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

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REV.	DATA	DESCRIPTION OF CHANGES	DRAFTED BY	APPROVED BY
8	14/10/2024	General revision, chapter ordering and modifications on first visit activities Module C2	F. Nicchiarelli	E. Serra

1. Purpose

This Regulation defines the general practices adopted by INTERTEK Italia S.p.A. (INTERTEK) for the conduct of conformity assessment activities of products designed or intended, whether exclusively or not, for use as personal protective equipment (PPE) as referred to in Regulation (EU) 2016/425, which the Manufacturer or entity considered as such under the Regulation itself, must follow in order to obtain and maintain EU Product Certification.

INTERTEK makes the latest updated version of the Rules and Regulations available on its website at http://www.intertek.it, at its offices in Lastra S. (FI) or, at the request of the Manufacturer, provides an electronic copy.

Amendments and additions to the Rules and Regulations are managed by issuing successive revisions, in which the amended portions of the text are highlighted with vertical lines alongside. The Rules are an integral part of the contract signed between INTERTEK and the Manufacturer. INTERTEK always applies the latest revision issued.
In the event that the changes made may interfere with or in any way affect certifications already issued or with an existing contract, INTERTEK shall send a copy of the Rules in electronic format to the client who is the owner of the certificate or contract. Such changes shall only be valid if agreed by both parties.
The customer has 5 days to accept or not accept the changes made, after which time silence consent applies.

Acceptance by the customer is not required for changes of a legislative nature.
Where changes do not affect, affect or interfere with certifications already issued, the updated version is made available on the website at http://www.intertek.it.

2. Scope of application

The Rules describe the commitments and responsibilities undertaken by INTERTEK and the Manufacturer applying for conformity assessment for:

1. PPE category II (second): for EU Type Examination assessment - Annex V of Regulation (EU) 2016/425 (Module B) followed by conformity to type based on internal production control (Module C) as referred to in Annex VI of Regulation (EU) 2016/425;

2. PPE category III (third): for the evaluation 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 testing under official control carried out at random intervals (Module C2) as 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
- Ministerial Decree (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 European Commission working groups;
- 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: Notifications for accreditation - Characteristics
- 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 refer to standards and technical specifications issued by International Standardisation Committees such as UNI, EN, ISO, IEC, CEI, CEN and CENELEC. The harmonised standards referring 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 Rules (referred to in this document simply as the Rules), the following definitions are given:
Manufacturer for certification ('Manufacturer'): a natural or legal person who manufactures PPE, or has it designed or manufactured, and markets it under his 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 its behalf in connection with certain tasks;
Importer: a natural or legal person established in the Community who places an PPE originating from a third country on the Community market;
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 under his own name. European legislation considers the OBM manufacturer to be the legal manufacturer even when this person has nothing to do with the physical production of the device.
EU Type Examination: EU Type Examination is the part of a conformity assessment procedure whereby a Notified Body examines the technical design of a product and verifies and certifies that the technical design of the product meets the requirements of the legislative instrument applicable to it;
Identification number of the Notified Body: No. 2575 is the number assigned to INTERTEK to be affixed to the marking (CE 2575) of the Cat. III PPE subjected to production supervision (MODULE C2) by means of a contract and the 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 calibration, testing, certification and inspection, as a third party and to issue certificates of conformity;
Conformity assessment (verification)**:** the process of demonstrating whether specific requirements relating to a product, process, service, system, person or body have been met;
Production surveillance: procedure provided for PPE category III and as described in Annex VII of Reg. 2016/425 - Module C2
Program for sampling: program of visits and tests useful for taking samples for the purpose of carrying out the activity under Module C2.
Relief: objective finding of an event or condition highlighting a NC;
Non-conformity (NC): failure by the manufacturer to meet a requirement, referred to in a regulation, a law in force or a standard applicable to the field in question.
Comment: it is a recommendation that is not considered as a non-conformity and the manufacturer is not obliged to give evidence of receipt.
Responsibility: a burden assumed by or arising from the conduct of a process, the performance of a job, or the management of an assignment (or task) entrusted and to be performed with due diligence;
Complaint: manifestation of dissatisfaction, either verbal or written, by entitled Parties (direct customers, indirect customers, Public Authorities, ACCREDIA), with regard to the services provided by the Body and, in general, to its work;
Appeal: formal appeal, by persons having specific cause, against decisions taken or assessments made or certificates issued by the body.
The terminology and definitions used in the documentation supporting the performance of the activities required to issue the EC attestation of conformity comply with 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 requirements 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 organisation or association, or number of certifications obtained. The only exception is made for entities subject to legal restrictions preventing them from marketing products subject to EU conformity certification.
In order to guarantee the utmost fairness and transparency in the performance of audit and certification activities, INTERTEK specifies, also through the signing of appropriate codes of conduct, that its management and technical staff are not subject to undue internal or external pressure, of a commercial, financial or other nature, that may negatively affect the work performed.
The personnel involved in the verification activities aimed at issuing the EU attestation of conformity are not involved in activities that could undermine confidence in their independence, impartiality and professional integrity. Furthermore, the Body does not carry out design activities either directly or in a consultancy capacity, does not market products and/or systems subject to the audits or EU Certification, nor does it provide technical assistance services to subjects, subject to the audits or certification, for the sectors covered by the Accreditation, nor does it carry out other activities that may undermine confidence in its work.

