TITLE	Technical regulation for certification pursuant to Regulation (EU) 2016/425
CODE	RG-PC-DPI-01-01
REVIEW	1.0
DATE	08.06.2026

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Rev.	Date	Written by	Verified by	Approved by	Description of changes
0.0	02.11.2017	PPE Scheme Manager	Quality Manager	Quality Manager	First issue
0.1	22.03.2018	PPE Scheme Manager	Quality Manager	Quality Manager	Change of company name and clarifications
0.2	19.11.2018	PPE Scheme Manager	Quality Manager	Quality Manager	Product sampling (OBL)
0.3	09.08.2019	PPE Scheme Manager	Quality Manager	Quality Manager	Updated following ED-PRD Accredia
0.4	04.01.2021	PPE Scheme Manager	Quality Manager	Technical Director	General overhaul
0.5	15.10.2021	PPE Scheme Manager	Quality Manager	Technical Director	Updated following ED-PRD Accredia
0.6	08.02.2022	PPE Scheme Manager	Quality Manager	Technical Director	Sampling and certificate validity (C2)
0.7	20.10.2023	PPE Scheme Manager	Quality Manager	Technical Director	Revision of paragraphs 5.2 and 7.5
0.8	18.09.2024	Quality Manager	Quality Manager	Top Management	General overhaul
0.9	30.01.2026	Quality Manager	Quality Manager	Top Management	Revision par.3.4,3.1.1,3.9.1, , 4.1.1,4.1.2,4.5 , 5.9,5.10 (deleted) 6.4, 6.4.1and 7.5
1.0	08.06.2026	Quality Manager	Quality Manager	Top Management	Revision par. 3.1, 3.2, 4.2 and 6.4

1 Foreword

These Technical Regulations must be read in conjunction with the General Terms and Conditions (RG-GQ-01-01) published on the website www.mtic-group.org.

2 Purpose and scope

These Technical Regulations define the rules and methods for providing the certification service implemented by MTIC INTERCERT S.r.l. (hereinafter MTIC) in accordance with the provisions of Regulation (EU) 2016/425 in the following areas:

- EU Type Examination (Module B) referred to in Annex V to Regulation (EU) 2016/425;
- Conformity to Type assessment based on internal production control combined with tests of the product under official control carried out at random intervals (module C2) as set out in Annex VII to Regulation (EU) 2016/425;
- Type conformity assessment based on the quality assurance of the production process (module D) referred to in Annex VIII to Regulation (EU) 2016/425.

These Technical Regulations specify the rights and obligations of the Organization and MTIC in the context of the certification process pursuant to Regulation (EU) 2016/425, without prejudice to the provisions of the General Contractual Conditions referred to in chapter 1.
For all the activities specified in these Technical Regulations, MTIC applies the provisions of current legislation.

In case of future updates and changes to these Technical Regulations, MTIC will make the new document available on the website www.mtic-group.org and will notify the Manufacturer thereof by fax, registered letter or e-mail. The Manufacturer will have 60 days to formally communicate any non-acceptance of the changes, which entails the waiver of certification. After the 60-day deadline without communication from the customer, the new edition of these Technical Regulations will be considered accepted by silence - consent.

2.1 Reference documents

In general, the reference documents cited are applicable in the latest valid edition and/or revision.

- Regulation (EU) 2016/425 on personal protective equipment and repealing Directive 89/686/EEC.

The Standards referred to and/or harmonized pursuant to Regulation (EU) 2016/425 will be applied as published in the Official Journal.

- UNI CEI EN ISO/IEC 17065 Requirements for Bodies that certify products, processes and services.
- UNI CEI EN ISO/IEC 17067 Fundamental Elements of Product Certification and Guidelines for Product Certification schemes.
- UNI CEI EN ISO/IEC 17020 General criteria for the operation of the various types of bodies carrying out inspection activities.
- UNI CEI EN ISO/IEC 17021-1 Conformity assessment - Requirements for bodies that provide audits and certification of management systems.
- UNI CEI EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
- UNI EN ISO 9000 Quality management systems - Fundamentals and vocabulary.
- UNI EN ISO 9001 Quality management systems - Requirements.
- UNI EN ISO 19011 Guidelines for audits of management systems.

- RG01 Regulation for the accreditation of Certification, Inspection, Verification and Validation Bodies - General Part.
- RG01-01 Regulation for the accreditation of Management Systems Certification Bodies.
- RG01-03 Regulation for the accreditation of Product/Service Certification Bodies.
- Other applicable EA/IAF documents.

2.2 Terms and definitions

All definitions set out in Article 2 of Regulation (EU) 2016/425 shall apply in addition to the following.

Organization: Company that requires (or has obtained) certification. Whereby Company we mean a company, enterprise, firm, entity or association, legally recognized or not, public or private, which has its own functions and its own administration or natural person.

Plant or Manufacturing Unit: site where the Manufacturer manufactures or has the devices manufactured.

EU declaration of conformity: document according to which the Manufacturer declares that the product is in conformity with Regulation (EU) 2016/425.

TM: Technical Director of the Organization

Steering committee*:* Certification Resolution Committee

RT: Technical Manager of the Body

Module: conformity assessment procedure established in Art. 19 of Regulation (EU) 2016/425, as defined in Decision no. 768/2008/EC.

Approval: recognition, through a specific procedure, that a particular skill (knowledge and experience) is suitable for a specific product/activity.

Verification: procedure followed by the Notified Body to evaluate the products built and certify that they comply with the certified type in compliance with the reference legislation used.

Additional verifications: verifications not provided for during the period of validity of the certification and necessary to verify the continued conformity of the products manufactured, for example, in the case of changes made to the Type, by extension of the certification, as a result of the changed conditions imposed by the state of the art, etc.

Unannounced visits: procedure by which MTIC ascertains that the production/product complies with the certification issued and the requirements of the Regulation and the proper functioning of the management system.

***Sampling* (or *Sample*):** a set of products of the same type or of different types.

OJEU: Official Journal of the European Union.

Certification: A Third Party declaration that the requirements applicable to a product/process have been complied with, on a given date.

RESS: Essential Health and Safety Requirements set out in Annex II to Regulation (EU) 2016/425.

Application for certification: Request for activation, by the Manufacturer or his authorised representative, of one or more conformity assessment procedures referred to in Regulation (EU) 2016/425. Pursuant to these Technical Regulations, the application for certification may be the application for EU Type Examination (module B) or the request for activation of the conformity assessment procedures to the Type referred to in modules C2 and D described in Regulation (EU) 2016/425.

2.3 Affiliates and subcontractors

If MTIC intends to entrust, in part or in full, the certification activities to affiliates and/or subcontractors, the Organization will be informed in advance and explicit consent will be requested.

In any case, MTIC retains responsibility for the certification decision.

3 Certification Process

3.1 General

Organizations wishing to obtain certification for the Type they intend to place on the market must send by fax, post or e-mail a specific request containing the information necessary, according to the applicable requirements of Regulation (EU) 2016/425, to formulate the service proposal.
MTIC accepts requests without discrimination, prejudice or favourable conditions, deriving from any membership of particular associations and/or categories.
It should be noted that the certification procedures are always addressed to the Manufacturer, who holds the responsibility deriving from the product placed on the market. All documents relating to certification are always in the name of at least the Manufacturer as reported on the application.
Certification can only be requested by the Manufacturer of the product, or by a person or organization in possession of specific authorization (e.g. the authorized representative), from a single Notified Body of his choice. The EU Type Examination application contains a statement to that effect.
Interested parties not directly involved with the production, service or process cannot apply for any certification procedure, provided for by Regulation (EU) 2016/425.
Assessment activities aimed at certification can only begin after the submission of the certification application.
The Manufacturer or his representative retains the responsibility of indicating any harmonised standards that may be used during the design / production / control phase of the PPE for which certification is requested.
Similarly, the responsibility for correctly categorizing the PPE for which certification is requested is borne by the Manufacturer. MTIC reserves the right not to accept, with due justification, an application for certification that provides for a categorization considered incorrect. At the same time, MTIC may request the application of a different category.
MTIC shall request, for examination, the documents better specified in these Regulations, applicable according to the chosen form or combination of forms.
(*) Any communication relevant to the certification process (e.g. technical documentation, schedules, or any procedural changes) must be sent exclusively by email. Such communications must be filed in the 'Communications' folder.

3.2 Reporting obligation

MTIC is obliged to inform the Notifying Authority, in accordance with Article 34 of Regulation (EU) 2016/425:

- any refusal, restriction, suspension or withdrawal of a certificate or an approval;
- any circumstances that may affect the scope or conditions of the notification;
- any requests for information they have received from market surveillance authorities in relation to conformity assessment activities;
- upon request, the conformity assessment activities carried out as part of their notification and any other activities, including cross-border and subcontracting activities.

In addition, MTIC shall inform its Notifying Authority of the EU Type Examination Certificates and/or their supplements issued or withdrawn by it and, periodically or upon request, shall make available to it the list of such certificates and/or their supplements that have been refused, suspended or otherwise restricted.

MTIC is obliged to provide other Notified Bodies with relevant information on issues related to negative and, upon request, positive results of conformity assessments.
The European Commission, Member States and other Notified Bodies may obtain, upon request, a copy of the EU Type Examination Certificates and/or their supplements. The European Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by MTIC upon justified request.

Only if applicable, this obligation is also extended to the National Accreditation Body.

3.3 Authorized representative or representative

The Manufacturer may appoint, by means of a written mandate, an authorised representative. The mandate must respect the limits and prerogatives set out in Regulation (EU) 2016/425. The mandate must allow the authorised representative to carry out at least the following tasks:

a. keep the EU declaration of conformity and technical documentation available to national market surveillance authorities for a period of ten years from the last date of placing the PPE on the market;
b. following a reasoned request from a national competent authority, provide the latter with all the information and documentation necessary to demonstrate the compliance of the PPE;
c. if the national competent authorities so request, cooperate with them in any action taken to eliminate the risks presented by the IPR falling within its mandate.

