

REGULATION FOR PRODUCT CERTIFICATION PPE REGULATION (EU) 2016/425





Index

| | |
|---------------------------------------------------------------------------------|----|
| 1. Purpose..... | 4 |
| 2. Scope | 4 |
| 3. Reference documents..... | 4 |
| 4. Definitions | 5 |
| 5. Principles of impartiality and transparency | 6 |
| 5.1 Committee for the Safeguarding of Independence and Impartiality (CSI) | 6 |
| 6. Certification Resolution Committee (CDC)..... | 6 |
| 7. Responsibility..... | 6 |
| 7.1 Manufacturer's Commitments | 6 |
| 7.2 Commitments of the Body | 8 |
| 8. Assessment and certification process | 9 |
| 8.1 Access to conformity assessment services | 9 |
| 8.2 Submission of the Application for EU Type Examination | 9 |
| 8.3 Review of the application and submission of the offer | 9 |
| 8.4 Order review | 10 |
| 8.5 Start of the Certification Process for the EU Type Examination | 10 |
| 8.6 Document Verification | 11 |
| 8.7 Outcome of the verification and communication of the findings | 11 |
| 8.8 Execution of tests | 11 |
| 8.9 Additional Checks | 12 |
| 8.10 Review and decision on certification | 12 |
| 8.11 Failure of the Conformity assessment | 12 |
| 8.12 Certification with the "Own Brand Manufacturer" (OBM) process | 12 |
| 9. CE marking and warnings on the safety of use | 13 |
| 9.1 CE marking | 13 |
| 10. Certification Communications..... | 13 |
| 11. Record-keeping | 13 |
| 12. Validity of the EU Type Examination Certificate | 13 |
| 13. Certificate renewal with simplified procedure | 13 |
| 14. Certificate renewal..... | 14 |
| 15. Transfer of the certificate | 14 |
| 16. Certificate Review..... | 14 |
| 17. Evolution and technological progress | 14 |
| 18. Minor PPE Modifications – Release Letter | 14 |
| 19. Certificate extension | 15 |
| 20. Waiver and Suspension | 15 |
| 20.1 Renunciation | 15 |
| 20.2 Certificate Suspension – Module B | 15 |
| 20.3 Effects of Suspension – Module B | 15 |
| 21. Conformity assessment according to MODULE C2 | 16 |
| 21.1 Application Submission - Form C2 | 16 |
| 21.2 PHASE 1 – Visit and product/documentation check | 16 |
| 21.3 STEP 2 – Product Verification and Testing | 16 |
| 21.4 First issue of the certificate | 17 |
| 21.5 Certificate renewal | 17 |
| 21.6 Negative outcome of the checks | 17 |
| 21.7 Certificate Suspension – Form C2 | 18 |
| 21.8 Effects of Suspension – Form C2 | 18 |
| 22. Revocation | 18 |
| 23. Complaints and Appeals | 19 |
| 23.1 Complaint | 19 |



| | | | |
|------|-------------------------------------------------------------------|----|----|
| 23.2 | Recourse | 19 | |
| 23.3 | Litigation | 20 | |
| 24. | Confidentiality..... | | 20 |
| 25. | Amendments to the Rules..... | | 20 |
| 26. | Economic conditions | | 20 |
| 27. | Changes to the Offer, the Tariff and the Right of Withdrawal..... | | 20 |
| 27.1 | Variation of the Offer | 21 | |
| 27.2 | Variation of the Tariff | 21 | |
| 28. | Advertising and Use of Certification | | 21 |



1. Purpose

These Regulations define the general practices adopted by INTERTEK Italia S.p.A. (INTERTEK) for conducting conformity assessment activities for products designed or intended, exclusively or not, to be used as personal protective equipment (PPE) referred to in Regulation (EU) 2016/425, which the Manufacturer or subject deemed as such pursuant to the Regulation itself, must follow to obtain and maintain the EU Product Certification.

INTERTEK makes the latest updated version of the Regulations available on its website WEB at the address <http://www.intertek.it>, at its headquarters in Lastra S. (FI) or at the request of the Manufacturer, sends a copy in electronic format.

Amendments and additions to the Regulations are managed by issuing successive revisions, in which the portions of the amended text are highlighted with vertical lines on the side of the same. The Regulation is an integral part of the contract signed between INTERTEK and the Manufacturer. INTERTEK always applies to the latest inspection issued.

In the event that the changes made may interfere or affect in any way the certifications already issued or with a contract in place, INTERTEK will send a copy of the Regulations in electronic format to the customer who owns the certificate or contract. This type of change will only be valid if agreed by both parties.

The customer has 5 days to accept or reject the changes made, after this period the silent consent is valid.

For legislative changes, customer acceptance is not required.

In the event that the changes do not affect, do not affect and do not interfere with certifications already issued, the updated version is made available on the website WEB at <http://www.intertek.it>.

2. Scope

The Regulation describes the commitments and responsibilities assumed by INTERTEK and the Manufacturer submitting an application for conformity assessment for:

1. PPE category II (second): for the assessment of the EU Type Examination - Annex V of Regulation (EU) 2016/425 (Module B) followed by conformity to type based on internal production control (Module C) referred to in Annex VI of Regulation (EU) 2016/425;
2. PPE category III (third): for the assessment of the EU Type Examination - Annex V of Regulation (EU) 2016/425 (Module B) and conformity to type based on internal production control combined with product tests under official control carried out at random intervals (Module C2) referred to in Annex VII of Regulation (EU) 2016/425.

The list of Personal Protective Equipment in which INTERTEK is accredited is available on the EU website in the NANDO database (<https://ec.europa.eu/growth/tools-databases/nando/>).

3. Reference documents

For the definition of the relationship between INTERTEK and the Manufacturer, the requirements contained in the following documents apply:

- Regulation (EU) 2016/425 on the safety of PPE
- D.M. (Calenda) - of 12 December 2017
- Decision No. 768/2008/EC of the European Parliament and of the Council "on a common framework for the marketing of products and repealing Decision 93/465/EEC";
- Regulation (EU) No 765/2008 of the European Parliament and of the Council "setting out the requirements for accreditation and market surveillance relating to the marketing of products
- Guidelines issued by the European Community and Shared Opinions issued by the working groups of the European Commission;
- ISO/IEC 17065:2012 "Requirements for bodies certifying products, processes and services";
- ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories"



- EA -2/17 M:2020: Accreditation Notifications - Features
- General Regulations, Technical Regulations and provisions of the Single Accreditation Body (ACCREDIA), in the schemes and sectors covered by accreditation;
- The identification of mandatory standards and/or laws applicable to the product is the responsibility of the Manufacturer, who may take as a reference the standards and technical specifications issued by International Standardization Committees such as UNI, EN, ISO, IEC, CEI, CEN and CENELEC. The harmonised standards relating to the Regulation, published and periodically updated by the European Commission, can be consulted at the following Internet address: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment_en;

4. Definitions

For the purposes of these Regulations (referred to in this document as simply the Regulations), the following definitions are given:

Manufacturer for certification ("Manufacturer"): a natural or legal person who manufactures an PPE, or has it designed or manufactured, and markets it under his or her own name or trademark (ref. Regulation (EU) 2016/425);

Authorised representative: a natural or legal person established in the Community who has received a written mandate from a manufacturer authorising him to act on his behalf in relation to certain tasks;

Importer: a natural or legal person established in the Community who places on the Community market PPE originating in a third country;

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

Own Brand Manufacturer (OBM) or Own Brand Labelling (OBL): this refers to the particular procedure that a device manufacturer follows when placing a device already CE marked on the market in its own name. European legislation considers the manufacturer in OBM as the legal manufacturer even when this subject has nothing to do with the physical production of the device.

