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Rev.	***Reason for modification***	***Draw up***	***Approved***	***Date***
5	Definitions partial update Full modification of paragraph 4.4 Edited paragraph 5.9, 10 and 13 Added paragraph 9 Various minor generic clarifications / modification	Flavio Banfi	Roberto Cusolito	30/01/2024
6	Updating of some definitions Rewriting of par 4.4 Changes to 5.9, 10 and 13 Introduced paragraph 9 Various general minor clarifications/changes	Flavio Banfi	Roberto Cusolito	30/01/2024
7	Removal of references to the use of fax as a means of communication Update of par. 8.2 to include the term "Observation" Insertion of the paragraph "Joint audits with ISO 9001".	Flavio Banfi	Roberto Cusolito	20/01/2025

1 PURPOSE AND PREMISE

This Regulation sets out the procedures followed by ITALCERT for the certification of personal protective equipment (hereinafter also referred to as "PPE") in accordance with the provisions of EU Regulation 2016/425.
This certification covers the procedures for obtaining and maintaining the certifications according to Module B, Module C2 and Module D[1].
As a general principle, this Regulation of Certification does not intend to repeat or resume the obligations already identified by Regulation 2016/425 for Manufacturers and / or Notified Bodies, but instead aims to identify the reciprocal obligations between the two parties (Manufacturer and Notified Body) for all aspects not clearly identified by Regulation 2016/425.
Any paragraphs modified with respect to the previous edition are identified with a right sidebar. Any deleted paragraphs are identified by the symbol (...).

2 DEFINITIONS

For a better understanding of the content of this Regulation, the following definitions are specified:

MANUFACTURER: means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark.

AUTHORISED REPRESENTATIVE: means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with reference to the obligations of the manufacturer under the relevant legislation community. *(EU Regulation 765/2008)*

NOTE 1: Some activities may be carried out by an authorised representative on behalf of the manufacturer. However, for the better clarity, in the context of these Regulations, the term "manufacturer" will be used only in place of "manufacturer or his authorized representative". For details of activities that can be performed by an authorised representative reference should be made to Regulation 2016/425

OWN BRAND MANUFACTURER (OBM): any natural or legal person who labels ready-made products in order to place them on the Community market under his own name.

ORIGINAL MANUFACTURER (OM): the Manufacturer, or any natural or legal person responsible for the design and manufacture of a product in order to place it on the European Union market under his own name.

OBM PROCEDURE: procedure by which an OM produces specific PPE with a customization that provides for the identification of another person as a Manufacturer, said OBM, while remaining the OM responsible for the conformity of production. This product appears to be equal identical to the original product already CE marked, but different only for marking and instructions for use and packaging.

NOTE 2: the operational procedures for OBM process are described in the current revision of the Recommendation for Use PPE-R/00.047 issued by coordination Group of the Notify Bodies.

TECHNICAL FILE*:* the set of documentation requested by ANNEX III of Regulation EU 2016/425

3 GENERAL PRINCIPLES

3.1 Application and agreement

Evaluation activities with the purpose of certification may only be started after the manufacturer or his authorized representative submits the application for certification.
The manufacturer cannot apply for certification for the same product to different Notified Bodies.
It is the manufacturer's responsibility to indicate the standards used in the design / production / control phase of the PPE for which certification is requested. Any exceptions to the aforementioned standards should have already been highlighted at the application stage, possibly using a specific rationale.

3.2 PPE categorization and evaluation procedures

The correct categorization of the PPE (ref. Annex I of EU Regulation 2016/425) is mainly the responsibility of the manufacturer. ITALCERT reserves the right not to accept, with due justification, an application for certification where the classification of the PPE is deemed to be incorrect.
Conformity assessment procedures that require the involvement of a Notified Body are:

a) II category: EU type examination (module B) followed by conformity to the type based to internal production control (module C); the Notify Body is involved only for Module B.
b) II category: EU type examination (module B) and one of the following:

[1] *For the meaning of the above mentioned modules, please refer to the "Blue Guide to EU Product Implementation".*

i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2)

ii) conformity to type based on quality assurance of the production process (module D)

By way of derogation, for DPIs produced as single units to fit a single user and classified in Category III, the procedure referred to in (a) may be followed.

3.3 Reference language for evaluation

Unless otherwise agreed, the languages accepted by ITALCERT for the evaluation of the technical documentation, the quality system and any other documents that are necessary for the evaluation activities in ITALCERT are Italian and English. The manufacturer may, if it is considered appropriate, to include parts in different languages in the technical file, provided that they are also supplied in Italian or English; reference is made in particular to the instructions for use, for which ITALCERT only checks the correctness in one of the two languages indicated.
The correctness of translations into other languages remains the responsibility of the manufacturer.

3.4 Authorised Representative

The manufacturer may, by written mandate, appoint an Authorised Representative. The mandate must comply with the limits and prerogatives set out in Regulation 2016/425.
Based on the rules established and also dealt with in the Blue Guide, the Authorized Representative, if appointed, must be "only one" and it is not possible to appoint more than one person. The Authorized Representative shall be based in the EU.
It is specified that the mandate must allow the agent to carry out **at least** the following tasks:

a) keep the EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for 10 years after the PPE has been placed on the market;
b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;
c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

Therefore, where the manufacturer has identified an Authorized Representative and this aspect is relevant for the conformity assessment, ITALCERT could request evidence that the mandate contains at least the above. Furthermore, in these cases the name of the authorized representative will appear on the EU-type examination certificate.

3.5 Distributors and importers

The tasks of distributors and importers are defined in Regulation 2016/425. Although this does not necessarily have the expertise of ITALCERT, it is understood to make the manufacturers aware of their responsibilities in the relevant documents (contractual agreements, etc.).

3.6 Reference languages for instruction for use and for declaration of conformity

Compliance with the language requirements to be used for the instructions for use and for the Declaration of Conformity shall in charge to the manufacturer. ITALCERT will examine the proper management of this aspect during the verification of module D, where applicable.

3.7 Safety on production site

During the visits at its headquarters, the Manufacturer, in accordance with current legislation on safety and prevention of accidents at work, undertakes to provide ITALCERT with the necessary information on possible risks in the environment Workplace where they are intended to carry out their business, and ensure the adoption of all possible precautions for their protection in terms of health and safety.