Therefore, if the Manufacturer has identified an authorised representative, MTIC will require evidence that the mandate contains at least the above.
The authorised representative may submit the EU Type Examination Application and generally fulfil the administrative obligations provided for in Regulation (EU) 2016/425 on behalf of the Manufacturer, provided that they are specified in the mandate.
The obligations to ensure that PPE comply with the requirements of Regulation (EU) 2016/425 and the obligations to create the Technical Manufacturing Documentation referred to in Annex III to Regulation (EU) 2016/425, which are the responsibility of the Manufacturer, do not fall within the mandate.
For the purposes of these Technical Regulations, any reference to "the Manufacturer" or "the Organisation" shall read as "the Manufacturer or its authorised representative".

3.4 Validity, renewal and surveillance

The duration and validity of the Certificates vary according to the form applied.
Typically, certificates have the following validity:

Activities	Cat.	Mod.	Validity	Surveillance
EU type-examination	II	B	Maximum 5 years	Not provided Revision is envisaged following adaptation of the technological process, changes made to the product or introduction of new models
Conformity to type based on internal production control combined with officially controlled product testing carried out at random intervals	III	C2	1 year	Tests on sampling from production performed at least once a year and at random intervals established by the Notified Body. The first sampling is carried out on the first production carried out after the approval of the certified Type (module B); subsequent sampling no later than one year from the date of issue of the Module C2 Certificate.
Conformity to type based on quality assurance of the production process	III	D	3 years	Certification and surveillance audits scheduled every year. Unscheduled surveillance as needed or in specific cases. See par. 7.5

The expiry date of the Certificate issued following the conformity assessment procedure referred to in Form C2 is described in paragraph 6.7

The expiry date of the certificate issued following the conformity assessment procedure referred to in Module D is determined as three years, corresponding to a certification cycle + 2 surveillance or renewal cycle + 2 surveillance, starting from the date of issue of the Certificate.

The validity of the Certificates is maintained following the positive outcome of the surveillance activity conducted by MTIC.

However, MTIC keeps up to date with technological progress and regulatory updates, particularly regarding project approvals. If there are substantial changes that affect compliance with the ENIs of Regulation (EU) 2016/425, MTIC informs the Manufacturer so that it can make the necessary adjustments. In this case, the validity of the certificates may be lower than that shown in the table.

3.5 Maintaining certification

The Organization must maintain the conformity of the products with the applicable reference standards, is required to periodically verify the state of the art, as well as changes to the legislation in force or to the harmonized standards to which conformity is declared.
The Organization undertakes to notify MTIC of any significant changes that may affect the requirements that led to the certification.
The Organization shall keep records of any complaints received from its customers regarding the products covered by the Certificate and of the related corrective actions taken and shall make them available to MTIC.
MTIC also reserves the right to carry out additional checks at the Organization in the event of complaints or reports, considered particularly significant, relating to the non-compliance of the products with the requirements of the reference standards and Regulation (EU) 2016/425, or for the purpose of verifying the conformity of the product following the changes communicated by the Manufacturer itself or following the verification of the closure of non-conformities that emerged during the audit surveillance
In the event of refusal, without valid reasons, by the Organization, MTIC may initiate the process of suspension of certification.
In the event that complaints and reports are deemed justified by MTIC, the cost of carrying out the additional inspection is borne by the Organization.
If, during the period of validity of the certificate, changes occur to the certification requirements required by the applicable standards or to the certification scheme, MTIC will notify the Organization in order to define the actions to be taken or any additional verifications.

3.6 Changing and Extending Certificates

In the event of changes to the certification requirements, made necessary as a result of changes or updates to the legislative landscape, such as revision of Regulation (EU) 2016/425, these changes will be promptly communicated in writing by MTIC to the manufacturers concerned, with an indication of the date on which they will enter into force. For all regulatory changes or updates, it is the responsibility of the Manufacturer to adapt its products to any new requirements.
Adaptation to the new provisions will be mandatory by the date of entry into force of the same. If necessary, the certifications issued and the manufacturers holding them may be verified for a supplementary assessment by that date.
The applicant is also required to notify MTIC of the intention to put into production products of new design or with modifications, compared to the certified ones, which may require the adaptation of the certification of the quality assurance of the products or production and is required to prepare the new or modified production plans.
If the outcome of the checks certifies that the variants to the system or the modified type continue to comply with the requirements of the reference standard, MTIC grants an extension of the pre-existing Certificate.

3.7 Waiver, Suspension and Withdrawal of Certification

In the event of suspension, withdrawal or renunciation of the Certificate, the Manufacturer must suspend the sale and notify MTIC of the presence of the products already manufactured and marked ready to be placed on the market whose marketing authorization will be subject to specific evaluation by MTIC.
The Manufacturer must also stop affixing the CE marking on products under manufacture from the date of suspension/revocation.

3.7.1 Waiver

The Certified Organization may send a formal notice of waiver of certification to MTIC, prior to the expiration of the Certificate, including in the event that the Organization itself is unwilling or unable to comply with the changes in the certification conditions communicated by MTIC.
MTIC, upon receipt of this communication, initiates the process to make the status of the certificate invalid.
In the event that surveillance activities are envisaged, a written request must be sent within three months from the date of surveillance in the case of an evaluation of the Quality System or within two months in other cases.
After this deadline, it is still possible to renounce the certification, however, the Organization is required to pay 40% of the amount accepted in the offer for the surveillance not carried out.
The Manufacturer is required to provide MTIC with the list of products and their factory numbers, made in the period between the last surveillance and the date of renunciation of certification.
MTIC reserves the right to verify the conformity of these products, according to the applied evaluation form, before they are placed on the market.
The verification will be paid for by the Manufacturer, even if he has renounced the certification.
In the event of natural expiration, the date is on the certificate itself. Once the expiration date is reached, the customer has the power to choose whether to keep the certification or terminate it.
In the event of a termination decision, the following conditions shall be established:

- The customer must remove any reference to certification on the product documentation (brochures, advertisements, labels, etc.);
- The customer has the right to put on the market the products that have been manufactured by the expiry date of the certification, for a period not exceeding six months from the expiry date;
- Products that are not in stock on the date of expiry of the validity of the certification cannot refer to the certificate itself and cannot be placed on the market.

The Manufacturer provides MTIC with a list of the products in stock and their factory numbers, which show the MTIC notification number in order to keep their marketing under control.
The Manufacturer also undertakes not to allow certifications relating to the same product issued by different Notified Bodies to coexist.

3.7.2 Suspension

A certification may be suspended due to situations that may jeopardise the conformity of the product with the legislative instrument applied. The decision is always taken by the deliberation committee, for example, for the following reasons:

- The product does not comply with the relevant RESS;
- The product has modified characteristics compared to the approved type;
- Production with inadequate and/or undocumented internal controls to ensure compliance with the approved type;
- Complaints from the field or from the authority in charge of market surveillance;
- Non-conformities in the management system, not resolved within the established time;

- Changes in product, process, place of manufacture without timely communication;
- Refusal of the Manufacturer to provide samples necessary for the repetition of tests for conformity assessment;
- Refusal of the Manufacturer to access the production facilities and/or technical documentation by MTIC staff and/or inspectors of the Accreditation Body or the Authority in charge of market surveillance (if applicable);
- Variation of requirements in relation to mandatory legal changes (taking into account the adaptation time established by the legislation itself);
- Exceeding the surveillance date.
- Incorrect references to the certification scheme or the misleading use of licenses, certificates, trademarks, or any other mechanism to indicate that a product is certified, identified in documentation or other advertising

The suspension can be accepted if requested by the customer.
The Manufacturer will be notified in writing of the suspension of the certification. The disclosure will contain the reasons for the suspension and the temporary expiration date for any corrective actions.
During the period of suspension of the certification, the Manufacturer may not mark the products covered by the certification and may not put them on the market, either directly or through other organizations, placing this prohibition also on any OBL manufacturers, under his responsibility.
The time taken to reduce the non-conformities that gave rise to the suspension ranges from a minimum of 30 to a maximum of 180 calendar days.
After six months without any solution, the certification will be automatically revoked (see next paragraph).
The customer who believes that he has resolved all the non-conformities asks for verification to confirm the resolution; MTIC carries out the assessment or appoints competent figures in order to take the decision, notifying the Organization.
The restoration of the certification is subject to the verification of the elimination of the deficiencies that had caused its suspension.
The reinstatement is notified in writing to the Organization and made publicly known by MTIC if the news of the suspension had been made public at the time.

3.7.3 Revocation

MTIC, following the decision of the Resolution Committee, may withdraw a Certificate for the following reasons (in brackets is given the maximum calendar time within which to resolve non-conformities to avoid revocation):

- Violation of RG-GQ-01-01 "General Contractual Conditions" or Regulation (EU) 2016/425 or these Technical Regulations (30 days);
- Exceeding the suspension period of 180 days (immediate);
- Serious non-compliance in the manufacture of the product and/or raw materials that may affect the safety of the product (immediate);
- Serious non-compliance of the quality management system with process control that may affect product safety (15 days);
- Non-payment of the certification invoice, partial or total (30 days);
- Denial of access to the production site to the staff of the Authority in charge of market surveillance or the accreditation body (15 days);
- If the Organization suspends its activities or services subject to the certified Quality System and/or product Conformity Assessment (6 months);
- Non-acceptance of the new economic amounts relating to surveillance activities, according to the procedures described in RG-GQ-01-01 "General Contractual Conditions".

- For any other serious reason such as, for example and not limited to, the proven inability of the system to pursue its objectives of compliance with legislative or contractual constraints or product safety (according to MTIC's judgment).

The Organization whose certification has been revoked must:

- Return the revoked certificate by notifying MTIC. If the certificate is not received within 30 days, MTIC will consider the destroyed certificate to be the responsibility of the Organization;
- Remove all references to certification and CE marking including the notification number of MTIC, where applicable;
- If applicable, remove all references to the ACCREDIA mark granted to certified Organizations (see RG-09 on the www.accredia.it website for details);
- Do not use copies and/or reproductions of the revoked certificate.