EU Type Examination: The EU Type Examination is the part of a conformity assessment procedure by which a Notified Body examines the technical design of a product, as well as verifies and certifies that the technical design of the product complies with the requirements of the legislative instrument applicable to it;

Notified Body identification number: no. 2575 is the number assigned to INTERTEK to be affixed to the marking (CE 2575) of Cat.III PPE subject to production surveillance (MODULE C2) by means of a contract and the related necessary activities, in accordance with the Regulation.

Notified Body (NB): Body authorised by a Member State of the European Community to carry out conformity assessment tasks, including calibrations, tests, certifications and inspections, as a third party and to issue certificates of conformity;

Conformity assessment (verification): the procedure to demonstrate whether the specific requirements relating to a product, process, service, system, person or body have been complied with;

Production surveillance: procedure provided for category III PPE and as described in Annex VII of Reg.2016/425 - Form C2

Sampling program: program of visits for the collection of samples useful for tests for the purpose of carrying out the activity envisaged by Module C2.

Survey: objective verification of an event or condition that highlights a NC;

Non-conformity (NC): failure by the Manufacturer to comply with a requirement, referred to in a Regulation, a law in force or a standard applicable to the area in question.

Comment: it is a recommendation that is not considered as non-compliance and the Manufacturer is not obliged to give evidence of reception.

Liability: burden assumed or deriving from the conduct of a process, the execution of a work, or the management of an assignment (or task) entrusted and to be carried out with due commitment;

Complaint: expression of dissatisfaction, both verbal and written, by entitled parties (direct customers, indirect customers, Public Authorities, ACCREDIA), with regard to the services provided by the Body and, in general, to the work of the same;

Appeal: formal appeal, by Parties with specific causes, adverse decisions taken or express evaluations or certifications issued by the Body.

The terminology and definitions used in the documentation to support the performance of the activities necessary for the issuance of the EC certificate of conformity comply with the contents of the following documents:

- Regulation (EU) 2016/425 on the safety of PPE;
- Decision No. 768/2008/EC of the European Parliament and of the Council "on a common framework for the marketing of products and repealing Decision 93/465/EEC";



- Regulation (EC) No. 765/2008 of the European Parliament and of the Council "setting out the standards for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93";
- ISO/IEC 17065 "Requirements for bodies certifying products, processes and services";
- UNI CEI EN ISO/IEC 17000 standard "Conformity assessment – Vocabulary and general principles".

5. Principles of impartiality and transparency

INTERTEK grants equal access to Certification services to all entities, public or private, without making any distinction on the basis of Company size, membership of any organization or association, or the number of certifications obtained. The only exception is made for companies subject to legal restriction measures, which prevent them from marketing products subject to EU certification of conformity.

In order to ensure maximum correctness and transparency in the performance of verification and certification activities, INTERTEK specifies, also through the signing of appropriate codes of conduct, that its managerial and technical staff is not subject to undue internal or external pressures, of a commercial, financial or other nature, that may negatively affect the work carried out.

The personnel involved in the verification activities aimed at issuing the EU certificate of conformity are not involved in activities that may undermine confidence in their independence, impartiality and professional integrity. In addition, the Body does not carry out design activities either directly or in a consultancy form, does not market products and/or systems subject to inspections or EU Certification, nor does it provide technical assistance services to the subjects, subject to audits or certifications, for the sectors covered by the Accreditation, nor does it carry out other activities that may compromise confidence in its work.

5.1 Committee for the Safeguarding of Independence and Impartiality (CSI)

Independence and impartiality is ensured by the CDI which is regulated by the RG. NB.03. Intertek's Management ensures that the Committee for the Safeguarding of Independence and Impartiality has the opportunity to formulate the political guidelines for Intertek's operation and to supervise their implementation, including monitoring of financial aspects. It is the responsibility of Intertek's Management to raise awareness among CSI members so that they are aware of the importance of their role with respect to Intertek's impartiality, independence, impartiality, competence and overall operational compliance.

6. Certification Resolution Committee (CDC)

In order to issue the certificate, Intertek has set up the Certification Committee which expresses the final opinion and then the resolution for the issuance of the certificate. The CoC is regulated by its own RG regulations. NB.04.

7. Responsibility

These Regulations detail the reciprocal responsibilities and commitments that the Manufacturer and INTERTEK are required to comply with in order to allow the correct performance of the individual phases envisaged by the Certification process, according to the methods and timing described in the following paragraphs and in the contractual documents signed by the parties.

INTERTEK premises that some phases of the activity may be carried out by third parties such as laboratories or other contractual subjects. The execution of the tests is generally entrusted to laboratories accredited by bodies that have signed EA, IAF, ILAC Mutual Recognition agreements. If this condition is not possible, INTERTEK will verify the suitability by means of an audit based on EN ISO 17025, in particular for the competence of the product under investigation.

The assignment of these activities is usually included in the offer and is always subject to the approval of the Manufacturer. In the event of disagreement, a Laboratory that has the above characteristics will be agreed upon written communication and countersigned for acceptance.

The ultimate responsibility for the activity remains exclusively with INTERTEK.

7.1 Manufacturer's Commitments

The Manufacturer undertakes to provide maximum cooperation to INTERTEK's representatives during all phases of the Certification process (Module B) and/or conformity control based on internal production control combined with product tests (Module C2) described in these Regulations.



It prepares any permits and authorizations to allow access to the areas affected by the performance of the above-mentioned activities, whether they are internal or external to the company examined. It allows on-site access, or the provision of copies, of all documents that INTERTEK deems useful to examine for the purposes of the required compliance.

The Manufacturer who does not grant his approval to access the areas, information and documentation necessary for the inspection or sampling visit to INTERTEK and/or ACCREDIA personnel, will proceed with the interruption of the process and the suspension/revocation of the certificate, if issued by INTERTEK.

The Manufacturer, before submitting to INTERTEK the application for Certification (Module B) and/or the control of conformity based on internal production control combined with product tests (Module C2), is responsible for preparing at least the following in compliance with the requirements of Regulation (EU) 2016/425.

All the documentation provided by the Manufacturer to support the verification activities must be prepared in English and Italian if deemed necessary in agreement with the customer.

For the EU Type Examination (Module B):

- Documentation attesting to the risk assessment and analysis

In compliance with the requirements set out in Article 5 of Regulation (EU) 2016/425, the Manufacturer must provide evidence that he has carried out an analysis of the chemical, physical-mechanical and electrical hazards, flammability, hygiene and radioactivity that the PPE may present and that he has carried out an assessment of the potential exposure to these hazards.

- Technical Construction File

In compliance with the requirements set out in Article 8 of Regulation (EU) 2016/425, the Manufacturer must provide evidence that it has drawn up the required technical documentation containing, to the extent that it is relevant for the assessment, the provisions of Annex III of Regulation (EU) 2016/425, except for what is to be supplemented downstream of the positive closure of the certification process. The technical documentation must demonstrate the compliance of the PPE with the requirements set out in Regulation (EU) 2016/425 and any requirements referred to therein.

