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| 3           | Modification to paragraph 5.11<br>New paragraph 5.12<br>New paragraphs 6.4 and 8.10<br>Modifications to paragraph 7.4 and 7.5<br>Modification to paragraph 9<br>Modification to paragraph 13 | Flavio Banfi   | Roberto Cusolito |

## **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.

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.

*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 Community 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 actually 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

*NOTE 2: the operational procedures for OBM process are taken from 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 aimed at certification may only be initiated after the manufacturer or his authorized representative submits the application for certification.

It is recalled that the manufacturer can not apply for certification for the same product to different Notified Bodies.

It is also clarified that it is the responsibility of the manufacturer to indicate the harmonized standards that may be used during the design / production / control of the PPE for which certification is required.

### **3.2 PPE categorization and evaluation procedures**

Proper categorization of the PPE (I, II or III category) is primarily the responsibility of the manufacturer. ITALCERT reserves the right not to accept, with due justification, an application for certification where it provides for an incorrect classification of the PPE, requiring a different categorization.

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); Notify Body is involved only for Module B.
- b) II category: EU type examination (module B) and one of the following:
  - 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.

### **3.4 Authorised Representative**

The manufacturer may, by written mandate, appoint a authorised representative. The mandate must comply with the limits and prerogatives set out in Regulation 2016/425.

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.

### **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. The presence of such observers will always be accompanied by staff of ITALCERT. Notification of the presence of such observers may take place with minimum notice (less than 3 days), 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.

## **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 Harmonised 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 (eg by applying existing technical specifications, including all other available standards). If the manufacturer applies only 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 harmonised standards and certificate validity**

Harmonized standards are subject to change (revision).

In accordance with the rules of procedure, the relevant European standardization organization shall fix the date of withdrawal of the overdue version of the rule. The transition period is typically between the date of publication of the revisions of the new version of the rule in the GUUE and the date of retiring of the outdated version. During this time, both harmonized standards give presumption of conformity, provided that the conditions necessary for this purpose are fulfilled. After this transitional period has been completed, only the harmonized standard gives presumption of conformity. However, the Commission shall fix and publish in the relevant acts any dates of transitional periods.

Unless otherwise decided on the basis of a Commission proposal, the withdrawal of a harmonized standard does not invalidate existing certificates issued by notified bodies, but concerns only the conformity granted on the basis of new conformity assessments of the new harmonized standard. Products manufactured according to the old certificate still satisfy the essential requirements and may continue to be marketed until the validity of the relevant certificates issued by the notified bodies.

It is the manufacturer's responsibility to check each publication of the list of standards harmonized and verify the validity of the harmonized standards it applied to assess the conformity of its product.

#### **4.5 Other standard reference**

An harmonized standard may contain regulatory references to other standards. By virtue of such references, such other rules or parts thereof become indispensable for the application of a harmonized standard. Changes to regulatory references should be kept under control as, by virtue of such changes, a harmonized standard (some of it) may have been altered.

#### **4.6 Compliance to 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, enjoy the presumption of conformity. This can be the case, for example, where there is no harmonized name for the DPI object being evaluated.

This involves a more detailed demonstration, in the technical file of a particular product, of how the technical specifications used ensure compliance with the essential requirements. In short, the manufacturer does not benefit from the presumption of conformity and is required to demonstrate it in person.

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 conform. ITALCERT reserves the right not to accept the use of non-configurable technical specifications 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 the EU type-examination certificates issued or withdrawn and, on a regular or on 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 documentation Technique and the results of the tests carried out by ITALCERT.

## **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, this event is explained in the offer itself.

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](http://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 to 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 at the same time as the EC 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.<sup>1</sup>

The request for modification is examined by ITALCERT, which will evaluate the conditions for the extension requested, based on the characteristics that share the DPI extension with the ones already certified.

The certification process follows the same steps as for the first certification. However, it may be possible to extend it without carrying out tests or verifications or by carrying out a number of partial tests with respect to a new certification. The procedures for extending a certificate are detailed by ITALCERT through an economic offer.