The revocation of a Certificate may also be requested by the Manufacturer in writing, accompanied by objective reasons.

The Organization that after revocation intends to access the certification again, must submit a new application following the entire procedure provided for by these Technical Regulations.

If necessary, an appeal procedure is provided against MTIC's decision, as set out in the General Terms and Conditions (RG-GQ-01-01) published on the website www.mtic-group.org.

3.8 Takeover

If a Manufacturer with an approved management system requests MTIC to take over the surveillance, the first surveillance will be performed by MTIC within one year of the last surveillance carried out by the previous Notified Body. Such monitoring shall be carried out on the entire management system as if it were a certification audit in accordance with paragraph 7 below.
The Certificate will show the date of issue and the expiry date provided by MTIC, however at the request of the Customer it is possible to enter the date of first approval obtained by the Customer with the previous ON
In order to be able to proceed, the applicant must provide, in addition to what is provided for in paragraph 7 below, at least:

- Copy of the Certificate of Approval of the SQ, previously obtained and related attachments;
- Copy of the last inspection report issued by the previous O.N.;
- Copy of the complaint/withdrawal register;
- Declaration in lieu of affidavit that there are no proceedings in progress by the competent authority for market surveillance, on the products subject to the transfer/takeover.

3.9 OBL

A Manufacturer who has obtained an EU Type Examination Certificate may grant other Organisations the placing on the market of the product in their name and under their trade mark under the conditions set out below.
The Manufacturer who has obtained the EU Type Examination Certificate from MTIC and who manufactures the PPE (and in the case of category III guarantees its conformity to the certified type according to the procedures set out in Module C2 or Module D), is called OEM.
The Manufacturer who resells the same product from the OEM in its own name and under its own brand is called OBL.

3.9.1 General conditions

The OEM Manufacturer must have obtained an EU Type Examination Certificate (Module B) for the PPE that will be placed on the market by the OBL in its own name and trademark. In the case of category III PPE, it must also have obtained a Module C2 or Module D2 certificate to ensure the conformity of production to the certified Type

The OEM Manufacturer and the OBL Manufacturer must enter into a joint contract that provides for at least the following.

3.9.2 Contract between OEM and OBL

Both OEM and OBL organizations must sign a joint document in which in addition to accepting these Technical Regulations they mutually commit themselves to at least:

For OEM :

- ensure that the products (including models and variants) supplied to OBL are the same as the Object Type of the Certificate obtained from the OEM (any differences must be listed in the contract).
- Inform the OBL of any suspensions, revocations, expiration of the Certificate or renunciation of the same.
- If the PPE is Category III, inform the OBL of any suspensions, revocations, deadlines, or waiver of the Module C2 or D Certificate, depending on the production conformity assessment procedure adopted by the OEM.
- Provide the minimum technical documentation described below for the OBL to draw it up in its own name.
- Inform MTIC and the OBL of any changes it intends to make to the certified product (including models and variants) and the related documentation referred to in the previous point before proceeding to produce the modified product.
- Report to OBL and MTIC any complaints you may receive regarding the products.
- Report to the OBL and MTIC any incident involving the products covered by the Certificate.

For OBL:

- Guarantee that you do not make any changes to the products that are the subject of the contract with the OEM, referred to in the Certificate.
- Report to the OEM and MTIC any complaints they may receive regarding the products
- Report to the OEM and MTIC any incident involving the products covered by the Certificate.
- Take responsibility for the drafting of the EU Declaration of Conformity for the products covered by the Certificate.
- To cease the sale of the products if the OEM communicates the suspension, expiration, revocation or renunciation of the Certificate.
- Declare that you are aware that the Certificate you obtain from MTIC as an OBL will have the same expiration date as the Certificate obtained from the OEM and that the validity of the same will expire at the same time as the OEM's Certificate following the expiration, renunciation, revocation or temporary suspension of the certification.
- Cease selling the products if the OEM reports that they are potentially dangerous to users.

3.9.3 Application for OBL Certification

The OBL must send MTIC a request for certification for the products covered by the contract with the OEM and following the acceptance of the offer produced by MTIC, to access the certification process which provides:

- The review of the technical documentation.
- The verification of conformity of the Type.
- Verification of conformity of products to the type by means of production checks, tests, etc.
- The verification of the conformity of the products to the type on the basis of the management system adopted by the OEM.

The Technical Documentation must provide at least:

- Use and maintenance manual.
- The scheme of markings and labelling where the OBL references are found that differ from those described in the OEM Manufacturer's Technical Documentation.
- The EU Declaration of Conformity of the PPE manufactured by the OEM.
- the list of production sites (if different from the sites declared by the OEM).

Note: in the case of production sites other than those declared by the OEM, the same must be indicated and additional checks and/or laboratory tests may be necessary, to be evaluated on a case-by-case basis.

If applicable, the Technical Documentation must also include:

- the EU Type Examination Certificate and the EU Declaration of Conformity concerning the accessories incorporated in the device';
- attestations and certificates relating to the methods of manufacture and/or inspection and/or control of the device or accessory;
- a copy of the EC declaration of conformity of the device/accessory

All documentation must be produced in the name and under the responsibility of the OBL.
Following the positive outcome of the conformity assessment conducted by MTIC, the review and the decision taken by the Resolution Committee, MTIC will issue a Certificate that will be traceable to the certificates issued to the OEM Manufacturer.
Certificates issued to the OBL will have the same expiration date as certificates issued to the OEM and will be suspended or revoked if the certificates issued to the OEM are.
For PPE belonging to category III, the OBL must have submitted an application for conformity assessment to the Type of production (Module C2 or Module D) at MTIC or at a Notified Body of his/her choice.
Only after the issuance of the Certificate of Form C2 or Form D, the OBL will be able to use the number 0068 and references to MTIC as required by Regulation (EU) 2016/425.

3.9.4 Ancillary conditions

For the purposes of Regulation (EU) 2016/425, the OBL is the Manufacturer of the product marked and sold in its own name.

MTIC:

- will keep together with the Certificates issued to the OBL the copy of the OEM certificates.
- during production, it will verify the data relating to the OBL, the marking, the technical documentation (this may require surveillance at the OBL headquarters).
- If the products covered by the contract are referable to an EU Type Examination Certificate issued by another Body, MTIC, without prejudice to the adoption of the practices deemed suitable for the acquisition of information relating to the technical documentation, certification, etc. from the OEM, will evaluate the most appropriate methods for the verification of production according to the evaluation procedure required by the OEM and the OBL.

- You will keep track of the references between the certificates issued to the OEM and the OBL even if it is decided not to make such references explicit on the Certificates issued to the OBL

3.10 Advertising – use for CE marking purposes

The Organization may disclose in the most appropriate ways the obtaining of certification by MTIC. The Organization must in any case clearly indicate any limitations and conditions imposed by MTIC at the time of issuing the aforementioned certification.
The Organization may reproduce the Certificate in its entirety, enlarging or reducing it, provided that it remains legible and is not altered in any way.
In using the Certificate, the Organization must avoid that the certification can be understood as extended to products not included among those covered by the certification issued by MTIC.
In the event of use of the Certificate that does not comply with the above points or in the event of their unlawful use, MTIC will take appropriate measures against the Organization, including the use of appropriate legal actions.
The Body may verify the conformity of the promotional material made public by the manufacturer, for example, through the website of the same or of distributors and retailers, etc. These checks will be carried out on a sample basis and any findings that may emerge will be formalised to the manufacturer who will have to deal with them by giving evidence to the Body within the communicated timeframes. Failure to process the findings could result in the suspension or revocation of the certificate according to the procedures adopted by the Body.

3.11 Preservation of samples and documentation

MTIC ensures the correct handling of samples during testing. Storage at MTIC or at the manufacturer's premises of samples already subjected to verification is not required.
MTIC ensures the storage of the tested PPE for a period of at least 3 (three) months from the date of issue of the EU Type Examination Certificate And unless otherwise agreed will dispose of it

- Any disposal costs are borne by the Manufacturer.
- The Manufacturer must ensure their traceability and safekeeping 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 Examination Certificate.

In the event of disputes during the period in which the PPE is marketed, the Manufacturer must make available to MTIC all the PPE described above sealed.
The Manufacturer must also ensure the traceability and custody of all the certification documentation relating to the PPE for a period of at least 10 years from the date of the last placing on the market of the PPE itself. Copies of the Certificates and the significant files of technical documentation listed in the Certificates are kept by MTIC for the time required by current legislation. At the end of this period, the paper documentation is digitised and stored together with the relevant documentation already in digital format, after which it can be destroyed.
Digital documents are archived and stored until MTIC exists, except for unforeseen and extraordinary events that may compromise normal digital archiving techniques.

3.12 Use of trademarks and logos

MTIC does not provide for the granting of the use of its certification mark for conformity assessment activities conducted in the notified area.
For this reason, Organizations that have obtained the certificate from MTIC are not allowed to use the Accredia mark which, according to the provisions of the RG09 of the Accreditation Body, can be granted for use to them exclusively in combination with the Body's mark.

The only marking that can be used by the Organization downstream of obtaining the Certificate by MTIC is the "CE" according to the requirements indicated in Annex II to Regulation (EC) 2008/765. The methods for affixing the marking are defined in Regulation (EU) 2016/425.

4 Conformity Assessment Procedures

4.1 Application for certification

After the first contact with the customer (telephone, fax or e-mail) all the information necessary to start the certification process is requested.
MTIC carries out a preliminary examination to verify whether the information provided is sufficient to formulate a service proposal, reserving the right, if necessary with reference also to what is reported in these Technical Regulations, to request further details.
Once the information has been obtained, MTIC prepares, on the basis of the price list, an economic offer for testing and certification activities and sends it to the interested customer together with the forms necessary for the submission of the certification application.

If the application is submitted by the authorised representative established in the Community, it must contain, in addition to the name and address of the manufacturer, place of production, description of the type of product and the intended use, also the name and address of the authorised representative.