5.1 Committee to Safeguard Independence and Impartiality (ISC)

Independence and impartiality is ensured by the ISC which is regulated by the RG. NB.03. Intertek's Management ensures that the Committee for Safeguarding Independence and Impartiality has the ability to formulate Intertek's operating policies and oversee their implementation, including monitoring financial aspects. It is the responsibility of the Intertek management to make the members of the ISC aware of the importance of their role with respect to Intertek's overall third party, independence, impartiality, competence and conformity of operation.

6. Certification Resolution Committee (CDC)

For the purpose of issuing the certificate, Intertek has established the Certification Committee, which issues the final opinion and thus the resolution for issuing the certificate. The CoC is governed by its own RG regulation. NB.04.

7. Responsibility

These Rules 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, in accordance with the methods and timescales described in the following paragraphs and in the contractual documents signed by the parties.
INTERTEK points out that some phases of the activity may be carried out by third parties such as laboratories or other contracted parties. The performance of tests is generally entrusted to laboratories accredited by bodies that have signed Mutual Recognition Agreements EA, IAF, ILAC. If this condition is not possible, INTERTEK will verify suitability through an audit based on EN ISO 17025.
The assignment of such activities is usually included in the offer and is always subject to the Manufacturer's approval. In the event of disagreement, a Laboratory with the above-mentioned characteristics will be agreed upon, subject to written communication and countersigned for acceptance.
The ultimate responsibility for the activity remains solely with INTERTEK.

7.1 Commitments of Manufacturer

The Manufacturer undertakes to provide full cooperation to INTERTEK representatives during all stages of the Certification process (Module B) and/or conformity control based on internal production control combined with product testing (Module C2) described in these Rules.
Arranges any permits and authorisations to allow access to the areas involved in the performance of the above-mentioned activities, whether internal or external to the company being examined. Allows on-site access, or the supply of copies, of all documents that INTERTEK considers useful to examine for the purposes of the required compliance.

If the Manufacturer does not grant INTERTEK and/or ACCREDIA personnel access to the areas, information and documentation necessary for the inspection or sampling visit, the process will be interrupted and the certificate, if issued by INTERTEK, will be suspended/withdrawn.

The Manufacturer, before submitting the application for Certification (Module B) and/or conformity control based on internal production control combined with product testing (Module C2) to INTERTEK, is responsible for preparing at least the following in compliance with the requirements of Regulation (EU) 2016/425.
All documentation provided by the Manufacturer in support of the verification activities shall be prepared in English and in Italian if deemed necessary in agreement with the customer.

For the EU Type Examination (Module B):

- *Documentation of risk assessment and analysis*

In compliance with the requirements of Art. 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 assessed the potential exposure to such hazards.

- *Technical Construction File*

In compliance with the requirements of Art. 8 of Regulation (EU) 2016/425, the Manufacturer shall provide evidence of having prepared the required technical documentation containing, to the extent relevant to the assessment, the contents of Annex III of Regulation (EU) 2016/425, except as to be supplemented following the successful completion of the certification process. The technical documentation shall demonstrate the conformity of the PPE with the requirements of Regulation (EU) 2016/425 and any requirements referred to therein.

- *PPE samples*

The Manufacturer shall prepare an adequate number of samples representative of the intended production of the PPE subject to EU Type Examination, constructed as prescribed in the technical documentation. The number of samples shall be communicated by INTERTEK and must allow the controls and tests considered necessary for conformity assessment to be carried out.
The Manufacturer shall also issue or procure the necessary authorisations or permissions to allow access by representatives of INTERTEK to the place where production of the Type is carried out, should this be necessary.
The witness sample received and examined shall be retained by INTERTEK for at least 90 days from the date of issue of the certificate. If reclaimed, it may be returned to the client, at the client's own expense. If the client fails to collect the sample, it shall be disposed of in accordance with the regulations in force.

- *Internal control process on production*

The Manufacturer must provide evidence that it has established 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 PPE Type and related corrective actions taken;
- the documented updating of the mandatory standards or laws applicable to the product and the identification of new requirements applicable to it;
- the documented update of the technical documentation with regard to changes or variations made to the Type with reference to the requirements of Regulation (EU) 2016/425.

The Manufacturer must provide copies of all procedures and documentation that INTERTEK deems necessary for the evaluation of the requirement. If the Manufacturer fails to provide the required documentation, INTERTEK will issue a negative certification opinion.

- *EU Declaration of Conformity*

In compliance with the requirements of Art.15 of Regulation (EU) 2016/425, the Manufacturer must prepare the EU Declaration of Conformity of the PPE subject of the application, which certifies that conformity with the requirements

defined in Art.10 and Annex II of Regulation (EU) 2016/425 has been demonstrated. Any information concerning the outcome of the Certification Process must be reported in draft form, until its successful conclusion.
The declaration must be attached to the file without signature and date, as the date and signature can only be affixed following successful completion of the Certification process.

