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0.1	10.06.2022	Scheme manager ATEX	Scheme manager ATEX	Quality Manager	Update following Accredia findings
0.2	18.07.2022	Scheme manager ATEX	Scheme manager ATEX	Quality Manager	Updated tranfer and fingindg management
0.3	13.04.2023	Scheme manager ATEX	Scheme manager ATEX	Quality Manager	Updated tranfer and fingindg management
0.4	21.02.2025	Scheme manager ATEX	Scheme manager ATEX	Quality Manager	Updated par. 3.3 and par. 3.12
0.5	17.11.2025	Scheme manager ATEX	Scheme manager ATEX	Quality Manager	Updated par. 3.3 par. 3.11 and par. 4.6

1 Premises

Refer to the General Contractual Conditions published on the website www.mticert.org in the "About Us" section as regards:

- Purpose and scope
- Terms and definitions
- General conditions
- Certification contract
- Duration of the contract - withdrawal
- Impartiality and conflict of interest
- Object of the verification and reference standard
- Faculty of using external resources
- Rights and obligations of MTIC
- Rights and obligations of the organization
- Access to information
- Obligation to inform about legal proceedings
- Inspection verification and safety in the workplace
- Economic conditions
- Additional checks
- Suspension of the system, product and personnel certificate
- Revocation of the system, product and personnel certificate
- Limits of certification and liability
- Limitations of liability and charges
- Termination clause
- Indemnification and release
- Cause of force majeure
- Renunciation, suspension, revocation of accreditation (where applicable)
- confidentiality and privacy
- Privacy disclaimer
  Claims, appeals and arbitration
- Exclusive jurisdiction
- Confidentiality and protection of intellectual and industrial property
- Change management
- Transfer of the certificate
- Certificate list
- Administrative liability of legal persons

All the documentation required for certification must be submitted to MTIC in Italian or English

2 Scope

This regulation defines the rules and procedures for providing the certification service implemented by MTIC INTERCERT S.r.l. (hereinafter MTIC) in accordance with the provisions of Directive 2014/34/UE (hereinafter ATEX Directive or simply ATEX) in the following areas:

- Annex III, IV, V, VI, VII, IX (Conformity assessment procedures)
- Article 13 point1 (b) (ii) (Procedure for depositing the technical dossier)

The Regulations specify the rights and duties of the Organization and of MTIC in the context of the certification process pursuant to the ATEX Directive, without prejudice to the provisions of the General Contractual Conditions referred to in chapter 1.
For all the activities specified in these Regulations, MTIC applies the provisions of the binding legislation issued by the competent authorities.
This regulation applies to conformity assessment procedures under Directive 2014/34/UE.
Any changes to the regulation itself will be communicated by e-mail when it is published on the website.
These modifications are understood to be accepted unless explicit communications are received from the customer.

2.1 Reference documents

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

- Directive 2014/34/UE of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast).

The Standards referred to and/or harmonized under the ATEX Directive 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 functioning of the various types of bodies that carry out inspection activities
- UNI CEI EN ISO/IEC 17021-1 Conformity assessment - Requirements for bodies providing audit 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 auditing management systems
- UNI CEI EN ISO/IEC 80079-34 Explosive atmospheres - Part 34: Application of quality management systems for the manufacture of appliances.
- RG01 Regulation for the accreditation of Certification and Inspection Bodies - General Part
- RG01-01 Regulation for the accreditation of management system Certification Bodies
- RG01-03 Regulation for the accreditation of Product Certification Bodies
- Other applicable EA/IAF documents

2.2 Terms and definitions

For the purposes of this Regulation, all the definitions set out in Article 2 of Directive 2014/34/EU apply in addition to the following.
Company: Organization that requires (or has obtained) the certification. Where by Organization we mean a company, firm, firm, body or association, legally recognized or not, public or private, which has its own functions and its own administration or a natural person.
Production Site: site where the Manufacturer produces its products subject to certification.
EU declaration of conformity: document according to which the Manufacturer declares that the product complies with Directive 2014/34/UE
TM: Technical director of the body

Steering committee: Certification deliberation committee
Module: conformity assessment procedure established in the ATEX Directive
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 verify the manufactured products and certify that they conform to the certified type in compliance with the reference standard used.
Supplementary checks: checks not foreseen during the period of validity of the certification and necessary to verify the continued conformity of the manufactured products, for example, in the case of changes made to the Type, by extension of the certification, following the changed conditions set by the state of art, etc.
Unannounced visits: procedure by which MTIC ascertains that the production/product complies with the certification issued and with the requirements of the Regulations and the proper functioning of the management system.
OJEC: Official Journal of the European Community.
Certification: Third Party declaration that the requirements applicable to a product / process have been complied with on a specific date.

2.3 Subcontractor and affiliates

If MTIC intends to entrust all or part of 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 products they intend to place on the market must send a specific request by fax, mail or e-mail which contains the information necessary, according to the applicable requirements of the Directive, for the formulation of the service proposal.
The Manufacturer is solely responsible for the conformity of the product and assigns the conditions of use, on which membership of the Group and Category referred to in Annex I depends and, consequently, the applicable assessment procedures.
MTIC welcomes applications without discrimination, prejudice or favorable conditions, deriving from belonging to particular associations and/or categories.
MTIC carries out a preliminary examination to verify whether the information provided is sufficient to formulate a service proposal, reserving the possibility of requesting further details, if necessary also with reference to what is reported in these Regulations.
On the basis of these indications, a proposal for services is formulated by MTIC which will be sent with reference to this Regulation and to the Application for Certification, which constitutes a contractual document to all intents and purposes
Upon receipt of the Certification Application duly filled in for acceptance of the service proposal issued, MTIC will have 10 working days to comment on said requests or reject them; once this deadline has elapsed, the request must be considered automatically accepted and therefore the MTIC interventions carried out according to these Regulations must be considered contractually formalized.
The Organization declares that it has not submitted a similar application for certification to another Notified Body.
MTIC requires, for examination, the documents better specified in these Regulations, applicable on the basis of the module or combination of modules chosen.
MTIC will communicate to the Organization the names of the members of the verification team who will carry out the assessments. The Organization has the right to request the replacement of the inspector, within 5 days, by giving reasoned written communication to MTIC, which reserves the right to evaluate the reasons for the recusal and the possibility of replacing the persons in charge.

The Organization undertakes to allow access to observers designated by the Accreditation Body or by the competent Ministry for notification, in carrying out their tasks of control and monitoring of the activities carried out by MTIC as a Certification Body/Notified Body.
The presence of these observers will always take place accompanied by MTIC personnel. Also in relation to the timing of the communication to MTIC by the accreditation body, 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 Customer of the their presence.
The MTIC technicians, and possibly ACCREDIA personnel, must be guaranteed free access to the production sites, personnel and documentation and the necessary assistance from the responsible personnel in charge of the verification.
At the end of each evaluation, a report is delivered to the Organization.

In the event of a negative outcome of the assessments conducted during the EU type examination, MTIC allows up to 3 reassessments to be completed within 6 months of the certification application.
In case of production surveillance, any non-conformities and recommendations found are reported.
The Organization can write down any reservations or observations, regarding the findings expressed by the MTIC technicians, in a special space in the audit report.
The Organization, after having analyzed the causes of any non-conformities reported on the above report, must propose to MTIC, by the date indicated on the report itself, the necessary corrective actions and the times foreseen for their implementation.
The acceptance of these proposals and the times foreseen for their implementation is communicated in writing by MTIC to the Organization.
In the event of non-compliance, the certification process is suspended.
In such cases, within six months, MTIC can carry out a supplementary check aimed at ascertaining the correct application of the proposed corrective actions; with a successful outcome of this verification, the certification process resumes.
Once the aforementioned six-month period has elapsed without a positive conclusion of the evaluation, MTIC can consider the certification procedure closed, charging the times 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 particular cases be varied upon a reasoned request by the Organization, in the judgment of MTIC.