3.8 Presence of Control Bodies / Accreditation Body

The Manufacturer agrees to allow access to its premises during the activities carried out by ITALCERT of observers appointed by the Control / Accreditation Bodies in carrying out their duties of monitoring and monitoring the activities carried out by ITALCERT as a Certification Body and Inspection.
Such observers will always be together with ITALCERT staff. Notification of the presence of such observers may take place with minimum notice (less than 3 days) or even without notice, without this being the reason for the manufacturer not accepting their presence.
Failure to accept the presence of such observers by the Manufacturer determines the suspension of the certificate in force and its possible subsequent revocation in the event of any such denial being maintained.

3.9 Faculty of recusal

The manufacturer has the right not to accept, with valid reasons, the personnel that ITALCERT has appointed to carry out the assessment activities. This option must be exercised within 5 days of notification from the personnel involved.
This possibility, for Module B, is foreseen only in the case in which ITALCERT entrusts the evaluation to a subject external to ITALCERT (non-employee collaborator), but it is not envisaged that the manufacturer is notified of the internal person or people of ITALCERT in charge of the assessment. In the event that ITALCERT intends to subcontract some tests pertaining to the Module B or Module C2 procedure, ITALCERT will report the name of the appointed laboratory to the manufacturer who will have the right not to accept the laboratory itself.

3.10 Application of the Recommendations issued by the Notified Bodies.

Based on what is applicable, ITALCERT uses for the assessment activities the guidelines issued by the working groups of the Notified Bodies, in application of article 24 paragraph 11 of the Regulation (EU) 2016/425.

4 STANDARDS USED FOR PPE CONFORMITY AND FOR PRODUCTION SYSTEM QUALITY

4.1 Harmonized standards

Harmonized standards are European standards to which Regulation (EU) No. 1025/2012 and the relevant harmonization legislation of the Union have given a particular significance. Harmonized standards retain their character of voluntary application. The particular role of a harmonized standard does not materialize until its title is published in the EU Official Journal.
Harmonized standards issued under the PPE regulation generally have explicit correspondence with the relevant essential safety requirements. Essential requirements or other legal requirements that are intended to cover are generally indicated in a separate disclosure attachment to a harmonized standard.
Apart from the above, there are also harmonized "transversal" standards, such as the requirements of the quality system of production.
A clear distinction should be made between "compliance with a standard" and "presumption of conformity (applying a harmonized standard)". "Compliance with a Standard" generally refers to a situation in which a standard is "fully implemented", for example in the case of voluntary certification against a standard. For the "presumption of conformity", it is sufficient to apply only the provisions relating to the essential requirements or other legal requirements that are to be covered.
Therefore only in the first case the manufacturer can cite full compliance with the standard used. However, certification can also be obtained even in the case of partial application of the rule, based on considerations that need to be assessed case by case.
Harmonized standards never replace legally binding legal requirements. A specification in a harmonized standard is not an alternative to a relevant essential requirement or other legal requirement, but only a possible technical tool to conform to it. In risk-harmonization legislation, this means in particular that the manufacturer, even when applying harmonized standards, remains fully responsible for assessing all the risks of his product in order to determine which essential (or other) requirements apply.
After this evaluation, the manufacturer may choose to apply the specifications in the harmonized standards to implement "risk reduction measures" specified by harmonized standards.

4.2 Harmonized standard publication

The publication of references in the Official Journal of EU indicate the date from which the presumption of conformity has effect. The publication of references to harmonized standards is a Commission administrative act, which is carried out without further consultation with relevant Member States or relevant specific committees. This is the ultimate goal of a harmonized standard that is the subject of a mandate and the end of the process initiated by the conferral of the relevant Commission mandate.
It is not automatic that the references to a CEN standard are published in the Official Journal; therefore, the mere fact that a provision is published in the context of CEN does not automatically imply that it acquires the status of a harmonized standard.
The use of the harmonized standards mentioned in the EU acts and conferring a presumption of conformity remains voluntary. The manufacturer may decide whether or not to refer to harmonized standards; if it decides not to do so, it must demonstrate that its products comply with the essential requirements by using other means of its choice (e.g. by applying existing technical specifications, including all other available standards). If the manufacturer applies only to part of a harmonized standard or if the applicable harmonized standard does not cover all the essential requirements applicable, the presumption of conformity applies only to the extent that the standard meets the essential requirements

4.3 Withdrawal of presumption of conformity

The challenge of a harmonized standard can lead to the withdrawal of the rule itself; this means that the rule in question will no longer give the presumption of compliance with the essential requirements.

4.4 Revision of harmonized standards and certificate validity

Harmonized standards are subject to change (revision).
The harmonization of a standard provides a transition period during which both the most recent version of the norm and the previous one give presumption of conformity. After this transitional period is completed, only the harmonized standard gives presumption of conformity. Unless otherwise decided based on a Commission proposal, the withdrawal of a harmonized standard does not invalidate existing certificates issued by notified bodies and products manufactured according to the old standard with a valid EU type certification that still satisfies the essential requirements; products may continue to be sold on the market until the certificate issued by the notified bodies expires.
It is the manufacturer's responsibility to check each publication of the list of standards harmonized and verify the validity of the harmonized standards applied to assess the conformity of the product.
In case of the publication of a new edition of a harmonized standard, the manufacturer needs to assess the effects of the changes to verify if the product still complies with the essential requirements of health and safety according to the new state of the art and need to inform the Notify Body about the results of the evaluation.
The result of this analysis may lead to a revision of the EU type-examination certificates or, in case of "formal" changes with no effect on the product's conformity, the certificate keeps its validity until the expiry date.
The manufacturer's analysis should be included in the technical file related to the product subject of the assessment.
In any case, ITALCERT monitors the state of the art and assesses if the certified type still complies with the essential health and safety requirements. They determine whether such changes require further investigation. If so, the manufacturer accordingly is informed accordingly.

4.5 Other standard reference

A harmonized standard may contain regulatory references to other standards. By virtue of such references, such other rules or parts thereof become essential for the application of a harmonized standard.
As a general principle and on the basis of the indications of the Blue Guide, in the event that a product standard includes an undated support standard, ITALCERT will continue to apply the version of this standard valid on the date of harmonization of the product standard, even in the event of variation of the support standard.