- PPE Standards

The Manufacturer must prepare an adequate number of samples representative of the expected production of the PPE subject to EU Type Examination, constructed in accordance with the requirements of the technical documentation. The number of samples will be communicated by INTERTEK and must allow the checks and tests deemed necessary for the conformity assessment to be carried out.

The Manufacturer must also issue or procure the necessary authorizations or permits to allow access to INTERTEK's representatives to the place where the Type is manufactured, if necessary.

The witness sample received and examined is kept by INTERTEK for at least 90 days from the date of issue of the certificate. If claimed, it can be returned to the customer, at their own expense. If the customer does not collect the sample, the sample will be disposed of in accordance with current legislation.

- Internal production control process

The Manufacturer must provide evidence that it has set up an internal PPE manufacturing process, as described in the technical documentation. The manufacturing process must be adequate to ensure the conformity of the PPE to the Type described in the technical documentation and to the requirements of Regulation (EU) 2016/425.

The process must also include:

- the documented management of complaints received in relation to the Type of PPE and the related corrective actions taken;
- the documented updating of the mandatory standards or laws applicable to the product and the identification of new requirements referring to it;
- the documented updating of the technical documentation, relating to changes or variations made to the Type with reference to the provisions of Regulation (EU) 2016/425.

The Manufacturer must provide copies of all procedures and documentation that INTERTEK deems necessary for the purpose of assessing the requirement. In the event that the Manufacturer does not provide the required documentation, INTERTEK will issue a negative opinion on the certification.

- EU Declaration of Conformity

In compliance with the requirements set out in Article 15 of Regulation (EU) 2016/425, the Manufacturer must prepare the EU Declaration of Conformity of the PPE subject to the application, which certifies that compliance with the requirements defined by Art.19 and Annex II of Regulation (EU) 2016/425. Any information relating to the data referring to the outcome of the Certification Process must be reported in draft, until the successful conclusion of the same.

The declaration must be attached to the file without signature and date, as the date and signature can only be affixed following a positive outcome of the Certification process.



- Compliance with the Regulations and the contractual relationship

the Manufacturer undertakes to comply with every point of these Regulations and to honors any further commitment deriving from the signing of the contractual documents required by the Certification process. In addition, it undertakes to ensure the following:

- allow free access to the inspectors (and any observers) of the Certification Body and, if necessary, to the staff of ACCREDIA who may support that of the Certification Body in the conduct of the assessment and surveillance, including the supply, for the purposes of examination, documentation and registrations, to the production sites, to the personnel working at the Certification Manufacturer customer and to any subcontractors of the customer;
- provide support to INTERTEK representatives, making its responsible staff available for the activities involved in the conformity assessment activities, during working hours and for the entire period involved in the Certification process;
- to facilitate the performance of evaluation activities, in the times and in the ways agreed in the official communications;
- facilitate the access of INTERTEK representatives to all areas involved in evaluations, registrations (changes to the technical file, resolution of complaints, etc.), personnel involved in design and manufacturing, etc.;
- facilitate the resolution of the NCs that emerged during the Certification process, allowing INTERTEK to verify the resolution of the same, through evidence of the corrective actions taken;
- not to market the PPE subject to the Certification until the positive conclusion of the Process;
- promptly notify INTERTEK of any changes made to the PPE covered by the EU Type Examination Certificate and to the manufacturing process adopted;
- to fulfil payments in the manner and within the time frame defined by the contractual documents signed;
- not omit or omit to communicate to INTERTEK any information pertaining to the Certification process or to the PPE subject to the EU Type Examination requested;
- use and advertise the EU Type Certificate only within the limits for which it was granted, avoiding discrediting the Body;
- allow the performance of the required checks, communicated even with minimum notice, to the personnel appointed by INTERTEK, even if supported by staff of ACCREDIA or the relevant bodies;
- allow INTERTEK to carry out additional checks motivated by serious reports relating to certified PPE, also alongside the staff of the competent authorities or ACCREDIA. These checks can be carried out without notice or with a minimum notice of 5 working days, refusal will result in the revocation of the Certification.
- use the certification only for the product for which the certificate was issued and for the quantities subject to control;
- not to use the certification in such a way as to bring discredit to the Certification Body;
- not to use the product certification in a way deemed misleading or not authorized by the Certification Body;
- not to use the certification (e.g. on advertising material) if it has been suspended, revoked or expired;
- in the case of the provision of certification documents (such as certificates), reproduce them in their entirety in accordance with the provisions of the certification scheme;
- use references to their certification on the means of communication (such as documents, brochures, advertising material) in accordance with the provisions of the (regulated or mandatory) legislation of the sector;
- comply with the requirements prescribed by the certification scheme relating to the use of conformity marks and product information;
- keep a record of all complaints and/or appeals received and/or of which they have become aware relating to the products checked and certified by the Certification Body and, if requested, make them available to the same. If this is true, identify, implement and document corrective actions to remove the cause of the complaint and/or the recourse or defect found in the product that affects compliance with the certification requirements;
- promptly communicate - in accordance with the provisions of the sector regulations - to the Certification Body any changes that may affect the Customer's ability to meet the requirements of the certification:
- The customer must also notify the Certification Body of the changes relating to:
 - legal, commercial, organizational status or relating to the property or the legal representative;
 - contact addresses and websites;
 - introduction of new activities/products/services that have an impact on the control activity.

7.2 Commitments of the Body

INTERTEK undertakes to make the necessary resources available, to plan and carry out conformity assessment activities in accordance with the requirements of the Regulation. It also undertakes to make available the resources necessary to carry out any additional checks and all the activities required for the purpose of monitoring and maintaining the Certification granted.



INTERTEK also guarantees adequate insurance coverage with respect to the risks that may arise to the Manufacturer from the conduct of the conformity assessment activities referred to in these Regulations.

Force majeure

INTERTEK cannot be held responsible for any non-compliance that may occur due to objectively unforeseeable circumstances, prior to the assumption of the task given to it by the Manufacturer for the assessment of the conformity of PPE.

Equally, INTERTEK cannot be held responsible for failure to comply with the agreed deadlines if they are attributable to delays on the part of the Manufacturer, or for the occurrence of NCs attributable to its actions.

8. Assessment and certification process

The Certification process conducted by INTERTEK involves carrying out the phases described in the following paragraphs. The process is carried out according to the requirements of Regulation (EU) 2016/425, product standards or technical specifications and mandatory laws. With regard to the concepts of harmonized standards and other documents to be used for compliance, please refer to the Blue Guide "implementation of product regulations" available on the EU website.

Each phase is carried out according to procedures and internal regulations prepared by INTERTEK, which can be consulted by the Manufacturer at the Organization's headquarters, in the sector relevant to PPE Certification activities.

In cases where the customer is required to use non-harmonized standards or technical specifications, INTERTEK reserves the right to evaluate on a case-by-case basis, before accepting the assignment.

In addition, in order to properly interpret the requirements of the standards, INTERTEK uses the Recommendations for Use (RfU) published by the working groups of the Notified Bodies and also published on the EU website.

8.1 Access to conformity assessment services

In order to access the conformity assessment services offered by INTERTEK, the Manufacturer must apply for certification according to the form prepared by INTERTEK with which it communicates its data and the information of the PPE for which it is requesting certification and the related offer.