In the case of Conformity Assessment of Quality Systems (Annexes IV and VII), MTIC carries out an assessment visit at the Manufacturer's premises, previously communicating the names of the assessment team.
Markings erroneously or unduly affixed (formal non-conformities) as provided for by art. 38 of directive 2014/34/UE.
The assessment of the management system is in accordance with the provisions of the ISO/IEC 17021 standard with a Phase 1 audit in which an initial documentary review is carried out and a Phase 2 audit in the field, the reference standard is UNI CEI EN 80079-34 to the last published edition.

Upon successful completion of all the exams and tests envisaged by the certification procedures and by these 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 complete file of all the documentation to one or more competent and independent technicians (deliberation committee) for the complete review of the same and the assumption of the decision regarding the granting of the certification. Following the positive outcome of the decision of the deliberation committee, MTIC will issue the certificate required by the chosen evaluation form.
In the event of a negative outcome, an appeal procedure is envisaged and a new certification application can be presented by the Organization, which will be accepted without prejudice and with impartiality.

If non-conformities are found during the surveillance audits (where envisaged) the report is submitted to the deliberation committee, which will have to decide for the suspension of the certification and if necessary to proceed with the revocation according to the provisions of this regulations.

3.2 Obligation to report

MTIC has the obligation to inform the Notification Authority:

- of any refusal, limitation, suspension or withdrawal of a certificate;
- any requests for information they have received from market surveillance authorities in relation to conformity assessment activities;
- upon request, of the conformity assessment activities carried out as part of their notification and of any other activity, including cross-border and subcontracting activities.

Furthermore, it has the obligation to provide access to the list of certified organizations.
MTIC has the obligation to provide the other notified bodies with relevant information on issues related to negative and, upon request, positive results of conformity assessments.

3.3 Validity, renewal and surveillance

The duration and validity of the Certificate of Conformity vary according to the applied module.

- The approval of the management system (Annexes IV and VII) lasts three years, and is subject to the positive outcome of the surveillance;
- The UE type examination certificate (Annex III) lasts ten years (after 5 of which a confirmation of the initial certification conditions is requested);
- The certificates issued following the inspections referred to in Annex VI, last for one year, and are in any case subject to the positive outcome of the periodic surveillance;
- The certificates issued against the assets referred to in attachments V and IX do not expire;
- The deposit receipt of the technical file, pursuant to art. 13 of directive 2014/34/UE paragraph 1 (b) (ii), lasts ten years (after 5 of which confirmation of the initial deposit conditions is requested).

Pursuant to art. 41 of directive 2014/34/UE, the certifications issued by 19/04/2016 pursuant to directive 94/9/CE remain valid until their natural expiry or until situations arise which require their suspension and withdrawal.
The renewal assessment must be done within 60 days of the expiry date of the certificate.
Renewal is subject to successful surveillance and positive decision by the Steering Committee.
In the event that the renewal audit is exceptionally carried out too close to the expiry date of the certificate or in the event that the evaluation of the corrective actions is still in progress by the body or in the event that it is necessary following the results of the renewal assessment to carry out an additional audit, the validity of the certificate may be extended by the body for up to six months from the expiry date of the certificate. The six-month extension does not change the expiry cycle compared to the original one
However, MTIC keeps up to date with technological progress and regulatory updates, especially with regards to project approvals. If there are substantial changes such as to affect compliance with the RES of the MTIC directive, it informs the manufacturer so that he can make the necessary adjustments.

3.4 Maintaining Certification

The Organization must maintain the conformity of the products to the applicable reference standards, it is required to periodically check 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 communicate to MTIC any significant change such as to influence the requirements that led to the certification.
The Organization must keep records of any complaints received from its customers concerning the products covered by the certificate and the related corrective actions undertaken and must make them available to MTIC.
MTIC reserves the right to carry out additional checks at the Organization in the event it receives complaints or reports, deemed particularly significant, relating to the non-compliance of the products with the requirements of the reference standards and with these Regulations, or for the purpose of verifying the conformity of the product to following the changes communicated by the same manufacturer.
In case of refusal, without valid reasons, by the Organization, MTIC can start the certification suspension process.
In the event that complaints and reports are deemed justified by MTIC, the cost of carrying out the supplementary 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 undertaken or any additional checks.

3.5 Modification and extension of certificates

In the event of changes to the certification requirements, made necessary as a result of changes or updates to the legislative panorama, by this regulation and by the general contractual conditions, these changes will be promptly communicated in writing by MTIC to the manufacturers concerned, with an indication of the date in which they will come into effect. For all regulatory changes or updates, it is the manufacturer's responsibility to ensure that its products are adapted to any new requests.
The 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 subject to verification for an additional assessment by that date.
If the outcome of the checks certifies that the products have been adapted to the new applicable requirements and therefore comply with the requirements of the reference legislation, MTIC will maintain the pre-existing certificate of conformity. Otherwise it will revoke the same.
The applicant is also required to communicate to MTIC the will to produce new-concept products or products with modifications, compared to the certified ones, which could require the adaptation of the certification of the quality assurance of the products or of the production and is required to prepare new or modified production plans. MTIC will conduct extraordinary checks for the conformity assessment of the new variants to the Type or of the modified Type
If the outcome of the checks certifies that the variants or the modified type comply with the requirements of the reference standard, MTIC grants an extension of the pre-existing type certificate.

When the attestation of conformity of production is based on the surveillance procedures envisaged by Annexes IV and VII, the applicant has the obligation to notify MTIC of any changes envisaged to the previously approved quality system, before adopting them.
In any case, the documentation with the modifications and production plans, new or modified, must be submitted to MTIC which verifies them, decides on the need for a new visit and communicates it to the manufacturer.
If the outcome of the checks 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 to the certificate of conformity of the pre-existing production.

In addition to the above, the following is expected in the event of changes to the product.

The customer must promptly inform MTIC of any substantial modification he intends to make to the product; these changes can make it no longer compliant with the certification already issued.
In relation to the type of proposed changes, 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, a revision of the certificate or the start of a new certification process may follow from MTIC.
In the conditions described above, the customer cannot proceed with the commissioning or placing on the market of the product until MTIC has communicated its consent. In case of refusal or non-compliance by the customer with the aforementioned conditions, MTIC may proceed with the suspension of the certificate or withdrawal from the contract with thirty days notice.

The extension request related to:

- Certificates of a different kind than the original one;
- New applicants than the one indicated in the original certificate;
- Conformity of a single product or of a different project;
- Certificate of conformity assessment of production for a different procedure than the original one.

are treated as new certification applications.

3.6 Renunciation, Suspension and Withdrawal of certification

In the event of suspension, withdrawal, waiver of the certificate, the manufacturer must notify MTIC of the presence of products already manufactured and marked ready to be placed on the market whose marketing authorization will be subject to specific assessment by MTIC.
The manufacturer must also interrupt the CE marking of the products being manufactured starting from the date of the suspension/withdrawal.