The applicant must submit the application by filling in the form provided by MTIC in its entirety, filling in one form for each model or for each homogeneous series of products.

If the application and the documents provided are incomplete, MTIC requests the necessary additions to continue with the certification process.

The documentation provided by the applicant shall include, in accordance with the applicable conformity assessment procedures, at least:

- A detailed description of the product, technical specifications and other data deemed necessary;
- A list of characteristics/requirements falling within the field of interest of the conformity assessment activity and the list of reference documents (technical regulations, standards, etc.);
- Detailed drawings of the product (general design and manufacturing drawings, diagrams of components, sub-assemblies, circuits, etc.; including descriptions and explanations necessary for the understanding of these drawings and diagrams and of the operation of the product);
- The instructions for use and maintenance;
- The available test reports and certificates relating to the product, the technical documentation regarding the materials procured, the methods of control and test during the production cycle, etc.;

Where applicable, the application for certification must be accompanied by a sufficient number of samples for laboratory tests to be carried out.

Upon acceptance of the offer by the Customer and receipt of the completed application, a file number is assigned and the application is reviewed.

4.2 Review of the application

The review of the certification application is the phase by which the conformity assessment procedure is initiated. The review of the application for certification takes into consideration the conditions and information on the basis of which the economic offer was prepared and verifies its continued existence through the application itself, the documentation and the samples received, if any.

If the application for certification is not accompanied by the elements necessary for the start of activities, MTIC requests integration and the conformity assessment procedure is put on hold until the conditions are met.
If these conditions are not met, MTIC rejects the application received.

NB: The documentation and sampling, necessary to carry out the estimated tests, must be received at the MTIC offices and warehouse no later than 6 months from the submission of the application, under penalty of rejection of the application for certifications.
In the event of rejection of the certification application due to non-compliance with the time limits indicated above, a penalty of 10% of the entire amount (tests + certification) will be applied.

NB: In the case of offer for Category III PPE, for which surveillance is required in accordance with Annex VII of EU Regulation 2016/425 (Module C2), the offer must be accompanied by the Test Plan specific to the applicable standard, covering the entire period of validity of the Module B certificate (5 years).

4.3 Planning and execution of audits

The inspection activities envisaged for the products are carried out by MTIC inspectors, based on the requirements of the applicable assessment procedures (modules) described in detail later in these Technical Regulations.
Upon successful completion of all the examinations and tests required by the certification procedures and by these Technical Regulations, applicable on the basis of the chosen module, and specified in the service proposal sent to the Organization and accepted by it, the technical secretariat sends the file complete with all the documentation to one or more competent and independent technicians of MTIC (deliberation committee) for the complete review of the same and the decision on the granting certification.
Following the positive outcome of the decision of the deliberation committee, MTIC issues the certificate/authorization/approval required by the chosen evaluation form and sends it to the Organization following payment of the relevant invoice.
In the event of a negative outcome, MTIC shall notify the Organization of this outcome and agree with the Organization on the modalities for any re-evaluation.
In the event of refusal of the MTIC certification, it shall inform the competent authority in accordance with the reporting obligation referred to in point 3.2 of these Technical Regulations.
If necessary, there is a procedure for appeal against MTIC's decision, as set out in the General Terms and Conditions (RG-GQ-01-01) published on the website www.mtic-group.org.

4.4 Equipment used

MTIC has internal laboratories for carrying out certification and control tests. If MTIC does not have the tools, it may proceed with subcontracting as provided for in the following paragraph, or it may evaluate the use of tools made available by the requesting organizations.
These instruments must be adequate to the tests envisaged.
All instruments used must be accompanied by the relevant calibration certificate, issued by an accredited calibration laboratory, or, where the measurement is not highly critical, they may be accompanied by a non-accredited calibration report that ensures metrological traceability. In the case of non-accredited calibration reports, the metrological chain must be identified with evidence of the calibration certificates of the primaries used, issued by accredited calibration laboratories. In any case, all calibrations must be referable to primary samples with valid calibration certificates. MTIC inspectors verify the identification of the instruments and the related calibration certificates with metrological traceability, as well as the procedures for managing the instrumentation and the methods of storing them, and may acquire copies to demonstrate the validity of the measurements carried out.
In general, special and exceptional situations can be evaluated, for example in the event that an accredited laboratory does not exist for an instrument necessary to perform a given measurement, or there is no

standardized calibration method, or even where LAT calibration is not feasible. In these cases, the use of instruments with non-accredited calibration reports may be assessed, if the above conditions are met, and MTIC inspectors may request and obtain copies, by way of non-exhaustive example, not only of the calibration reports, but also of the calibration certificates of the primaries, the calibration procedures applied and any other reference documents for the instruments (e.g. the instrument sheet and status information) of use and maintenance). In the event that the instruments necessary for the performance of the tests are not made available or the adequacy and calibration of such instruments is not guaranteed, these tests shall not be considered valid for certification purposes.

4.5 Requirements for testing laboratories and related reports

Applicants may submit to MTIC Test Reports in their possession in support of the technical documentation, if issued by laboratories accredited according to ISO/IEC 17025 for the standards/tests relevant to the ongoing certification process.
In addition, Test Reports from laboratories that have been qualified by MTIC for the standards/tests relevant to the ongoing certification process may be accepted.
Should the Test Reports relating to the tests conducted on the representative sample of PPE, submitted by the applicant to MTIC, show a date of execution of the same, prior to the date of submission of the application for the EU Type Examination or renewal of the Certificate, MTIC reserves the right to accept the same only following verification that:

- except in special cases to be specifically assessed, the Test Report(s) has not been issued more than five years before the date of submission of the application for the EU Type Examination;
- no changes have been made to the reference standards for these tests;
- the Manufacturer can demonstrate that there have been no changes to the materials, the production process, or other changes to the PPE subject to certification, with respect to the sample covered by the Test Reports submitted.

4.6 Language

The documents and correspondence relating to the conformity assessment of a PPE and/or the quality system must be in Italian or English. The Technical Documentation and/or the Quality System Documentation may contain, if necessary, some parts in different languages as long as they are also provided in Italian or English. In particular, the instructions for use are always evaluated in the Italian language only, and only in the absence of this are they evaluated in the English language.
For other Community languages, an additional offer for the translation of documents will be produced, if necessary.
Please note that compliance with the obligations regarding the language to be used for the instructions for use and for the EU declaration of conformity of PPE placed on the European market is the responsibility of the Manufacturer. MTIC may examine how this is properly handled during type verification where applicable.

4.7 Safety in the workplace

On the occasion of visits to its operational headquarters, the Manufacturer, in accordance with current legislation on safety and prevention of accidents at work, undertakes to provide MTIC's employees with the necessary information regarding any risks existing in the working environment in which they are intended to carry out their work, and ensures that all possible precautions are taken for their protection with regard to health and safety.

4.1 Survey management

4.1.1 Module B

The certification cannot be granted or maintained until any non-conformities have been adequately removed and MTIC has ascertained, with a favorable outcome (through a special additional audit and/or additional tests/calculations and/or examination of documentary evidence) the correction/corrective actions and closure of the same.

	Module	**Root cause analysis and actions**	**Time to corrective action**	**How to check the resolutions**	**Recordings**
NC Mag	B	15 days	30 days	- Documentary analysis within six months -Additional checks within six months	Applicable Modules
NC Min	B	15 days	3 months	- Documentary analysis within six months -Additional checks within six months	Applicable Modules
Racc	B	-			

The RGVI, in compliance with the indications in the table, defines and formalizes the timing, depending on the specific situation detected and the influence that probably/likely the non-conformity may have on the manufacturer's ability to ensure products that comply with the applicable prescriptions/requirements and/or to ensure the constancy of their performance.

4.1.2 Module C2 and Module D

The certification cannot be granted or maintained until any major non-conformities have been adequately removed and MTIC has ascertained, with a favorable outcome (through a special additional audit and/or additional tests/calculations and/or examination of documentary evidence) the correction/corrective actions and closure of the same. A similar procedure is followed in the case of other surveys, the number and extent of which, in MTIC's opinion, is such as to jeopardize safety requirements and/or to cause the delivery of a product that does not comply with the applicable prescriptions/requirements. During the subsequent audit, the MTIC will be responsible for verifying the effectiveness of the corrective action. For findings classified as minor non-conformities, the certification can be granted or maintained only following the approval by MTIC of the treatment proposal and AC/AP formulated by the manufacturer and the related implementation times. During the subsequent audit, MTIC will be responsible for verifying the effectiveness of the corrective action. For surveys classified as "Recommendations", the manufacturer is not obliged to define and implement any treatments (corrections) and/or corrective/preventive actions. MTIC merely verifies in the subsequent surveillance audit whether, and how, the manufacturer has taken charge of these observations.
The Timing of notification and closure of corrections and/or accepted CA/APs and Observations, any implementation and effectiveness checks, and related registrations, follow the following application scheme:

	Type of audit	Root cause analysis and actions	Time to corrective action	How to check the resolutions	Recordings
NC Mag	D C2	15 days	30 days under penalty of suspension from 30 to a maximum of 180 days	Document analysis within six months Additional audit within six months	Applicable Modules
NC Min	D C2	15 days	3 months	Document analysis Subsequent surveillance audit	Applicable Modules
Racc	D C2	-	-		

The RGVI, in compliance with the indications in the table, defines and formalizes the timing, depending on the specific situation detected and the influence that probably/likely the non-conformity may have on the manufacturer's ability to ensure products that comply with the applicable prescriptions/requirements and/or to ensure the constancy of their performance.
The periodicity and extent of surveillance is established/confirmed by the resolution (decision) of the Resolution Committee (Deliberative Function) for the issuance of the certificate and communicated/confirmed to the manufacturer at the same time as the transmission of the certificate. The periodicity and extent of surveillance audits may be modified by MTIC on the basis of the results of the assessments carried out, these changes, approved/approved by the Deliberation Committee (Deliberative Function), are communicated to the manufacturer. The Resolution Committee also defines additional audits and may request documentary evidence.

