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RESPONSIBILITIES OF THE APPLICANT AND THE INDIVIDUAL PROTECTION EQUIPMENT CERTIFICATION BODY

(Modules: B, C2 and D of (EU) Regulation 2016/425)

Responsibilities of the applicant / manufacturer:

That knowing and understanding my responsibilities and those of the certification body detailed below, I commit to:

• Comply with the certification requirements[1] including the implementation of appropriate changes when communicated by the certification body[4].

• If the certification is applied to the production in progress, the certified product continues to meet the requirements of the product[2].

• Take the necessary measures to:

- Perform the evaluation[6] and monitoring (if required), including provisions to examine documentation and records, and have access to the equipment, locations, areas, personnel and client[3] subcontractors that are relevant.
- Investigate complaints;
- The participation of observers, if applicable.

- Make statements about certification consistent with the scope of the certification[7].
- Do not use product certification in a way that causes a bad reputation for the certification body[4], and makes no statement related to its product certification, which the certification body may consider misleading or unauthorized.
- Immediately after suspending, withdrawing or finalizing the certification, stop using it in all advertising material that contains any reference to it, and take the actions required by the certification scheme[5] (for example, the return of certification documents) and any other measure that is required.
- When providing copies of the certification documents to others, reproduce them in their entirety or as specified by the certification scheme[5].
- When referring to product certification in media such as documents, brochures or advertising, comply with the requirements of the certification body or those specified by the certification scheme[5].
- Comply with all the requirements that may be stipulated in the certification scheme[5] in relation to the use of conformity marks and information related to the product.

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- Keep a record of all known complaints regarding compliance with the certification requirements[1] and make such records available to the certification body[4] when requested, and:
- When providing copies of the certification documents to others, reproduce them in full or as specified by the certification scheme[5].

- When referring to product certification in media such as documents, brochures or advertising, comply with the requirements of the certification body or those specified by the certification scheme[5].

- Comply with all the requirements that the certification scheme may stipulate[5] in relation to the use of the conformity marks and the information related to the product.

- Keep record of all known complaints regarding compliance with the certification requirements[1] and make such records available to the certification body[4] when requested, and:

  - Take appropriate actions with respect to such complaints and the deficiencies found in products that affect compliance with the certification requirements[1].
  - Document the actions taken.

- To inform the certification body[4], without delay, about changes that may affect the ability to meet the certification requirements[1]. (Examples of changes may include the following: The legal, commercial, organizational or ownership status. Organization and management (for example, key directives, decision-makers or technical personnel). Modifications to the product or method of production, contact addresses and production sites, important changes in the quality management system).

- Not to use incorrect references to the certification scheme, or to make deceptive use of licenses, certificates, conformity marks or any other mechanism to indicate that the product is certified, that they are in the documentation or in other advertising, knowing that this may include actions by the Certification Body[4] such as: corrective actions, withdrawal of the certificate, publication of the transgression and, if necessary, legal action.

- To consult the Certification Regulations that the Certification Body has made available to the public and details the information related to certification schemes, evaluation procedures and rules to grant, maintain, expand, reduce the scope of certification, or to suspend, withdraw or deny it; rights and duties of applicants and clients, with requirements, restrictions or limitations of the use of the name of the Certification body and the brand, or how to refer to the certification granted.