4.6 Compliance with essential requirements other option

The conformity of a product can be demonstrated, in addition to harmonized standards, with other technical specifications, which do not, however, have the presumption of conformity. This can be the case, for example, where there is no harmonized name for the PPE object being evaluated.
This means a more detailed demonstration of how the technical specifications used to ensure compliance with the essential requirements in the technical file of a particular product is required. In short, the manufacturer does not benefit from the presumption of conformity and is required to demonstrate it.
In addition, even if the manufacturer has not applied harmonized standards, a change in the relevant harmonized standard could lead to a change in state of the art, so its product may no longer be compliant. ITALCERT reserves the right not to accept the use of technical specifications which cannot be considered as harmonized standards by the manufacturer in the context of conformity assessment procedures.

4.7 Third part communication

ITALCERT is obliged to inform its notifying authorities of issued or withdrawn EU type-examination certificates and, on a regular or on a request basis, make available to its notifying authorities the list of such certificates and / or their supplements refused, suspended or otherwise limited.
ITALCERT is also obliged to inform other notified bodies about EU refused, withdrawn, suspended or otherwise restricted EU examination certificates and, upon request, certificates issued.
Finally, the European Commission, the Member States and other notified bodies may obtain, on request, a copy of the EU type examination certificates of the type issued by ITALCERT and, upon a reasoned request, the European Commission and the Member States may obtain a copy of the technical file, and the results of the tests carried out by ITALCERT.

4.8 Supplementary declarations by the manufacturer

It is the faculty of the manufacturer to declare that its product has additional characteristics, which do not strictly fall within the scope of type certification by ITALCERT. For example, a respiratory protection PPE could also have additional optical performance characteristics compared to the minimum requirements set by the

reference product standard. In these cases, these declarations do not fall within the Module B certification implemented by ITALCERT. However, ITALCERT may request that the technical file contain documentation to support the truthfulness of such declarations.

4.9 Accessories

It is up to the manufacturer to ensure that his PPE can be used with certain accessories.
If the accessories contribute to the achievement of the declared protection, they must be part of the type conformity assessment.
If, on the other hand, they provide performances that do not fall within the scope of the protection subject to certification, the manufacturer will still have to demonstrate that they do not produce additional risks for the user and that they do not reduce the protection performances subject to certification.
This demonstration can be obtained by inserting appropriate supporting documentation in the technical file (tests, rationale, risk analysis, etc.); In any case, ITALCERT reserves the right to carry out specific analysis under its own responsibility.

5 EU TYPE EXAMINATION (MODULE B)

5.1 Generality

The EU type examination is part of a conformity assessment procedure in which ITALCERT, as a notified body, examines the technical design of the PPE and verifies and certifies that such technical design meets the requirements of EU Regulation 2016/425.
The EU type examination is based on both of the following actions:

1) assessment of the adequacy of the technical design of the PPE by examining the technical documentation.
2) Examination of a complete PPE sample, representative of the expected production (type of production).

5.2 Application

Based on the information provided by the manufacturer, ITALCERT issues an economic offer. Where tests or some of the tests have to be carried out at other laboratories outside of ITALCERT, details are included in the offer.
Acceptance of the offer by the manufacturer also requires the submission of the certification application, which must be done using the form provided and made available on the website www.italcert.it or available upon request. The submission of the application implies acceptance of this Regulation.
At the time of submission of the application or in successive stages, the manufacturer must deliver ITALCERT:

a) the technical documentation described in Annex III to Regulation 2016/425
b) one or more specimens of the PPEs covered by the certification, representative of the production envisaged. The number of samples required to carry out the tests is as indicated in the economic offer and depends on the requirements of the standards. However, ITALCERT reserves the right to request further samples where, during the tests, there is a need for sampling greater than initially requested.

5.3 Evaluation process

ITALCERT evaluation process involves the following steps:

- Examination of technical documentation to assess the adequacy of the DPI technical design.
- Verification, mainly by visual examination, that the samples have been manufactured in accordance with the technical documentation.
- Performing the necessary tests to verify compliance with the applicable harmonized standards or any other technical specifications that may be identified.

In case of unsatisfactory outcome of the above assessments, according to the applicable circumstances, ITALCERT may require the manufacturer to take the necessary actions to resolve the non-compliance situation, including:

- to modify / integrate the technical documentation
- to review and modify as appropriate the PPE project
- to Provide a new sampling to perform the repetition of non-successful tests.

Upon completion of the evaluations and their success, the above assessment results are finalized and documented in one or more test reports that are provided by the customer with the EU Certificate.
Except for different agreements, a test report is not foreseen in the event of a negative test, whose results are nevertheless communicated in writing to the customer by email.

5.4 EU type examination certificate

As a result of the evaluations carried out, ITALCERT issues to the manufacturer an EU type examination certificate of 5 years validity if it is a new issue.

However, the validity of the certificate is bound to maintain the conditions that allowed it to be issued.
For category III PPE manufacturers, the EU type-certificate alone is not sufficient for the placing on the market of certified PPE, because it is also necessary that the manufacturer also have a production control certificate in accordance with module C2 or Module D. There is, however, no obligation that the manufacturer entrusts production control to the same body that issued the EU type-certificate.

5.5 Certificate review

ITALCERT follows the evolution of the generally recognized state of the art and has the right to assess whether the type approved does not comply with the essential health and safety requirements applicable and has the power to decide whether such an evolution requires an update of the type and / or of the technical documentation, resulting in the updating of the certificate.
In turn, the manufacturer must inform ITALCERT of any modifications made to the approved type and of any changes to the technical documentation that could affect the compliance of the PPE with the essential health and safety requirements applicable or the validity conditions of the certificate, following the steps described in the next paragraphs.

5.6 Modification of the EU type certificate

The manufacturer may request ITALCERT to change the scope of a certificate in force by inserting new PPE models in addition to existing ones. This can happen, for example, in the case of a range extension.[2]
The request for modification is examined by ITALCERT, which will evaluate the conditions for the extension requested, based on the common characteristics between the PPE object of the extension and the certified PPE.
The certification process follows the same steps as for the first certification. However, it may be possible to extend the certificate without carrying out tests or verifications, or by carrying out partial tests, compared to a new certification. The procedures for extending a certificate are detailed by ITALCERT in an economic offer.
In the case of extension of the range, for a simpler a priori definition of the necessary tests and verifications, it is preferable that the Manufacturer prepares and transmits to ITALCERT, prior to the issue of the economic offer, a rationale explaining the common features of the PPE extension object and PPE already certified.
To initiate the extension process, the Manufacturer must send a copy of the accepted offer and the application for certification.
The expiry date of the EU type certificate issued following an extension request does not change compared to the first certificate.