3.6.1 Renunciation

The certified Organization can send a formal communication of renunciation of the certification to MTIC, before the expiry of the Certificate, including the case in which the Organization itself does not want or cannot adapt to the changes of the certification conditions communicated by MTIC.
MTIC, upon receipt of this communication, starts the process to make the status of the certificate invalid.
In case surveillance activities are foreseen, a written request must be sent within three months from the surveillance date in case an evaluation of the Quality System is involved or within two months in other cases. Beyond this deadline, it is still possible to renounce the certification, however, the Organization is required to pay 40% of what was accepted in the offer for the surveillance not carried out.
The manufacturer is required to provide MTIC with the list of products and related factory numbers, manufactured 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 evaluation module applied, before placing them on the market.
The verification will be paid for by the manufacturer, even if he has renounced the certification.
In case of natural expiry, the date is on the certificate itself. Once the expiration date is reached, the customer has the power to choose whether to maintain the certification or terminate it. In the event of a termination decision, the following conditions are established:

- The customer must remove any reference to the certification on the product documentation (brochures, advertisements, labels, etc.);
- The customer has the right to put on the market products that have been manufactured within the expiry date of the certification, for a period not exceeding six months from the expiry date;

- The products not present in the warehouse 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 products in the warehouse and the related NFs, which report the MTIC notification number in order to keep their marketing under control.
The manufacturer also undertakes not to have certifications relating to the same product issued by different Notified Bodies coexist.

3.6.2 Suspension

A product certification can be suspended due to situations that may compromise the conformity of the product itself with the relevant directive or with the applied legislative instrument, the decision is always taken by the deliberation committee, for example, for the following reasons:

- The product does not comply with the relevant safety requirements;
- The product has modified characteristics compared to the approved type;
- Production with inadequate and/or undocumented internal controls to ensure conformity to the approved type;
- Complaints from the field or from the Authority in charge of market surveillance;
- Non-compliance in the management system, not resolved in the established time;
- Changes in the product, process, place of manufacture without timely communication;
- Refusal of the manufacturer to provide samples necessary for the repetition of the tests for the assessment of conformity;
- Refusal by the manufacturer to access the production facilities and/or technical documentation by MTIC personnel and/or inspectors from the accreditation body or the Authority in charge of market surveillance (if applicable);
- Variation of the requirements in relation to mandatory legal changes (taking into consideration the adaptation time established by the legislation itself);
- Surveillance date exceeded

The surveillance audit can be postponed up to three months upon written request from the manufacturer and acceptance by the Technical Manager. This request must contain a valid reason, for example: "No equipment to view at the time of the surveillance visit".
The suspension can be accepted if requested by the customer.
The suspension of the certification will be notified to the manufacturer in writing. The information will contain the reasons for the suspension and the temporary expiry date for any corrective actions.
During the period of suspension of the certification, the manufacturer cannot mark the products covered by the same and cannot put them on the market, either directly or through other organizations, placing this prohibition also on any OBL manufacturers, under his responsibility.
The times for reducing the non-conformities that gave rise to the suspension range 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 requests verification to confirm the resolution; MTIC carries out the assessment or appoints competent figures in order to make the decision, notifying the Organization.
Restoration of certification is subject to verification that the deficiencies that had caused the suspension have been eliminated by checking the product and the Organization to ensure compliance with all the requirements of the reference standard.
It is notified in writing to the Organization and made publicly known by MTIC if the news of the suspension had previously been made public.

3.6.3 Withdrawal

MTIC, following the decision of the approval committee, can withdraw a Certificate of Conformity for the following reasons, the maximum time within which to resolve the non-conformities is given in brackets to avoid withdrawal:

- Violation of the Contractual Conditions or of the ATEX Regulation (30 days);
- Exceeding the suspension period of 180 days (immediate);
- Serious non-compliance in product manufacturing and/or raw materials that may affect product safety (immediate);
- Serious non-compliance of the quality management system with the process control that can 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 personnel of the Authority in charge of market surveillance or of the accreditation body (15 days);
- If the Organization suspends its activities or services covered by the certified Quality System and/or the product conformity assessment (6 months);
- Non-acceptance of the new economic amounts relating to surveillance activities, according to the methods described in the RG-GQ-01-01 "General contractual conditions".
- For any other serious reason, in MTIC's judgment such as, for example, but not limited to, the proven inability of the system to pursue its objectives of compliance with legislative or contractual obligations or product safety (according to MTIC's judgment) .

MTIC will always communicate the revocation of certifications:

- To the Notification Authority responsible for market surveillance;
- To the National Accreditation Body (if required);
- To all other Notified Bodies

There is an appeal procedure. The manufacturer can request the withdrawal of the certification in writing, accompanying it with objective reasons.

The organization whose certification has been withdrawed must:

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

The Organization that after the revocation intends to access the certification again, must present a new application following the entire procedure foreseen by these Regulations.

3.7 Transfer

If a manufacturer has obtained a management system certification, he can ask MTIC to take over the management of the certificate.

3.7.1 Requirements and Review for transfer

Only valid certifications issued by Notified Body will be transferred. Certifications that are known to be suspended and are researched to be suspended will not be accepted for transfer. Furthermore, the certifications will be transferred only if the site or sites wishing to transfer the certification are in possession of a valid certification issued by a notified body; It is necessary to verify that the client's certification falls within the notified scope of the issuing and accepting certification body.

3.7.2 Transfer management

The manufacturer who wishes to take over must make a formal request and must provide all the documentation necessary to carry out a review of the certification documentation of the same. If this review deems it necessary, for example in the presence of major non-conformities, it must include a pre-transfer visit to the customer's premises in order to continue and confirm the validity of the certification. MTIC shall appoint the person or team conducting the review and any pre-transfer visit to ensure the same competency required for an audit team appropriate to the scope of certification being reviewed. The pre-transfer review will be carried out ensuring that the persons in charge have the requisites for carrying out the latter.
With the process described, MTIC ensures that the takeover process is complete and guaranteed.
In order to proceed with the pre-transfer review, the applicant must provide, in addition to the system documentation, at least:
1. The reasons for requesting the transfer
2. Copy of the previously obtained QMS Approval Certificate and related attachments;
3. Copy of the latest inspection report issued by the previous ON;
4. The status of all pending non-conformities that may arise from them and any other available and relevant documentation relating to the certification process.
5. Copy of complaints/withdrawal log and actions taken;
6. Substitutive declaration of notary deed that there are no proceedings in progress by the competent authority for market surveillance, on the products subject to transfer / takeover.
7. The audit reports of the initial certification or the last recertification;
The accepting certification body will not be able to proceed with the takeover until after having verified the following points:
1. the implementation of corrections and corrective actions against all outstanding major non-conformances;
2. accepted the transferring customer's plans for correction and corrective action for all outstanding minor nonconformances;
When the pre-transfer review identifies issues that prevent the completion of the transfer, the accepting certification body will treat the transferring client as a new client resulting in a new certification cycle.
If no issues are identified by the pre-transfer review, the certification cycle should be based on the previous certification cycle and the accepting certification body should establish the audit program for the remainder of the certification cycle.
The certificate subject to takeover can be issued by MTIC only after carrying out an audit, in accordance with the audit program (during a scheduled surveillance or in the case of renewal depending on the moment in which the takeover request was made).
Once MTIC has issued the certification to be taken over, the process ends.
In case the certification was issued by a certification body that has gone out of business or whose accreditation has expired, suspended or withdrawn, the transfer must be completed within 6 months or upon expiry of the certification, whichever comes first.
The issue date and the expiry date foreseen by MTIC will be reported on the notification; however, upon customer request, it is possible to enter the date of first approval obtained by the customer with the previous NB.

3.7.3 Cooperation between the issuing and accepting certification bodies

Cooperation between the issuing and accepting certification bodies is essential for the effectiveness of the transfer process and the integrity of the certification. When requested, the issuing certification body shall provide the accepting certification body (MTIC) with all documents and information.
In the event that it was not possible to communicate with the issuing certification body, MTIC must record evidence of the communications sent.
The customer must authorize the issuing certification body to provide the requested information to MTIC.
The issuing certification body shall not suspend or withdraw the organization's certification following the MTIC organization's transfer request if the client continues to meet the certification requirements.
The relocating customer should contact the accreditation body that accredits the issuing certification body in case the issuing certification body:
• has not provided the requested information to the accepting certification body
• suspends or withdraws the certification of the transferor customer without reason.