INTERTEK receives the application, reviews and reviews it and, in the event of a positive evaluation, issues the offer.

At its sole discretion, INTERTEK may consider the results of the tests presented by the Manufacturer to be suitable if they are carried out at laboratories accredited for the specific test (e.g. ILAC/CNAS) or by laboratories recognized by INTERTEK on the basis of the applicable requirements and procedures described in these Regulations.

The Manufacturer can always express his choice motivated by specific needs for the execution of the tests through the dedicated forms or with an express request sent to the secretariat of the Notified Body.

INTERTEK, after careful verification and evaluation, reserves the right to decide whether or not to accept the tests.

The certification application form is available by writing to the email address:

infoitaly.dpi.organismonotificato@INTERTEK.com

The application must be signed by the legal representative of the Manufacturer, or by an authorized person.

If the Manufacturer has appointed an Authorised Representative, a copy of the written mandate must be submitted, specifying the tasks assigned, as required by the Regulation

8.2 Submission of the Application for EU Type Examination

The Manufacturer must fill in the form prepared by INTERTEK for each Type of PPE for which it requests the conformity assessment with Regulation (EU) 2016/425, attaching the following documents:

- The details of the Manufacturer (company name, address and legal status, etc.) and, if the request is submitted by the Representative, also the details of the latter;
- The name and contact details of the person in charge of maintaining relations with INTERTEK;
- A description of the PPE, its use and its intended use
- Photos of the PPE in the different views (e.g. above, below, side), such as to highlight its characteristics.

8.3 Review of the application and submission of the offer



Upon receipt of the application, INTERTEK checks that it has been filled in correctly and accompanied by any necessary attachments. If the documentation is lacking, INTERTEK will request additional documentation and/or additions for a correct assessment.

Following the review carried out, INTERTEK sends the Manufacturer an offer for the requested activities. The offer, in addition to containing the technical and economic quantification for conformity assessment services, contains in the attachment the declaration that the legal representative of the Manufacturer must return signed and stamped (where possible). The statement specifies, inter alia, that:

- the application for certification or surveillance has not been submitted to another Notified Body;
- the approval of each point of these Regulations and the consequent commitment to comply with it throughout the course of the course of the requested service process and for the entire duration of the contract.

Should the Manufacturer verify inconsistencies in the PPE data, it must notify INTERTEK in order to revise the document. The Manufacturer may not modify the offer in any way. INTERTEK is the only one authorized to modify such data.

By accepting the offer, the Manufacturer simultaneously accepts the laboratories indicated for the execution of the tests, if any. If the Manufacturer wishes to communicate reservations regarding the laboratories indicated, it must specify this prior to signing the offer, adequately justifying them. Following the reservation received, INTERTEK will evaluate the reasons for the same and, if deemed valid, will revise the offer indicating the alternative that complies with the requirements for what is proposed.

8.4 Order review

Upon receipt of the relevant signed offer, INTERTEK checks that it has been filled in correctly and accompanied by the necessary attached documents. If the documentation is missing some data or attachments, INTERTEK will request further documentation and/or additions before proceeding.

8.5 Start of the Certification Process for the EU Type Examination

Once the offer has been accepted, the Manufacturer must send the following to the Body:

- Copy of the technical documentation relating to the Type of PPE drawn up in accordance with the requirements of Annex III of Regulation (EU) 2016/425 and Annex II Module B, paragraph 3 of Decision 768/2008/EC. The technical documentation must allow the conformity of the product to be assessed;
- It must include appropriate risk analysis and assessment. The documentation shall specify the applicable standards and shall illustrate, to the extent necessary for such assessment, the design, manufacture and operation of the product.
- Samples sufficient to carry out the tests required for verification (if necessary), plus a representative sample;

The technical documentation shall contain, where applicable, at least the following:

- a) a full description of the PPE and its intended use;
- b) an assessment of the risks from which the PPE is intended to protect;
- c) a list of essential health and safety requirements applicable to PPE;
- d) drawings and diagrams of the design and manufacture of PPE and its components, subassemblies and circuits;
- e) the descriptions and explanations necessary for understanding the drawings and diagrams referred to in letter d) and the operation of the PPE;
- f) the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of PPE. In the case of partial application of harmonised standards, the documentation must specify the parts that have been applied;
- g) if the harmonised standards have not been applied or have been applied only partially, a description of the other technical specifications that have been applied in order to meet the applicable essential health and safety requirements;
- h) the results of design calculations, inspections and examinations carried out to verify the compliance of the PPE with the applicable essential health and safety requirements;
- i) reports on the tests carried out to verify the compliance of PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
- j) a description of the means used by the manufacturer during the production of the PPE to ensure compliance of the manufactured PPE with the design specifications;
- k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
- l) for PPE produced as single units to suit a single user, all the instructions necessary for the manufacture of such PPE on the basis of the approved basic model;



- m) for mass-produced PPE in which each item is manufactured to fit an individual user, a description of the measures to be taken by the manufacturer during assembly and the production process to ensure that each PPE complies with the approved type and the applicable essential health and safety requirements;

Acceptance of the Application for Certification and the Offer constitute an **Order** and **Contract** for the required conformity assessment activities.

Following receipt of the forms, it verifies the completeness of the documentation and the representative sample. Subsequently, INTERTEK informs the Manufacturer of the start of the certification process and the name of the technician in charge of carrying out the activity with the possibility of recusal of the same.

8.6 Document Verification

The first phase of the process consists in verifying the conformity of the technical documentation produced by the Manufacturer. The assessment is carried out at the Body, unless otherwise agreed with the Manufacturer.

The technical documentation must make it possible to assess the compliance of the PPE with the requirements of Regulation (EU) 2016/425 and include an appropriate risk analysis and assessment, specify the applicable standards and illustrate, to the extent necessary for such assessment, the design, manufacture and operation of the product.

Where applicable, it shall contain at least the following:

- a general description of the product;
- drawings relating to the general design and fabrication, diagrams of components, subsystems, circuits, etc.;
- descriptions and explanations necessary for the understanding of these drawings and diagrams and of the operation of the PPE;
- a list of harmonised standards and/or other relevant technical specifications;
- results of the design calculations carried out, the analyses carried out, etc.;
- the test reports and the results of tests carried out by the manufacturer's test laboratory or by another testing laboratory;
- the documentation attesting to the adequacy of the solutions of the technical project;
- a copy of the PPE instructions and any attached documentation bearing the "warnings";
- a copy of the EU declaration of conformity of PPE in accordance with Annex IX of Regulation (EU) 2016/425.

8.7 Outcome of the verification and communication of the findings

If, at the end of the verification of the technical documentation, Non-Conformities (NC) emerge, INTERTEK will indicate to the Manufacturer the obligation to resolve them as a requirement for access to the next phase of the Certification Process, which involves the execution of tests and examinations on the representative samples of the Production. The list shall be communicated in writing.

Following the communication, the Manufacturer must adapt its documentation.

If the Manufacturer decides to continue with the Certification, he must proceed to adapt his documentation, resolving the findings that have emerged, notifying INTERTEK.

The time period may not exceed six (6) months, unless otherwise provided and needs that will be assessed and agreed upon on a case-by-case basis.

After six (6) months, without the Manufacturer having contacted the Notified Body, the activity must be closed with a refusal of certification, with the debiting of the amounts relating to the activities conducted. In the face of such a refusal, in addition to the Authorities, the other N.O. must be informed, in the manner provided.