In the case of extension of the range, for a more simple 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 PPEs already certified.

To initiate the extension iteration, the Manufacturer must send a copy of the accepted bid and the application for certification.

The expiry date of the EU type certificate issued following an extension request remains the same as the original EC 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 PPEs, 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 release**

There are conditions under which the Manufacturer may make some modifications to the PPE subject to certification, resulting in the updating of the Technical File but without changing the PPE identifier and without the need for additional tests and verifications than those made at the certification.

In these cases, the change does not require to update the certificate and does not require to issue a test report. The amendment will be examined by ITALCERT, which, if it considers it appropriate, will issue a letter of release.

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<sup>1</sup> 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.

### **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 can not be filed 12 months before the certificate expires. ITALCERT also provides for the completion of the necessary renewal actions 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. However, in the case of an expiration of the deadline, if the manufacturer did 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](http://www.italcert.it), or unsorted on request. Among the required data and information are:

- confirms that the certificate PPEs are still in production
- confirms that no changes to the certified DPI have been implemented
- transmission of the copy of the information note in force
- evidence of updating regulatory and regulatory innovations (if applicable)
- Confirmation of the body entrusted with production control for PPE of category III, if different from ITALCERT.

Upon renewal of the EU type certificate ITALCERT may request to deliver a sample of certified products for testing and / or visual examination. The need to carry out tests and the size of the sample to be verified is determined by ITALCERT at its discretion, taking into account also the results of the checks carried out by ITALCERT in the context of the tests carried out in accordance with module C2 and any modification of the standards used for PPE certification.

In the event of a successful review of the information above, ITALCERT will decide on renewal for a further 5 years of the certificate.

Where, however, situations of criticality emerge, ITALCERT will require the Manufacturer of the necessary additions and updates to be adopted.

If during renewal process it shows that the standards on which the attestation of conformity has been based are changed or updated, ITALCERT will make an assessment of the modified requirements and will prepare new tests where it is necessary to demonstrate the compliance with the new requirements.

It is not generally expected that a test report will be issued to support the renewal of the certificate, unless it is necessary to carry out specific tests and audits following regulatory updates.

### **5.10 Storage of the examined samples**

ITALCERT ensures the storage of the tested PPE for a duration of at least 3 (three) months from the date of issue of the EU type certificate. At the end of this period, ITALCERT will ask the manufacturer to provide to collect them; if the manufacturer refuse to collect them, ITALCERT will dispose the samples.

Moreover, one or more witness samples will be marked and sealed and sent to the Manufacturer at their costs. The Manufacturer shall ensure their traceability and storage in order to maintain their integrity and preserve 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 when the PPE is marketed, the Manufacturer must make available to all ITALCERT all the above described PPEs sealed.

### **5.11 Transfer of Directive 89/686/EEC type certificate to Regulation EU 2016/425 type certificate**

EC type certificate issue in reference to Directive 89/686/EEC maintain their validity in compliance to Regulation UE 2016/425 until their expiry date.

On expiry, they must be renewed pursuant to EU Regulation 2016/425.

The modification of the certificate can also take place before the expiry of the certificate, in different situations than the renewal procedure. In this case, the procedure follows what has already been described in the previous point 5.6. In particular, a documentary assessment will be carried out and, to a positive outcome, the issue of the updated certificate, which will keep the same expiry date as the previous certificate.

### **5.12 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.

ITALCERT informs the manufacturers about the state of modification of the validity of a standard used as a reference for certification, also providing clarifications on the management of a possible update of the certificates, as clarified below.

The harmonized standards are subject to withdrawal and / or modification in the manner deemed appropriate by the European Commission.



If a transitional period is established, both harmonized standards confer presumption of conformity, provided that the necessary conditions for this are met. Once this transitional period has ended, only the amended harmonized standard confers presumption of conformity.