3.8 OBL

Manufacturers and/or their authorized representatives, who have obtained type certification, may grant other organizations the marketing of the product under their name and with their brand under the conditions set out below.
The manufacturer who has obtained the EU-type examination certificate from MTIC, manufactures the product and guarantees its conformity to the certified type is called OEM
The Manufacturer who resells the same product from the OEM under its own name and with its own brand is called OBL.

3.8.1 General Condition

The OEM Manufacturer must have obtained a certificate for the products that will be placed on the market by OBL under its own name and brand.
The OEM Manufacturer and the OBL Manufacturer must sign a joint contact with the body which provides for at least what is indicated below.

3.8.2 Contract between OEM, OBL and NB

Both the OEM and OBL organizations must sign a joint document with the Body in which, in addition to accepting this regulation, they mutually undertake at least to:

OEM:

- ensure that the products supplied to the OBL comply with the type covered by the certificate (any differences must be listed in the contract).
- Inform the OBL of any suspension, revocation, expiry of the certificate or renunciation of the same.
- Provide the minimum technical documentation described below for the OBL to draw up in its own name
- Inform the OBL of any changes it will make to the products and related documentation referred to in the previous point
- Notify the OBL and the Body of any complaint it may receive with reference to the products
- Notify the OBL and the Body of any accident involving the products covered by the CE certificate

OBL:

- Guarantee not to make any changes to the products covered by the contract with the OEM, referred to in the Certificate

- Notify the OEM and the Body of any complaint it may receive with reference to the products
- Notify the OEM and the Body of any incident involving the products referred to in the Certificate
- Assume responsibility for drafting the EC Declaration of Conformity for the products referred to in the Certificate
- Cease the sale of the products if OEM communicates the suspension, expiry, revocation or renunciation of the Certificate.
- Declare to be aware that the Certificate that will be obtained from the Body as OBL will have the same expiry date as the Certificate obtained from the OEM and that the validity of the same will lapse at the same time as the OEM Certificate following expiry, renunciation, revocation or temporary suspension of certification.
- Cease the sale of the products if the OEM communicates the finding of potential dangers for the users of the same

3.8.3 OBL Application for Certification

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

- The review of the technical documentation
- Verification of conformity of the Type
- Verification of conformity of products to the type through production checks, tests, etc. (ref. paragraph 4.6.1).
- Verification of conformity of the products to the type on the basis of the management system adopted by the OEM (ref. paragraph 4.6.3).

The technical documentation must provide:

- Use and maintenance manual
- Copy of the CE plate
- the UE declaration of conformity of the product
- the list of production sites (if different from the sites declared by the OEM)

Possibly also the following documents:

- the UE type examination certificate and the EU declaration of conformity concerning the accessories incorporated in the appliance;
- attestations and certificates relating to the manufacturing and/or inspection and/or control methods of the appliance or accessory;
- the marking and labeling scheme where the OBL references are found and which differ from those described in the FT of the OEM manufacturer.
- a copy of the CE declaration of conformity of the appliance/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, the Body will issue a certificate which will be attributable to the certificates issued to the OEM manufacturer.
The certificates issued to the OBL will have the same expiry date as the certificates issued to the OEM, they will be suspended or revoked if the certificates issued to the OEM are.
Only after the certificate has been issued, the OBL will be able to use the number of the notified body 0068 and the references to MTIC as required by the Regulation.

3.8.4 Additional conditions

For the purposes of the Regulation, the OBL is the Manufacturer of the product marked and sold under its own name.
The Organism:

- will keep a copy of the OEM certificates together with the Certificates issued to the OBL.
- will verify the data relating to the OBL, marking and technical documentation during production (this may require surveillance at the OBL headquarters)
- If the products covered by the contract refer to a 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. at the OEM, will evaluate the most appropriate methods for verifying production according to the evaluation procedure required by the OEM and by the OBL.
- It will keep track of the references between the certificates issued to the OEM and to the OBL even if it is decided not to make such references explicit on the certificates issued to the OBL

3.9 Advertising – use for CE marking purposes

The Organization can announce the obtainment of the certification by MTIC in the ways it deems most appropriate. However, the Organization must clearly indicate any limitations and conditions set by MTIC when 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.
When using the Certificate, the Organization must avoid that the certification can be considered extended to products not included among those covered by the certification issued by MTIC.
In case of use of the Certificate that does not comply with what is indicated in the previous points or in the case of their illicit use, MTIC will take the appropriate measures against the Organization, including the use of appropriate legal actions.

3.10 Conservation of samples and documentation

MTIC ensures the correct handling of the samples during the checks. Storage at MTIC or at the manufacturer's of the samples already subjected to checks is not prescribed.
A copy of the certificates and the significant files of the 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 digitized and stored together with the pertinent documentation already in digital format.
The manufacturer is requested to return the paper document, in case of no response within 30 days, the documents are destroyed. Digital documents are archived and stored until the existence of the institution.

3.11 Findings management

3.11.1 Annex III, Annex V, Annex IX

The certification cannot be granted or maintained until any major non-conformities (MaNC) have been adequately removed and MTIC has ascertained, with a favorable outcome (through a specific supplementary audit and/or supplementary tests/calculations and/or examination of documentary evidence) the correction/ corrective actions and closing them.
In particular, refer to the table below:

	Type of evaluation	Action and root cause analysis	Corrective action time	Evidence of resolution/efficency	Records

NC +	Each Type	15 dd	3 months	Additional evaluation within 6 months (*)	Applicable forms
NC -	Each Type	15 dd	6 months	Additional evaluation within 6 months (*)	Applicable forms

(*)The inspector/scheme manager, in compliance with the indications in the table, defines and formalises the timing, according to the specific situation detected and the influence that the non-compliance probably/probably may have on the ability of the same to ensure products that comply with the applicable prescriptions/requirements.

3.11.2 Annex IV, Annex VI, Annex VII

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 specific supplementary audit and/or supplementary tests/calculations and/or examination of documentary evidence) the correction/ corrective actions and closing them. A similar procedure is followed in the case of other findings, the number and extent of which, in the opinion of MTIC, is such as to compromise safety requirements and/or to cause the delivery of a product that does not comply with the applicable prescriptions/requirements. During the next 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 CA/AP formulated by the manufacturer and the related implementation times. During the next audit, MTIC will be responsible for verifying the effectiveness of the corrective action.

For findings classified as "Recommendations", the manufacturer is not obliged to define and implement any treatments (corrections) and/or corrective/preventive actions. MTIC limits itself to verifying in the subsequent surveillance audit if, and how, the manufacturer has accepted these observations.

The timing of notification and closing of the corrections and/or of the accepted AC/AP and of the Observations, any implementation and effectiveness checks, and the related registrations, follow the following application scheme:

	Type of evaluation	**Action and root cause analysis**	**Corrective action time**	**Evidence of resolution/efficency**	**Records**
NC +	Each Type	15 dd	3 months	Additional evaluation within months	Applicable forms
NC -	Each Type	15 dd	6 months	During surveillance evaluation (**)	Applicable forms
Racc	Each Type	---	---	During surveillance evaluation (**)	Applicable forms

(*) The RGVI/the Scheme Manager, in compliance with the indications in the table, defines and formalises the timing, according to the specific situation detected and the influence that the non-compliance probably/probably may have on the ability of the same to ensure products that comply with the applicable prescriptions/requirements.

