TITLE/TITOLO	General regulation for the certification of medical devices
CODE/CODICE	RG-PC-DM-01-01
REVISION/REVISIONE	0.2
DATE/DATA	09.08.2019

CHECKED COPY /COPIA CONTROLLATA	☑
UNCHECKED COPY /COPIA NON CONTROLLATA	☐

Rev.	Date/Data	Issued by Emesso da	Verified and approved by Verificato ed Approvato da	Description of changes Descrizione delle modifiche
0.0	07.08.2017	Responsabile di schema DM	Responsabile qualità	First issue/Prima emissione
0.1	22.03.2018	Responsabile di schema DM	Responsabile qualità	Change of company name/Modifica ragione sociale
0.2	09.08.2019	Responsabile di schema DM	Responsabile qualità	Durata della Certificzione/Duration of Certification

Sommario

1. Premise

Please refer to the General Contractual Conditions published on the website www.mticert.org in the About us section regarding:

1195/5000

- Purpose
- Field of application
- 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
- MTIC rights and obligations
- Rights and obligations of the organization
- Access to information
- Information obligation on legal proceedings
- Inspection and safety at the workplace
- Economic conditions
- Additional checks
- Suspension of system, product and personal certificate
- Revocation of the system, product and personal certificate
- Certification limits and responsibilities
- Limitations of liability and charges
- Termination clause
- Indemnification and indemnity
- Cause of force majeure
- Waiver, suspension, withdrawal of accreditation (where applicable)
- Professional secrecy, confidentiality and privacy
- Privacy disclaimer
- Complaints and appeals
- Confidentiality and protection of intellectual and industrial property
- Change management
- Certificate certificate
- Register of certificates and record keeping
- Administrative liability of legal persons

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

2. Purpose and field of application

This regulation defines the rules and procedures for the provision of the certification service implemented by MTIC INTERCERT S.r.l. (hereinafter MTIC) in accordance with the provisions of Directive 93/42 / EEC and subsequent amendments and additions (hereinafter the Directive).
The regulations specify the Customer's and MTIC's rights and duties within the certification process pursuant to the Directive, without prejudice to the provisions in the General Contractual Conditions referred to in chapter 1. If there are provisions in this regulation that are contrary to what is indicated in the Conditions General Contracts, the provisions of the regulation prevail.
These Regulations apply to medical devices and related accessories (hereinafter "devices"), for which MTIC has obtained appropriate authorization to carry out the related conformity assessment procedures.
For the purposes of these Regulations, EC certifications are all activities of assessment and attestation of conformity, according to the various procedures provided for by art. 11 of the Directive. The documents issued by MTIC in this area are:

- Certification (complete quality assurance system), according to Annex II excluding point 4 of the Directive;
- EC Type Examination Certificate, according to Annex III of the Directive;
- EC Verification Certificate, according to Annex IV of the Directive;
- Certification (guarantee of production quality), according to Annex V of the Directive;
- Certification (Product quality guarantee), according to Annex VI of the Directive.

3. General conditions

3.1. Contract

The contract is considered to have entered into force and is binding for all legal purposes, when the Manufacturer of the device or its European Agent (hereinafter "the Customer") will have accepted the estimate in writing within the relative term of validity and MTIC will have confirmed it. in writing the Customer's order (hereafter, the "Certification Contract").
The presentation of the Certification Application also implies full acceptance of these Regulations, which are an integral part of the Certification Contract.

3.2. Certification Activity

893/5000
The Customer who intends to make use of MTIC for the issue of the CE certifications relating to its devices is responsible for the destination assigned to each device and the relative classification according to the criteria set out in Annex IX of the Directive.
MTIC is responsible for verifying that the information provided by the Customer is correct and in compliance with the reference requirements.
If there is a disagreement between the Customer and MTIC on the application of the classification rules, MTIC, after informing the Customer, reports the terms of the matter to the competent Authority so that it can be resolved, according to the provisions of art. 9, paragraph 2 of the Directive.