The objective evidence of the required adjustments is evaluated by INTERTEK before the required tests and examinations are carried out.

If the number of NCs and their extension do not allow the normal continuation of the process, INTERTEK will inform the Manufacturer of the need to carry out a new verification of the technical documentation following the resolution of the findings that have emerged. The expected amount will be communicated to the customer.

8.8 Execution of tests



The PPE conformity assessment activity is carried out at the Body's headquarters, by subcontracted INTERTEK Laboratories or by Laboratories recognized and accredited or qualified by INTERTEK Italia.

The verifications required to complete the Certification process include:

- any adjustments to the documentation following the NCs that emerged during the documentary verification for the continuation of the certification process;
- verification of the documents accompanying the PPE as indicated in the technical documentation;
- the execution of tests, aimed at verifying the conformity of the PPE.

Should findings emerge, INTERTEK will notify the Manufacturer of the same. Unless expressly indicated, the time for termination may not exceed six (6) months, unless otherwise provided and necessary which will be assessed and agreed upon on a case-by-case basis.

8.9 Additional Checks

INTERTEK reserves the right to carry out additional checks on all occasions in which the need arises to verify the compliance of the Manufacturer with the requirements set, both during the certification process and after the granting of the same. The costs for carrying out the additional verification activities are intended to be borne by the Manufacturer and communicated by means of an appropriate economic offer.

8.10 Review and decision on certification

At the end of all the inspections and obligations envisaged, INTERTEK draws up a report that reports the results obtained and summarizes the activities carried out for the purpose of assessing the conformity of the PPE, reviews the contents of the file and decides on the Certification.

In the event of a positive decision, INTERTEK notifies the Manufacturer of the issue of the "EU Type Examination Certificate" making the sending of the certificate subject to the payment of all fees. The EU Examination Certificate is drawn up in accordance with Annex V, paragraph 6 of Regulation (EU) 2016/425.

The Manufacturer may use the Certificate received only for the purposes provided for by Regulation (EU) 2016/425 and with reference to the Type of PPE for which it was issued by INTERTEK, entering the necessary data on the declaration of conformity and for all the obligations required by the placing on the market of the PPE, keeping it in the technical documentation.

8.11 Failure of the Conformity assessment

If the Manufacturer does not comply within the established terms with the resolution of the findings that emerged as a result of the verification, INTERTEK will not be able to proceed with the Certification resolution.

INTERTEK will draw up a report reporting the results obtained from the activities carried out for the purpose of the PPE conformity assessment concluded with a negative outcome. The Manufacturer may submit a new request for EU Type Examination, within a time agreed with INTERTEK, or if it deems it appropriate, may appeal in accordance with the procedures provided for in these Regulations.

The communication, in accordance with Article 34 of the Regulation, is forwarded to the Notified Bodies and to the competent ministry.

8.12 Certification with the "Own Brand Manufacturer" (OBM) process

The procedure defines the relationship between the company that is in possession of the certificate issued by INTERTEK, known as *the Original Manufacturer (OM)*, and the company that intends to market it in OBM (or OBL). This relationship must be governed by a contract, which defines the roles of the parties involved, as well as the methods of communication and access to sensitive information

If an OBM certification is requested, the Manufacturer must provide the following documentation:

- Copy of the OBM contract in which the original manufacturer undertakes to:
 - Provide certification documentation for your product
 - Have the certificate in a valid state;



- In the case of third-category PPE, provide a copy of the latest surveillance report Form C2/D carried out

9. CE marking and warnings on the safety of use

Before placing it on the market, the Manufacturer must affix the CE Marking to the PPE.

The manufacturer who has applied for the EU type certificate, for a third (III) Category device, will not be able to place such PPE on the market without having obtained a Report and/or the Certificate for the surveillance of production according to Module C2 or D.

9.1 CE marking

In addition to the general principles referred to in art. 30 of European Regulation 765/2008/EC, the CE Marking must comply with the following rules and conditions:

- The CE marking is affixed in a visible, legible and indelible way to the PPE or to a label affixed to it or to the packaging. In the case of small PPE or small parts, the CE marking can be affixed to a label or an information sheet. If this is technically impossible, in the case of PPE sold in displays and provided that the display was initially used as packaging for PPE, the CE marking must be affixed to the display. If the CE mark is not visible from the outside of the packaging, it must be placed at least on the packaging.
- The CE marking is affixed to the PPE before it is placed on the market. It may be followed by a pictogram or any other mark indicating a particular risk or use.
- In the case of issue of the C2 Module, issued by Intertek Italia, the CE marking is followed by no. 2575, which identifies the N.I., and is affixed to the PPE before it is placed on the market.
- In the case of issue of the C2 Module, issued by another N.N., the CE marking is followed by the relative N.O. number, and is affixed to the PPE before it is placed on the market.

10. Certification Communications

INTERTEK makes available a list of certifications issued to the notifying authorities with the necessary information required. In the case of justified requests from other authorities of member states or the European Commission, information relating to certification will be provided.

11. Record-keeping

The Manufacturer undertakes to keep a copy of the technical documentation, the EU Declaration of Conformity and the EU Type Examination Certificate, for a period of ten (10) years from the date of placing the PPE on the market. INTERTEK shall keep a copy of the EU Type Examination Certificate, the Annexes and the Supplements, as well as the technical archive containing the documentation submitted by the manufacturer, for a period of 5 years after the expiry of the certificate.

12. Validity of the EU Type Examination Certificate

The newly issued Certificates are valid for five years, within this period the Manufacturer asks INTERTEK to review their validity. The contracts signed between INTERTEK and the Manufacturer have a duration equal to the validity of the Certification. The Manufacturer has the right to withdraw from the contract in accordance with the procedures set out in these Regulations. INTERTEK informs the Manufacturer of any significant change affecting the validity of the Certificate by communicating the date after which the Certificate ceases to be valid. If the validity limit has been exceeded, the revision process follows the same procedure as for a new certification.

13. Certificate renewal with simplified procedure

The manufacturer must submit his application no later than twelve months and not less than six months before the expiry date of the EU-type examination certificate. Any delays will not be able to guarantee renewal by the expiry date and therefore must be considered as new certifications.

If the conditions set out in EU Regulation 2016/425, Annex V paragraph 7.6 are met, INTERTEK renews the certification by applying the simplified procedure. The review process follows the normal certification process.



In relation to the documentation received, INTERTEK will evaluate the release of the renewal which will have a duration of a further 5 years.

INTERTEK reserves the right to request a sample for the performance of a visual examination confirming or not that the approved type has not undergone modifications and that it corresponds to the approved technical documentation; If the conditions are not met, the renewal procedure described below will apply.

14. Certificate renewal

In cases where the above-mentioned conditions for simplified renewal do not exist and therefore changes have been made, the process will be carried out in relation to the documentation received. INTERTEK will evaluate the actions to be carried out according to any regulatory updates that occurred during the period and what is necessary for the issue of the renewal of a new certification. The Manufacturer must in any case submit his application no more than twelve months and no less than six months before the expiry date of the EU type-examination certificate. Any delays will not be able to guarantee renewal by the expiry date and therefore must be considered as new certifications.

If the review is successful, INTERTEK renews the validity of the Certificate for a further 5 years, starting from the expiry date of the previous one.