(**) The periodicity and extent of the surveillance is established/confirmed with the resolution (decision) of the Resolution Committee (deliberating function) for the issue of the certificate and communicated/confirmed to the manufacturer at the same time as the transmission of the certificate. The frequency and extent of the surveillance audits can be modified by MTIC on the basis of the results of the assessments carried out, these modifications, approved/resolved by the Resolution Committee (deliberation function), are communicated to the manufacturer. The approval committee also defines the supplementary audits and may request documentary evidence.

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 RG09 of the Accreditation Body, can be granted for use to them exclusively in combination with the mark of the Body.
The only marking that can be used by the Organization after obtaining the Certificate from MTIC is the "CE" according to the provisions indicated in Annex II to Regulation (EC) 2008/765. The methods for affixing the marking are defined in Directive 2014/34/EU.

4 Conformity Evaluation Procedure

4.1 Application for certification

After the first contact with the Customer (telephone or fax) all the information necessary to start the certification process is requested.
Once the information has been obtained, MTIC prepares, on the basis of the tariff, an economic offer for the testing and certification activities and sends it to the interested Customer together with the forms necessary for the presentation of the application.
The certification can only be requested by the manufacturer of the product or by a person or organization in possession of specific authorization from the manufacturer.
Interested parties not directly involved with the production, service or process cannot apply for any certification scheme.
If the application is presented by the authorized representative established in the community, it must contain, in addition to the name and address of the manufacturer, place of production, designation of the type of product and the intended use, also the name and address of the authorized representative.
The applicant must submit the application by filling in all its parts the form provided by MTIC, filling in one 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 the certification process.

The documentation provided by the applicant must include according to the applicable attestation of conformity systems:

- Detailed description of the product, technical specifications and other data deemed necessary;
- List of characteristics/requirements falling within the field of interest of the conformity assessment activity and the list of reference documents (technical rules, standards, etc.);
- Product detail drawings (conceptual and manufacturing design drawings, diagrams of components, sub-assemblies, circuits, etc.; including descriptions and explanations necessary for understanding said drawings and diagrams and the operation of the product);
- Installation and use instructions;
- Test reports and certificates available regarding the product, technical documentation regarding the materials supplied, etc.;

Upon acceptance of the offer by the Customer and upon receipt of the completed application, a file number is assigned and the application is re-examined.

4.2 Application review

The product certification will be issued following the certification schemes identified by RT on the basis of the information and requests provided by the manufacturer. RT establishes the feasibility of the project on the basis of the authorizations obtained and on the basis of the qualified personnel and resources available to MTIC. If these conditions are not met, MTIC rejects the application received.

4.3 Planning and execution of audits

The inspection activities foreseen for the products are carried out by the MTIC inspectors, based on the requirements of the applicable assessment procedures (modules) described in detail later in this Regulation.
Upon successful completion of all the examinations and tests envisaged and specified in the service proposal sent to the Organization and accepted by the latter, the technical secretariat sends the file, complete with all the documentation, to one or more competent and independent technicians of MTIC (committee of resolution), for review and resolution.
Following the successful outcome of this verification and the approval of the relative certification proposal, MTIC will issue the certificate/authorization/approval required by the chosen evaluation form and will send it to the Organization following the payment of the relative invoice.
In the event of a negative outcome, MTIC will communicate this outcome to the Organization and agree with the latter the methods for any re-evaluation. Each certification refused is also communicated to the Authority in charge of market surveillance and to the other notified bodies.

4.4 Instrumentation

The tools necessary for carrying out the tests can be made available by the requesting organisations.
These instruments must be suitable for the foreseen tests, must have an accredited calibration certificate, must be managed in compliance with the ISO/IEC 17025 standard.
All instruments used must be accompanied by the relevant LAT calibration certificate or certificate issued by an ISO/IEC 17025 accredited laboratory as a calibration laboratory. All calibrations must be traceable to primary standards.
In the case of non-critical measurements for the purposes of certification, the instruments used can be calibrated internally by the manufacturer through the use of primary instruments calibrated at accredited calibration centers which always allow identification of the metrological chain and traceability to the international measurement system . A non-critical measurement is a measurement whose associated uncertainty does not affect the compliance of the measured value with the applicable requirements. The MTIC inspectors verify the identification of the instruments and the relative calibration certificates with metrological traceability, as well as the instrument management procedures and their storage methods.
In the event that the instruments necessary for carrying out the tests are not made available or the adequacy and calibration of these instruments is not guaranteed, these tests are not considered valid for the purposes of certification.

4.5 Requirements of test laboratories and related reports

Applicants can submit test reports in their possession to MTIC, if issued by laboratories accredited according to ISO/IEC 17025 for the standards/tests relevant to the certification process in progress.
Furthermore, test reports from laboratories that have been qualified by MTIC for the standards/tests relevant to the ongoing certification process are accepted.
If the test reports relating to the tests conducted on the representative sample of the product, presented by the applicant to MTIC, should report a date of execution of the same, prior to that of submission of the application for EU Type Examination or renewal of the certificate, the reserves the right to accept the same only after verifying that:

- 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 product subject to certification, with respect to the sample subject of the test reports presented

MTIC reserves the right to use ISO/IEC 17025 accredited laboratories or those qualified by the Body to carry out the required tests on the products. In these circumstances, MTIC will report in the offer document, the request to the applicant for certification, to report any unwelcome Organizations.

4.6 Conformity Assessment Procedures

4.6.1 General for Annexes IV and VII

In the case of Quality Systems Conformity Assessment (Annexes IV and VII), MTIC carries out an assessment visit at the Organization, communicating in advance the names of the assessment group in charge of verifying the correct application of all the applicable procedures relating to the design , construction and control of the products covered by the application for evaluation.
The evaluation of the system takes place according to the provisions of the ISO/IEC 17021 standard with a Phase 1 audit in which an initial document review and a Phase 2 audit are carried out.

The Phase 2 visit consists of:

- An initial meeting with the Organization to agree on the methods of the visit itself;
- Review of the relevant quality documentation for the purposes of the Directives;
- An inspection of the offices, the production site(s), and, where necessary, the raw material storage site(s), as well as the laboratory(s) to verify the compliance of the quality control system factory production to the applicable reference standards;
- A final meeting to illustrate the outcome of the visit

The assessment group verifies the adequacy of the Organization's Quality System in order to comply with all the applicable essential safety requirements, envisaged by the Directive and, in the event of deficiencies or discrepancies from what is declared in the system documentation, can notify to the Organization one or more non-conformities.

During the visit, the Organization must demonstrate, in addition to possession of the reference standards applicable to it, that the system is fully operational and effectively implemented.
For this purpose, also during the surveillance checks (specified below), the MTIC technicians, and possibly ACCREDIA staff, must be guaranteed free access to the production sites, personnel and documentation and the necessary assistance from the responsible personnel in charge of verification.
At the end of the assessment visit, an audit report is delivered to the Organization, which shows any non-conformities and recommendations found.

The Organization can write down any reservations or observations, regarding the findings expressed by the MTIC technicians, in a special space in the audit report.
In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
The Organization, after analyzing the causes of any non-conformities reported on the above report, must propose to MTIC, by the date indicated on the report itself, the necessary corrective actions and the times foreseen for their implementation.

The acceptance of these proposals and the times foreseen for their implementation is communicated in writing by MTIC to the Organization.

In the presence of major non-conformities, the certification process is suspended; in the case of other findings, the number of which, in the opinion of the assessment team, is such as to jeopardize the correct functioning of the system, the certification process is equally suspended.
In such cases, within three months, MTIC can carry out a supplementary check aimed at ascertaining the correct application of the proposed corrective actions; with a successful outcome of this verification, the certification process resumes.