- *Compliance with the Rules and the contractual relationship*

the Manufacturer, undertakes to comply with every point of these Rules and to honour any further commitments deriving from the signing of the contractual documents envisaged by the Certification process. Furthermore, it undertakes to guarantee the following

- allow free access to the inspectors (and to any observers) of the Certification Body and, if necessary, to ACCREDIA personnel that may accompany those of the Certification Body during the assessment and surveillance phase, including the provision, for examination purposes, of documentation and registrations, to production sites, personnel working at the client Certification Body and any subcontractors of the client;
- provide support to INTERTEK representatives by making its own personnel available for activities involved in conformity assessment, during working hours and throughout the period involved in the certification process;
- facilitate the conduct of evaluation activities, at the times and in the ways agreed in official communications;
- Facilitating access for INTERTEK representatives to all areas involved in the evaluations, to records (changes to the technical file, resolution of complaints, etc.), to personnel involved in design and manufacture, etc;
- facilitate the resolution of NC that have emerged during the certification process, enabling INTERTEK to verify their resolution, through evidence of corrective actions taken;
- not market the PPE covered by the Certification until the successful conclusion of the Iter;
- promptly notify INTERTEK of any changes made to the PPE covered by the EU Type Examination Certificate and to the manufacturing process adopted;
- make payments in the manner and within the timeframe defined in the signed contractual documents;
- not omit or neglect to communicate to INTERTEK any information relevant to the certification process or to the PPE subject to the requested EU Type Examination;
- use and publicize the EU Type Certificate exclusively within the limits for which it has been granted and avoid bringing the organisation into disrepute;
- allow the performance of the required inspections, communicated even with minimum notice, to the personnel appointed by INTERTEK, even if assisted by personnel of ACCREDIA or of the competent bodies;
- allow INTERTEK to carry out additional audits motivated by serious reports concerning the certified PPE, also in collaboration with personnel from the competent Authorities or ACCREDIA. These audits may be performed without prior notice or with a minimum of 5 working days' notice; refusal will result in the revocation of Certification.
- use the certificate only for the product for which it was issued and for the quantities subject to control;
- not to use certification in such a way as to bring the certification body into disrepute;
- not to use product certification in a manner deemed misleading or not authorised by the Certification Body;
- not use the certification (e.g. on advertising material) if it has been suspended, revoked or expired;
- when providing certification-related documents (such as certificates), reproduce them in their entirety in accordance with the certification scheme;
- use references to its certification in the media (e.g. documents, brochures, advertising material) in accordance with the (regulated or mandatory) industry regulations;
- comply with the requirements of the certification scheme concerning the use of conformity marks and product information;
- keep a record of all complaints and/or appeals received and/or of which they become aware relating to products controlled and certified by the Certification Body and, if requested, make them available to the same. If justified, identify, implement and document corrective actions to remove the cause of the complaint and/or appeal or the defect found in the product that affects conformity with the certification requirements;
- promptly notify - in accordance with the sector regulations - the Certification Body of any changes that may affect the client's ability to meet the certification requirements:
- The customer must also notify the Certification Body of changes relating to:
  - legal, commercial, organizational or ownership status or legal representative;
  - contact addresses and sites;
  - introduction of new activities/products/services that have an impact on control activities.

7.2 Commitments of the Body

INTERTEK undertakes to make available the necessary resources, to plan and carry out the conformity assessment activities as prescribed by the Rules. It also undertakes to make available the necessary resources to carry out any additional audits and all activities required for the surveillance and maintenance of the Certification granted.
INTERTEK also guarantees adequate insurance coverage for risks that may arise for the Manufacturer from conducting conformity assessment activities under these Rules.
Force majeure
INTERTEK cannot be held liable for any non-compliance that may occur due to objectively unforeseeable circumstances, prior to the engagement of the Manufacturer to assess the conformity of the PPE.
INTERTEK shall not be held liable for failure to meet the agreed deadlines in the event of delays on the part of the Manufacturer, or for the occurrence of NCs attributable to its actions.

8. Iteration of evaluation and certification processes

The certification process carried out by INTERTEK includes the steps 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. Regarding the concepts of harmonised standards and other documents to be used for conformity, please refer to the Blue Guide "Implementation of product standards" available on the EU website.

Each phase is carried out according to internal procedures and regulations drawn up by INTERTEK, which can be consulted by the Manufacturer at the Head Office of the Body, in the area relevant to PPE Certification activities.
In cases where the use of non-harmonised standards or technical specifications is requested by the client, INTERTEK reserves the right to assess this on a case-by-case basis before accepting the assignment.
Furthermore, 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 provided by INTERTEK, in which it communicates its data and information on the PPE for which it is requesting certification and its offer.
INTERTEK receives the application, reviews it and, in the event of a positive evaluation, issues the offer.
At its sole discretion, INTERTEK may deem suitable the results of tests submitted by the Manufacturer if they are carried out in accredited laboratories (e.g. ILAC/CNAS) or by laboratories recognised by INTERTEK on the basis of the applicable requirements and procedures described in these Rules.
The manufacturer may always express his choice motivated by specific requirements for the performance of tests by means of the dedicated form or by an express request sent to the N.O. secretariat.
INTERTEK reserves the right, after careful examination and evaluation, to decide whether or not to accept the evidence.
The certification application form is available by e-mail: infoitaly.dpi.organismonotificato@INTERTEK.com

The application must be signed by the legal representative of the manufacturer, or by an authorised person.
If the manufacturer has appointed an authorised representative, a copy of the written mandate must be submitted, specifying the tasks assigned, as provided for in the Regulation

8.2 Submission of Application for EU Type Examination

The Manufacturer shall complete the form provided by INTERTEK for each Type of PPE for which it requests 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 made by the Representative, also the latter's details;
- The name and contact details of the person responsible for maintaining relations with INTERTEK;
- A description of the PPE, its use and its intended purpose
- Photos of the PPE in different views (e.g. top, bottom, side) to highlight its characteristics.