It is the Customer's prerogative to choose the conformity assessment procedure to follow in order to affix the CE marking on its devices according to the provisions of art. 11 of the Directive.
The Client cannot advertise the current application until the positive outcome of the related conformity assessment activities.
The tests and checks on the devices and assessments of the Customer's Quality System are performed by MTIC; in addition to its own resources, MTIC, while maintaining full responsibility for the evaluation activity and giving prior notice to the Customer, may also make use of external resources (laboratories and / or external collaborators), in compliance with the requirements established by the reference standards and by the competent authority.
The Customer may oppose the choice of such external resources, demonstrating any conflicts of interest of the same with the activities subject to evaluation.
During its activity, MTIC reserves the right to recognize documents issued by other Notified Bodies pursuant to the Directive, such as certificates, declarations of approval, test reports, reports attesting the conformity of devices or quality systems.

3.3. Obtaining and maintaining certification

The certification, and its updating where applicable, are subordinated:

- the willingness of the Customer to submit to ordinary and supplementary assessments, documents and at the premises of the Customer and / or other locations involved (for example, the locations of subcontractors and critical suppliers of the Customer), in the timescales envisaged and indicated by MTIC;
- the positive outcome of the aforementioned conformity assessment activities, performed by MTIC;
- the payment of the amounts due, for whatever reason, to MTIC (eg for the activities of issuing and renewing the certification, for the variation / re-issue of the certificates, etc.).

The maintenance of any type of Certificate and the performance of any surveillance activity are subject to payment of the amount envisaged for the surveillance phase, in accordance with the MTIC Tariff in force.
Otherwise, MTIC suspends the surveillance activity, notifying the competent Authority and the other Notified Bodies. The continuation of the suspension of the surveillance activity entails, in the case of the Quality System approved pursuant to the Directive, the subsequent revocation of the Statement of Approval.

4. Certification process

4.1. Presentation of the certification application

The Customer must submit the application by completing the appropriate form distributed by MTIC.
In particular, the Customer must specify in this form the classification of the devices covered by the application (Article 9 and Annex IX of the Directive) as well as the procedures chosen for the assessment of conformity (Article 11 of the Directive).
The documentation required in the certification application must be attached to each question.
Further documentation may also be attached to the application (for example: certificates, declarations of approval, test reports, reports attesting the conformity of the devices or their quality systems).
Upon receipt of the request, MTIC will examine it, for the purposes of its acceptance.

4.2. Approval of the Quality System

Where approval of the Quality System is required according to one of the procedures described in Annexes II (excluding point 4), V and VI of the Directive, the Customer may submit only one application for homogeneous types of devices, provided that such application is accompanied by appropriate documentation designed to support the applied homogeneity criteria. The final judgment on the possible aggregations in the same question belongs to MTIC.

The presentation of the application according to one of the aforementioned procedures implies the automatic acceptance by the Customer of the activation of the continuous surveillance procedures, including the unannounced visits.

Once accepted, MTIC examines the technical product documentation (where applicable) and the Quality System to assess compliance with the requirements of the Directive.

In the case of class I devices placed on the market in sterile packaging or class I devices with measurement function, the conformity assessment is relative respectively:

- only aspects of manufacturing that concern the achievement and maintenance of the sterile state;
- only aspects of manufacturing that relate to compliance with metrological requirements.

At the conclusion of the evaluation activity, if the Quality System complies with the requirements of the Directive, MTIC issues the relevant Certification to the Customer.

4.3. EC Type Examination

If an EC type examination is required according to the procedure described in Annex III of the Directive, the Customer must submit a separate application for each type of device, ie for each specimen representative of a specific production. The type may also include product variants, as long as they do not involve different types of risks with respect to the essential requirements of the Directive.

Once accepted, MTIC will draw up a specific test plan and notify the customer of the number of copies of the type that must be provided free of charge for the compliance examination. On these specimens and on the related documentation, MTIC will carry out the appropriate tests and verifications as well as the necessary examinations, according to the provisions of point 4 of Annex III of the Directive.