15. Transfer of the certificate

If the Manufacturer changes its name or address, but maintains the same identity, it must notify INTERTEK in writing of the changes made, sending:

- a copy of the variation and/or registration with the Chamber of Commerce or equivalent document;
- updating the technical file and the details reported in the manual and on the label.

Following the examination of the documentation, if the outcome of the tests is positive, it will issue a new Certificate, which cancels and replaces the previous one, with the same date.

INTERTEK reserves the right to carry out additional checks to verify that the requirements necessary to maintain the Certification are safeguarded.

16. Certificate Review

The EU Type Examination Certificate is revised at any time where the need arises, in particular if changes occur to the product, components or manufacturing process. .

It is the Manufacturer's obligation to immediately inform INTERTEK of the changes that have occurred, in order to assess the correct procedure to be applied on the basis of the changes that have occurred, as described below.

17. Evolution and technological progress

The issuance of new editions of harmonised standards, or the change in the legislative landscape relating to PPE, may change the requirements for obtaining and maintaining the Certification.

INTERTEK undertakes to promptly notify the Manufacturer of the need to implement the new requirements, also informing him of the deadline for compliance with the new provisions and formalizing a detailed economic proposal for the conduct of additional checks necessary to verify the Manufacturer's adaptation to the new requirements.

INTERTEK follows the evolution of generally recognized technological progress and assesses whether the Type of PPE for which it has granted the EU Type Certificate no longer complies with the applicable requirements. On the basis of the agreement, it decides whether this progress requires further verification. In this case, the Body shall inform the Manufacturer of the need to carry out new conformity assessments with the new requirements.

Once the evaluation procedure to be carried out has been defined, INTERTEK formalizes the decision to the Manufacturer with the issuance of a specific and detailed offer based on the provisions of the price list.

In cases where the above-mentioned conditions have a partial impact, it can be done as an extension and still follows the steps described by the certification process. The expiry date of the new certificate remains the same as the original certificate. In cases where the conditions have changed completely and/or the customer expressly requests the application of a new standard, the same procedure is carried out as for the new certification activity and the validity of the Certificate will be 5 years. The conditions of validity of the previous certificate will be communicated in the contractual conditions.

18. Minor PPE Modifications – Release Letter



They can be considered minor if the modification is not of a technical nature and you do not consider carrying out any activity on the PPE.

In this case, after careful verification, if this change does not require a revision of the certificate, the “release letter” is sent. The letter will contain the references of the technical documentation checked, which will be archived together with that of the EU type examination and therefore subject to the same obligation on conservation by the Manufacturer.

19. Certificate extension

When the Manufacturer communicates the intention to modify or extend the scope of the Certificate (e.g. range extension), INTERTEK will evaluate the contents of the request in order to determine the modalities of the service requested.

Once the evaluation procedure to be carried out has been defined, the decision is formalized in the tender. The verification of extensions follows the phases described by the Certification process.

In any case, the activity requires the issuance of a new certificate that maintains the same expiration date as the original certificate.

20. Waiver and Suspension

20.1 Renunciation

Waiver during the certification process is not allowed by the Regulations.

In cases where the Manufacturer renounces the certificate for his own needs, before its expiry, only communication to the competent Ministry is required.

20.2 Certificate Suspension – Module B

The validity of the Certification may be suspended for a defined time by INTERTEK, if it deems that a

- a) Any non-conformities subsequent to the issuance of the certificate;
- b) Serious reports from the market;
- c) Improper use of the Certificate, which does not comply with the provisions of Regulation (EU) 2016/425;

Failure to comply with contractual obligations and economic conditions the suspension measure is communicated to the Manufacturer by letter and/or e-mail.

The communication shall contain the reason for the suspension and the deadlines within which the Manufacturer must implement the required corrective actions. The Manufacturer has five (5) days to notify INTERTEK of the acceptance of the measure, the adaptation to the requirements of these Regulations and any other information useful for informing INTERTEK on the methods of resolving the disputed findings. The communication must be made by letter or e-mail.

The Manufacturer shall remove the causes, providing evidence to INTERTEK which shall assess their effectiveness. Following the positive outcome, the customer is notified of the lifting of the suspension.

If the Manufacturer does not comply with the required communications or does not remove the disputed causes for suspension within the indicated period, INTERTEK will revoke the validity of the Certification, notifying the authorities in the manner provided for by the Regulation

The period for adjustment is indicated by INTERTEK and, except in exceptional cases assessed by INTERTEK, may not exceed six (6) months.

If the suspension period has ended without the conditions for reinstatement having been implemented, INTERTEK shall inform the manufacturer of the need to withdraw (revoke) the certificate. It is the responsibility of the manufacturer to take the necessary corrective action on the products placed on the market.

20.3 Effects of Suspension – Module B

The suspension of the Certification entails the prohibition of placing PPE on the market, starting from the date of suspension. Following the suspension, the Manufacturer:

- loses the right to affix the CE marking and must stop using the Certificate;
- must refrain from publicizing the Certification until the end of the suspension period;



- must suspend the provision of PPE;

Suspensions are made public by INTERTEK in the manner provided for by the Regulation and are always communicated to the competent Ministry and other Notified Bodies;

The costs incurred by INTERTEK to carry out any checks or activities caused by suspension measures shall be borne by the Manufacturer.

21. Conformity assessment according to MODULE C2

For Category III PPE, the Manufacturer must compulsorily submit to one of the two options provided by the EU Regulation. One of these is internal production control combined with product tests under official control carried out at random intervals, corresponding to MODULE C2.

21.1 Application Submission - Form C2

The Manufacturer must fill in the form prepared by INTERTEK for each Type of PPE for which it requests surveillance, attaching the following documents:

- The Manufacturer's personal details (company name, address and legal status, etc.)
- The place of sampling for the sampling, the name and contact details of the person in charge of relations with INTERTEK;
- Copy of the Module B certificate(s) associated with the surveillance activity, in case the Module B has been issued by another N.O.
- Copy of the Technical File, in case Module B has been issued by another N.O.
- Information related to production for the purpose of the sampling program (production batches, quantities, etc.) tag.
- Information relating to the checks carried out in production during all the required phases, aimed at verifying conformity with the certified type.

Additional documentation may be attached to the Application that the Manufacturer deems necessary and useful for the assessment.

The review of the application is carried out as described in p.8.3

Following the review carried out, INTERTEK sends the Manufacturer an offer for the requested activities.

The review of the tender is carried out as described in p. 8.4.

Acceptance of Supply and Demand constitute an **Order** and **Contract** for the requested activities.

Subsequently, INTERTEK notifies the Manufacturer of the start of the activity and the name of the technician in charge of carrying out the activity with the possibility of recusal of the same.

21.2 PHASE 1 – Visit and product/documentation check

The Manufacturer ascertains and declares that the PPE subjected to the surveillance activities conforms to the type covered by the EU Type Examination Certificate and that the manufacturing process guarantees the homogeneity of production.

INTERTEK examines the documentation produced, on the basis of the information received and agrees with the Manufacturer on a sampling visit program that will be implemented and verified on site. The place of sampling must be communicated and agreed in advance at a place such as the production site, its own warehouse or that of a distributor.

The sampling methods are aimed at ascertaining the homogeneity of production on homogeneous batches and randomly picked such as to reach the quantity necessary for the tests in accordance with the agreed program. In case of impossibility, they will be evaluated on a case-by-case basis.