If the aforementioned deadline is exceeded, the management system adopted by the Organization is subjected to a complete review within a period of six months from the date of the finding.
Once the aforementioned six-month period has elapsed without a positive conclusion of the evaluation, MTIC can consider the certification procedure closed, charging the times 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 particular cases be varied upon a reasoned request by the Organization, in the judgment of MTIC.
Upon successful completion of all the exams and tests envisaged by the certification procedures and by these 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 complete file of all the documentation to one or more competent and independent technicians (Steering Committee) for the verification of completeness. Following the successful outcome of this verification and the approval of the relative certification proposal, MTIC will issue the certificate/authorization/approval required by the chosen evaluation module.

In the event of a negative result, an appeal procedure is envisaged and a new certification application can be presented by the Organization, which will be accepted without prejudice and with impartiality.
If major non-conformities are found during the surveillance audits, the report is submitted to the steering committee, which will have to decide on the possible suspension of the certification, and then possibly proceed with the revocation according to the provisions of this regulation

Protection level	ATEX Category	Zone	Certification Procedure	
			Mechanical	Electrical
Very High	1G, 1D	0,20 1,21 2,22	All. III + All. IV All. III + All. V All. IX	All. III + All. V All. III + All. IV All. IX
High	2G, 2D	1,21 2,22	Deposit of the technical dossier + All. VIII	All. III + All. VIII All. III + All VI All. IX
Normal	3G, 3D	2,22	Self-certification (internal production control Annex VIII)	

4.6.2 Receipt of deposit of the technical file

This procedure is based on the provision of the technical dossier according to Article 13 paragraph 1 b) (ii) of Directive 2014/34/EU.

The applicant must submit to MTIC a duly signed application for each receipt that he intends to obtain together with a declaration of acceptance of these regulations. The application must clearly indicate the identification of the products to which the file refers, to allow their registration and availability in the archives.
The technical file must preferably be placed in an A4 format binder, must be sealed and signed by the manufacturer, must bear on the cover page a copy of the CE plate which shows the Ex marking of the product.
Upon receipt of the file, MTIC registers it, archives it and issues the receipt.
MTIC does not operate any checks on the completeness and correctness of the documents that make up the technical file.
Before the expiry of the ten years, MTIC consults the applicant in order to confirm his interest in keeping the file on file, in the event of a negative response, it will proceed with the return of the file and in the event of no response in the following 30 days, it will proceed with the destruction of the documentation.

4.6.3 Annex III – UE Type certificate

As part of this procedure, MTIC ascertains and declares that a specimen representative of the production in question meets the provisions of the directive.
The manufacturer or his authorized representative established in the Community sends the application for EU-type examination enclosing, for each 'type', the following documentation:

- A general description of the product;
- Nominal characteristics and protection mode;
- Design and manufacturing drawings, as well as the diagrams of components, sub-units, circuits, etc., complete with the description and explanations necessary for the understanding of these drawings and diagrams and the functioning of the product;
- A list of the standards applied in full or in part and the description of the solutions adopted to meet the essential requirements of the Directive where harmonized standards have not been applied;
  The results of project calculations;
- The reports of the tests carried out

The Applicant must submit to MTIC a declaration certifying that the same certification request has not been submitted to any other Notified Body in the European Union.
Furthermore, the applicant must make available, in accordance with the reference standards, one or more specimens representative of the production, hereinafter referred to as the "type". The same type can cover several variants of a product as long as the differences between the variants do not affect the security level.

Following this, MTIC:

- Examines and evaluates the documentation, to ascertain its adequacy in order to give a complete and correct definition of safety against explosion and verifies that all aspects of the project comply with the applicable standards or the requirements of the Directive, send any comments;
- Verify, with visual and dimensional checks, that the type has been manufactured in compliance with the submitted documents, with identification of both the elements designed in compliance with the harmonized standards, and the elements designed in compliance with the other normative references;
- Performs or has performed the appropriate examinations and type tests necessary to verify compliance with the applicable standards or with the applicable essential safety requirements listed in Annex II of the Directive

The place where the examinations and tests are to be carried out is agreed between MTIC and the applicant.

In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
If the results of the investigations and tests are favourable, MTIC issues the applicant with an UE Type Examination Certificate containing the name and address of the applicant, the conclusions of the examination and the data necessary for the identification of the approved type. A list of the significant files of the technical documentation is attached to the Certificate, of which MTIC keeps a copy.
In the event that the applicant, to whom MTIC has issued an UE-Type Examination Certificate, makes modifications to the approved product that may affect compliance with the applicable essential requirements or the prescribed methods of use, such modifications must be notified to MTIC and will need to be subject to further evaluation and approval.
This new approval is issued in the form of an addition to the original UE-type examination certificate.
Although the directive does not provide for a deadline for UE type examination certificates, MTIC verifies the validity requirements every 5 years or whenever changes are made to the technical standards or to the directive.
Any necessary adjustments will be communicated within 15 working days to the manufacturer who will have to provide a written response with reference to the will to adjust and implementation times.

4.6.4 Annex IV –Production quality assurance

As part of this procedure, the manufacturer must use an approved quality system for production, final inspection and tests on the finished product, as indicated in the 'Quality System' point, and must be subject to surveillance by MTIC as indicated in the 'Surveillance' section.
The manufacturer ensures and declares that the products conform to the type described in the UE-Type Examination Certificate and meet the requirements of the Directive that apply to them.
The manufacturer or his authorized representative established in the Community affixes the CE marking to each product, when required, indicating the identification number of the MTIC and draws up a Declaration of Conformity.

Quality System

The manufacturer prepares and implements a quality management system based on the EN 80079-34 standard. The manufacturer sends an application for assessment of his quality system for the products concerned, attaching the following documentation:

- A general description of the product;
- Identification of production sites;
- Identification of the test laboratories where the tests prescribed for the certification procedure adopted will be carried out;
- Certification procedure adopted (for the purposes of CE marking and the relative Declaration of Conformity);
- Any technical documentation relating to the approved type;
- Copy of the quality manual and relevant procedures/instructions for ATEX purposes;
- Copy of the EU-Type Examination Certificate, including its attachments;
- Copy of any ISO 9001 Certificate;
- Copy of any certificates from bodies notified to the quality system of the production units for the purposes of the Directive;
- Copy of any accreditation certificate in compliance with the ISO/IEC 17025 standard of the testing laboratories issued by national or international accreditation bodies.

All the criteria, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.
The quality system documentation must include in particular an adequate description:

- The quality objectives, the organizational structure, the management responsibilities in terms of product quality;
- Manufacturing processes, systematic interventions and quality control and quality assurance techniques;
- Of the examinations and tests carried out before, during and after manufacturing with an indication of the frequency with which it is intended to carry them out;
- quality documentation, such as inspection reports and test data, calibration data, personnel qualification reports, etc.;
- The means of surveillance which allow for the control of the required quality and the effective functioning of the quality system

The quality system must guarantee the conformity of the products to the type described in the EU type examination certificate and to the applicable essential requirements.
Please note that it is essential that the manufacturer has its own quality system, the certification of this management system according to the UNI EN ISO 9001 standard is preferential but not mandatory; different cases will be evaluated from time to time.
MTIC evaluates all the documentation received to verify that it adequately describes what is requested and that the chosen certification procedure complies with the provisions of art. 13 of the Directive and send any comments to the manufacturer.
During the first certification audit, MTIC will evaluate the fundamental points of the Quality System with respect to what is required by the ATEX Directive using an appropriate checklist, and will also evaluate the Quality System as a whole if this has been certified by a body other than MTIC.
At the end of the audit, MTIC issues a copy of the audit report.
In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
MTIC evaluates the quality system in accordance with its procedures for the certification of quality systems.
MTIC also ascertains the compliance of the test laboratories with the requirements of the ISO/IEC 17025 standard and verifies that the quality control procedures ensure the satisfaction of the correct execution of the tests and examinations of the products indicated in the EU-Type Examination Certificate.
At least one expert in the production technology relating to the equipment in question will be present in the group in charge of the evaluation.
The evaluation activity will include a visit to the manufacturer's plants.
Upon successful completion of the assessment activities, i.e. in the event that minor non-conformities or simple comments have been detected, MTIC issues a Production Quality Assurance Notification. MTIC will carry out a new visit to verify that the changes agreed during the audit have been implemented within the times agreed upon at that venue.
The Production Quality Assurance Notification is valid for three years.
In the event that the second audit also has a negative outcome, MTIC will inform the other Notified Bodies about the refusal of certification.
The manufacturer undertakes to fulfill the obligations deriving from the approved quality system and to ensure that it remains adequate and effective.