At the conclusion of the evaluation activity, if the type complies with the requirements of the Directive, MTIC issues the Customer with the EC Type Examination Certificate.

Whatever the outcome of the exam, MTIC keeps a copy of the documentation attached to the application. The devices tested, if returned, are sent to the Customer - at his expense - in the conditions in which they are found after the tests.

MTIC reserves the right to request that the Customer store the samples subjected to testing, or parts of them, duly marked or sealed, at their premises.

4.4. EC Verification

If the EC verification is required according to the procedure described in Annex IV of the Directive, the Customer must specify whether it intends to proceed with the verification by checking and testing of each device or the statistical verification.

Depending on the choice made, the Customer proposes a plan for carrying out the checks, a program that MTIC reserves the right to accept.

In case of acceptance, MTIC carries out the checks in the set times; in case of non-acceptance, MTIC communicates to the Customer the relative reasons and asks for a new plan to be submitted.
Unless otherwise agreed, the CE verification will be carried out at the Customer's site. However, MTIC has the right to request that some or all of the tests be carried out at its own laboratories.
In this case, the Customer undertakes to deliver the products concerned to MTIC free of charge; these samples will then be returned, at tests carried out, in the condition in which they are found after the tests themselves, at the Customer's expense and risk.

4.4.1. Verification for checking and testing of each device

Once the application is accepted, MTIC plans the verification and defines the specific test plan.
On each device and on its documentation, MTIC will carry out the appropriate tests and verifications, according to the provisions of points 4 and 5 of Annex IV of the Directive.
At the conclusion of the evaluation activity, if the devices are compliant with the requirements of the Directive and the technical documentation, MTIC issues the Customer with the EC Verification Certificate, which will specify the products to which it refers.
If one or more of the tested devices were found to be non-compliant with the requirements of the Directive, MTIC will inform the Customer in writing and take appropriate measures to prevent them from being placed on the market.

4.4.2. Statistical verification

Once the application is accepted, MTIC plans the verification and defines the specific test plan. The criteria for accepting the lot are those established by the Directive.
On this lot and on the related documentation, MTIC will carry out the appropriate tests and verifications, according to the provisions of points 4 and 6 of Annex IV of the Directive.
At the conclusion of the evaluation activity, if the lot complies with the requirements of the Directive and the technical documentation, MTIC issues the Customer an EC Verification Certificate, related to the lot itself.
If the lot is rejected, MTIC will inform the Customer in writing and take appropriate measures to prevent the lot from being placed on the market.

4.5. Outcome of the certification activity

In the performance of certification activities, non-conformities may be detected, defined as failure to meet a requirement or deviation from the reference specifications and classified in:

- Major Non-Conformity: non-conformity related to the requirements of the Directive and applicable legislation, which affects the safety of the device and / or the integrity of the Quality System;
- Minor non-conformity: non-conformity related to the requirements of the Directive and applicable legislation, which does not affect the safety of the device and the integrity of the Quality System.

Furthermore, MTIC can detect opportunities for improvement, which however do not fall within the classification of non-compliance described above.
MTIC informs the Customer about the Non-conformities found during the evaluation activity. The Customer must present, within the term indicated by MTIC, the documentation and / or copy with the appropriate modifications to the resolution of these remarks; the cost for repeating the evaluation will be charged to the Customer.

In the event that the Customer does not proceed in this sense, the application will be considered lapsed and MTIC will inform the competent Authority.

MTIC determines the outcome of the certification activity by applying the principles set out below:

- In the absence of non-compliance, MTIC decides to issue the certification.
- If Non-conformances are detected Minor whose combination does not compromise the safety of the device and the integrity of the Quality System, MTIC asks the Customer to present, within 15 working days, the plan of the corrective actions adopted for the minor Non-conformities detected, with indication of the time required for resolution. MTIC must verify the corrective actions and the timing proposed by the Customer and, if accepted, MTIC decide to issue the certification. The verification of the effectiveness of the corrective actions will be evaluated by MTIC during the surveillance audit. In the event that the customer does not proceed in this sense, MTIC will suspend the certification.
- If major non-conformities or non-conformities are detected Minors whose combination could compromise the safety of the device and / or the integrity of the Quality System, MTIC suspends the decision on the certification until the result of the verification of the effectiveness of the corrective actions made by the Customer which must be completed within a maximum of 6 months from the date of detection of the non-conformities. Within 6 months from the date of detection of non-conformity MTIC will have to carry out a further supplementary assessment activity; the cost of this activity will be charged to the Customer. In the event that the Customer does not proceed in this sense, the certification will be refused and MTIC will inform the competent Authority. If the Customer provides evidence of resolution of the Non-conformities and demonstrates compliance with the requirements of the Directive, MTIC decides to issue the certification. On the contrary, MTIC deliberates the refusal to certify giving information to the competent Authority.
- If Major Non-conformities and / or Non-conformances are detected Minors whose combination compromises the safety of the product and / or the integrity of the Quality System, MTIC resolves the refusal to certify providing information to the competent Authority.
- If improvement opportunities are formulated, it is not necessary for the Customer to send MTIC the related corrections, corrective and / or preventive actions; during the subsequent audit, the Customer will be asked to provide evidence of the taking in charge of such reports, or to motivate the eventual decision not to take any action.

4.6. Interruption of the certification process

After twelve months (12) from the acceptance of the application, without the Customer being able to demonstrate the compliance, possibly also in more integrative evaluation activities, the process is interrupted and the Certification Contract with the Customer is canceled.
If the Certification is not issued, the reasons are communicated to the Customer and the minimum time deemed necessary is indicated before being able to proceed with a new evaluation.

4.7. Duration of validity of the Certificates

320/5000

The Certificates issued by MTIC have the time validity indicated in the following table, which is confirmed following the successful completion of the surveys required by the individual conformity assessment procedures requested by the Manufacturer when the application was submitted..

Certificate	Validity	Surveillance
Complete quality assurance system (Annex II)	5 (five) years	- Annual - Without notice par. 6.3
EC Verification (Annex IV)	Never Expires	No Surveillance
Production quality assurance (Annex V)	5 (five) years	- Annual - Without notice par. 6.3
Product quality assurance (Annex VI)	5 (five) years	- Annual - Without notice par. 6.3

5. Compliance with the customer

5.1. Customer's obligations

The Customer undertakes to:

- guarantee the constant compliance of the device and / or the quality system with the requirements of the Directive;
- undergo the ordinary / extraordinary audits required for the maintenance / renewal of the certification, in the terms indicated by MTIC;
- promptly notify MTIC of any changes to the device or the quality system or the field of application of the certification (eg changes of location, activities, organizational changes, etc.); in such cases, MTIC may order the performance of one or more additional checks (the cost of which is charged to the Customer), proceeding if necessary with the formulation of an updated offer;
- not to make any declaration or to advertise their certification in such a way as to be considered misleading or unauthorized, or use their own certification in order to discredit MTIC;
- as part of the Management System, where applicable, keep a record of complaints and corrective actions and, where required by MTIC, provide evidence of the related management;
- in relation to the MTIC qualification status, to allow access to the competent Authority's inspectors, so that they perform the verification activities required by the applicable provisions;
- immediately notify MTIC of any non-compliant situations detected by the Control Authorities, as well as any suspensions or revocations of authorizations, concessions, etc .;
- immediately notify MTIC of any ongoing judicial / administrative proceedings concerning the subject of the certification, subject to the limits imposed by the provisions;
- communicate at the beginning of the year to MTIC the periods of the year in which the production of the devices subject to certification is not expected to be carried out.

The Customer must establish and implement a systematic procedure for evaluating the experience acquired in the use of the devices after their production, as well as providing an appropriate system of corrective actions, in particular in the case of accidents occurring during the use of the devices.