The technician applies to the sampling program and takes samples for sending to INTERTEK or the chosen test laboratory. In both cases, the identification of the samples must be ensured by signature/date or by sealing (identification with seal) and then shipped. Shipping is always at the expense of the customer.

21.3 STEP 2 – Product Verification and Testing

INTERTEK verifies the conformity of PPE by means of examinations and tests, in accordance with the procedures described below. It carries out the necessary tests to ascertain the conformity of the samples with the model examined in the EU Type



Examination Certificate (Module B). By necessary tests we mean the most important and/or significant tests chosen with a distribution criterion over the period of validity of the contract (e.g. three years).

The verification is aimed at ensuring that the production process is capable of guaranteeing the homogeneity of production to the device covered by the EU Type Examination.

INTERTEK will issue a Surveillance Report and the Certificate of Conformity of the finished product with a validity of one year.

The renewal can only be carried out by the expiry date, by means of an appropriate request received at least 3 months in advance.

INTERTEK makes at least one visit per year at random intervals established in agreement with the customer. INTERTEK reserves the right to conduct unscheduled visits more frequently than required based on the results of the tests and information from the market.

Any suspensions of production must be communicated to INTERTEK for the purpose of the relevant verifications.

The Surveillance Report and the Certificate of Conformity of the finished product are drawn up in English or Italian if requested by the customer.

The issuance of the certificate entitles the Manufacturer to affix the marking provided for with the number of the N.O. on each personal protective equipment and to draw up the Declaration of Conformity.

21.4 First issue of the certificate

For the issuance of the first Module C2, an initial assessment must be carried out before the PPE is placed on the market with the identification of INTERTEK (2575), based on the information received from the Manufacturer. The verification must ascertain that the PPE produced is actually the one covered by the certificate with Module B including the marking, packaging and user manual.

The certificate will expire one year from the date of issue.

In the case of Form C2 requested on Module B issued with the OBM procedure, the aforementioned checks must still be carried out. This activity may be carried out on the occasion of the visit by the OEM (Origin Equipment Manufacturer), if entrusted to INTERTEK.

21.5 Certificate renewal

For the renewal of the certificate, the application must be submitted every year in order to verify the correspondence of the products to be verified together with the information relating to the batches produced. Sampling must be conducted at least within three months of the expiry date of the valid Form C2. The validity of the certificate may in no way exceed the validity of the relevant Module B.

In the event of a temporary suspension of production, the manufacturer must send written notice to the notified body INTERTEK to the e-mail address, which will suspend the certificate.

If the Module B certificate is updated (e.g. for a regulatory extension or adaptation) the certificate relating to Module C2 must be renewed.

The contract generally has a duration of three years while the certificate is always valid for one year and must be renewed by the expiry date.

21.6 Negative outcome of the checks

In the event that the tests are negative, INTERTEK will notify the customer that:

1. must take charge of the NC and inform INTERTEK of the proposed CAs, within 15 days; the NCs should in any case be closed within a month.
2. INTERTEK will determine the actions to be taken and any additional tests needed.
3. If the outcome of the tests has been satisfactory, the surveillance activity proceeds according to the normal procedure.



4. If the outcome of the tests is NOT satisfactory, a new sampling is carried out by repeating a second sampling and the tests following the procedure of the previous points (from 1 to 4) within an agreed time limit (e.g. one month).
5. If the second repetition of tests continues to give negative results, in general, the certificate will not be issued or renewed. Any cases with a double negative outcome will be evaluated on a case-by-case basis.

As required by Regulation 2016/425, the negative outcome must be communicated to the competent Ministry and to the Notified Bodies.

21.7 Certificate Suspension – Form C2

The suspension of Form C2 may occur following an impossibility of carrying out the scheduled visit or due to evidence that the production process does not guarantee compliance with the PPE covered by the certificate.

The suspension has a limited duration and cannot exceed six (6) months.

During the suspension, the manufacturer may not use the INTERTEK certification (certificate number and identification of Notified Body 2575) on the manufacturer's declaration of conformity for the purpose of CE marking the product in question for placing on the market.

If the manufacturer makes himself available for the execution of the sampling in good time (before the deadline) and following the positive outcome of the tests, INTERTEK restores the validity of the Certificate Module C2 and notifies the manufacturer of such reinstatement.

If the suspension period has ended without the conditions for reinstatement having been implemented, INTERTEK shall inform the manufacturer of the need to withdraw (revoke) the certificate. It is the responsibility of the manufacturer to take the necessary corrective action on the products placed on the market.

The suspension may also affect all or part of the EU Type Examination Certificate (Module B) and in this case actions may be requested on a case-by-case basis.

In the event that the manufacturer is forced to stop the production of PPE, he may request the temporary suspension of the certificate. If the certificate is restored, it will go to its natural expiry.

The reactivation follows the same procedure as for the first issue.

21.8 Effects of Suspension – Form C2

The suspension of the Certification entails the prohibition of placing PPE on the market, starting from the date of suspension. Following the suspension, the Manufacturer:

- loses the right to affix the CE marking and must stop using the Certificate;
- must refrain from publicizing the Certification until the end of the suspension period;
- must suspend the provision of PPE;

Suspensions are made public by INTERTEK in the manner provided for by the Regulation and are always communicated to the competent Ministry and to the Notified Bodies;

The costs incurred by INTERTEK to carry out any checks or activities caused by suspension measures shall be borne by the Manufacturer.

22. Revocation

The revocation measure adopted by INTERTEK consists in the definitive withdrawal of the certificate, with the consequent loss of validity of the certification and the use of the 2575 identification marking.

In addition, INTERTEK will notify the revocation of the Certification in all cases ordered by the competent authorities or in which it finds objective evidence:

- fraudulent and illegitimate use of the Certification;
- following the suspension
- serious non-compliance with these Regulations;
- the non-conformity of the product, with respect to the technical documentation submitted to INTERTEK;



- the ascertained and repeated arrears towards INTERTEK;
- the misleading use of the Certification and/or the trademark, such as to cause damage or discredit to INTERTEK;

The revocation of the Certification, decided by the Certification Resolution Committee, is notified to the Manufacturer by letter or e-mail and containing an indication of the reasons for the measure adopted.

The revocation may also affect all or part of the EU Type Examination Certificate (Module B) and in this case actions will be taken on a case-by-case basis, which may require a new issuance of the same.

Revocations are made public by INTERTEK in the manner provided by the Regulation, communicated to the competent Ministry and to the other Notified Bodies.

In cases in which the Manufacturer renounces production of the product, communication is considered necessary only to the Ministry and not to the Notified Bodies.

23. Complaints and Appeals

23.1 Complaint

A complaint is defined as an expression of dissatisfaction, whether verbal or written, by the customer or other interested parties with the service offered and/or received.

The Manufacturer may make a complaint regarding the activities carried out by INTERTEK. The Body analyzes the content of the complaint to identify the actions necessary for its management and resolution in accordance with the internal procedures adopted, if deemed well-founded. INTERTEK always provides a written and reasoned response to complaints received, whether they are unfounded or well-founded. In the latter case, it proposes the decisive actions of the same.