8.3 Reviewing the Application and Submitting the Offer

Upon receipt of the application, INTERTEK will check that it has been correctly completed and accompanied by any necessary annexes. If the documentation is deficient, INTERTEK will request further documentation and/or additions for a correct assessment.
Following the review, INTERTEK sends the Manufacturer an offer for the requested activities. In addition to containing the technical and economic quantification for the conformity assessment services, the offer also includes an attached declaration to be returned signed and stamped (where possible) by the Manufacturer's legal representative. The declaration shall specify, inter alia, that:

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

Should the Manufacturer discover inconsistencies in the PPE data, he must notify INTERTEK in order to revise the document. The Manufacturer may not change the offer in any way. INTERTEK is solely authorised to change this data.

By accepting the offer, the Manufacturer simultaneously accepts the laboratories indicated for carrying out the tests, if applicable. If the Manufacturer wishes to communicate reservations concerning the indicated laboratories, it must specify this before signing the offer, giving adequate reasons. Following the reservation received, INTERTEK will evaluate the reasons for the same and if considered valid, will revise the offer indicating the alternative that complies with the requirements for what is proposed.

8.4 Review of the order

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

8.5 Start of Certification Process for EU Type Examination

Once the offer has been accepted, the manufacturer must send the following to the body:

- Copy of the technical documentation for 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 enable the conformity of the product to be assessed;
- must include an adequate risk analysis and assessment. The documentation must specify the applicable standards and illustrate, to the extent necessary for this assessment, the design, manufacture and operation of the product.
- Samples in sufficient number to perform the tests foreseen for the verification plus a representative sample;

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

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 the essential health and safety requirements applicable to the PPE;
d) drawings and diagrams of the design and manufacture of the PPE and its components, sub-assemblies and circuits;
e) descriptions and explanations necessary for understanding the drawings and diagrams referred to in (d) and the operation of the PPE;
f) the references of the harmonized standards referred to in Art. 14 which have been applied for the design and manufacture of the PPE. In the event of partial application of the harmonised standards, the documentation must specify the parts that have been applied;
g) if the harmonised standards have not been applied or have only been partially applied, a description of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
h) the results of design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant class of protection;
j) a description of the means used by the manufacturer during the production of the PPE to ensure conformity of the manufactured PPE with the design specifications;

k) a copy of the manufacturer's instructions and information as set out in Annex II, point 1.4;
l) for PPE manufactured as single units to fit a single user, all necessary instructions for the manufacture of such PPE on the basis of the approved basic model;
m) in the case of mass-produced PPE where each item is manufactured to fit an individual user, a description of the measures to be taken by the manufacturer during the assembly and production process to ensure that each PPE item conforms to 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 appointed to carry out the activity, with the possibility of rejecting the same.

8.6 Documentary Verification

The first stage consists of verifying the conformity of the technical documentation produced by the Manufacturer. The evaluation is carried out at the body, unless otherwise agreed with the Manufacturer.
The technical documentation must enable the conformity of the PPE with the requirements of Regulation (EU) 2016/425 to be assessed and must include an adequate analysis and assessment of the risks, specify the applicable standards and illustrate, to the extent necessary for such assessment, the design, manufacture and operation of the product.

Where applicable, it must contain at least the following elements:

- a general description of the product;
- conceptual design and manufacturing drawings, diagrams of components, sub-systems, circuits, etc;
- descriptions and explanations necessary for understanding these drawings and diagrams and the functioning of the PPE;
- a list of harmonised standards and/or other relevant technical specifications;
- results of design calculations performed, analyses carried out, etc;
- test reports and results of tests carried out by the manufacturer's own laboratory, or by another test laboratory;
- documentation proving the adequacy of the technical design solutions;
- a copy of the PPE instructions and any accompanying documentation containing 'warnings';
- a copy of the EU declaration of conformity of the PPE in accordance with Annex IX of Regulation (EU) 2016/425.

8.7 Outcome of the Verification and Notification of Findings

If non-conformities (NC) emerge at the end of the audit of the technical documentation, INTERTEK will inform the Manufacturer that they must be resolved as a requirement for access to the next stage of the Certification procedure, which involves carrying out tests and examinations on representative samples of the Production. The list is communicated in writing.
Following the communication, the manufacturer must adapt its documentation. If this is not the case, the activity must be closed with a denial of certification, with the amounts relating to the activities carried out being debited. In the event of such a refusal, not only the Authorities but also the other N.O.s must be informed, in the manner provided for.
If the Manufacturer decides to continue with the Certification, it may proceed to adapt its documentation, resolving the findings, by notifying INTERTEK.
In any event, the time period shall not exceed six (6) months, unless otherwise stipulated and agreed on a case-by-case basis.
Objective evidence of the required adjustments is assessed by INTERTEK before the required tests and examinations are carried out.
If the number of NC and their extent do not permit the normal continuation of the process, INTERTEK will inform the Manufacturer of the need to carry out a new inspection of the technical documentation following the resolution of the findings. The expected amount will be communicated to the client.

8.8 Performing the tests

PPE conformity assessment activities are carried out at the body's premises, by subcontracted INTERTEK Laboratories or by Laboratories qualified by INTERTEK Italia.

The checks required to complete the Certification process include:

- any adjustments to the documentation as a result of the NC that emerged during the document audit for the continuation of the certification process;
- verification of the documents accompanying the PPE as indicated in the technical documentation;
- the execution of the tests to verify the conformity of the PPE.