5.7 Certificate update

There are conditions where it could be necessary to update the certificate even if no technical changes are made, such as:

a) Changes in the company name of the manufacturer (keeping the same legal identity, or without VAT variation) or the address of the registered office.
b) Misconduct / errors on the issued document.

In the event that the manufacturer sells or rents the holding company for the manufacture of certified PPE, ITALCERT is not obliged to modify the certificates in favor of the subsidiary. This possibility will be examined case by case.
The updated certificate keeps the previous expiry date.

5.8 Letter of authorization

There are conditions in which the Manufacturer could implement some changes to the PPE subject to certification, with consequent updating of the Technical File, but which can be considered as "minor".
This case includes, purely by way of example, the request for authorization to use a new or additional raw material supplier. In these cases, as a general rule, the modification does not determine the modification of the certificate and can be approved by means of an authorization letter.

5.9 EU type certificate renewal

The renewal of the certificate at its expiry date is not an automatic act; it is therefore in charge of the manufacturer to make a formal request for renewal of the certificate.
The request cannot be submitted more than 12 months before the certificate expiry date. ITALCERT ensures the completion of the necessary renewal procedure if the application is submitted no later than six months before the expiry of the certificate; otherwise, completing the procedures before the expiration date is not guaranteed.

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[2] *If the manufacturer ask to modified the identification code of the PPE without modification to the products itself, shall be managed as an extension, because a modification of the technical file is required.*

However. in the case of an expiration of the deadline, if the manufacturer has not send the renewal application, ITALCERT will notify the manufacturer of the next expiration of the certificate.
The application for renewal is presented using the form provided by ITALCERT and downloadable from www.italcert.it, or unsorted on request. The required data and information are:

- confirmation that the certificate PPE are still in production
- confirmation that there has been no modification to the approved type
- transmission of the copy of the current revision instruction for use
- evidence of update if there are changes in the regulatory framework (if applicable)
- Confirmation of the body entrusted with production control for PPE of category III, if different from ITALCERT.

Where the conditions exist, ITALCERT carries out the certification renewal by applying the simplified procedure referred to in EU Regulation 2016/425, Annex V, paragraph 7.6. However, the implementation of the simplified procedure requires the manufacturer to send ITALCERT a sample of certified products for a visual inspection to confirm or not that the approved type has not undergone modifications and that it corresponds to the approved technical documentation; in the event of a negative outcome of this check, ITALCERT can apply the standard renewal procedure.
Where there are no conditions for applying the simplified procedure, the need to carry out tests and the size of the samples to be verified is established by ITALCERT at its own discretion, possibly also taking into account the available results of the checks carried out by ITALCERT as part of the verifications carried out according to module C2, as well as any modification of the standards used for the certification of PPE.
In the event of a successful review of the information above, ITALCERT will decide on renewal of the certificate, whose validity can't exceed 5 years. This can be fulfilled in two possible ways:
Option a: the certificate is issued on the same date as the decision of certification, but the validity starts after the expiry date of the previous certificate. Therefore, the expiry date will be equal to 5 years starting from the expiry date of the certificate to be renewed.
Option b: the certificate is issued with the same date as the decision of certification and has immediate effect. In this case the expiry date will be equal to 5 years starting from the issue of the new certificate, regardless of the expiring date of the certificate to be renewed.
Whenever the procedure of certification ends after the expiring date of the certificate to be renewal, the expiring date will be equal to 5 years starting from the expiring date of the certificate subject the renewal.
Where, however, situations of criticality emerge, ITALCERT will require the Manufacturer of the necessary additions and updates to be adopted.

5.10 Storage of the examined samples

Italcert may ask the manufacturer to conserve under their responsibility some specimens' representative of the approved type, such as "standard control" properly sealed.
In certain situations, the conservation of some specimen representative of the approved type is foreseen, in addition to the photographic report of the examined specimens.
In these cases, ITALCERT can ask the manufacturer to collect them and request their storage. The cost of the shipping remains the responsibility of the manufacturer. The Manufacturer must ensure their traceability and custody in order to maintain their integrity and keep them for a period of at least 10 years from the date of the last placing on the market of the PPE covered by the EU type certificate.
In the event of disputes during the period in which the PPE is sold, the Manufacturer must make all the sealed PPE described above available to ITALCERT.
Furthermore, for the samples subjected to testing and not included in the above typology, ITALCERT may request collection at the manufacturer's expense. In this case the products can be managed freely by the manufacturer.

5.11 Maintenance of the certificate in case of updating of the reference standards

EU type certificates are based on an assessment based on compliance with one or more standards, which can be harmonized or not.
It should also be specified that the use of the harmonized standards mentioned in the OJEU, and which confer a presumption of conformity remains voluntary.
Regarding the management of the standard harmonization updates, please refer to the previous paragraph "Revision of harmonised standards and certificate validity".
It is also possible the case in which the Standardization Bodies issue a new edition of a harmonized standard, without however that this new edition is recognized as harmonized by the European Commission. In this situation, if the manufacturer requests to certify his product (or to renew the certificate) according to the standard no longer in force but still harmonized, ITALCERT will accept the application in question and proceed with the evaluation on the basis of the harmonized standard. Vice versa, a possible request for certification

according to the updated edition of the standard (but not harmonized) is subject to evaluation by ITALCERT which may or may not accept the application by evaluating case by case.

6 OBM procedure

6.1 Conditions of applicability and general principles

The OBM procedure can be activated only if OM is in possession of the EU-type examination Certificate relating to PPE, covered by the procedure, issued by ITALCERT and still valid.
As far as the production control procedure is concerned, if OBM intends to entrust it to ITALCERT, the application can only be accepted if OM has entrusted such control to ITALCERT and whether the choice of control type (module C2 or D) coincides between OBM and OM. In this case, ITALCERT does not need to carry out any further control over production on OBM, but control will only take place at OM. However, it is foreseen that ITALCERT issues a certificate according to module C2 or D to OBM, as applicable.