INTERTEK does not consider complaints submitted anonymously. The Complaints and Appeals Handling Procedure adopted by INTERTEK is available and the procedures are summarized below:

1. Sending the complaint by certified email indicating your personal details and contact details, arguing your complaint, attaching any document deemed useful;
2. Within 30 days of receipt, INTERTEK communicates any acceptance by certified email or email;
3. Within 45 days from the date of acceptance, INTERTEK notifies the outcome of the complaint by certified email or email;

The complaint form can be found on the INTERTEK website at www.Intertek.it

The complaint can also be submitted by users, understood as natural or legal persons or trade associations.

This type of complaint is handled in the same way as the complaint by the Manufacturer.

Regardless of the type of complaint, it will be subject to careful evaluation, if founded, by a competent person other than personnel who have carried out certification activities.

23.2 Recourse

An Appeal means an official action of the certified or certifying entity with the aim of requesting the revision of a decision on certification (e.g.: suspension, revocation or reduction measure, non-grant, etc.) taken by INTERTEK as a Certification Body and is to be considered as a right.

The Manufacturer certifying or holding certification may appeal the decision on the certification of INTERTEK. The Body analyzes the content of the appeal. INTERTEK undertakes to handle any appeal filed regardless of its merits.

The Procedure for the Management of Appeals adopted by INTERTEK is available and the procedures are summarized below:

1. The appeal must be submitted in writing, by certified email or email, detailing the reasons for the appeal and the evidence necessary to support one's thesis. The appeal must be filed within fifteen (15) working days of notification of the decision against which the appeal is made.
2. Within five (5) working days following receipt of the appeal, INTERTEK shall communicate by email the acknowledgement of the same and the names of the persons entrusted with the management. The transposition and management of the appeal do not suspend the validity of the decisions taken by INTERTEK until the conclusion of the relevant processing.
3. Within 90 days of receipt, INTERTEK communicates the outcome of the appeal by certified email or email;



The form of appeal is available on the INTERTEK website at www.intertek.it

If the Manufacturer is not satisfied with the resolution of the appeal or complaint, he can always act against INTERTEK.

23.3 Litigation

For any dispute that may arise between the parties regarding the interpretation, implementation, execution, validity and effectiveness of the Certification Regulations, the Court of Milan shall have exclusive jurisdiction.

24. Confidentiality

The activities carried out by INTERTEK cannot disregard the evaluation of data and documents that represent sensitive elements of the Company's know-how and/or information subject to the guarantee of the Manufacturer's privacy. To ensure the necessary confidentiality of the same, INTERTEK adopts the provisions of Regulation (EU) 2016/679 regarding the processing of data provided by the Manufacturer. In conjunction with the offer, the customer is informed about the processing of data and can express his opinion.

It also adopts measures aimed at protecting the data and information obtained during conformity assessment activities, testing and/or measurement activities and more generally during all phases involving the processes relating to the provision of the services offered.

INTERTEK does not disclose the above data and information, except where required or required by law.

When the certification body is required by law or is authorized by contractual arrangements to release confidential information, the customer or the person concerned, unless prohibited by law, must be informed of the information provided.

In any other case, the customer's consent will be requested. The customer can access, at any time, their personal data to make updates or additions through the dedicated portal or request PPE Certification - Via di Stagno 17/F - 50055 Lastra a Signa (FI), email: infoitaly.dpi.organismonotificato@intertek.com.

INTERTEK extends the obligation of confidentiality to all internal and external personnel involved in the activities referred to in these Regulations and adopts appropriate measures for the control, management and storage of information conveyed on computer media.

The Manufacturer explicitly approves that the information and documents relating to the Certification are accessible to ACCREDIA and the INTERTEK Certification Committee for the control activities required by the reference standards and to the competent bodies and institutions upon request.

25. Amendments to the Rules

The continuous updating of the regulatory and legislative framework applicable to the activities conducted by INTERTEK and affected by these Regulations may require the modification of one or more paragraphs of the same.

Similarly, the Regulation may be amended for reasons other than updating the regulatory and legislative landscape.

INTERTEK makes the latest updated version of the Regulations available on its website WEB highlighting the new publication also in the usual correspondence with the customer.

The Manufacturer undertakes to adapt to the new conditions set by the Regulation, as indicated in paragraph 1. The updating of the Regulations cannot be considered just cause for withdrawal from the contract signed with INTERTEK.

26. Economic conditions

The economic conditions set out in the Offer drawn up by INTERTEK for the activities referred to in these Regulations are based on the information contained in the request and/or Application for certification sent by the Manufacturer and refer to the items of the Tariff List, defined by the Management of the Body.

The Manufacturer who wishes to access the Certification services must accept the INTERTEK Offer, also undertaking to comply with the payment conditions contained therein.

27. Changes to the Offer, the Tariff and the Right of Withdrawal



Changes to the economic conditions signed by the Manufacturer may be applied by INTERTEK if it detects discrepancies between the data communicated by the Manufacturer at the time of filling out the request and/or the Application and what is found during the subsequent verification activities provided for by the Assessment Process. Or following revisions of the Tariff.

27.1 Variation of the Offer

In the event that conditions are found that differ from those stated in the request and/or in the Application, which justify an additional verification activity, INTERTEK will notify the Manufacturer of the necessary economic integrations by suspending the evaluation process until they are accepted.

To the Manufacturer who refuses the economic integration submitted, INTERTEK communicates the interruption of the evaluation process, quantifying the amounts for the activities already carried out only.

27.2 Variation of the Tariff

The Tariff applied by INTERTEK is periodically reviewed by the Management of the Body. In the event of changes with respect to the economic conditions signed, INTERTEK will notify the Manufacturer of the new amounts applied to the verification activities, email or ordinary mail.

The Manufacturer has the right to refuse the new economic conditions within one (1) month from the date of communication. By refusing the new amounts, the Manufacturer will see the validity of the Certification lapse at the natural expiry of the contract.

For any activities already carried out during the month scheduled for the cancellation, INTERTEK will apply the economic conditions prior to the change in the Tariff.

28. Advertising and Use of Certification

The Manufacturer may make known and advertise in the ways it deems most appropriate the obtaining of the Product Certification, reproducing the Certificate or Certificate obtained in its entirety, enlarging or reducing it, in colour or black and white, provided that it remains legible and does not undergo any alteration.

Solutions other than those defined in this paragraph shall be authorized, in writing, by INTERTEK.

The Manufacturer must avoid misleading or ambiguous use of the Certification issued by INTERTEK and must prevent the Certification from being understood as extending to products not covered by the certificate issued by INTERTEK.

In the event of non-compliant use of the certificate with respect to what is indicated in this paragraph, INTERTEK reserves the right to take appropriate measures against the manufacturer, including the use of appropriate legal actions and the revocation of the Certification granted.

The use of the Body's Trademark and the Accredia Trademark, on the advertising documentation prepared by the Manufacturer, must be approved by INTERTEK, according to the procedures indicated in the "Regulations for the use of the Trademark" Accredia Regulation RG-09.

INTERTEK Italia S.p.a., pursuant to the legislation on the protection of personal data (EU Regulation 2016/679, so-called "GDPR"), which it undertakes to comply with, declares to proceed with the processing of personal data for the purposes inherent in the provision of the service, as well as to comply with all legal and/or administrative provisions necessary for its execution. The complete information and procedures for exercising the rights of the data subject are available on the Company's website, www.intertek.it.

You may exercise your rights at any time by sending requests to INTERTEK Italia S.p.A. with registered office in Via Miglioli 2/A – 20063 Cernusco sul Naviglio (MI), even by registered mail.