If findings emerge, INTERTEK shall notify the Manufacturer of the same. Unless expressly stated, the time for resolution shall not exceed six (6) months, unless otherwise provided for and agreed on a case-by-case basis.

8.9 Supplementary Verifications

INTERTEK reserves the right to carry out additional audits whenever the need arises to verify the Manufacturer's compliance with the requirements, either during the certification process or after certification has been granted. The costs for carrying out 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 conclusion of all the required inspections and fulfilments, INTERTEK draws up a report summarising the results obtained and summarising the activities carried out for the conformity assessment of the PPE, reviews the contents of the file and decides on Certification.
In the event of a positive decision, INTERTEK notifies the Manufacturer of the issuance of the "EU Type Examination Certificate" subject to payment of all fees. The EU Type 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 in Regulation (EU) 2016/425 and with reference to the Type of PPE for which it has been issued by INTERTEK, inserting the necessary data on the Declaration of Conformity and for all the fulfilments required for placing the PPE on the market, keeping it within the technical documentation.

8.11 Negative outcome of conformity assessment

If the Manufacturer does not comply with the resolution of the findings resulting from the audit within the prescribed time limit, INTERTEK shall not be entitled to proceed with the certification decision.
INTERTEK shall draw up a report containing the results of the activities carried out for the conformity assessment of the PPE concluded with a negative result. The Manufacturer may submit a new application for EU Type Examination, within a time agreed with INTERTEK, or if it considers it appropriate, it may lodge an appeal in accordance with these Regulations.
The communication, according to Art. 34 of the Regulation, is forwarded to the Notified Bodies and the competent ministry.

8.12 Own Brand Manufacturer (OBM) process certification

The procedure defines the relationship between the company that holds the certificate issued by INTERTEK, known as *Original Manufacturer* (OM), and the company that intends to market it in OBM (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 certification under OBM 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 a valid certificate;
  - In the case of third category PPE provide a copy of the last Form C2/D surveillance report carried out

9. CE marking and safety instructions for use

Before placing the PPE on the market, the Manufacturer must affix the CE Marking to the PPE.
A manufacturer who has applied for an EU Type Certificate, for a third (III) Category device, may not place such PPE on the market without having obtained a Report and/or Production Surveillance Certificate according to Module C2 or D.

9.1 CE Marking

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

- The CE marking shall be affixed visibly, legibly and indelibly to the PPE or on an affixed label or packaging. In the case of PPE of small dimensions or made up of small parts, the CE marking may be affixed to a label or information sheet. Where this is technically impossible, in the case of PPE sold in display stands and provided that the display stand was initially used as packaging for the PPE, the CE marking must be affixed to the display stand. If any CE marking is not visible from the outside of the packaging, it must at least be affixed to 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 Module C2, the CE marking is followed by No. 2575, which identifies the O.N., and is affixed to the PPE before it is placed on the market.

10. Communication of Certifications

INTERTEK provides a list of certifications issued to notifying authorities with the necessary information requested. In the case of justified requests from other member state authorities or the European Commission, certification information will be provided.

11. Preservation of Documentation

The Manufacturer undertakes to retain 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 the PPE is placed on the market. INTERTEK shall retain a copy of the EU Type Examination Certificate, its annexes and supplements, as well as the technical file 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

Newly issued Certificates are valid for five years, within which period the Manufacturer shall request INTERTEK to review their validity. Contracts signed between INTERTEK and the Manufacturer have a duration equal to the validity of the Certificate. The Manufacturer has the right to withdraw from the contract in accordance with the provisions of these Rules.
INTERTEK informs the Manufacturer of any significant changes that affect the validity of the Certificate, 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 certificate. .

13. Renewal of the certificate by simplified procedure

The manufacturer must submit its 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 guarantee renewal by the expiry date and must therefore be considered as new certification.
If the conditions of EU Regulation 2016/425, Annex V paragraph 7.6. are met, INTERTEK carries out the certification renewal applying the simplified procedure. The review process follows the normal certification process.
On the basis of the documentation received, INTERTEK will consider issuing a renewal for a further 5 years.
INTERTEK reserves the right to request a sample for a visual examination to confirm or otherwise that the approved type has not been modified 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 are not met and therefore changes have occurred, the process will proceed in relation to the documentation received. INTERTEK will evaluate the actions to be taken in relation to any regulatory updates that have occurred during the period and to what is necessary to issue a new certification renewal. The Manufacturer must in any case submit its 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 guarantee renewal by the expiry date and must therefore be considered as new certification.
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 company name or address, but retains the same identity, it must notify INTERTEK in writing of the changes by sending

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

Following examination of the documentation if the outcome is positive, a new Certificate, which cancels and replaces the previous one, will be issued with the same date.
INTERTEK, reserves the right to carry out additional audits to ascertain that the requirements necessary to maintain certification have been met.

16. Certificate Review

The EU Type Examination Certificate shall be reviewed at any time if the need arises, in particular if changes occur in the product, components or manufacturing process. .
It is the Manufacturer's obligation to inform INTERTEK immediately of any changes that have occurred, in order to assess the correct procedure to be applied on the basis of the changes, as described below.