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Manufacturers obligations

- To incorporate the additional requirements regarding (EU) Regulation 2016/425, to my obligations, upon its entry into force (04/21/2018).
- When introducing a PPE into the market, make sure that it has been designed and manufactured in accordance with the essential health and safety requirements established in Art. 8.1 and Annex II of (EU) Regulation 2016/425.
- To prepare the necessary technical documentation and carry out the applicable conformity assessment procedures, according to Art. 14, Art 8.2 and Art. 19 of (EU) Regulation 2016/425 and Chapter IV Art. 7 and Annex II,to take responsibility for the classification of the PPE in one of the three categories established.
- To prepare the EU declaration of conformity referred to in Art. 15 and to place the CE marking referred to in Art 8.2, Art. 8.8 and Art. 16 of (EU) Regulation 2016/425 (To provide with the PPE the EU declaration of conformity, or to include in the instructions and in the specified information in Annex II, point 1.4, the internet address where the EU declaration of conformity can be accessed.)
- To keep the technical documentation and the EU declaration of conformity for 10 years from the introduction of the PPE in the market according to Art 8.3 of (EU) Regulation 2016/425
- To ensure that there are procedures for serial production to maintain its conformity with (Eu) Regulation 2016/425. Due consideration shall be given to changes in the design or characteristics of the PPE and the modifications to the harmonized standards or other technical specifications in accordance with which the conformity of the PPE is declared, according to Art 8.4 of (EU) Regulation 2016/425.
- Whenever it is considered appropriate with respect to the risks that an PPE presents, and in order to protect the health and safety of consumers and other end users, to test samples of commercialized PPE, to investigate and if necessary, keep a record of claims, non-compliant PPE and recovered ones, and inform distributors of any follow-up of this type according to Art 8.4 of Regulation (EU) 2016/425.
- To ensure that the PPE that you enter in the market, carries a type, lot or serial number or any other element that allows its identification or, if the size or nature of the PPE does not allow it, that the information required It appears on its packaging or in a document that accompanies it, according to Art 8.5 of (EU) Regulation 2016/425.

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- To indicate in the PPE my name, registered commercial name or registered trademark and the postal address of contact or, if this is not possible, on the packaging or in a document that accompanies the PPE. The address will indicate a single place where you can contact me. The contact details will appear in a language easily understood by end users and market surveillance authorities, according to Art. 8.6 of (EU) Regulation 2016/425.

- To ensure that the PPE is accompanied by the instructions and information specified in Annex II, point 1.4 of (EU) Regulation 2016/425 and written in a language easily understood by consumers and other end users, as determined by the member State in question. These instructions and information, as well as any labeling, will be clear, understandable, intelligible and legible, according to Art 8.7 of (EU) Regulation 2016/425.

- To immediately take the necessary corrective measures, withdraw from the market or recover the PPE, as the case may be, when it considers or has reasons, to believe that a PPE that has entered the market is not in accordance with (EU) Regulation 2016/425. In addition, when the PPE presents a risk, to immediately inform the competent national authorities of the member States in which it has marketed it, providing details, in particular, about the nonconformity and the corrective measures adopted, according to Art. 8.9 of (EU) Regulation 2016/425.

- To provide, upon reasoned request from a competent national authority, all necessary information and documentation, in paper or electronic format and written in a language easily understood by that authority, to demonstrate the compliance of the PPE with (EU) Regulation 2016/425. At the request of that authority, cooperate with it in any measure adopted to eliminate the risks presented by PPE that have entered the market, according to Art. 8.10 of Regulation (EU) 2016/425.

Authorized representatives

- Manufacturers may designate, by written mandate, an authorized representative. The obligations established in article 8, paragraph 1, and the obligation to prepare the technical documentation referred to in article 8, paragraph 2, shall not be part of the mandate of the authorized representative, according to Art. 9.1 of (EU) Regulation 2016/425.

- Authorized representatives will perform the tasks specified in the mandate received from the manufacturer. The mandate must allow the authorized representative to perform at least the following tasks, according to Art. 9.2 of (EU) Regulation 2016/425:

  a) keep the EU declaration of conformity and technical documentation available to national market surveillance authorities for a minimum of ten years after the introduction of the PPE into the market;

  b) upon a reasoned request from a competent national authority, provide all necessary information and documentation to prove the PPE compliance;

c) cooperate with the competent national authorities, at their request, in any action aimed at eliminating the risks presented by PPE subject to their mandate.