4.2 Conformity Assessment Procedures

The conformity assessment procedures to be followed, for each of the risk categories set out in Annex I to Regulation (EU) 2016/425, are as follows:

- For PPE category II: EU type-examination (module B) referred to in Annex V to the Regulation, followed by conformity to type based on internal production control (module C) referred to in Annex VI to the Regulation (note: for PPE category II there is no provision for the intervention of a Notified Body in the conformity to type assessment phase based on internal production control - module C);
- For category III PPE: EU type-examination (module B) referred to in Annex V to the Regulation, followed by (procedures as an alternative to each other and at the Manufacturer's choice):
    a. conformity to type based on internal production control combined with tests of the product under official control carried out at random intervals (module C2) as set out in Annex VII to the Regulation;
    b. conformity to type based on the quality assurance of the production process (module D) referred to in Annex VIII to the Regulation.

By way of derogation, for PPE produced as single units to fit a single user and classified according to category III, the procedure set out in the first indent (category II PPE) may be followed.

5 MODULE B: EU-type examination

The EU-type examination is the part of a conformity assessment procedure in which MTIC examines the technical design of the PPE and verifies and certifies that such technical design meets the requirements of Regulation (EU) 2016/425 applicable to it.
The EU Type Examination involves assessing the adequacy of the PPE technical design through examination of the technical documentation, as well as examining a complete PPE sample, representative of the planned production (type of production).

5.1 Application for EU type-examination

The Manufacturer must submit the application for EU Type Examination to only one Notified Body of his choice. The application, to be submitted using the appropriate forms on the MTIC website, implies acceptance of these Technical Regulations and contains at least:

- the name and address of the Manufacturer and, if the application is submitted by the authorised representative, also the name and address of the latter;
- a written declaration stating that the same application has not been submitted to any other Notified Body;
- the technical documentation described in Annex III to Regulation (EU) 2016/425;
- the PPE sample(s) representative of the expected production (where applicable). MTIC may request additional samples if they are needed to carry out the test programme. For mass-produced PPE where each item is manufactured to fit a single user, the samples provided shall be representative of the range of different users, and for PPE produced as individual units, to meet the specific needs of a single user, a basic model shall be provided.

In general, the delivery of technical documentation and/or samples for tests is granted not at the same time as the application for certification.

5.2 EU type-examination

Upon receipt of the EU Type Examination Application and the corresponding countersigned offer for acceptance, as well as upon receipt of the technical manufacturing documentation and, if applicable, samples (see NB §4.2), MTIC:

- examines the technical documentation to assess the adequacy of the PPE technical design. In conducting this examination, Annex III, letter j) of Regulation (EU) 2016/425 does not need to be taken into account;
- for mass-produced PPE where each item is manufactured to suit an individual user, examine the description of the solutions undertaken in order to assess their appropriateness;
- for PPE produced as single units to suit a single user, review the manufacturing instructions for such PPE on the basis of the approved basic model, to assess their suitability;
- verifies that the samples have been manufactured in accordance with the technical documentation and identifies the elements designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements designed in accordance with other technical specifications;
- carries out or has carried out appropriate examinations and tests to check whether, where the Manufacturer has chosen to apply the solutions set out in the relevant harmonised standards, these solutions have been correctly applied;
- carries out or has carried out appropriate examinations and tests to check whether, where the solutions set out in the relevant harmonised standards have not been applied, the solutions adopted by the Manufacturer, including those in other applied technical specifications, meet the corresponding EHSRs and have been correctly applied.

MTIC will communicate to the Manufacturer the names of the members of the verification team. The Manufacturer has the right to request the replacement of the inspector, within 5 days, by giving reasoned written notice to MTIC, which reserves the right to evaluate the reasons for the recusal and the possibility of replacing the persons in charge.

The Manufacturer undertakes to communicate in writing, possibly in the Technical Documentation and in relation to category III PPE whose control procedure is not assigned to MTIC, the references of the Notified Body to which the Manufacturer intends to assign this control procedure. This is to allow MTIC to verify that the body in charge can actually carry out the planned activity (for example: whether it is notified for the type of PPE in question) and that the number placed next to the CE is correct. It should be emphasized that it remains the sole responsibility of the Manufacturer to activate the control procedure referred to in modules C2 or D, whatever the procedure chosen.

5.3 Evaluation report

At the end of the evaluations and upon their positive outcome, the results of the above evaluations are finalized and documented in one or more test reports, which are delivered to the Manufacturer at the same time as the EU Type Examination Certificate.
Unless otherwise agreed, a test report will not be issued in the event of a negative outcome of the tests, the results of which are in any case communicated in writing to the customer, by e-mail.
In the event of an unsatisfactory outcome of the above assessments, based on the applicable situations, MTIC may require the Manufacturer to carry out the necessary actions to resolve the non-compliance situation, including:

- modify/integrate the technical documentation prepared;
- review and amend the draft IPR as appropriate;
- provide a new sample to carry out the repetition of unsuccessful tests.

In general, and without prejudice to a case-by-case assessment, in the event of a negative outcome of the assessments conducted during the EU Type Examination phase, MTIC admits up to 3 reassessments to be completed within 6 months of the certification application.

If the condition of non-compliance persists despite the actions of the Manufacturer, MTIC refuses to issue an EU Type Examination Certificate and informs the Notifying Authority and the Notified Bodies for the same type of product, as well as the Manufacturer, giving detailed reasons for its refusal.

5.4 EU Type Examination Certificate

If the type meets the applicable EHSRs, MTIC issues the Manufacturer with an EU Type Examination Certificate.
The period of validity of a newly issued Certificate and, where applicable, of a renewed Certificate shall not exceed five years. The validity of the certificate is in any case subject to the maintenance of the conditions that allowed it to be issued.
For category III PPE, the EU Type Examination Certificate alone is not sufficient for the placing on the market of certified PPE, an action for which it is necessary that the Manufacturer is also in possession of a certificate relating to production control according to module C2 or module D. However, there is no constraint that requires the Manufacturer to assign the control of production to the same Notified Body that issued the EU Type Examination Certificate.

The EU-type examination certificate shall contain at least the following information:

- MTIC's name and identification number;

- name and address of the registered office of the Manufacturer and, if the application is submitted by the authorised representative, the name and address of the registered office of the latter;
- the identification of the PPE covered by the certificate (type number);
- a statement that the type of PPE meets the applicable EHSRs;
- whether the harmonised standards have been applied in whole or in part, the references of those standards or parts thereof;
- if other technical specifications have been applied, their references;
- where applicable, the performance level or protection class of the PPE;
- for PPE produced as single units to suit a single user, the range of permitted variations of the relevant parameters based on the approved base model;
- the date of issue, the expiry date and, where applicable, the renewal date(s);
- any conditions related to the issuance of the certificate;
- for category III PPE, a declaration that the certificate must only be used in combination with one of the conformity assessment procedures referred to in Article 19(c) of Regulation (EU) 2016/425.

The EU-type examination certificate may have one or more annexes.

5.5 Review of the EU Type Examination Certificate

MTIC follows the evolution of the generally recognised state of the art and assesses whether the certified type no longer complies with the applicable EHSRs. MTIC has the right to decide whether such developments require further investigation and, if so, it shall inform the Manufacturer.
The Manufacturer informs MTIC, which holds the technical documentation relating to the EU Type Examination Certificate, of all changes made to the certified type and all changes made to the technical documentation that could affect the compliance of the PPE with the applicable EHSRs or the conditions of validity of the certificate. These amendments entail a new approval in the form of a supplement to the original EU Type Examination Certificate.
The Manufacturer agrees with MTIC to introduce any changes to the configuration of the product, even if of an entity deemed insignificant. The Manufacturer must ensure that the PPE continues to meet the applicable EHSRs in the light of the state of the art of technical regulatory development.

The Manufacturer requests MTIC to revise the EU Type Examination Certificate:

- in the event of a change in the certificate type; or
- in the event of a development of the state of the art; or
- at the latest, before the expiration date of the certificate.

and applies the procedures provided for in the following paragraphs.

5.6 Extension of the EU Type Examination Certificate

The Manufacturer may request MTIC to modify the scope of a certificate in force by modifying existing PPE or by inserting new PPE models in addition to existing ones.
The request for modification is examined by MTIC which will evaluate its conditions on the basis of the modified characteristics of the PPE or the characteristics that the new PPE has in common with those already certified.
A request to amend an EU Type Examination Certificate may also involve the removal of PPE from the certificate.
The certification process follows the same steps as for the first certification, however it is possible that the change may take place without carrying out tests and verifications or with the carrying out of a number of partial tests, compared to a new certification.

In relation to the type of changes proposed, MTIC communicates its assessments to the customer and reserves the right to carry out additional checks to assess the influence of the changes made; following the additional checks carried out, MTIC MAY FOLLOW a revision of the certificate or the start of a new certification process.
Under the conditions described above, the customer may not proceed with the commissioning or placing on the market of the product until MTIC has given its consent.
The EU Type Examination Certificate issued has the same number as the amended Certificate, with an increased revision index. The expiry date of the EU Type Examination Certificate issued following a request for change remains the same as the original Certificate.

Extension requests related to:

- certificates of a different gender than the original one;
- new applicants than the one indicated in the original certificate;
- conformity of a single product or a different project;
- certificate of conformity assessment of production for a procedure different from the original one;

are treated as new certification applications.

5.7 Certificate update

In cases where an update of the EU Type Examination Certificate is necessary for non-technical reasons, such as:

- Change in the company name of the Manufacturer (maintaining the same legal identity, therefore without changing the VAT number) or the address of the registered office;
- Finding of inaccuracies/errors on the issued document;

MTIC provides for the reissue of the updated EU Type Examination Certificate. The expiration of the previous certificate remains unchanged.
In the event that the Manufacturer sells or leases the business unit relating to the manufacture of the certified PPE, MTIC is not obliged to modify the certificates in favour of the successor company. This possibility will be examined on a case-by-case basis.