6.2 Documents to be submitted to ITALCERT

OBM manufacturer shall submit the technical documentation required by Annex III of regulation EU 2016/425, without exception.
The documentation shall also include the agreement between the two parties (OBM and OM); the agreement shall detail at least:

a) Declaration that PPE brand extension models are physically identical to the PPE models from which they are derived, and which are the subject of an EU type certificate (the reference of which must be indicated);
b) Details of any changes between the trademark extension and the original extension procedure.
c) Declaration by the OM that only devices conforming to those covered by the EU type certificate "XXX" will be sold at OBM.
d) A statement that the OM undertakes to notify the OBM of any change affecting the validity of the EU certificate of the type which, in the case of Class III PPE, issued a certificate in accordance with module C2 or D, as applicable
e) The commitment of the OM to communicate, both to Italcert and to OBM, any modifications made to the product before it has been put into effect.
f) Declaration of commitment by both parties to report any accidents that may have occurred and concern the products covered by the agreement

The OBM procedure does not require tests on the products.
Therefore, the evaluation is based solely on the evaluation of the documentation submitted to ITALCERT.

6.3 Issue of the EU certificate

Following the successful completion of the Italcert technical documentation review, it will issue the relevant EU Certificate of the type that will identify the OBM as a manufacturer and will only indicate the OBM PPE model.
The certificate issued may not refer to the certificate issued for the original PPE; ITALCERT could be requested to make available the certificate issued for the original PPE when requested by the competent authorities.
On the basis of what is appropriate and at the discretion of ITALCERT, the certificate may take reference, without attaching them, the test reports that constitute evidence of conformity in relation to the EU OM type certificate.
As a general rule and unless otherwise agreed, the EU type certificate issued in the OBM procedure will have the same expiry date as the certificate issued to OM; It will therefore generally have a duration of less than five years. It may also be revoked in advance if the validity of the certificate issued to OM becomes invalid.

6.4 Conditions for maintaining the certificate

The validity of the certificate issued according to the OBM procedure is bound by the validity of the certificate issued to the OM manufacturer.
If the OM certificate is suspended and / or revoked automatically, this provision will also be applied to the OBM certificate. In addition, ITALCERT may apply the suspension and revocation sanctions provided for in point 9 to the OBM certificate, if the conditions exist.

6.5 Category III devices

In the absence of rules defined for the procedures according to Annex VII or Annex VIII for category III PPE certified in OBM, ITALCERT has established the following general rules:

a. Where the OBM requests to apply Module D, ITALCERT will carry out an evaluation of the OBM quality system, also including an audit at the OM headquarters. The OM quality system can rely on that of OM for the production processes, but must also include everything concerning the costs borne by the manufacturer.

b. As a general rule, where the OBM requires the application of Module C2, the agreed inspection "place" will be that of the PPE manufacturing, i.e. the OM headquarters. In this case, OBM is required to keep a few examples of the finished product for each lot, so that a check as "complete" as possible is possible. However, it is possible that ITALCERT deems it appropriate or preferable to carry out the inspection at the OBM site.

7 CONFORMITY TO TYPE IN ACCORDANCE TO MODULE C2

7.1 Generality

The III category PPE manufacturer may choose between the two options for ensuring conformity to the type of certificate, the one that provides for internal production control combined with official testing of products under random control, corresponding to MODULE C2.
The next paragraphs describe the relevant responsibilities in case the manufacturer decides to entrust such control to ITALCERT.

7.2 Application

The manufacturer who intends to entrust the control to ITALCERT must submit a request for certification using the appropriate form provided by ITALCERT and made available, on request, on its website www.italcert.it.
The application for assignment to ITALCERT can take place at the same time as the application for type certification, therefore using the same form.
If ITALCERT is not the EU type-examination body, the application must also include a copy of the technical file approved by the body in question and a copy of the EU type examination certificate.

7.3 First issue of the certificate

The verification procedure set out in Annex VII must be completed before the PPE is placed on the market with the identified ITALCERT number associated with the CE marking. The aim is to verify that the product ready for sale is actually the one approved with the Module B procedure. This therefore always involves examining the markings, packaging and instructions for use. In some cases, ITALCERT can also carry out a repetition of the tests carried out for the type certification.
The certificate will report as a due date on 31 December of the year following the issue date.

7.4 Production control

After the first issue of the certificate, ITALCERT proceeds with product testing to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type examination certificate and the applicable essential health and safety requirements.
Product tests are carried out at least once a year at random intervals established by ITALCERT. This means that at the beginning of each year, ITALCERT will notify the manufacturer of the number of planned controls and the expected period; such data may change from year to year, based on random elements, and based on statistical considerations such as:

- Production size in terms of number of PPEs produced.
- Degree of homogeneity of the products verified with respect to the certified type

The control is carried out on an appropriate statistical sample of the manufactured DPI; the sample is taken to a place agreed by the manufacturer, which should be one of the following:

- the production site
- the finished product warehouse operated by the manufacturer
- the seat / warehouse of a PPE distributor

The tests are carried out on the basis of the standards used for certification of the type; it is not generally expected to repeat all the above-mentioned tests, but a part of them, taking into account the requirements considered more critical.
The purpose of the tests is not only to verify the conformity of the PPE to the standard requirements, but also to determine whether the manufacturing process ensures homogeneity of production and works within acceptable limits.
The testing output will be recorded by the issue of a test report whit the details of the obtained results. This document will be transmitted to the manufacturer.

7.5 Control output and renewal of the certificate

If the examination and the tests reveal that the production is not homogeneous or that the PPE does not conform to the type described in the EU type examination certificate or the essential health and safety requirements applicable, ITALCERT shall communicate the data to the manufacturer, requiring at the same time an assessment of the causes that led to the negative outcome. In that case, ITALCERT may also activate one or more of the following actions:

- Require the manufacturer to modify the production process;

- Require the manufacturer to send further samples of the PPE tested to improve the statistical evaluation of homogeneity of production;
- Temporarily suspend or temporarily suspend module C2 certificate;
- Revoke or limit the C2 certificate.

ITALCERT also has an obligation to notify its authority of notification of any suspension or withdrawal procedures.
As a result of verifications, ITALCERT issues one or more test reports, documenting the verifications and the results obtained, and the certificate is renewed for a further 12 months.

7.6 Certificate extension

The manufacturer may request ITALCERT to extend a certificate based on Module C2, by submitting the application, as foreseen for the first certification.
As a general rule, if the new product belongs to an already existing typology/family, the Module C2 certificate is automatically updated following the issuance of the Module B certificate. Otherwise it is necessary to follow the same procedure as for the first certification. The certification offer will indicate the procedure that ITALCERT intends to follow.

7.7 Production cessation

In the event that the manufacturer has temporarily ceased producing the PPE subject to certification, he may request ITALCERT to suspend the certificate temporarily. Where the certificate cannot be reactivated, it ceases to be valid at the expiry date.
Any re-activation follows the same path for the first certification.