As a general principle, the withdrawal of a harmonized standard does not invalidate the existing certificates issued by ITALCERT, but only concerns the conformity conferred on the basis of new conformity assessments relating to the new harmonized standard. Products manufactured according to the old certificate still enjoy compliance with the essential requirements and can continue to be marketed until the expiry of the validity of the relative certificates issued by notified bodies.

However, ITALCERT, in following the evolution of the generally recognized state of the art, can assess whether the approved type ceases to comply with the applicable essential health and safety requirements. In this case ITALCERT may request the updating of the project and certification.

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 EC-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 detailed 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 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 CE 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 required tests on the products.

In caso di procedura OBM non è prevista l'effettuazione di prove e verifiche sul prodotto. 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 DPI 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.

## **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 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](http://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.

### **7.3 First issue of the certificate**

ITALCERT will issue a certificate according to Form C2, although it is not expressly required by EU Regulation 2016/425, in order to identify, as far as possible, also to third parties and to the market, the list of PPEs on which the Manufacturers may affix the ITALCERT 0426 identification number in association with the CE marking.

The first issue of the certificate does not require any inspection or testing by ITALCERT, but only verification of the completeness of the delivered documentation. ITALCERT also reserves the right to request confirmation from the issuing body of the EU type-examination certificate regarding the validity of the certificate issued.

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 first tests of the product are carried out no later than one year after the date of issue of the EU type examination certificate.

The control is carried out on an appropriate statistical sample of the manufactured DPI; the sample is taken to a place agreed with 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 with 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 DPis tested to improve the statistical evaluation of homogeneity of production
- Temporarily suspend or temporarily suspend module C2 certificate
- Revoke or limit the C2 form 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.

The certificate update follows the same procedure as the first certification, but the certificate expiration date is not changed.

### **7.7 Production cessation**

In the event that the manufacturer has temporarily ceased producing the PPEs subject to certification, he may request ITALCERT to suspend the certificate temporarily. Where the certificate can not be reactivated, it ceases to be valid when reach the date of expiry.

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 Definizioni specifiche**

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.

**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.

### **8.3 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](http://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

### **8.4 Minimum requirements for the Quality Systems**

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 Audit process**

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.

At the end of each audit an audit 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 can not 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

### **8.6 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 EU Regulation 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 can not 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.

### **8.7 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

### **8.8 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.

### **8.9 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 can not 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 some 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](http://www.italcert.it).

### **8.10 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 SUSPENSION AND REVOCATION OF THE CERTIFICATES**

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.

Suspension of EU-type certificates may be implemented by ITALCERT in the event that a change or update of the reference standards used to demonstrate the conformity of the DPIs covered by the certificate has occurred and the Manufacturer has not provided sufficient evidence To the DPI adjustment. 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.

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.

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 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 marking on the PPE involved.

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.

## **10 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](http://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 and fax numbers, 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.

## **11 AMOUNTS**

The amounts for the activities planned under this Regulation are established in the TARIFF and / or in specific offer documents, according to the applicable.

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

## **12 APPEALS**

The Manufacturer may appeal against a decision taken by ITALCERT through written communication to be transmitted by fax or registered letter R.R. To be eligible, the application must:

- a) contain a description of the disputed decision
- b) a clear and detailed reason supporting the appeal
- c) be transmitted to ITALCERT within 45 days from the date of the notified decision, subject to the appeal.

Upon receipt of the appeal, ITALCERT formally communicate to the Customer within 7 days if the appeal was deemed to be eligible or not and, if eligible, the date by which a decision is made (within 30 days of receipt of the application).

The eligible appeals are evaluated by a Committee of Experts independent from the staff involved in the actions that led to the decision, subject to the appeal.

The decisions taken on the appeal shall be communicated to the Customer by fax and / or registered letter.

### **13 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, fax 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, fax 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, fax 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.

### **14 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](http://www.italcert.it), in the section dedicated to PPE certification and will notify the Manufacturer by fax, 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.

### **15 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