e.g. technology of materials / production and updating of harmonised standards) as referred to in point 7.3 of

Regulation (EU) 2016/425, the simplified review procedure is applied and the exams and tests referred to in point 7.5 of Regulation (EU) 2016/425 are not carried out. In such cases CIMAC renews the EU Module B Type-Examination Certificate.

- 12.6** If the review of the information and evaluation results and the certification decision (resolution) are positive, CIMAC issues the EU type-examination certificate renewal, which is valid for no more than 5 years from the date of issuance.

13 TERMINATION, DISCONTINUATION AND REDUCTION OF CERTIFICATION

- 13.1** The Customer may discontinue/terminate the Certification by giving written and signed – by the legal representative - notice to CIMAC in the following cases:

- a) upon the expiry of the validity of the certificate;
- b) in the case of non-acceptance of any revision of this Regulation;
- c) in the case of non-acceptance of changes in the Price List;
- d) in the case of changes in the harmonised standards;
- e) due to justified termination of the contract (e.g., cessation of PPE, sale of business branch, bankruptcy or liquidation).

- 13.2** Following the discontinuation/termination, the Customer agrees to:

- (a) not use the declaration of conformity and remove all references or symbols relating to certification from all products and documents;
- (b) immediately cease the manufacturing, distributing of the PPE and the use of the CE marking.

- 13.3** The manufacturer can request a reduction of the CE Certification by sending a written request to CIMAC. The changes that may require a reduction of the Certification may concern:
- a) the certified PPE model (e.g. reduction of variants, sizes);
 - b) the list of PPE subject to assessment of conformity to type (Annex VII and VIII of Regulation (EU) 2016/425).
- All changes made must be brought to the attention of CIMAC, by means of written communication from the Customer. CIMAC reserves the right to evaluate and accept the changes to be made to the Certificate. If the request is accepted, CIMAC issues the updated Certificate which maintains the same number (with indication of the revision carried out) and the same expiry date as the original Certificate.

14 CIMAC'S RESPONSIBILITIES

- 14.1** The results of the tests carried out by CIMAC are valid only for the samples tested and/or sampled; it is the exclusive responsibility of the Customer, with CIMAC not assuming any responsibility and/or obligation in this regard, to ensure the conformity of the PPE to the type described in the EU Type Examination Certificate and to the applicable requirements of Regulation (EU) 2016/425.
- 14.2** The Customer acknowledges and accepts that CIMAC accepts no liability for the use the Customer may make of the test results, the EU Module B Type-Examination Certificate, the C2 Module Test Report, the Module D Certificate.
- 14.3** In case of evolution of technological progress (updating of legislation, harmonised reference standards, etc.), CIMAC analyses the changes made and communicates to the Customer

any actions to be taken. CIMAC monitors the evolution of the state of the art and evaluates whether the certifications issued can therefore maintain their validity status or if they need to be revised.

- 14.4** CIMAC shall inform its Notifying Authorities of the EU Module B Type-Examination Certificates, Module C2 Test Reports, the Module D Certificates issued by it and, periodically or upon request, make available to its Notifying Authorities the list of such certificates issued, suspended or otherwise withdrawn. In case of revocation or suspension, CIMAC shall also inform ACCREDIA, the other Notified Bodies whose conformity assessment activities are similar and relate to the same types of PPE.
- 14.5** The Commission, the Member States and the other Notified Bodies may obtain, on request, copies of the EU Module B Type-Examination Certificates, Module C2 Test Reports, the Module D Certificates. Upon reasoned request, the Commission and the Member States may also obtain copies of the technical documentation and of the results of the conformity assessments carried out by CIMAC.
- 14.6** CIMAC keeps a copy of the EU Module B Type-Examination Certificates, Module C2 Test Reports, the Module D Certificates, technical documentation and related Test Reports for a period of 10 years after the issuance as from the date of the certifications.

15 RIGHTS AND OBLIGATIONS OF CUSTOMERS

- 15.1** The Customers who use the Services undertake to comply with the provisions of this Regulation.
- 15.2** Customers may not use the CIMAC logo without written permission from CIMAC.
- 15.3** Customers represent and warrant that they have the right to use the PPE covered by the EU Module B Type-Examination Certificate, Module C2 Test Report, and the Module D Certificate if it is the subject of a patent, trademarks and the like, as well as their lawfulness and is therefore solely and exclusively liable towards the Public Authorities and third parties.
- 15.4** Customers represent and warrant that all information, texts, graphics, data, news, images and anything else are not contrary to laws, regulations and/or other provisions and do not violate any copyright, distinctive sign, trademark, patent or other rights of third parties, whether absolute or relative.
- 15.5** It is the Customer's responsibility to keep copies of the complaints concerning PPE subject to EU Module B Type-Examination Certificate, Module C2 Test Report, and the Module D Certificate received from their customers, as well as the actions taken to correct the causes of these complaints. Without prejudice to the obligations set forth in the previous points, the Customer in any case releases and indemnifies CIMAC from any responsibility, claim and compensation that may be made against CIMAC, or by third parties, in the event of any breach by the Customer of the above-mentioned obligations, also being liable for any damage caused to CIMAC.
- 15.6** Customers undertake to maintain unchanged all the conditions that have determined a positive outcome of the conformity assessments carried out by CIMAC, that no changes have been made to the type approved Module B and/or to the technical documentation and that there has been no changes in the state of the art (e.g. material technology / production and updating of

harmonised standards) as per point 7.3 of Regulation (EU) 2016/425.