8 CONFORMITY TO TYPE IN ACCORDANCE TO MODULE D

8.1 Generality

The third category PPE manufacturer may choose between the two options for ensuring compliance with the type certificate, the one that provides for the quality assurance of the manufacturing process, corresponding to MODULE D.
The next paragraphs describe the responsibilities of the party in case the manufacturer decides to entrust such control to ITALCERT.

8.2 Joint audits with ISO 9001

If the manufacturer, in addition to having entrusted the control of production with Module D, has also entrusted ITALCERT with the certification of quality system according to ISO 9001, ITALCERT will plan and carry out the verifications jointly.
In this case, a single audit report will be issued, clarifying which findings are relevant for both schemes and which for ISO 9001 alone.
In this case, the specific certification regulation for management system certification also applies.

8.3 Specific Definitions

For the purpose of applying the conformity assessment of the production process, the following definitions are clarified:
Production plant: site where the Manufacturer produces equipment subject to verification and certification.
***Requirement*:** need expressed in the reference standard for certification or due to it.
Non-Conformity (NC): non-compliance of a requirement.
Non-Conformity Class 1: non-compliance of a requirement that represents a significant limitation of the management system compliance with the reference standard.
Non-Conformity Class 2: any non-compliance of a requirement non configured as Class 1.
Observation: situation related to one or more management system documents or technical documents that, although not constituting a non-conformity, requires an update and/or modification of the document itself, to be carried out by the next verification[3].
Recommendation (REC): non-binding indication about improvement and/or consolidation areas of the management system. Reports of situation that can potentially generate NC, belong to this area.
For every other definitions not mentioned is as defined in certification standards and in ISO 9000 and ISO 19011.

[3] *In the audit report, certain sharing of information between the manufacturer and ITALCERT that the Team leader considers appropriate to formalize may also be included as "observations".*

8.4 Application

The manufacturer who intends to entrust the inspection to ITALCERT must submit a request for certification using the appropriate form provided by ITALCERT and made available, on request, on its website www.italcert.it

If ITALCERT is not the EU type-examination body, the application must also include a copy of the technical file approved by the body in question and a copy of the EU type examination certificate.

8.5 Minimum requirements for the Quality Systems

8.5.1 Generality

The manufacturer must implement a quality management system to ensure the production of PPE identical to the Certified types and / or the requirements established by the relevant standards. To this purpose, the manufacturer can adopt a quality system in compliance with the ISO 9001 standard in force as a harmonized standard. In this case, the management model assumes compliance.

The manufacturer can also implement a quality system following a different model from ISO 9001, which however will not enjoy the status of "presumption of conformity"; This model must therefore be subject to preliminary assessment by ITALCERT, which may not approve it.

In any case, as a minimum the quality system should follow / refer to a model defined in standards / technical specifications / guidelines issued by authoritative organizations.

The quality system documentation must allow a uniform interpretation of the quality programs, schemes, manuals and documents and must comply with the elements identified in Annex VIII of EU Regulation 2016/425.

The key and characteristic features of the quality system must be delivered to ITALCERT, along with the list of documents in force.

8.5.2 Tests on manufactured products

The application of module D presupposes that the manufacturer is able to carry out tests on the PPE manufactured. These tests can be of two types:

- Production control tests, aimed at ensuring the correct execution of the manufacturing procedures. These tests should take into account the tests required by the reference standards, but they can also be performed in simplified form.
- Control tests of maintenance of conformity to the approved type. These are type tests which must be carried out as a repetition of the tests carried out during the type certification. These tests do not necessarily have to be performed on each lot and for each model, but on the basis of a documented control plan which must be made available to ITALCERT during the checks.

8.5.3 Management of accidents and adverse events.

The manufacturer must have documented procedures that establish methods and responsibilities for managing the provisions of EU Regulation 2016/425 Article 8 paragraph 9, which is reported: "*Manufacturers who believe or have reason to believe that a PPE they have placed on the market does not comply with this Regulation, they shall immediately take the corrective measures necessary to bring it into compliance or, as the case may be, to withdraw or recall it. Furthermore, if the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States on whose markets they have made it available, indicating in particular the details of the non-compliance and any corrective measures taken*".

The procedure must detail the methods of analysis of the events and in which cases the manufacturer deems withdrawal or recall necessary; moreover it must clarify the detailed modalities for the communication to the national authorities.

The absence of this type of procedure will be considered as non-compliance.

8.6 Audit process

8.6.1 Generality

ITALCERT performs the first evaluation of the quality system of the manufacturer through a two-step audit.

Except in special situations, both phases are carried out at the manufacturer's headquarters. Where there are multiple production sites, at first certification, during Stage 2 audits, all sites will be audited.

Subsequently, sampling may be carried out between the various secondary sites.

Any presence of critical process outsourcers may, at ITALCERT's sole discretion, involve the need to extend audits to the locations of such suppliers.

8.6.2 Stage 1 audit

The stage 1 audit aims to evaluate the degree of maturity of the management system and if the manufacturer is able to support the stage 2 audit.

Furthermore, the audit has the purpose of assessing the suitability and completeness of the management system documentation.
At the end of the verification, a report is issued which indicates whether, in the opinion of the verification team, there is or is not the possibility of continuing with the stage 2 audit.
By its nature, the stage 1 audit does not provide for the detection of non-conformities. However, the report will still indicate the emerged comments, which can be of three types:

- The need for changes to be made to the management system documentation (comments)
- The presence of situations which, if not resolved, could be configured as non-conformities during the stage 2 audit (non-critical comments)
- The presence of situations which, if not resolved, will lead to a major non-conformity during the stage 2 audit (critical comments)

Where the Audit Group deems that the prerequisites for carrying out the stage 1 audit are not met, the manufacturer must provide evidence of having resolved the problems considered to be impediments, before being able to perform the stage 2 audit.