17. Evolution and technological progress

The issuance of new editions of harmonised standards, or changes in the legislative landscape concerning PPE, may modify the requirements for obtaining and maintaining certification.
INTERTEK undertakes to promptly notify the Manufacturer of the need to implement the new requirements, informing it of the deadline for compliance with the new provisions and to formalise a detailed economic proposal for the conduct of additional audits necessary to verify the Manufacturer's compliance with the new requirements.
INTERTEK monitors generally recognised technological progress and assesses whether the PPE type for which it has granted the EU Type Certificate no longer complies with the applicable requirements. Based on this, it decides whether such progress requires further verification. If so, 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 formalises the decision to the Manufacturer by issuing a specific and detailed offer on the basis of the price list.

In cases where the above-mentioned conditions have a partial impact, it can proceed as an extension and still follow the steps described by the certification process. The expiry date of the new certificate remains the same as that of 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 followed as for the re-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 Changes - Letter of Release

They may be considered minor if the change is not of a technical nature and no activity is considered to be performed on the PPE.
In this case, after careful verification, if this change does not require a revision of the certificate, the letter of release is sent. The letter will contain the references of the checked technical documentation, which will be filed together with that of the EU type-examination and therefore subject to the same obligation on the Manufacturer's consevation.

19. Certificate Extension

When the Manufacturer communicates its intention to change or extend the scope of the Certificate (e.g. range extension), INTERTEK will evaluate the contents of the request in order to determine the terms of the requested service.
Once the evaluation procedure to be performed has been defined, the decision is formalised in the offer. The verification of extensions follows the steps described in the Certification process.
In any case, the activity requires the issuance of a new certificate with the same expiry date as the original certificate.

20. Renunciation and Suspension

20.1 Renunciation

Renunciation during the certification process is not permitted under the Rules.
In cases where the manufacturer renounces the certificate for his own reasons before its expiry, only the notification of the competent Ministry is foreseen.

20.2 Suspension of Certificate - Form B

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

a) Any non-compliance following the issue of the certificate;
b) Serious reports from the market;
c) The improper use of the Certificate, not in accordance with Regulation (EU) 2016/425;

Non-compliance with contractual obligations and economic conditions the suspension measure is communicated to the Manufacturer by letter and/or e-mail.
The communication shall include the reason for the suspension and the deadlines within which the Manufacturer must implement the requested corrective actions. The Manufacturer has five (5) days to notify INTERTEK of the action taken, the compliance with the requirements of these Rules and any other information useful to inform INTERTEK on how to solve the contested issues. The communication shall be made by letter or by e-mail.
The manufacturer removes the causes, giving evidence to INTERTEK, which assesses their effectiveness. Following the positive outcome, the client is notified of the lifting of the suspension.

If the Manufacturer does not comply with the required communications or does not remove the causes contested for suspension within the period indicated, INTERTEK will proceed to revoke the validity of the Certification, notifying the authorities in the manner provided for by the Regulations
The period for adjustment is specified by INTERTEK and, except in exceptional cases assessed by INTERTEK, may not exceed six (6) months.

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

20.3 Effects of Suspension - Module B

Suspension of certification leads to a ban on placing PPE on the market from the date of suspension.
Following the suspension, the Manufacturer:

- loses the right to affix the CE marking and must discontinue use of the Certificate;
- must refrain from advertising the Certification until the end of the suspension period;
- must suspend the provision of the PPE;

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

The costs incurred by INTERTEK in carrying 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 obligatorily submit to one of the two options provided by the EU Regulation. One of these is the internal production control combined with product testing under official control carried out at random intervals, corresponding to MODULE C2.

21.1 Submission of Application - Form C2

The Manufacturer must complete the form provided by INTERTEK for each type of PPE for which it requires surveillance, attaching the following documents:

- The details of the Manufacturer (company name, address and legal status, etc.)
- The sampling location and the name and contact details of the person responsible for dealing with INTERTEK;
- Copy of the Module B certificate(s) associated with the surveillance activity, if the Module B was issued by another NGO.
- Copy of the Technical File, in case Module B was issued by another N.O.
- Production information for the purpose of the sampling programm (production batches, quantities, etc.), if applicable.
- Information on the checks carried out in production during all stages to verify conformity to the certified type.

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

21.2 PHASE 1 - Visit and product/ documentation control

The Manufacturer ensures and declares that the PPE subjected to the surveillance activities are in conformity with the type covered by the EU Type Examination Certificate and that the manufacturing process ensures homogeneity of production.

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

The sampling methods are aimed at ascertaining the homogeneity of production on homogeneous batches taken randomly in order to reach the necessary quantity for the tests according to the agreed programm. In the event of impossibility, the following will be assessed on a case-by-case basis
The technician applies the sampling program and takes the samples for dispatch to INTERTEK or the chosen test laboratory. In both cases, identification of the samples must be ensured by signature/date or by sealing (identification with seal) and then dispatched. Shipping is always the responsibility of the customer.

21.3 PHASE 2 - Product verification and testing

INTERTEK verifies the conformity of the PPE by means of examinations and tests, as described below. It performs the necessary tests to ascertain the conformity of the samples with the model examined in the EU Type Examination Certificate (Module B). Necessary tests are defined as the most important and/or significant tests selected on a distribution basis over the period of validity of the contract (e.g. three years).
The verification is designed to ensure that the production process is capable of guaranteeing homogeneity of production to the device subject to EU Type Examination.

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

Renewal may only be made by the expiry date, by means of an appropriate request received at least three months in advance.