5.8 Release letter

In the event that the Manufacturer intends to make changes to the configuration of the certified PPE, for which MTIC has assessed that there is no impact on the compliance of the device with the applicable RESS and Regulation (EU) 2016/425 (e.g. no laboratory tests or visual examinations are required), then a release letter authorising the changes may be issued.
The release letter is to all intents and purposes a supplement to the EU Examination Certificate of the reference Type, which is not modified, and is archived with it.

5.9 Renewal of the EU Type Examination Certificate

The renewal of the certificate upon its expiry is not an automatic act; it is therefore the responsibility of the Manufacturer to make
formal request for renewal of the certificate. In order for MTIC to fulfil its tasks, the Manufacturer submits its application no more than twelve months and no less than six months before the expiry date of the EU Type Examination Certificate.
MTIC ensures the completion of the actions necessary for renewal if the application is submitted no later than six months before the expiry of the certificate; otherwise, the completion of the procedures before the deadline is not guaranteed.

In any case, if the renewal application has not been received, MTIC shall notify the Manufacturer of the next expiry of the certificate as the expiry date approaches.
The renewal application is submitted using the forms prepared by MTIC and downloadable from the website www.mtic-group.org, or can be sent on request. Among the data and information required are:

- confirmation that the PPE covered by the certificate is still in production
- confirms that no changes have been implemented on certified PPE
- transmission of a copy of the information note in force
- evidence of updating in the face of legislative and regulatory changes (if applicable)
- confirmation of the body entrusted with the control of production for category III PPE, if different from MTIC.

On the occasion of the renewal of the EU Type Examination Certificate, MTIC may request to deliver a sample of certified products for testing and/or visual inspection. The need to carry out tests and the size of the sample to be tested is determined by MTIC at its own discretion, possibly also taking into account the available results of the checks carried out by MTIC as part of the checks carried out according to module C2, as well as any changes to the standards used for the certification of PPE.

If MTIC has confirmed that no changes have been made to the approved type and that no development of the state of the art has taken place, partial examinations of the documentation shall be carried out. MTIC will comply with the sampling plan for annual controls in case (MODULE C2) and reserves the right to carry out tests which, although not considered critical, are deemed necessary to confirm the initial performance of the type certified in the previous Module B.

If, at the time of renewal, it appears that the reference standards on which the original conformity assessment was based have changed or been updated, MTIC will carry out an assessment of the amended requirements and arrange for new tests to be carried out where they are necessary to demonstrate compliance with the new requirements.

In the event of a positive outcome of the review of the above information, MTIC resolves to renew the certificate for a further 5 years. Where, on the other hand, critical situations emerge, MTIC will ask the Manufacturer for the necessary additions and updates to be adopted.

A test report is generally not required to support the renewal of the certificate, unless specific tests and verifications have been carried out following regulatory and/or regulatory updates.

5.10 Waiver of the certification procedure prior to the issuance of the EU Type Examination Certificate

CE certification is not a necessary act. In the event that the Manufacturer decides to withdraw from the existing certification procedure, for any reason and before it is completed, this formally entails the refusal to issue an EU Type Examination Certificate.
This situation in any case provides for the payment by the Manufacturer of all the activities carried out at that time, and may involve the charge of additional charges related to the management of the order and which must be quantified on a case-by-case basis.
Refusal to issue an EU Type Examination Certificate is subject to the reporting obligation set out in point 3.2 of these Technical Regulations.

5.11 CE marking and EU declaration of conformity

On each individual PPE conforming to the type described in the EU Type Examination Certificate and meeting the applicable EHSRs of Regulation (EU) 2016/425, the Manufacturer shall affix the CE marking and, for category III PPE:

- under the responsibility of MTIC, the identification number 0068 if the control procedure referred to in Form C2 or Form D is assigned to MTIC;
- under the responsibility of another Notified Body, the relevant identification number if the control procedure referred to in Module C2 or Module D is assigned to another Body.

Example of CE marking for PPE belonging to category II as defined in Regulation (EU) 2016/425. The CE marking can be reduced, while maintaining the proportions, up to a minimum height of 5 mm.

CE

Example of CE marking followed by the MTIC notification number for PPE belonging to category III as defined in Regulation (EU) 2016/425. The marking can be reduced, while maintaining the proportions, up to a minimum height of 5 mm.

CE 0068

The Manufacturer draws up a written EU declaration of conformity for each PPE model and keeps it available to the national authorities for ten years from the last date of placing the PPE on the market. The EU declaration of conformity identifies the PPE model for which it was drawn up.
A copy of the EU declaration of conformity is made available to the competent authorities upon request.

6 MODULE C2: Conformity to type based on internal production control combined with product tests under official control carried out at random intervals

Conformity to type based on internal production control combined with product tests under official control carried out at random intervals is the part of the conformity assessment procedure by which the Manufacturer complies with the obligations laid down and guarantees and declares under his sole responsibility that the PPE conforms to the Type described in the EU Type Examination Certificate and meets the EHSR of Regulation (EU) 2016/425 as well as the applicable requirements of these Technical Regulations.

6.1 Fabrication

The Manufacturer shall take all necessary measures to ensure that the manufacturing process and its control ensure the homogeneity of production and the conformity of the PPE manufactured to the Type described in the EU Type Examination Certificate and to the applicable requirements of these Technical Regulations.

6.2 Demand for product testing under official control at random intervals

Before placing category III PPE on the market, the Manufacturer submits an application for certification for the performance of tests of the product under official control carried out at random intervals to a Notified Body of his choice.
The Notified Body chosen may be the same as the one that issued the EU Type Examination Certificate.

The Manufacturer who intends to entrust the control to MTIC must submit an Application for Certification using the form made available, as well as on request, on the MTIC website at the following address: www.mtic-group.org.
The Application for Certification is submitted by the Manufacturer to a single Notified Body of his choice and contains at least:

- the name and address of the Manufacturer and, if the application is submitted by the Manufacturer's authorised representative, the name and address of the latter;
- a written declaration stating that the same application has not been submitted to any other Notified Body;
- the identification of the PPE in question.

If MTIC is not the Notified Body that conducted the EU Type Examination procedure, then the Application must also include:

- copy of the approved technical documentation;
- a copy of the EU Type Examination Certificate.

6.3 Issuance and renewal of the Form C2 Certificate

In the event that the EU Type Examination Certificate has been issued by MTIC, the issuance of the first Certificate of Form C2 is subject to the verification of the conformity of the first production of the PPE. Subsequently, the renewal of the validity of the Form C2 Certificate is subject to the positive outcome of the tests provided for by Regulation (EU) 2016/425 according to the procedures described in the following paragraphs.
To verify the conformity of PPE, an adequate number of PPE samples taken from MTIC are examined and appropriate tests defined in harmonised standards or necessary to certify compliance with the essential requirements of the PPE Directive are carried out.

In the event that the EU Type Examination Certificate has been issued by another body, MTIC issues the C2 Module Certificate and subsequent renewals of the same, following the positive outcome of the tests provided for by Regulation (EU) 2016/425, which will be carried out in accordance with the procedures described in the following paragraphs. MTIC reserves the right to ask the Body that issued the EU Type Examination Certificate as to the validity of the certificate issued before issuing or renewing the Form C2 Certificate.
In case of difficulties related to the conformity assessment of the samples, in the event that the EU Type Examination certificate has been issued by another MTIC body, it will contact the latter in order to clarify what has been found

6.4 Sampling

The sampling procedure aims to establish whether the manufacturing process ensures the homogeneity of production, within acceptable limits, and the conformity of the PPE to the type described in the EU Type Examination Certificate and the applicable EHSRs.
Sampling of the product is carried out at least once a year, at random intervals established by MTIC. The first sampling of the product is carried out immediately after the issuance of the EU Type Certificate (Module B) and before the placing on the market of the PPE and no later than one year after the date of issue of the EU Type Examination Certificate by MTIC .

As a matter of practice, in the event that the control procedure attributed to MTIC refers to a product certified by another Notified Body, sampling is carried out immediately. In any case, in these cases, the performance of sampling is assessed on a case-by-case basis, also depending on whether the control procedure has just been activated or whether a control procedure is already in place for other products of the same manufacturer.

MTIC will communicate to the Organization the names of the members of the verification team who will carry out the sampling. The Organization has the right to request the replacement of the inspector, within 5 days, by giving reasoned written notice to MTIC, which reserves the right to evaluate the reasons for the recusal and the possibility of replacing the persons in charge.

MTIC carries out an appropriate statistical sampling of the product at the Manufacturer's premises or at a location agreed with the Manufacturer, including:

- the production site;
- the warehouse of finished products managed by the Manufacturer;
- the headquarters / warehouse of a PPE distributor.

The discriminating factor for the choice of the sampling site is represented by the presence, at the chosen site, of the entire production of the model covered by the EU Type Examination Certificate.
In special cases, where the above criterion cannot be met, sampling may be carried out at several locations where necessary, the costs of which will be borne by the Manufacturer.
The number of planned controls and the expected period may change from year to year both on the basis of random choices and on the basis of information such as the size of the production of the PPE subject to the control and their degree of homogeneity with respect to the certified type.

In the event that production remains inactive for a certain period, with the consequent impossibility of implementing module C2 . the EU-type certificate remains valid and the C2 process is activated when production starts or resumes. It is the responsibility of the manufacturer to inform the notified body.
The C2 process must be completed satisfactorily before the product can be placed on the market.

6.4.1 Remote sampling

Remote sampling via video call is not prohibited by the Regulation and, in accordance with Rfu PPE-R/00.081 Version 01 of 2025/11/13, MTIC InterCert Srl has decided, in compliance with Article 32 par. 2 of Regulation (EU) 2016/425, namely “Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens on economic operators.” (in this case, this refers to travel and accommodation expenses for going to and coming back from a place), to provide this possibility after a risk assessment. Remote sampling may not be appropriate where identifiable and unacceptable risks exist. The decision is up to the Notified body.