- 15.7 Customers undertake to place/make available on the market only PPE that complies with the health and safety requirements established by Regulation (EU) 2016/425, the harmonised standards and the technical documentation sent to CIMAC.
- 15.8 Customers undertake to inform CIMAC of any changes that may affect their ability to meet the requirements laid down in Regulation (EU) 2016/425, such as legal, organizational or ownership status, changes to the PPE, production methods, production sites and/or to the technical documentation. Any change that customers wish to make to the certified PPE must be expressly approved by CIMAC before its implementation.
- 15.9 Customers undertake that they will not use the certifications resulting from the conformity assessment in such a way as to bring CIMAC into disrepute and that they will not make any statement regarding their certification that may be misleading or unauthorised.
- 15.10 In the event of suspension, revocation or expiry of the conformity assessments, Customers undertake that the use of the certifications and all advertising material containing references to the certifications is discontinued.
- 15.11 Customers have the right to advertise the EU Type-Examination Certificate and the Quality System Certificate, as long as correct reference is always made to the scope and limits indicated. In the information intended for users, the Manufacturer shall refrain from providing any information that might indicate that the certificate includes services not provided for by Regulation (EU) 2016/425 and the Harmonised Standards.
- 15.12 The Customer has the right/obligation to affix the CE marking to the PPE for which it has obtained the EU Module B Type-Examination Certificate followed by the number 0465 for the PPE covered by the Module C2 test reports and Module D certificates (i.e., issued by CIMAC). The graphics and minimum size of the marking must comply with the requirements of Annex II of Regulation No. 765/2008. Should it appear that the CE marking has been affixed incorrectly or unlawfully, or has been used incorrectly, CIMAC has the right to suspend and revoke the certificates issued, notifying the Customer, the Notifying Authorities, Accredia and the other Notified Bodies, whose conformity assessment activities are similar and focus on the same types of PPE.

16 COMPLAINTS, APPEALS AND LITIGATION

- 16.1 Complaints: the Customer, its Customers, or the market in general has the right to make complaints in writing to the e-mail address: qualita@cimac.it, if they feel that the quality of the conformity assessment does not comply with what is stated in this Regulation. CIMAC communicates to the Customer the receipt of the complaint within 7 working days, declaring the commitment to verify the issue within 30 days and to then provide clear and complete answers in writing.
- 16.2 If, after careful evaluation, it is found that the complaint is without foundation, CIMAC shall inform the reporting party of the reasons for this.
- 16.3 The complaints management process is subject to confidentiality constraints, both with regard to the reporting party and the content of the complaints. CIMAC ensures that decisions

resulting from the complaint are taken, reviewed and approved by persons not previously involved in the subject matter of the complaint.

- 16.4 Appeals: consist in the request made by the Customer through a written communication or using the M33 form (available on request), in order to obtain a decision that is opposite or in any case different from that adopted in the various conformity assessment phases. CIMAC acknowledges receipt of the appeal within 7 working days, undertaking to verify the issue within 30 days and to then provide clear and complete answers in writing. CIMAC ensures that decisions resulting from the appeal are taken, reviewed and approved by persons not previously involved in the subject matter of the complaint.
- 16.5 Litigation: the resolution of any and all disputes directly or indirectly arising between the parties from the application or interpretation of this Regulation that could not be settled amicably by the parties, shall be subject to the sole jurisdiction of the Court of Milan.

17 APPLICABLE LAW

- 17.1 This Regulation is subject to Italian law.

18 VALIDITY STATUS AND CHANGES TO THE REGULATION

- 18.1 CIMAC ensures the compliance of this Regulation with the legislative requirements and the operational aspects related to the conformity assessment activity with Regulation (EU) 2016/425 and, where necessary, it reviews them.
- 18.2 Should CIMAC make amendments to this Regulation, CIMAC shall forward the revised Regulation to the Impartiality Committee called to express its opinion. The same revised Regulation is then forwarded to all Customers in possession of a Certification or with an application already submitted, using suitable means to demonstrate safe transmission and receipt. Customers are required to adapt to the new requirements within the period indicated and deemed most appropriate by CIMAC, depending on the extent of the changes made. In the case of non-acceptance of the amendment(s), Customers may discontinue the Certification, provided they give written notice to CIMAC in such a way as to guarantee its transmission and receipt. After 30 days from the communication without notice from the Customer, the new revision of the Regulation will be considered accepted by tacit consent. CIMAC reserves the right to check the conformity of the products to the new requirements, through the repetition of type tests on new samples, or the request for additional documents. The expenses for any checks shall be borne by the Customer.
- 18.3 It is understood that by signing the Offer and Quotation the Customer accepts and approves the provisions of this Regulation as in force at the time of such acceptance.