8.6.3 Stage 2 audit

The stage 2 audit aims to evaluate the manufacturer's ability to implement the management processes required by EU regulation 2016/425 Annex VIII. The verification is based on observation of the activity carried out, examination of documents and interviews with personnel. At the end of the audit, an audit report is issued, with the conclusions of the same.
At the end of the audit a report is issued, with the conclusions of the audit.
The manufacturer shall respond to any non-compliance within a maximum of 15 days, indicating, for each of them, cause, correction, corrective action and implementation timing. ITALCERT has the right not to accept the proposals received and to request a different formulation.
In the case of NC of grade 1 the certificate cannot be issued until the full resolution of the same or at least a partial resolution so that the NC can be reclassified to a lesser extent.
The presence of lower grade Non Conformities is not an obstacle to certification, provided the motion for a resolution has been deemed acceptable.
The recommendations are not binding; however, the manufacturer shall examine them and, if it considers that no action is appropriate, that situation must be justified in a documented form.
The duration of the audit is estimated on the basis of international charters established by the International Accreditation Forum (IAF). The lengths of subsequent surveillance and renewal audits are also calculated on the basis of these tables.
The manufacturer may request the replacement of one of the members of the audit team within 5 days of receipt of the communication, for justified reasons and in writing.

8.7 Issue of the certificate

At the conclusion of the evaluation, a certificate of conformity is issued, lasting three years. Once the certificate has been issued, the manufacturer may affix the CE marking in association with the ITALCERT (0426) identification number, in accordance with the rules set out in Regulation EU 2016/425 and Decision 768/2008 /EC.
The maintenance of the certificate is subject to subsequent surveillance checks, at least one per solar year.
However, the first surveillance must be carried out not later than 12 months after the certificate has been issued. NC management is similar to the one for the first certification, with the exception of the management of NC of grade 1, which will have to be managed and closed within 90 days, so as not to incur certification restraint actions (suspension, revocation, Reduction of the certification field).
Third Surveillance has the function of renewing certification. NC management is similar to that of the first certification. Renewal audit is scheduled for 3 months before the certificate expires. Where renewal verification is made, at the manufacturer's request, at a time after three months before the expiry date, ITALCERT cannot guarantee completion of the renewal process before the certificate expires. Where the renewal practice should extend beyond the expiration date, the manufacturer will not be able to use the certification or use the number of ITALCERT 0426 in association with the products to be placed on the market until the certificate is renewed.
Where it is not possible to carry out the renewal audit before the certificate expires, it ceases to be valid for its expiration and for its restoration ITALCERT will have to carry out an audit of the duration of a new certification, but in a single step. However, after 12 months from the expiration of the certificate, any restoration of certification will not be possible and you will have to restart it as if it were a new certification. In the case of renewals completed after the expiration of the certificate, the certificate will report the only current issue date and expiration date; the latter will be calculated starting from the previous deadline with the addition of 3 years.

8.8 Quality system modifications

The manufacturer keeps ITALCERT informed of any changes he intends to make to his quality system. ITALCERT evaluates the proposed changes and decides whether the modified quality system will continue to meet the requirements on the basis of a purely documented evaluation or whether audit work is required to take the place of the manufacturer.
Failure to communicate changes to the approved quality system results in the issue of a nonconformity during the surveillance audit.
In the event of changes that require an evaluation of more than one hour, the rate set for disclaimer letters will be applied.

8.9 Extension of the certificate

The manufacturer may request to include additional products in Module D certificate by submitting a specific application, as for the first certification. ITALCERT evaluates whether the approved production system needs a new evaluation or not and communicates it to the manufacturer.

8.10 Additional audit

In addition to the scheduled audits, ITALCERT may undertake further audits, as follows:

- Extension Audit: Can be implemented if the manufacturer requires an extension of certification to additional products
- Supplementary surveillance audits due to the need to check the closure of NC or decision of the deliberation committee, where the quality system of the manufacturer shows critical elements of weakness. Such audits may also be implemented as a result of complaints received on the products being certified.
- Audit without notice. ITALCERT has the right to make an audit without notice. For such audits, the manufacturer cannot exercise the right of rejection of the audit team. Such audits generally have a reduced purpose compared with a normal scheduled audit, and are not considered to be significant substitutes for it. Usually during such audits the auditors will sample by the warehouse some products, asking the manufacturer to repeat come tests on them, as well as documentary verification of production and control records. ITALCERT could also sample some products for further testing at their laboratories.

All additional audits are at manufacturer cost, according to the ITALCERT tariff, available on request or downloaded from www.italcert.it.

8.11 Maintenance of the certificate

The maintenance of the certificate is tied to the positive output of the audit and to the possibility for ITALCERT to conduct the audit at the planned range of time.

9 INDIVIDUATION OF CERTIFIED PRODUCT'S NON-CONFORMITY

As stated in article 8 paragraph 9 of the Regulation EU 2016/425, manufacturer have specific responsibilities and obligations in case there is evidence or even just a doubt that the PPE they sell are not conform with the Regulation EU 2016/425.
Any identification of non-compliance situations by ITALCERT during Module C2 checks or during the renewal/ modification of Module B needs to be analyzed and managed following the provisions of article 8 paragraph 9.
Where there is a need to make a withdrawal or recall from the market, or where the manufacturer is required to communicate to the competent national authorities of the Member States on whose markets they have made it available, the manufacturer must promptly inform ITALCERT.
Although not expressly required by the Regulation, it is to be considered as good practice and strongly recommended that the manufacturer adopt operational procedures that can be activated in this type of cases.

10 SUSPENSION AND REVOCATION OF THE CERTIFICATES

10.1 Generality

Suspension is the act by which the validity of certificates (or part of it) is suspended for a definite time.
Revocation is the act that determines the final cancellation and withdrawal of the certificate.
In the event of suspension and / or revocation ITALCERT may also request actions on the PPE already made and / or present in the warehouse on the basis of assessments to be made on a case-by-case basis.
Suspension / revocation may also cover only part of the DPIs covered by the certificate. In this case, the revocation will in fact result in a remission of the EU-wide type of duly reduced type in its scope.

10.2 Suspension

Suspension of an EU-type certificates may be implemented by ITALCERT in case there are reasonable grounds to believe that the certified PPE doesn't comply with the requirements of the EU Regulation 2016/425. This includes, but is not limited to:

- The commercial issue of PPE non-corresponding to the approved type
- Evidence of severe problematics with PPE designed and/or produced

The suspension may last up to 6 months, after which, in the absence of resolution of the aspects that led to the suspension, the certificate will be revoked.

The suspension of a production control certificate in accordance with module C2 or D may take place if:

a) ITALCERT has demonstrated that the production process is not able to guarantee the conformity of the PPE with regulatory requirements or homogeneity with respect to the type of certificate.
b) ITALCERT did not have the opportunity, for reasons attributable to the manufacturer, to carry out the checks required.