The Customer must also immediately inform the competent Authority upon the occurrence of the incidents as identified in the Directive (Annex II point 3.1; Annex IV point 3; Annex V point 3.1; Annex VI point 3.1); these reports must also be simultaneously transmitted to MTIC, via certified mail.
The Customer must allow the personnel appointed by MTIC to access the production, control and testing rooms and the warehouses, accompanied, where appropriate, by officials from the competent Authority.
In relation to the fulfillment of the obligations envisaged in this point, MTIC may perform extraordinary control visits for valuable consideration, and possibly adopt certification suspension or revocation measures, based on the gravity of the situation and / or the impact of the event occurred.

6. Continuous monitoring

6.1. Generality

The maintenance of the Certificates issued by MTIC pursuant to Annexes II, except for point 4, V and VI of the Directive, is subject to the Customer's willingness to undergo continuous surveillance and the positive outcome of such control activities performed by MTIC.

6.2. Periodic monitoring of the approved Quality System

MTIC periodically carries out surveillance visits to ensure that the Customer maintains and applies the approved Quality System.
The surveillance audits must be carried out every 12 months, always calculated from the date of issue of the certification (eg the first surveillance at 12 months, the second at 24 months, etc.).
Failure to carry out surveillance audits entails the suspension of the certification for a maximum period of 6 months. The delayed execution of a surveillance audit does not produce effects in the calculation of the date of the subsequent audit activity (always calculated starting from the date of issue of the certification).
In the presence of serious and justified reasons it is possible to postpone the surveillance verification for 30 days.
These visits are announced in advance to the Customer, who undertakes to allow MTIC all the necessary inspections, both at its premises and at those of its subcontractors and critical suppliers, if deemed necessary to ensure effective control; the Customer also undertakes to make available to evaluators all useful information, in particular the technical documentation, the documents relating to the Quality System and the registrations made regarding quality.

6.3. Unannounced checks

MTIC also carries out, at least once every five (5) years, unannounced inspections (unannounced inspections) at each Customer. This frequency can be increased if the medical devices subject to the certification present a high potential risk (eg medical devices in class III), are often non-compliant or if specific information leads them to believe that they or the relative Quality System have non-conformities .
In general, unannounced inspections last at least one day, are performed by at least two assessors and are conducted at the Customer's premises; in place of or in addition to these, they can be conducted at the premises of subcontractors or critical suppliers, if this can guarantee greater control effectiveness. If a visa is required to visit the country where the customer is located, an invitation must be provided with the date of the signature and the date of the visit open, to allow the audit to be conducted without prior notice. Similar invitations must be issued by subcontractors and critical suppliers.

To allow the effectiveness of the visit, the Client must communicate, with the necessary frequency, to MTIC the periods of the year in which the production of the medical devices covered by the certification is not envisaged, with particular attention to company closures, holidays, etc.
The Customer must have documented practices or procedures to manage the verifications without notice in accordance with the Commission Recommendation of 24 September 2013 (2013/473 / EU).
On the occasion of unannounced visits, MTIC performs checks on an adequate sample of recent manufacture, preferably a device taken from the current manufacturing process, in order to ascertain compliance with the technical documentation and the provisions of the law with tests. These tests may also be carried out by the Customer, a subcontractor or a critical supplier, under the supervision of MTIC.
They are charged to the Customer, according to the MTIC rates:

- the costs of unannounced inspections - including, if necessary, those for the activity of acquiring the device and for the tests performed on it and the safety devices;
- the costs of any unannounced inspections that MTIC was unable to carry out due to a lack of the above communications by the Customer.

Furthermore, in the event that permanent access without notice to the Customer's premises, its subcontractors or critical suppliers is lost, MTIC is authorized to terminate the existing Certification Agreement.