The manufacturer or his authorized representative established within the Community shall keep MTIC who has approved the quality system informed of any planned modifications to the quality system.
MTIC evaluates the proposed changes and decides whether the modified system continues to meet the requirements described above or if a re-evaluation is required.
MTIC communicates its decision to the manufacturer. The communication must contain the conclusions of the examination and the detailed motivation of the decision.

Surveillance
The purpose of surveillance is to make sure that the manufacturer duly fulfills the obligations arising out of the approved quality system.
The surveillance of the quality system is carried out by MTIC implementing a temporal program which foresees a maintenance visit at the end of the first year, a maintenance visit at the end of the second year and some unannounced visits.
The scheduled visits are implemented in such a way that a complete review of the management system is carried out in the three-year certification cycle.
Unannounced visits must be sufficient to ensure that each type of product is checked at least once a year.
The determination of the number of unannounced visits is made on the basis of these considerations:

- The group and category of the product;
- The results of previous surveillance visits;
- The need to ensure the implementation of corrective actions;
- If applicable, the special conditions associated with the approval of the system;
- Significant changes in the organization of manufacturing directives or manufacturing techniques.

During scheduled and unannounced visits, the manufacturer must make the following documentation available:

- Documentation relating to the quality system;
- Internal inspection reports;
- Design and manufacturing drawings, as well as diagrams of components, sub-units, circuits, etc., complete with descriptions and explanations necessary for understanding these drawings and diagrams and the operation of the appliance;
- Traceability procedures;
- Test equipment calibration certificates;
- Non-conformity reports issued in production and related resolutions;
- Operating instructions (assembly and commissioning, use and maintenance, limits of use, residual risks associated with use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- Declaration of conformity

MTIC also makes sure that the CE marking, the Ex marking and its notification number are affixed correctly.
At the end of the inspection, MTIC issues a final verification report.
In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
At the expiry of the validity period of the Certificate, the manufacturer must re-submit the application for evaluation of its quality system and MTIC will thoroughly review the entire company quality system.
The manufacturer shall keep it at the disposal of the national authorities for ten years after the last date of manufacture of the product:

- The documentation relating to the quality system;
- Adjustments to the quality system;
- The decisions and reports issued by the MTIC relating to the approval of the SQA, the changes made and the scheduled and unannounced visits made

4.6.5 Annex V –Product checks

As part of this procedure, the manufacturer or his authorized representative established in the Community ensures and declares that the products subjected to the surveillance activities carried out by MTIC and described in the 'Product verification' paragraph, conform to the type described in the UE Examination Certificate of the type and meet the applicable essential requirements.
The manufacturer also takes all the necessary measures so that the manufacturing process guarantees the conformity of the products to the type described in the above Certificate.
The manufacturer affixes the CE marking to each product and draws up a Declaration of Conformity.
The manufacturer sends a product verification request, attaching the following documentation for each type of product:

- A general description of the product and its operation;
- Identification of each production site;
- Schemes and drawings complete with descriptions and explanations necessary for their understanding;
- A list of the standards applied in whole or in part;
- Copy of the EU type examination certificate and related technical attachments;
- Copy of the relevant procedures and instructions for product compliance with the directive;
- Copy of any ISO 9001 Certificate.

MTIC examines the documentation produced and sends the appropriate comments.
MTIC verifies the conformity of each product with the requirements of the Directive by examining and testing each individual product, according to the methods described in the following paragraph.

Product Checks
All products are examined individually by MTIC, and all the tests and examinations foreseen by the existing harmonized standards are carried out on them, or equivalent examinations and tests aimed at guaranteeing the conformity of each product to the type and essential safety requirements of the Directive applicable.
If the outcome of these checks is satisfactory, MTIC issues a Certificate of Conformity for each product and affixes or causes to be affixed its identification number on each of them.
In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
The manufacturer must be able to show the certificates of conformity issued by MTIC upon request.

4.6.6 Annex VI – Conformity to type

As part of this procedure, the manufacturer or his authorized representative established in the Community ensures and declares that the products are in conformity with the type described in the UE-type examination certificate and satisfy the applicable essential requirements.
The manufacturer sends an application for conformity to type attaching the following documentation for each product:

- A general description of the product and its operation;
- Identification of each production site;
- Schemes and drawings complete with descriptions and explanations necessary for their understanding,
- A list of the standards applied in whole or in part;
- Copy of the EU type examination certificate and related technical attachments;
- Copy of the relevant procedures and instructions for product compliance with the directive;
- Copy of any ISO 9001 Certificate.

First visit

MTIC evaluates all the documentation received to verify that it adequately describes what is requested and that the chosen certification procedure complies with the provisions of art. 13 of the Directive and send any comments to the manufacturer.

MTIC, carries out a first visit to the manufacturer to verify the methods and ways of performing the final tests concerning the technical aspects of protection against explosions performed or commissioned by the applicant.

MTIC also ensures that suitable procedures have been established to document the monitoring of production systems and final product controls.

At the end of these activities MTIC issues an inspection report.

In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.

If the result is positive, the manufacturer or his authorized representative established in the Community affixes, under the responsibility of MTIC, the CE marking with the indication of the MTIC identification number on each appliance and draws up a declaration of conformity.

MTIC issues a Certificate of conformity to type.

Surveillance

Surveillances take place on a quarterly basis for new customers and can become six-monthly after three years, in the event of always positive outcomes of the inspections. Upon the occurrence of a negative outcome, the frequency reverts to quarterly.

Unannounced visits must be sufficient to ensure that each type of product is checked at least once a year. The determination of the number of unannounced visits is made on the basis of these considerations:

- The group and category of the product;
- The results of previous surveillance visits;
- The need to ensure the implementation of corrective actions;
- If applicable, the special conditions associated with the approval of the system;
- Significant changes in the organization of manufacturing directives or manufacturing techniques

Upon completion of each inspection visit, MTIC issues an inspection report to the manufacturer.

In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.

4.6.7 Annex VII – Product quality assurance

As part of this procedure, the manufacturer must use an approved quality system for final inspection and tests on the finished product, as indicated in the "Quality System" point, and must be subject to surveillance by MTIC as indicated in point "Surveillance".
The manufacturer ensures and declares that the products conform to the type described in the EU-Type Examination Certificate and meet the applicable essential requirements.
The manufacturer or his authorized representative in the Community affixes the CE marking to each product indicating the MTIC identification number and draws up a Declaration of Conformity.