Minimum requirements:

- Cameras with autofocus;
- stable images (tripod);
- use of headphones or directional microphones for the on-site operator, to enable the inspector to direct operations despite ambient noise;
- software platform and security;
- the inspection must be carried out in accordance with the same privacy conditions as set out in form RG-GQ-01-99.

If any of the following conditions arise during the inspection, the ON has the option to switch to an on-site audit:

- suspicious video interruptions: repeated line drops occurring specifically whilst samples are being selected;
- refusal to show areas: the operator avoids showing specific sections of the line requested by the inspector;

- documentary inconsistencies: the data displayed on screen does not match the records previously sent by email;
- suspected tampering: markings that appear to have been applied 'ad hoc' or measuring instruments with expired or tampered calibration seals.
- The inspector is obliged to terminate the remote inspection at any time if they consider that the transparency or integrity of the process is compromised by technical or behavioural factors on the part of the manufacturer.

6.4.2 Batch production

In the case of batch production, the Manufacturer shall keep a sample (of a size to be defined according to the number of production and the type of product) per production batch of the certified type and any of its variants, as described in the EU Type Examination Certificate. The samples must be taken randomly and made available to the Body during surveillance checks (e.g. in the case of filtering half masks at least 10 pieces per batch, in the case of bulky/expensive PPE at least 1 per batch). The samples not taken may be placed on the market by the manufacturer upon receipt.

6.4.3 Continuous production

In the case of continuous production, the Manufacturer must keep a sample (size to be defined according to the number of production and the type of product) per week of production of the certified type and any of its variants, as reported in the EU Type Examination Certificate. The samples must be taken randomly and made available to the Body during surveillance checks.

6.4.4 Production per order (on sales)

In the case of production against orders (production on sales), the Manufacturer must keep a sample (of a size to be defined according to the number of production and the type of product) for production order of the certified type and any of its variants, as reported in the EU Type Examination Certificate. The samples must be taken randomly and made available to the Body during surveillance checks.

6.4.5 Reduced sampling

For discontinuous productions or for complex or expensive products, MTIC defines with the Manufacturer the minimum number of samples necessary to ensure the conduct of all the required tests, over the time frame defined for the conformity assessment procedure.

During the surveillance audit, the inspector collects all the samples referable to the same types of product made available by the manufacturer. From the total set of samples thus obtained, the inspector shall randomly take the number of samples sufficient to carry out all the necessary tests.
In the event that the samples necessary for the verification of the homogeneity of the production are not available, MTIC will apply one of the following criteria:

- verification of production records and tests carried out;
- verification of production control;

The Manufacturer undertakes to allow access to its premises on the occasion of the activities carried out by MTIC of observers designated by the Control / Accreditation Bodies in the performance of their control and monitoring tasks of the activities carried out by MTIC as a Certification and Inspection Body. The presence of these observers will always be accompanied by MTIC personnel.
Also, in relation to the timing of communication to MTIC by the Control/Accreditation Bodies, the notification of the presence of these observers could take place with minimum notice (**less than 3 days**) without this being a reason for non-acceptance by the Manufacturer of their presence. Failure by the Manufacturer to

accept the presence of such observers will result in the suspension of the Certificate in force and its possible subsequent revocation in the event of continuation of the denial in question.

The planned sampling may be postponed for up to three months upon written request by the Manufacturer and acceptance by the Technical Manager. Such a request, the acceptance of which remains in the opinion of MTIC, must be based on valid reasons.

6.5 Product Trials

All PPE specimens in the sample shall be examined and the appropriate tests referred to in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU Type Examination Certificate and the applicable EHSRs.
The tests are carried out on the basis of the standards used for type certification; it is generally not planned to repeat all the aforementioned tests, but a part of them, also taking into account the requirements considered most critical.
If MTIC is not the Body that issued the relevant EU Type Examination Certificate, it shall contact the latter in case of difficulties related to the conformity assessment of the sample.
If the examination and 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 applicable EHS, MTIC communicates the data in question to the Manufacturer, while requesting an assessment of the causes that led to the negative result.
The Organization, after analyzing the causes of any reported non-conformities, must propose to MTIC within 15 days the identification of the cause and the necessary corrections and corrective actions and the expected times for their implementation. MTIC has the right not to accept the proposals received and to request a different formulation. In addition, in such a case MTIC may:

- Ask the Manufacturer to modify the production process;
- Ask the Manufacturer for additional samples of the PPE subjected to verification, to improve the statistical evaluation of the homogeneity of production;
- Temporarily suspend or restrict the Certificate of Conformity to Type (Form C2);
- Revoke or restrict the Certificate of Conformity to Type (Form C2);

MTIC shall take appropriate measures according to the defects found and, in the latter two cases, inform the competent authority in accordance with the reporting obligation referred to in point 3.2 of these Technical Regulations.

6.6 Test report

Upon successful conclusion of all conformity assessment activities, the Resolution Committee may resolve to issue a Certificate of Conformity to the Type. Starting from the date of issue of the Certificate and as long as it maintains its validity even after subsequent renewals, the Manufacturer may affix the CE marking in association with the MTIC identification number (0068) in accordance with the procedures established by Regulation (EU) 2016/425.

MTIC provides for the issuance of a Certificate according to module C2, although it is not expressly required by Regulation (EU) 2016/425, in order to identify in the best possible way, also towards third parties and towards the market, the list of PPE on which the Manufacturer can affix the MTIC identification number in association with the CE marking (0068).

Unused samples remain available to MTIC until the Certificate is issued. After the issuance of the Certificate, they can be re-entered into the sales cycle and placed on the market.

6.7 Validity of the Form C2 Certificate and expiration date.

The validity of the Form C2 Certificate until the expiry date of the same is subject to the maintenance of the conditions that allowed it to be issued following the positive outcome of the tests provided for by Regulation (EU) 2016/425.
The expiry date of a newly issued Form C2 Certificate is set at 31-12 of the year following the date of issue of the same, it being understood that the first tests required by Regulation (EU) 2016/425 must be carried out before the PPE is placed on the market.

The deadlines following the first are set at 31-12 of the year following the previous expiry date (see point 3.4 of these Technical Regulations) and the dates for the execution of the tests provided for by the Regulation (EU) 2016/425 are arbitrarily defined by the Body. The The validity of the Certificate is in any case subject to the maintenance of the conditions that allowed it to be issued.

The Manufacturer shall keep the Documentation available to the competent Authority for ten years from the last date of placing the PPE on the market.

6.8 Certificate extension

The Manufacturer may request MTIC to extend a certificate issued according to form C2, by inserting new forms, by submitting the application as also provided for the first certification.
Updating the certificate follows the same procedure as the first certification, but the expiration date of the certificate is not changed.

6.9 Cessation of production

In the event that the Manufacturer has temporarily ceased production of the PPE subject to certification, it must provide appropriate communication to MTIC, which will not carry out the surveillance visit. The manufacturer must immediately notify MTIC if it resumes production of the devices that cannot be placed on the market until MTIC has carried out the surveillance visit.

7 MODULE D: Type conformity based on quality assurance of the production process

Conformity to type based on quality assurance of the production process is the part of the conformity assessment procedure by which the Manufacturer complies with the obligations laid down and guarantees and declares under his sole responsibility that the PPE concerned conforms to the type described in the EU Type Examination Certificate and meets the RESS of Regulation (EU) 2016/425 as well as the applicable requirements of this Technical Regulation.

7.1 Fabrication

The Manufacturer adopts an approved quality system for the production, product inspection and testing of PPE, and is subject to surveillance.

7.2 Application for certification for surveillance of the production process

Before placing category III PPE on the market, the Manufacturer submits an application for certification for the surveillance of the production process to a single Notified Body of his choice.
The Notified Body chosen may be the same as the one that issued the EU Type Examination Certificate.
The Manufacturer who intends to entrust the control to MTIC must submit an Application for Certification using the form made available, as well as on request, on the MTIC website at the following address: www.mtic-group.org.

The Application for Certification contains at least:

- the name and address of the Manufacturer and, if the application is submitted by the Manufacturer's authorised representative, the name and address of the latter;
- a written declaration stating that the same application has not been submitted to any other Notified Body;
- the identification of the PPE in question;
- the documentation of the Quality Management System described in the following paragraph.

If MTIC is not the Notified Body that conducted the EU Type Examination procedure, then the Application must also include:

- copy of the approved technical documentation;
- a copy of the EU Type Examination Certificate.

7.3 Quality system

The quality system ensures that the PPE conforms to the Type described in the EU Type Examination Certificate and meets the applicable requirements of these Technical Regulations.
All criteria, requirements and provisions adopted by the Manufacturer are documented in a systematic and orderly manner in the form of measures, procedures and written instructions. The documentation relating to the quality system shall allow uniform interpretation of the programmes, schemes, manuals and documents relating to quality.
The Manufacturer may adopt a quality system that complies with the edition of the ISO 9001 standard in force, as it is a harmonized standard. In this case, the management model confers the presumption of compliance with the requirements of Regulation (EU) 2016/425.
The Manufacturer can also implement a quality system following a model different from ISO 9001 in which, however, cannot confer the presumption of conformity with the requirements of Regulation (EU) 2016/425. This system will therefore have to be subject to a preliminary assessment by MTIC, which has the right not to approve it.
As a minimum element, in any case, the quality system must follow/refer to a defined model in standards/technical specifications/guidelines issued by authoritative organizations.
The documentation relating to the quality system must allow a uniform interpretation of the programmes, schemes, manuals and documents concerning quality and must comply with the elements identified in Annex VIII to Regulation (EU) 2016/425.
The main and characteristic elements of the quality system must be delivered to MTIC, together with the list of documents in force.

The documentation relating to the quality system must include in particular an appropriate description:

- the quality objectives and organisational structure, responsibilities and powers of management staff in relation to product quality;
- the corresponding manufacturing processes, quality control and assurance techniques, processes and systematic interventions that will be applied;
- the examinations and tests that will be carried out before, during and after manufacture, with an indication of the frequency with which they are intended to be carried out;
- quality documentation, such as inspection reports and test and calibration data and reports on the qualifications of the personnel concerned; and
- the means of surveillance that make it possible to check that the required quality for the product is obtained and that the quality system is functioning effectively.