6.4. Outcome of the continuous surveillance activity

Following the checks referred to in points 6.2 and 6.3, MTIC issues appropriate documentation (audit report) with the results of the activities performed and the conclusions reached.
If Non-Conformances are detected in the approved Quality System, or in a device covered by CE certification, the Customer must adopt the appropriate corrections and corrective actions; these actions must be communicated to MTIC within the set deadlines, specifying implementation times and related responsibilities. The proposed actions are considered accepted if MTIC fails to send the Customer, within 30 calendar days from the date of receipt of the same, a specific request for integration or modification.
If Non-conformances are detected Minor whose combination does not compromise the safety of the device and / or the integrity of the system, the verification of the implementation and effectiveness of the corrections and corrective actions will be carried out by MTIC in the subsequent continuous surveillance audit. The Customer must in any case provide the plan of corrections / corrective actions he intends to take to resolve the non-conformities within 15 working days.
Whenever Major and / or Non-conforming Non-conformities are detected Minors whose combination compromises the safety of the product and / or the integrity of the system, MTIC suspends the Certification and warns the Customer to continue the production and supply to the market of all products covered by it.
Within a maximum of 6 months from the date of detection of non-conformities, the customer must provide evidence of the effectiveness of the corrective actions implemented.
The suspension will be canceled only after MTIC has ascertained that the technical measures have been adopted to guarantee future compliance. If the suspension cannot be canceled within six (6) months, MTIC will revoke or limit the EC certifications concerned.
MTIC also informs the competent Authority according to the provisions of the Directive.
If improvement opportunities are formulated, it is not necessary for the Customer to send MTIC the related corrections, corrective and / or preventive actions; during the subsequent audit, the Customer will be asked

to provide evidence of the taking in charge of such reports, or to motivate the eventual decision not to take any action.

7. Renewal of certification

The Customer must submit to MTIC the request to renew their validity within six (6) months from the expiry (5 years for the EC certifications issued according to Annexes II, except for point 4, III, V, VI). This term is also applicable in cases where the certification is suspended.

7.1. Submission of the renewal application

The Customer must submit the renewal application by completing the appropriate distribution form at MTIC and provide the necessary documentation as indicated in the form itself.
Upon receipt of the request, MTIC will examine it, for the purposes of its acceptance.
Failure to carry out the renewal activities within the certification validity term, involves the resolution of the certification Contract as from the day following the certificate's expiry date.

7.2. Certification renewal

Where the renewal of the Certification is required, MTIC reviews the technical product documentation based on representative samples (where applicable) and the approved Quality System to verify that they continue to comply with the requirements of the Directive.
With particular attention the following elements will be evaluated:

- the effectiveness of the Management System as a whole, in light of internal and external changes, and its continued relevance and applicability to the field of application of the certification;
- the effectiveness of the management system in reference to the achievement of the organization's objectives and expected results;
- the commitment shown to maintain effectiveness and improvement.

If the Quality System complies with the requirements of the Directive, MTIC renews the relevant Certification to the Customer.

7.3. Certificate renewal EC type examination

If the renewal of the EC type examination certificate is required, MTIC verifies that the certified type continues to comply with the requirements of the Directive.
The renewal activity includes the general review of the technical documentation of the product and the repetition of all the tests and checks carried out on the device in the initial certification phase.
If the type complies with the requirements of the Directive, MTIC renews the EC Type Examination Certificate to the Customer.

7.4. Outcome of the certification renewal activity

MTIC determines the outcome of the certification renewal activity by applying the same principles adopted for the issue of the initial certification (ref. Point 4.5).
Following the positive outcome of the renewal activities, the certificate is reissued; the costs of each re-issue of the certificate are charged to the Customer.

Following the negative outcome of the certification renewal activity or if this activity is not completed by the expiry date of the certificate, the latter loses its validity.

8. Use of EC certifications

8.1. Generality

On devices that have obtained the CE certifications from MTIC according to the following procedures:

- Certification (complete quality assurance system), provided in Annex II (excluding point 4) of the Directive;
- EC verification, foreseen in Annex IV of the Directive;
- Certification (Quality assurance of production), provided for in Annex V of the Directive;
- Certification (Product Quality Assurance), as per Annex VI of the Directive,

the EC marking is affixed by the Customer, according to the methods set forth in Article 16 of the Directive. This marking must be followed by the number 0068, MTIC identifier as Notified Body, to attest the MTIC intervention in the continuous surveillance phase.
For devices that have obtained the EC certification from MTIC according to the procedure set out in Annex III of the Directive (EC Type Examination), the Customer must subsequently obtain a further certification according to one of the procedures relating to the production phase (Annexes IV, V and VI of the Directive, taking into account the classification of devices), before affixing the ECmarking.
The affixing of the EC marking and the use of the EC certifications are incorrect when they can mislead the buyer on the nature, the quality, the origin of the device and in particular when the Customer has not satisfied the obligations specified by this Regulation.
It is forbidden to put marks or inscriptions on the devices that may be confused with the CE marking.
The Customer must unequivocally distinguish his EC marked devices from those that do not.

9. Sospensione, limitazione, revoca e rinuncia alla certificazione

9.1. Sospensione della certificazione

The CE certificates can be suspended by MTIC as a result of non-fulfillment by the Customer, and in particular:

- in the event of non-compliance, resulting in serious negligence, of the commitments undertaken with regard to maintaining the conformity of the product and the quality system;
- non-fulfillment by the Customer of the obligations provided for in the general contractual conditions;
- in the cases provided for in points 4.5, 6.4 and 7.4 above;
- in the case of embezzlement of the CE marking (ref. Point 8.1).

The suspension provision will take into account the principle of proportionality and may be canceled as soon as the Customer proves to have satisfactorily adopted the appropriate corrective measures, or in the event that the situation that gave rise to the suspension provision ceases. The suspension of certification and any provision for restoration are communicated to the Customer by registered letter with return receipt. or other modality valid for the purposes of the law.
During the suspension period:

- MTIC may suspend the surveillance activity referred to in paragraph 6 above, except as provided in point 6.3;
- MTIC communicates the suspension order to the competent Authority;
- the Customer cannot use the certificate (s) obtained and the marks referred to in point 8, unless otherwise indicated by MTIC, or qualify as a certified Organization;
- the Customer is still required to pay the amounts for the maintenance of the certification.

Before proceeding with the restoration of the certification, MTIC can carry out documentary checks and / or visits to the Customer in order to ascertain the effective resolution of the problems previously encountered; all costs related to these additional checks are charged to the Customer.
The duration of the suspension, which cannot exceed six (6) months, is indicated in the communication sent by MTIC to the Customer; once this period has elapsed without the suspension being able to be canceled, the certification is revoked.

9.2. Limitation and / or revocation of the certification

146/5000
The CE certificates can be revoked or subjected to limitation by MTIC as a result of non-fulfillment by the Customer, and in particular:

- in the event of Customer's bankruptcy or cessation of activity;
- serious non-compliance with the commitments made with respect to the general contractual conditions and point 6 of this regulation;
- in the event of failure to pay the amounts due to MTIC. In this case, before proceeding with the revocation, MTIC will send the Customer a warning notice; once a month has elapsed from such communication without the Customer having paid the balance of the amounts due, the certificate is revoked. During this period of notice all verification activities are suspended, similarly to what happens in the hypothesis of suspension;
- in the event of non-compliance, resulting in serious negligence, of the commitments undertaken with regards to maintaining the conformity of the devices and / or the quality system;
- serious irregularities or abuses in the use of the certificate and / or CE marking;
- failure by the Customer to adapt to regulatory and / or regulatory changes;
- suspension of the certification that exceeds six (6) months.

The provisions for limitation or revocation of the certification are communicated to the Customer by registered letter with return receipt. or other modality valid for the purposes of the law.
In the event of revocation, the Customer is required to immediately cease the application of the CE marking for the devices concerned and to eliminate any reference to the relevant attestations in catalogs and advertising in general.
MTIC will provide appropriate information on what has been implemented, in particular to the competent Authority and - upon request - the other Notified Bodies.
In the case of the presence on the market of a device for which the CE certification has been revoked due to defects that could represent a danger for the users, MTIC can invite the Customer to withdraw from the

market all the units of the same device, informing in each case the competent Authority and the other Notified Bodies.