Quality System

The manufacturer prepares and implements a quality management system based on the EN 80079-34 standard. The manufacturer sends an application for assessment of his quality system for the products concerned, attaching the following documentation:

- A general description of the product;
- Identification of production sites;
- Identification of the test laboratories where the tests prescribed for the certification procedure adopted will be carried out;
- Certification procedure adopted (for the purposes of CE marking and the relative Declaration of Conformity);
- Any technical documentation relating to the approved type;
- Copy of the quality manual and relevant procedures/instructions for ATEX purposes;
- Copy of the EC-Type Examination Certificate, including its attachments;
- Copy of any ISO 9001 Certificate;
- Copy of any certificates from bodies notified to the quality system of the production units for the purposes of the Directive;
- Copy of any accreditation certificate in compliance with the ISO/IEC 17025 standard of the testing laboratories issued by national or international accreditation bodies.

All the criteria, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.
The quality system documentation must include in particular an adequate description:

- The quality objectives, the organizational structure, the management responsibilities in terms of product quality;
- Manufacturing processes, systematic interventions and quality control and quality assurance techniques;
- Of the examinations and tests carried out before, during and after manufacturing with an indication of the frequency with which it is intended to carry them out;
- quality documentation, such as inspection reports and test data, calibration data, personnel qualification reports, etc.;
- The means of surveillance which allow for the control of the required quality and the effective functioning of the quality system.

The quality system must guarantee the conformity of the products to the type described in the EU type examination certificate and to the applicable essential requirements.

Please note that it is essential that the manufacturer has its own quality system, the certification of this management system according to the UNI EN ISO 9001 standard is preferential but not mandatory; different cases will be evaluated from time to time.
MTIC evaluates all the documentation received to verify that it adequately describes what is requested and that the chosen certification procedure complies with the provisions of art. 13 of the Directive and send any comments to the manufacturer.
During the first certification audit, MTIC will evaluate the fundamental points of the Quality System with respect to what is required by the ATEX Directive using an appropriate checklist, and will also evaluate the Quality System as a whole if this has been certified by a body other than MTIC.
At the end of the audit, MTIC issues a copy of the audit report.
In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
MTIC evaluates the quality system in accordance with its procedures for the certification of quality systems.
MTIC also ascertains the compliance of the test laboratories with the requirements of the ISO/IEC 17025 standard and verifies that the quality control procedures ensure the satisfaction of the correct execution of the tests and examinations of the products indicated in the UE-Type Examination Certificate.
At least one expert in the production technology relating to the equipment in question will be present in the group in charge of the evaluation.
The evaluation activity will include a visit to the manufacturer's plants.
Upon successful completion of the assessment activities, i.e. in the event that minor non-conformities or simple comments have been detected, MTIC issues a Production Quality Assurance Notification. MTIC will carry out a new visit to verify that the changes agreed in the audit phase have been implemented within the time frame agreed in that venue.
The Production Quality Assurance Notification is valid for three years.
In the event that the second audit also has a negative outcome, MTIC will inform the other Notified Bodies about the refusal of certification.
The manufacturer undertakes to fulfill the obligations deriving from the approved quality system and to ensure that it remains adequate and effective.
The manufacturer or his authorized representative established within the Community shall keep MTIC who has approved the quality system informed of any planned modifications to the quality system.
MTIC evaluates the proposed changes and decides whether the modified system continues to meet the requirements described above or if a re-evaluation is required.
MTIC communicates its decision to the manufacturer. The communication must contain the conclusions of the examination and the detailed motivation of the decision.

Surveillance
The purpose of surveillance is to make sure that the manufacturer duly fulfills the obligations arising out of the approved quality system.
The surveillance of the quality system is carried out by MTIC implementing a temporal program which foresees a maintenance visit at the end of the first year, a maintenance visit at the end of the second year and some unannounced visits.
The scheduled visits are implemented in such a way that a complete review of the management system is carried out in the three-year certification cycle.
Unannounced visits must be sufficient to ensure that each type of product is checked at least once a year.
The determination of the number of unannounced visits is made on the basis of these considerations:

- The group and category of the product;
- The results of previous surveillance visits;

- The need to ensure the implementation of corrective actions;
- If applicable, the special conditions associated with the approval of the system;
- Significant changes in the organization of manufacturing directives or manufacturing techniques.

During scheduled and unannounced visits, the manufacturer must make the following documentation available:

- Documentation relating to the quality system;
- Internal inspection reports;
- Design and manufacturing drawings, as well as diagrams of components, sub-units, circuits, etc., complete with descriptions and explanations necessary for understanding these drawings and diagrams and the operation of the appliance;
- Traceability procedures;
- Test equipment calibration certificates;
- Non-conformity reports issued in production and related resolutions;
- Operating instructions (assembly and commissioning, use and maintenance, limits of use, residual risks associated with use, identification of replaceable parts, documents necessary for a full understanding of these instructions);
- Declaration of conformity.

MTIC also makes sure that the CE marking, the Ex marking and its notification number are affixed correctly.
At the end of the inspection, MTIC issues a final verification report.
In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
At the expiry of the validity period of the Certificate, the manufacturer must re-submit the application for evaluation of its quality system and MTIC will thoroughly review the entire company quality system.
The manufacturer shall keep it at the disposal of the national authorities for ten years after the last date of manufacture of the product:

- the documentation relating to the quality system;
- adjustments to the quality system;
- the decisions and reports issued by the MTIC relating to the approval of the SQA, the changes made and the scheduled and unannounced visits carried out.

4.6.8 Annex IX – Checking the unit

As part of this procedure, the manufacturer ascertains and declares that the product covered by the Certificate of Conformity issued by MTIC complies with the requirements of the Directive that apply to it.
The manufacturer or his authorized representative established in the Community affixes the CE marking to the product and draws up a Declaration of Conformity.
The manufacturer or his authorized representative established in the Community sends an application for verification certification of a single product, attaching the following documentation for each product:

- A general description of the product;
- Nominal characteristics and protection mode;
- Design and manufacturing drawings, as well as the diagrams of components, sub-units, circuits, etc., complete with the description and explanations necessary for the understanding of these drawings and diagrams and the functioning of the product;

- A list of the standards applied in full or in part and the description of the solutions adopted to meet the essential requirements of the Directive where harmonized standards have not been applied;
- The results of project calculations;
- The reports of the tests carried out.

The Applicant must submit to MTIC a declaration certifying that the same certification request has not been submitted to any other Notified Body.
Following this, MTIC carries out the following examinations and checks:

- Examines and evaluates the documentation, to ascertain its adequacy in order to give a complete and correct definition of safety against explosion and verifies that all aspects of the project comply with the applicable standards or the requirements of the Directive, send any comments;
- Verification with visual and dimensional checks that the type has been manufactured in compliance with the submitted documents, with identification of both the elements designed in compliance with the harmonized standards and the elements designed in compliance with the other normative references;
- Performs or has performed the appropriate examinations and type tests necessary to verify compliance with the applicable standards or with the applicable essential safety requirements listed in Annex II of the Directive

In the event of any findings, MTIC will issue a specific findings form for which the Organization, after having analyzed the causes of any non-conformities reported in the above-mentioned report, must propose, by the date indicated in the paragraph of this regulation, the necessary corrective actions and the expected timescales for their implementation.
If the results of the checks and tests are favorable, MTIC affixes or causes its identification number to be affixed to the product and issues a Certificate of Conformity of a single product to the manufacturer.

4.7 Issue of Certification

If all the assessment activities have been concluded with a positive outcome, it is possible to proceed with the independent review of the complete file, by the Technical Certifier; if the latter is also successful, the Steering Committee can decide to issue the certification.
In the event of a negative result, MTIC informs the manufacturer of the reasons that led to the refusal of the certification.
Any refusal is communicated to the competent authority and to the other notified bodies. As required by the directive.
An appeal procedure is envisaged, as indicated in the General Contractual Conditions published on the website www.mtic-group.org in the Who we are section.