Importers obligations

- Importers will only enter the market the PPE that are compliant, according to Art. 10.1 of (EU) Regulation 2016/425.
- Before introducing a PPE into the market, importers shall ensure that the manufacturer has followed the due conformity assessment procedure referred to in Article 19. They shall ensure that the manufacturer has prepared the technical documentation, that the PPE has the CE marking and is accompanied by the necessary documents, and that the manufacturer has met the requirements established in Article 8, paragraphs 5 and 6, according to Art. 10.2 of (EU) Regulation 2016/425.
- When an importer considers or has reason to believe that a PPE is not in compliance with the essential health and safety requirements in Annex II, it will not introduce it into the market until it is compliant. In addition, when the PPE presents a risk, the importer shall inform the manufacturer and the market surveillance authorities accordingly, as per Art. 10.2 of (EU) Regulation 2016/425.
- Importers will indicate their name, registered business name or registered trademark, as well as the postal address of contact, in the PPE or, when not possible, in its packaging or in a document that accompanies the PPE. The contact details will appear in an easily understandable language for end users and market surveillance authorities, according to Art. 10.3 of (EU) Regulation 2016/425.
- Importers shall ensure that the PPE is accompanied by the instructions and information specified in Annex II, Point 1.4, written in a language easily understood by consumers and other end users, as determined by the member State concerned, as determined Art. 10.4 of (EU) Regulation 2016/425.
- While a PPE is under the responsibility of importers, they shall ensure that the storage or transport conditions do not compromise compliance with the essential health and safety requirements established in Annex II, according to Art. 10.5 of the (EU) Regulation 2016/425.
- Whenever deemed appropriate with respect to the risks that a PPE presents, and in order to protect the health and safety of consumers and other end users, importers will test samples of traded PPE, investigate and if necessary, they will keep record of the claims, non-compliant PPE and those recovered, and will inform distributors of any follow-up of this type, according to Art. 10.6 of Regulation (EU) 2016/425.

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- Importers who consider or have reason to believe that a PPE that they have entered into the market is not in accordance with (EU) Regulation 2016/425, will immediately take the necessary corrective measures to comply, withdraw it from the market or recover it, according to the case. In addition, when the PPE presents a risk, importers shall immediately inform the competent national authorities of the member States in which they have marketed it, providing details, in particular, of the non-conformity and the adopted corrective measures, according to Art. 10.7 of (EU) Regulation 2016/425.

- For a period of ten years after the introduction of a PPE into the market, importers will keep a copy of the EU declaration of conformity available to market surveillance authorities and ensure that, upon request, such authorities can have the technical documentation, according to Art. 10.8 of (EU) Regulation 2016/425.

- Upon motivated request from a competent national authority, importers will provide all necessary information and documentation to demonstrate PPE compliance, in paper or electronic format and written in a language easily understood by that authority. At the request of that authority, they will cooperate with it in any measure adopted to eliminate the risks of the PPEs intoduced in the market, according to Art. 10.9 of (EU) Regulation 2016/425.

Distributor obligations

- When marketing a PPE, distributors will act with due diligence in relation to the requirements of (EU) Regulation 2016/425.
- Before marketing a PPE, distributors shall ensure that it has the CE marking and is accompanied by the necessary documentation and instructions and information specified in Annex II, point 1.4, written in a language easily understood by consumers and other end users of the member State in which the PPE is to be marketed and that the manufacturer and importer have respected, respectively, the requirements set out in Article 8, paragraphs 5 and 6, and in Article 10, paragraph 3, Art. 11.2 of (EU) Regulation 2016/425.
- When a distributor considers or has reasons to believe that a PPE is not in compliance with the essential applicable health and safety requirements set out in Annex II, it will not introduce it into the market until it is compliant. In addition, when the PPE presents a risk, the distributor shall inform the manufacturer or importer thereof, as well as the market surveillance authorities, according to Art. 11.2 of (EU) Regulation 2016/425.
- While the PPE is under the responsibility of the distributors, they will ensure that the storage or transport conditions do not compromise their compliance with the essential health and safety requirements established in Annex II, according to Art. 11.3 of the (EU) Regulation 2016/425.

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(Modules: B, C2 and D of (EU) Regulation 2016/425)

- Distributors who consider or have reason to believe that a PPE that they have marketed is not in accordance with this Regulation, will ensure that the necessary corrective measures are taken to comply, withdraw it from the market or recover it, as the case may be. In addition, when the PPE presents a risk, distributors shall immediately inform the competent national authorities of the member States in which they have marketed it, providing details, in particular, of the non-conformity and the corrective measures adopted, according to Art. 11.4 of (EU) Regulation 2016/425.
- Upon reasoned request from a competent national authority, distributors will provide all necessary information and documentation, in paper or electronic format, to demonstrate the PPE compliance. At the request of that authority, they will cooperate with it in any measure adopted to eliminate the risks presented by the PPE they have marketed, according to Art. 11.5 of (EU) Regulation 2016/425.