9.3. Renounce

If the Customer wishes to renounce permanent control by MTIC (Quality System surveillance), he must give written notice with at least one (1) month's notice, also committing himself:

- to cease to affix the CE marking accompanied by the MTIC identification number (0068) and in any case to refer to MTIC as a Notified Body;
- to use up the devices involved in their plants or warehouses within the time limit set by MTIC;
- to communicate, three (3) days before the date of the last validity of the CE Certificate issued, the serial number or the batch of the last devices sold.

If the Customer wishes to cancel an EC Type Examination Certificate issued by MTIC, he must give written notice. This communication automatically entails the cancellation of the relative surveillance activity, if carried out by MTIC; in this case, the provisions of the preceding paragraph apply.
MTIC will cancel the EC certifications issued, informing the competent Authority of the renouncement and - upon request - the other Notified Bodies, according to the provisions of the Directive.
MTIC will also remove the name of the related types from the list of CE certified devices.

10. Change of notified body

A customer in possession of product certification issued by a Notified Body can request the certification, for the same product, from MTIC provided that the certification with the previous body expires.
The Customer must therefore provide MTIC with evidence of the cancellation sent to the previous Notified Body or a copy of the certificate which shows that the same has lapsed. The latter is an indispensable condition for the issue of the MTIC certificate.
The procedures for passing the certification of the other MTIC Body are always agreed with the Customer during the offer phase.

11. Certification procedure O.B.L

If a manufacturer (hereinafter OBL) requests the certification of a device already certified for the same intended use by another manufacturer (hereinafter OEM), created by the OEM for the OBL with the intent of entering it in its own name , MTIC can begin the certification procedure provided the following requirements are met:

- there is a contract between the OEM and the OBL in which the reciprocal responsibilities are clearly defined and the readiness of the OEM to declare the technical documentation relating to the product subject to certification available to the Competent Authority and MTIC were necessary; moreover the contract must declare the willingness to receive checks by MTIC and the Competent Authority;
- clear and irrefutable evidence of OEM certification is produced and that this certification does not in turn derive from a practical OBL;
- the OBL prepares an appropriate technical file complete with all its parts, in which documents compliance with the requirements of its relevance and implements a quality system in compliance

with the requirements of the attachment for which it requires certification and is consistent with the classification of the device certified by the OEM and with the evaluation procedure always chosen by the OEM. The technical file prepared may refer to tests relating to the product to be certified in the name of the OEM.

MTIC will begin a certification process in accordance with this regulation.
Any certificate issued by MTIC to the OBL will in any case be subject to the validity of the OEM certificate of conformity.
In the event of any suspension or revocation of the OEM certificate, the certificate will be contextually and immediately suspended or revoked also at the OBL.

12. Extraordinary checks

The customer, in the event that the evaluation results require extraordinary inspections / tests, or other extraordinary assessment activities for:

a) Checks following reports or complaints received deemed to be particularly significant regarding the subject of the certificate and its compliance with the reference standards and applicable regulations, or
b) Verification of changes made by the client to the subject of the certificate and considered relevant by MTIC, or
c) As a consequent action against customers whose certification has been suspended, or
d) Verification of the implementation and effectiveness of the processing of non-conformities and corrective actions implemented by the customer, or
e) In the face of necessity that emerged when the certificate was issued,
f) The restoration of the validity of the certificate following a suspension,
g) Where envisaged by the applied legislative instrument,

It is stated from now on that the same are carried out in order to allow the correct execution of the service.
In cases a), b), c) above, MTIC reserves the right to carry out extraordinary audits even without, or at short notice, excluding, or limiting, the possibility to challenge the assessors appointed by MTIC.
In case of refusal of extraordinary verifications, without valid reasons, by the customer, MTIC can block the certification process or start the process of suspension / revocation of the certification issued as established in the applicable contractual conditions.
All expenses related to any extraordinary checks are to be considered at the customer's expense; Exception is made for extraordinary checks following reports or complaints that will be charged to the customer only if they are considered justified by MTIC.
The rate applied will be the one contractually defined for the ordinary activity.