In addition to having experience in quality management systems, the audit team shall include at least one member with assessment experience in the field of IPR and the relevant technology field, who is also familiar with the applicable EHS. The audit includes an assessment visit to the Manufacturer's facilities. The audit team examines the technical documentation of the PPE in order to verify the Manufacturer's ability to identify the applicable SSRs and to carry out the necessary examinations to ensure the compliance of the PPE with these requirements.
The result of this assessment is communicated to the Manufacturer. The Communication contains the conclusions of the audit and the detailed justification for the evaluation decision.
The Manufacturer undertakes to fulfil the obligations deriving from the approved quality system and to ensure that this system remains adequate and effective.

The Manufacturer undertakes to allow access to its premises on the occasion of the activities carried out by MTIC of observers designated by the Control / Accreditation Bodies in the performance of their control and monitoring tasks of the activities carried out by MTIC as a Certification and Inspection Body. The presence of these observers will always be accompanied by MTIC personnel.
Also, in relation to the timing of communication to MTIC by the Control/Accreditation Bodies, the notification of the presence of these observers could take place with minimum notice (less than 3 days) without this being a reason for non-acceptance by the Manufacturer of their presence. Failure by the Manufacturer to accept the presence of such observers will result in the suspension of the Certificate in force and its possible subsequent revocation in the event of continuation of the denial in question.

7.4 Performing the Assessment

The system assessment takes place in accordance with the provisions of the ISO/IEC 17021-1 standard with a Phase 1 audit in which an initial documentary examination and a Phase 2 audit are carried out in the field.

Where there are multiple production sites, in first certification, during the Phase 2 audit, all sites will be audited. Subsequently, it will be possible to carry out any sampling between the various secondary sites.
The possible presence of outsourcers assigned to critical processes may entail, at MTIC's sole discretion, the need to extend audits to the sites of these suppliers as well.

MTIC will communicate to the Organization the names of the members of the verification team who will carry out the Phase 1 and Phase 2 activities. The Organization has the right to request the replacement of the inspector, within 5 days, by giving reasoned written notice to MTIC, which reserves the right to evaluate the reasons for the recusal and the possibility of replacing the persons in charge.

The Phase 2 visit consists of:

- an initial meeting with the Organization to agree on the modalities of the visit itself;
- review of documentation of relevant quality for the purposes of Regulation (EU) 2016/425;
- an inspection of the offices, the production site(s), and, where necessary, the raw material storage sites, as well as the laboratory(s) to verify the compliance of the factory production control system with the applicable reference standards;
- a final meeting to illustrate the outcome of the visit.

The evaluation team verifies the adequacy of the Organization's Quality System in order to comply with all applicable EHSRs and, in the event of deficiencies or discrepancies from what is stated on the system documentation, may notify the Organization of one or more non-conformities.
During the visit, the Organization must demonstrate, in addition to possessing the reference standards applicable to it, that the system is fully operational and effectively implemented.

At the end of each audit, an audit report is issued, with the conclusions of the same. The Organization may note any reservations or observations regarding the findings expressed by MTIC technicians in a special space in the audit report.

The Organization, after analyzing the causes of any non-conformities reported in the aforementioned report, must propose to MTIC by the date indicated in the report itself (15 days) the identification of the cause and the necessary corrections and corrective actions and the time frame envisaged for their implementation.
The acceptance of these proposals and the timeframe envisaged for implementation shall be communicated in writing by MTIC to the Organisation. MTIC has the right not to accept the proposals received and to request a different formulation.

In the case of NC grade 1, the Certificate cannot be issued until the NC has been completely resolved.
at least to a partial resolution such as to be able to reclassify the CN to a lower grade.
The presence of NCs of lower grade does not constitute an obstacle to the issuance of the certification, provided that the
motion for a resolution has been found acceptable.

In such cases, within six months, MTIC may carry out an additional verification aimed at ascertaining the correct application of the proposed corrective actions; upon successful completion of this verification, the certification process resumes.
If the aforementioned six-month period has elapsed without a positive conclusion of the assessment, MTIC may consider the certification file closed, charging the time and expenses incurred up to that moment. In such cases, the Organization wishing to continue with the certification must submit a new request and repeat the certification process.
The aforementioned time limits may in special cases be varied upon reasoned request by the Organization, in the opinion of MTIC.

The recommendations are not binding; however, the Manufacturer must take them into consideration and, if he deems it inappropriate to carry out any action, this situation must be justified in a documented form.
The duration of the assessment audit is estimated on the basis of international tables established by the International Accreditation Forum (IAF). The durations of subsequent surveillance and renewal audits are also calculated on the basis of these tables.

7.5 Surveillance under the responsibility of the Notified Body

The purpose of the surveillance is to ensure that the Manufacturer fulfils all the obligations deriving from the approved quality system.
For the purposes of the assessment, the Manufacturer allows MTIC to access the manufacturing, inspection, testing and storage sites by providing all the necessary information, in particular:

- the documentation relating to the quality system;
- quality documentation, such as inspection reports and test and calibration data, and reports on the qualifications of the personnel concerned.

MTIC carries out audits periodically, at least once a year, to ensure that the Manufacturer maintains and applies the quality system and provides the Manufacturer with a report on the audits carried out.
MTIC may, at its discretion, make unannounced visits to the Manufacturer. On the occasion of these visits, MTIC may carry out or have carried out, if necessary, examinations or tests on the PPE to verify the proper functioning of the quality system.

Erroneous or unduly affixed markings (formal non-conformities) as required by Regulation (EU) 2016/425 are also subject to assessment.

The surveillance verification may be postponed for up to three months upon written request by the Manufacturer and acceptance by the Technical Manager. Such a request, the acceptance of which remains in the opinion of MTIC, must be based on valid reasons.

As for the first assessment, MTIC will communicate to the Organization the names of the members of the verification team who will carry out the planned field visits. The Organization has the right to request the replacement of the inspector, within 5 days, by giving reasoned written notice to MTIC, which reserves the right to evaluate the reasons for the recusal and the possibility of replacing the persons in charge.

MTIC sends the Manufacturer a report on the visit in which any non-conformities and recommendations found are reported.

If major non-conformities are found during surveillance audits, the report is submitted to the resolution committee, which must decide on the possible suspension of the certification and possibly proceed with the revocation as provided for in point 3.7 of these Technical Regulations.

The third surveillance has the function of renewing the certification. The management of NCs is similar to that of the first certification. Its planning is usually scheduled 3 months before the expiration of the certificate. Where the renewal verification is scheduled, at the request of the Manufacturer, after three months before expiry, MTIC cannot guarantee the completion of the renewal process before the expiry of the certificate. If the renewal procedure extends beyond the expiry date, the Manufacturer may not use the certification or use the MTIC number (0068) in association with the products to be placed on the market, until the Certificate is reissued.
If it is not possible to carry out the renewal audit before the expiry of the Certificate, it shall cease to have value at its expiry and for its reinstatement MTIC will have to carry out an audit of the duration of a new certification, albeit in a single phase. However, after 12 months from the expiration of the certificate, any restoration of the certification will not be possible and you will have to start again as if it were a new certification.

In the case of renewals completed after the expiration of the certificate, the certificate will show only the current issue date and the expiration date; the latter will be calculated from the previous maturity with an addition of 3 years.

7.6 Unscheduled audits

In addition to the scheduled certification surveillance audits, MTIC may carry out additional audits, as follows:

- Extension audits: these can be carried out if the Manufacturer requests an extension of the certification to additional products;
- Extraordinary surveillance audits, due to the need to verify the closure of the CNs of higher grade or by decision of the deliberation committee, where the Manufacturer's quality system shows elements of weakness considered critical. These audits can also be carried out following complaints received on the products subject to certification.
- Unscheduled audit in the event that the time provided for the verification of production is not sufficient for the evaluation of all the PPE families subject to certification
- Unannounced audits. MTIC has the right to carry out audits without prior notice. For such audits, the Manufacturer may not exercise the right of recusal of the audit team.

Such audits are generally limited in scope compared to a normal scheduled audit and are not considered a substitute for it. As a rule, during these audits, some products are sampled in the warehouse, with a request for a repetition of the acceptance tests performed, as well as the verification on a documentary basis of the records relating to production and control. MTIC may also sample some products to perform further tests in its own laboratories or at external laboratories.
All unscheduled audits are at the customer's cost, according to the MTIC price list, available on request.

7.7 Changes to the quality system and extension of the certificate

The Manufacturer shall keep MTIC informed of any changes it intends to make to its quality system before adopting it. The Manufacturer is also required to communicate to MTIC the intention to put into production products of new conception or with modifications, with respect to the certified ones, which may require the adaptation of the certification of the quality assurance of the products or production and is required to prepare new or modified production plans.
MTIC evaluates the proposed changes and decides whether the modified quality system will continue to meet the requirements on the basis of a pure documentary assessment or whether audits are required at the Manufacturer's premises.
The Manufacturer may request the inclusion of additional products in the module D certificate, by submitting a specific application, as for the first certification. MTIC assesses whether the approved production system needs a new evaluation or not and notifies the Manufacturer.
If the outcome of the audits certifies that the changes to the quality system and the production plans also comply with the requirements of the reference standard, MTIC grants an extension of the certification.

7.8 Certification Release

Upon successful conclusion of all conformity assessment activities, the Resolution Committee may resolve to issue a Certificate of Conformity to the Type, with a duration of three years. Starting from the date of issue of the Certificate, the Manufacturer may affix the CE marking in association with the MTIC identification number (0068) in accordance with the procedures established by Regulation (EU) 2016/425.

In the event of a negative outcome, MTIC shall inform the Manufacturer of the reasons that led to the refusal of the certification and inform the competent authority in accordance with the reporting obligation referred to in point 3.2 of these Technical Regulations.

If necessary, an appeal procedure is provided against MTIC's decision, as set out in the General Terms and Conditions (RG-GQ-01-01) published on the website www.mtic-group.org.