INTERTEK carries out at least one visit per year at random intervals determined in agreement with the client. INTERTEK reserves the right to conduct unscheduled visits more frequently than required on the basis of audit results and information from the market.

Any suspension of production must be communicated to INTERTEK in order for the relevant checks to be carried out.

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

The granting of the certificate entitles the manufacturer to affix the prescribed marking with the O.N. number to each piece of personal protective equipment and to draw up the Declaration of Conformity.

21.4 First issue of the certificate

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

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

In the case of a C2 Module requested on a Module B issued under the OBM procedure, the above-mentioned checks must still be carried out. This activity may be carried out during the OEM (Origin Equipment Manufacturer) visit, if entrusted to INTERTEK.

21.5 Certificate Renewal

For the renewal of the certificate, the application must be submitted annually in order to verify the correspondence of the products to be tested together with information on the batches produced. Sampling must be conducted in good time before the expiry date of the valid Form C2. The validity of the certificate shall in no way exceed the validity of the relevant Form B.

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

If the Module B certificate is updated (e.g. for an extension or regulatory adaptation), the Module C2 certificate must be renewed.
The contract generally lasts for three years while the certificate is always valid for one year and must be renewed by the expiry date.

21.6 Negative outcome of verifications

If the tests prove negative, INTERTEK will notify the client:

1. must take charge of the NCs and inform INTERTEK of the proposed ACs within 15 days; the NCs should in any case be closed within a month.
2. INTERTEK will determine the action to be taken and any additional evidence required.
3. If the outcome of the tests is 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 testing following the procedure of the previous points (1 to 4) within an agreed time limit (e.g. one month).
5. If the second retesting continues to give negative results, the certificate will generally not be issued or renewed.
   Any cases with double negative results will be assessed on a case-by-case basis.

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

21.7 Suspension of Certificate - Form C2

Suspension of Module C2 may occur due to an inability to carry out the scheduled inspection or due to evidence that the production process does not guarantee conformity with the PPE covered by the certificate.

The suspension is of limited duration and may not exceed six (6) months.

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

If the manufacturer makes the sampling available in good time (before expiry) and following successful testing, INTERTEK reinstates the validity of the Module C2 Certificate and notifies the manufacturer of such reinstatement.

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

Suspension may also affect the EU Type Examination Certificate (Module B) in whole or in part, in which case action may be required on a case-by-case basis.

In the event that the manufacturer is forced to discontinue production of the PPE, it may request temporary suspension of the certificate. If the certificate is reinstated, it will expire naturally.
Reactivation follows the same procedure as for the first issue.

21.8 Effects of Suspension - Module C2

Suspension of certification leads to a ban on placing PPE on the market from the date of suspension.
Following the suspension, the Manufacturer:

- loses the right to affix the CE marking and must discontinue use of the Certificate;
- must refrain from advertising the Certification until the end of the suspension period;
- must suspend the provision of the PPE;

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

The costs incurred by INTERTEK in carrying out any checks or activities caused by suspension measures shall be borne by the manufacturer.

22. Revokes

The revocation measure taken 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 mark.
Furthermore, INTERTEK notifies revocation of Certification in all cases ordered by the competent authorities or in which it finds objective evidence:

- fraudulent and illegitimate use of certification;
- following suspension
- serious non-compliance with these Rules;
- the non-conformity of the product with the technical documentation submitted to INTERTEK;
- of the established and repeated arrears to INTERTEK;
- the misleading use of the Certification and/or the mark, such as to bring harm or discredit to INTERTEK;

Withdrawal of Certification, decided by the Certification Resolution Committee, is notified to the Manufacturer by letter or e-mail and containing the reasons for the measure taken.

Revocation may also affect the EU Type Examination Certificate (Module B) in whole or in part, and in this case action will be taken on a case-by-case basis, which may require a new issue of the same .

Withdrawals are made public by INTERTEK in the manner provided for in the Regulation and communicated to the competent Ministry and the other 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 regarding the service offered and/or received.
The Manufacturer may submit a complaint concerning the activities carried out by INTERTEK. The Body will analyse the content of the complaint to identify the actions necessary to manage and resolve it in accordance with the internal procedures adopted, if considered well-founded. INTERTEK always provides a written and reasoned response to complaints received, whether they are unfounded or substantiated. In the latter case it proposes actions to resolve them.
INTERTEK does not consider complaints submitted anonymously. The Procedure for the Handling of Complaints and Appeals adopted by INTERTEK is available and is summarised below:

1. Sending your complaint by pec or email stating your personal details and contact details, arguing your complaint, and attaching any documents you deem useful;
2. Within 30 days of receipt, INTERTEK communicates any acceptance by pec or e-mail;
3. Within 45 days from the date of acceptance INTERTEK notifies the outcome of the complaint by pec or email;

The complaint form can be found on INTERTEK's website at www.INTERTEK.it.
Complaints may also be filed by users, understood as natural or legal persons or trade associations.
This type of complaint is handled in the same way as the manufacturer's complaint.
Regardless of the type of complaint, it will be carefully assessed, if well-founded, by a competent person other than a person who has carried out certification activities.

23.2 Ricourse

Appeal means an official action by the certifying or certifying party with the aim of requesting a review of a certification decision (e.g. suspension, revocation or reduction, non-granting, etc.) taken by INTERTEK as Certification Body and is to be considered as a right.