The suspension of a certificate may be caused by administrative reasons, such as non-payment of the fee requested by ITALCERT and the unavailability of receiving periodic audits from ITALCERT.

The suspension may be for a maximum period of 6 months, after which, in the absence of resolution of the aspects that led to the suspension, the certificate will be revoked

The suspension of a certificate determines its temporary cessation of validity.

This means that the manufacturer cannot use the certificate towards third parties and that he cannot affix the CE mark on the PPE involved.

10.3 Revocation

In practice, the revocation of a certificate by ITALCERT follows an unresolved suspension provision. The revocation is formally communicated to the competent Italian Ministry and to the other Notified Bodies for that type of device.

The renunciation by the manufacturer of the certification before its expiry, for example due to the end of production, is not considered a revocation. Therefore, communication to the other Notified Bodies is not envisaged, but only to the competent Ministry.

11 CONFIDENTIALITY AND DATA PROTECTION

According to Regulation EU 2016/679 and to applicable Italian legislation about ***Data Protection***, the personal data provided by the owner to ITALCERT will be processed by ITALCERT (internal staff and external collaborators/professionals involved - the latter designated as external data processing managers) exclusively for the purpose of ensuring the correct execution of the contractual relationships and of the management of the service.

In relation to the aforementioned purposes, the processing of personal data takes place through IT, manual and telematic tools with logics strictly related to the purposes themselves and, in any case, in order to guarantee the security and confidentiality of the data. The provision of the customer's personal data is therefore essential in relation to the proper conduct of contractual relationships with the consequence that any refusal to supply them will determine the impossibility for ITALCERT to proceed with the same relationships.

The data of the Organization may be communicated by ITALCERT, as far as their respective and specific competence is concerned, to Bodies and in general to any public and private entity, as well as to the internal designated subjects, responsible and in charge of data processing, as well as to those external parties responsible and / or appointed by ITALCERT to whom the communication is necessary for the execution of the services provided by ITALCERT, and with respect to whom there is an obligation or need for communication for ITALCERT.

With the exemption of the publication of the data related to the certified Organizations through the website - www.italcert.it, the personal data of the Organization will not be disclosed.

The personal data (for example: company name, address, VAT number, name of the contact persons, telephone, email addresses) are collected and processed by ITALCERT with the exclusive purpose of managing and coordinating the planned activities according to this regulation and in order to carry out administrative / accounting procedures. The data related to products / services are collected and processed in order to comply with the requirements that ITALCERT shall fulfill as an Accredited Body.

When applying for a certification, ITALCERT will provide the Customer with information about EU Regulation 679/2016 and the Italian legislation applicable to ***Data Protection***, as a consequence the Customer may give his consent to the processing of data. Not all the required information are detailed in this regulation.

Remember that:

- the "Data Controller" is ITALCERT S.r.l., in the person of the Legal Representative, address: Viale Sarca 336, Milan (ITALY)
- The Customer has the right, at any time, to have access to his personal data processed by ITALCERT, for example in order to request its updating, correction or integration, without prejudice to the obligations and provisions of law that bind ITALCERT as an Accredited Body for the conservation of specific information.

The provided data are collected by ITALCERT for the unique purpose of carrying out administrative / accounting procedures and to comply with the duties requested by ACCREDIA as a Certification Body or by other subject that are in charge of control of ITALCERT activities.
Following the issuance of the certification, the customer data are entered in the "Register of Certified Companies", which is periodically transmitted to the Bodies to whom this information is due.
The register is also made available to any applicants who make a written request; in the same way ITALCERT makes available to those who request it the eventual renunciation, suspension or revocation of the certification.
ITALCERT guarantees also the confidentiality of all information that will be collected during the assessment procedures. The persons, in charge by ITALCERT are also bound by specific confidentiality restrictions in relation to all the information they will be aware of during the certification process.

12 AMOUNTS

The amounts for the activities planned under this Regulation are established in the PRICE LIST and / or in specific offer documents, as relevant.
In general the amounts are expected for the following activities:

- Technical documentation analysis.
- Tests and another kind of analysis on the products.
- Issue, renewal, update, reduction, modification of the certificate.
- Issue of letters of authorization.

13 APPEALS

Appeal against a decision taken by ITALCERT, with display of their dissent, may be done by the Client within 30 days from the notification of the decision taken from ITALCERT. The appeal must be transmitted by, registered letter, email or PEC. Relevant addresses can be found at www.italcert.it
To be eligible, the application must:

- contain a description of the disputed decision
- a clear and detailed reason supporting the appeal

Upon receipt of the appeal, ITALCERT formally communicate to the Customer if the appeal was deemed to be eligible or not and, if eligible, the date by which a decision is made.
The eligible appeals are evaluated by a Committee of independent from the staff involved in the actions that led to the decision subject to the appeal.
Any costs associated with the appeal are borne by the Customer, except where the appeal is granted.
Detailed rules for the management of the appeal are laid down in the ITALCERT's specific procedure, available on demand.
The appeal does not interrupt the effectiveness of the measure appealed against.

14 COMPLAINTS

The Manufacturer can make a complaint to ITALCERT for the activities under this Regulation.
Each complaints will be managed by expert people not involved in the activity object of the complaint.
ITALCERT formally manages any complaint received in writing (letter or e-mail); any verbal complaint will be handled in a documented way, as appropriate.
The management of the complaint states:

a) written response (letter or e-mail) within 7 days from receipt of the complaint, with the analysis of the complaint and any actions planned for its management, with its timing;
b) written response (letter or e-mail) upon completion of planned actions.

Furthermore, ITALCERT can also receive a report on the manufacturer from other interested parties. In this case, if the report is founded and relevant, the manufacturer is required to collaborate with ITALCERT for the analysis of the report and for the removal of any causes related to it.

15 UPDATE OF REGULATION

In the event of future updates and modifications to this Regulation, ITALCERT make the new document available on site www.italcert.it, in the section dedicated to PPE certification and will notify the Manufacturer by registered letter R.R. or e-mail. The Manufacturer has 60 days to formally communicate the rejection of the

modifications, that involves the waiver of the Certification. After 60 days without communications from the Customer, the new edition of this Regulation will be deemed accepted for tacit consent.

16 USE OF BRANDS AND LOGOS

With regard to the activities covered by these Regulations, neither the use of the logo of ITALCERT nor ACCREDIA is foreseen or permitted.