Cases of application of the obligations of manufacturers to importers and distributors

- For the purposes of (EU) Regulation 2016/425, it shall be considered a manufacturer and shall therefore be subject to the obligations of the manufacturer in accordance with Article 8, the importer or distributor entering a PPE in the market with his name or trademark, or to modify a PPE already introduced in the market, so that its compliance with (EU) Regulation 2016/425 may be affected.

Identification of economic agents

- Economic agents will identify, upon request, before the market surveillance authorities:

  a) any economic agent that has provided them with a PPE;

  b) any economic agent to whom they have supplied a PPE.

  Economic agents may submit the information referred to in the first paragraph of (EU) Regulation 2016/425, for ten years after the PPE has been provided and for ten years after they have supplied the PPE, according to Art. 13 of (EU) Regulation 2016/425.

Responsibilities of the Personal Protection Equipment Certification Body

- The certification body will verify compliance with the records of known complaints, with respect to compliance with the certification requirements[1] and will request them, as well as the documentation of the actions taken regarding such complaints or deficiencies found in products that affect compliance with certification requirements[1].
- About the use of the license, certificates and conformity marks

  The certification body shall exercise the control specified by the certification scheme[5] on the ownership, use and display of licenses, certificates, conformity marks or any other mechanism to indicate that the product is certified.

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(Modules: B, C2 and D of (EU) Regulation 2016/425)

Incorrect references to the certification scheme, or the misleading use of licenses, certificates, conformity marks or any other mechanism to indicate that the product is certified, that they are in the documentation or in other advertising, should be treated by adequate action, including corrective actions, withdrawal of the certificate, publication of the transgression and, if necessary, legal action.

- The certification body is impartial and does not allow commercial, financial or other pressures to compromise its impartiality.
- The certification service is accessible to all applicants whose activities are within the scope of their operations.
- The certification body reserves the right to accept a request or to maintain a contract with a client, based on substantiated or proven reasons, being able to decline in cases such as: client participation in illegal activities, a history of nonconformities repeated with product or certification requirements, or similar issues.
- The Certification Body is responsible for safeguarding and guarantees through this legal agreement, absolute confidentiality, for the management of all information obtained or created during the performance of certification activities. With the exception of the information that the client makes available to the public, or when there is an agreement between the Certification Body and the client (for example, for the purpose of responding to complaints), all information is considered private information and is considered therefore confidential. The Certification Body will inform the client, in advance, about the information it intends to make available to the public. When the Certification Body is required, by law or authorization of contractual provisions, the disclosure of confidential information, the client or person involved will be notified of the information provided unless it is prohibited by law. Information relating to the client, obtained from sources other than the client (for example, from a complaint or regulatory authorities) will be treated as confidential information.
- The Certification Body will inform the notifying authority of any denial, restriction, suspension or withdrawal of certificates; of any circumstance that affects the scope and the notification conditions; of any request for information on the conformity assessment activities carried out that they have received from the market surveillance authorities; upon request, of the conformity assessment activities carried out within the scope of its notification and of any other activity carried out, including cross-border activities and outsourcing.
- The Certification Body makes available to the client, upon request, the document called the Certification Regulation, the information related to certification schemes, evaluation procedures and rules to grant, maintain, expand, reduce the scope of certification, or to suspend, withdraw or deny it; rights and duties of applicants and clients, with requirements, restrictions or limitations of the use of the name of the Certification Body and the brand, or how to refer to the granted certification.