The certifying or certified manufacturer may lodge an appeal against INTERTEK's certification decision. The body analyses the content of the appeal. INTERTEK undertakes to handle any appeal submitted regardless of its merits.
The Appeals Management Procedure adopted by INTERTEK is available and is summarised below:

1. The appeal must be submitted in writing, by pec or email, detailing the grounds for the appeal and the evidence necessary to support its case. The appeal must be lodged within fifteen (15) working days from the notification of the decision against which the appeal is lodged.
2. Within five (5) working days after receipt of the appeal, INTERTEK shall notify by email the acknowledgement of the appeal and the names of the persons entrusted with its handling. Acknowledgement and handling of the appeal does not suspend the validity of the decisions taken by INTERTEK until the conclusion of the relevant handling.
3. Within 90 days of receipt, INTERTEK communicates the outcome of the appeal by pec or e-mail;

The appeal form can be found on INTERTEK's website at www.INTERTEK.it.
If the manufacturer is not satisfied with the resolution of the complaint or grievance, it may always take legal action against INTERTEK.

23.3 Litigation

Any dispute arising between the parties concerning the interpretation, implementation, execution, validity and effectiveness of the Rules for Certification shall be settled exclusively by the Court of Milan.

24. Confidentiality

The activities carried out by INTERTEK cannot disregard the evaluation of data and documents that represent sensitive elements of Company know-how and/or information subject to the Manufacturer's privacy guarantee. In order to guarantee

the necessary confidentiality on the same, INTERTEK adopts the provisions of Regulation (EU) 2016/679 concerning the processing of data provided by the Manufacturer. Together with the offer, the client is informed about the data processing and can express his or her opinion.
It also takes measures to protect data and information obtained during conformity assessment activities, test and/or measurement activities and, more generally, during all phases involving processes related to the provision of services.
INTERTEK does not disclose the above data and information, except where required or requested by law.
When the certification body is required by law or authorised by contractual agreement to release confidential information, the client or interested person shall, unless prohibited by law, be informed of the information provided.
In all other cases, the customer's consent will be requested. The customer may access his personal data at any time 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 Rules 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 related to Certification are accessible to ACCREDIA and INTERTEK's Certification Committee for the control activities foreseen 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 carried out by INTERTEK and affected by these Rules may require the amendment of one or more paragraphs of these Rules.
Similarly, the Rules may be amended for reasons other than updating the regulatory and legislative landscape.
INTERTEK makes the latest version of the Rules and Regulations available on its website highlighting the new publication also in the usual correspondence with the client.
The Manufacturer undertakes to adapt to the new conditions imposed by the Rules, as indicated in paragraph 1. The updating of the Rules cannot be considered as 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 Rules and Regulations are based on the information contained in the request and/or Application for Certification sent by the Manufacturer and refer to the items in the Price List, defined by the Management of the Body.
The Manufacturer wishing to access the Certification services shall accept INTERTEK's Offer and also undertake to comply with the payment conditions contained therein.

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

Modifications to the economic conditions signed by the Manufacturer may be applied by INTERTEK if INTERTEK detects discrepancies between the data provided by the Manufacturer when filling out the Application Form and/or the Application Form and what was found during the subsequent verification activities foreseen by the Evaluation Procedure. Or following revisions of the Rate Card.

27.1 Variation of the Offer

In the event that conditions differing from those declared in the Request and/or Application are found, justifying additional verification activities, INTERTEK informs the Manufacturer of the necessary economic integrations, suspending the evaluation process until their acceptance.
To the Manufacturer that refuses the economic integration presented, INTERTEK communicates the interruption of the evaluation process, quantifying the amounts only for the activities already carried out.

27.2 Tariff Variation

The Price List applied by INTERTEK is periodically reviewed by the Management of the Organisation. In the event of changes to the economic conditions subscribed to, INTERTEK notifies the Manufacturer of the new amounts applied to the audit activities, by email or regular mail.
The Manufacturer has the right to reject the new economic conditions within one (1) month from the date of communication. By rejecting the new amounts, the Manufacturer will see the validity of the Certification lapse upon the natural expiry of the contract.
For any activities already carried out during the month scheduled for the waiver, INTERTEK will apply the economic conditions preceding the change in the Tariff.

28. Publicity and use of certification

The Manufacturer may publicise and advertise the fact that it has obtained Product Certification in the manner it deems most appropriate, by reproducing the entire Certificate or Certificate obtained, enlarging or reducing it, in colour or black and white, provided that it remains legible and is not altered in any way.
Solutions other than those defined in this paragraph must be authorised in writing by INTERTEK.
The Manufacturer shall avoid misleading or ambiguous uses of the Certification issued by INTERTEK and shall prevent the Certification from being extended to products not covered by the certificate issued by INTERTEK.
In the event of non-compliant use of the certificate with respect to this paragraph, INTERTEK reserves the right to take appropriate action against the manufacturer, including recourse to appropriate legal action and revocation of the Certificate granted.
The use of the Organism's Mark and the Accredia Mark, on advertising material prepared by the Manufacturer, must be approved by INTERTEK, in accordance with the "Rules for use of the Mark" Accredia Regulation RG-09.

INTERTEK Italia S.p.a., in accordance with the legislation on the protection of personal data (EU Regulation 2016/679, so-called "GDPR"), which it undertakes to comply with, declares that it is processing personal data for the purposes inherent to 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 the 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, addressing your requests to INTERTEK Italia S.p.A. with registered office at Via Miglioli 2/A - 20063 Cernusco sul Naviglio (MI), also by registered mail.