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- Upon the suspension of a certification, the certification body[4] will formulate and communicate to the client the necessary actions to finalize the suspension and restore the certification of the products in accordance with the certification scheme and any other action required by the accreditation scheme.
- The certification body[4] will acknowledge receipt of a complaint or a formal appeal. It will gather and verify all the information necessary to reach a decision (reviewed and approved by the personnel involved) regarding the complaint or appeal.
- Whenever possible, the Certification Body[4] will request a formal notification of the outcome and completion of the appeal process to the appellant.
- The Certification Body[4] will inform the client[3] in advance about externally contracted activities in order to give the client the opportunity to object.
- The Certification Body[4] will inform the client[3] about all nonconformities, and if the client expresses interest in continuing the certification process, the Certification Body[4] will provide information regarding the additional evaluation work[6] necessary to verify that the nonconformities have been corrected. In case the client agrees to complete the additional evaluation work, the certification process will be restarted from the initial stage.
- The Certification Body will notify customers of the decision not to grant certification, as well as the identification of the reasons for such decision.
- The Certification Body has provided the client, together with this agreement, the Certification Regulations.
- The Notified Body will carry out conformity assessments following the conformity assessment procedures established in Annexes V, VII and VIII according to Art. 32.1 of (EU) Regulation 2016/425 and/or in Chapter IV and V of the Royal Decree 1407/1992.
- Conformity assessments will be carried out in a proportionate manner, avoiding imposing unnecessary burdens on economic agents. Conformity assessment bodies shall carry out their activities with due regard to the size of the companies, the sector in which they operate, their structure, the degree of complexity of the PPE technology in question and whether the production process is in series. However, they will respect the degree of rigor and the level of protection required so that the PPE meets the requirements of (EU) Regulation 2016/425, according to Art. 32.2.
- If a notified body verifies that a manufacturer does not meet the essential health and safety requirements set out in Annex II or the corresponding harmonized standards or other technical specifications, it will urge the manufacturer to take appropriate corrective measures and will not issue a certificate or will not issue an approval decision, according to (EU) Regulation 2016/425, according to Art. 32.3.

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(Modules: B, C2 and D of (EU) Regulation 2016/425)

- If, in the course of the verification of the conformity consecutive to the issuance of the certificate or the issuance of the approval decision, a notified body verifies that an PPE is no longer compliant, it will urge the manufacturer to take appropriate corrective measures and, if necessary, it will suspend or withdraw the certificate or will not issue the approval decision, according to (EU) Regulation 2016/425, according to Art. 32.4.
- If no corrective measures are taken or they do not have the required effect, the notified body will restrict, suspend or withdraw any certificate or approval decision, as appropriate, according to (EU) Regulation 2016/425, according to Art. 32.5.

DEFINITIONS AND TERMS USED IN THE AGREEMENT

1. **Certification requirement**: specified requirement, including product requirements[2], which the customer[3] meets as a condition for obtaining or maintaining the certification. The certification requirements include the requirements imposed on the client by the certification body[4] (generally through the certification agreement, to comply with ISO/IEC 17065:2012 and may also include the requirements imposed on the client[3] by the certification scheme[5] of certification, do not include the requirements imposed on the certification body by the certification scheme[5]. For example, the following are certification requirements that are not product requirements: formalize the certification agreement; pay the fees; provide information about the changes in the certified product; give access to certified products for surveillance activities.

2. **Product requirement:** Requirement that refers directly to a product, specified in standards or in other normative documents identified in the certification scheme (Regulations, standards and technical specifications).

3. **Client:** organization or person responsible to a Certification Body[4] to ensure that certification requirements[1] are met, including product requirements[2]. Whenever the term “client” is used, it applies to both the “applicant” and the “client”, unless something different is specified.

4. **Certification Body:** A third-party conformity assessment body that operates certification schemes. (N.B. AITEX No. 0161).

5. **Certification scheme:** certification system applied to certain products, to which the same specified requirements, rules and specific procedures apply.

6. **Evaluation:** combination of the selection and determination functions in the conformity assessment activity.

7. **Scope of the certification:** identification of the products for which the certification is granted, the applicable certification scheme and the standards and other normative documents, including their date of publication, with respect to which the product is considered to be compliant .

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(Modules: B, C2 and D of (EU) Regulation 2016/425)

Authorized certification applicant:

Date:

Position:

Signature and stamp:

To be completed by AITEX Certification Body:

Reviewed by:

Date:

Position:

Signature and stamp: