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1. Foreword

Refer to the General Terms and Conditions (RG-GQ-01-01) posted on the website www.mtic-group.org under the "About Us" section regarding:

- Purpose
- Scope of application
- General terms and conditions
- Certification contract
- Duration of the contract - termination
- Impartiality and conflict of interest
- Subject of the audit and reference standard
- Ability to use external resources
- Rights and obligations of **MTIC**
- Rights and obligations of the client
- Access to information
- Duty to inform about legal proceedings
- Inspection and safety in the workplace
- Economic conditions
- Additional audits
- Suspension of system, product and personnel certificate
- Withdrawal of system, product and personnel certificate
- Limitation of certification and liability
- Limitations of liability and charges
- Forfeiture clause
- Indemnification and hold harmless
- Force majeure
- Withdrawal, suspension, revocation of accreditation (where applicable)
- Professional secrecy, confidentiality and privacy
- Privacy policy
- Complaints and appeals
- Confidentiality and protection of intellectual and industrial property
- Management of changes
- Certificate vultures
- Register of certificates and record keeping
- Administrative responsibility of legal entities

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

2. Purpose and scope

These regulations define rules and procedures for the provision of the certification service put in place by MTIC INTERCERT S.r.l. (hereinafter **MTIC**) in accordance with the provisions of Regulation (EU) 2017/745 (hereinafter MDR).
The regulations specify the rights and duties of the Customer and **MTIC** in the certification process under the MDR without prejudice to what is provided in the General Contractual Conditions referred to in Chapter 1. Where there are provisions in these regulations that conflict with what is stated in the General Contractual Conditions, what is stated in these regulations shall prevail.
These Regulations apply to medical devices and related accessories (hereinafter, "devices"), for which **MTIC** has obtained appropriate authorization to carry out the relevant conformity assessment procedures.
For the purposes of these Regulations, EU certifications are defined as all conformity assessment and attestation activities, according to the different procedures provided for in Article 52 of the MDR. The documents issued by **MTIC** in this area are:

- Conformity assessment based on quality management system and technical documentation evaluation (Annex IX);
- Conformity assessment based on type examination (Annex X);
- Conformity assessment based on product conformity verification-Product quality assurance (Annex XI Part A);
- Conformity assessment based on product conformity verification-Product verification (XI Part B).

MTIC excludes the possibility of performing conformity assessment activities for manufacturers based in the U.S., Canada, Belarus, and Russia or using outsourcers based in the U.S., Canada, Belarus, and Russia.

3. General conditions

3.1. Contract

The contract shall be deemed to have come into force and binding for all legal purposes when the Device Manufacturer or its European Authorized Representative (hereinafter "the Client") has accepted in writing the quotation within the relevant validity period and MTIC has confirmed in writing the Client's order (hereinafter, the "Certification Contract").
Submission of the Application for Certification also implies full acceptance of these Rules, which form an integral part of the Certification Agreement.

3.2. Certification activities

The Customer who intends to use MTIC to issue EU certifications related to its devices is responsible for the destination assigned to each device and its classification according to the criteria given in Annex VIII of the MDR.
MTIC is responsible for verifying that what the Customer has indicated is correct and complies with the reference requirements.
In the event of a dispute between the Customer and **MTIC**, arising from the application of Annex VIII, the provisions of Article 51, paragraph 2 of the MDR shall apply.

It is the prerogative of the Customer to choose the conformity assessment procedure to be followed in order to be able to affix the CE marking to their devices in accordance with Article 52 of the MDR.
The Customer may not publicize the current application until the positive outcome of the relevant conformity assessment activities.
Tests and verifications on devices and assessments of the Customer's Quality Management System are performed by **MTIC**; in addition to its own resources, **MTIC**, while still retaining full responsibility for the assessment activity and giving prior information 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 the competent Authority.
The Customer may object to the choice of such external resources, demonstrating any conflicts of interest of the same with the activities subject to assessment.
In the course of its activities, **MTIC** reserves the right to recognize documents issued by other Notified Bodies under the MDR, such as certificates, approval statements, test reports, reports attesting the conformity of devices or quality systems.

3.3. Obtaining and maintaining certification

Certification, and its updating where applicable, is contingent upon:

- to the Customer's willingness to undergo routine and additional evaluations, documented and at the Customer's own and/or other involved locations (e.g., the locations of the Customer's critical subcontractors and suppliers), within the timeframes provided and indicated by **MTIC**;
- upon successful completion of the above conformity assessment activities, performed by **MTIC**;
- to the payment of the amounts due, for any reason, to **MTIC** (e.g., for certification issuance and renewal activities, for variation/reissue of certificates, etc.)..

The maintenance of any type of Certificate and the performance of any surveillance activity are subject to the payment of the amount provided for the surveillance phase, as provided in the current **MTIC** Tariff Schedule.
Otherwise, **MTIC** shall suspend the surveillance activity, notifying the Competent Authority and other Notified Bodies by means of the Electronic System (Eudamed) provided by the MDR. Continued suspension of surveillance activity shall result, in the case of a quality management system certified under the MDR, in the subsequent revocation of the certificate.

4. Certification process

4.1. Submission of application for certification

The Customer must submit the application by completing the appropriate form available at www.mtic-group.org or upon request from **MTIC**.
In particular, the Customer must specify in that form the classification of the devices being applied for (Art. 51 and All. VIII of the MDR) as well as the procedures chosen for conformity assessment (Art. 52 of the MDR).
The documentation required in the application for certification itself must be attached to each application.
Additional documentation may also be attached to the application (e.g.: certificates, approval statements, test reports, reports attesting to the conformity of the devices or their quality systems).

Upon receipt of the application, **MTIC** will review the application for acceptance.

4.2. Quality management system certification

Where certification of the quality management system is required according to one of the procedures described in Annexes IX (Chapter I) and XI (Part A) of the MDR, the Client may submit only one application for homogeneous types of devices, provided that this application is accompanied by appropriate documentation to support the homogeneity criteria applied. The final judgment on possible aggregations in the same application rests with **MTIC**.
Submission of the application according to any of the above procedures implies automatic acceptance by the Customer of the activation of continuous surveillance procedures, including unannounced audits.
Upon acceptance of the application, **MTIC** reviews the technical product documentation (where applicable) and the Quality Management System to assess its compliance with the requirements of the MDR.
If devices intended to be placed on the market are Class I and are sterile, have a measuring function, or are reusable surgical instruments, **MTIC**'s involvement in conformity assessment procedures is limited:

- in the case of devices placed on the sterile market, to aspects concerning the demonstration, achievement and maintenance of sterile status;
- in the case of devices with a measuring function, to aspects concerning the compliance of devices with metrological requirements;
- in the case of reusable surgical instruments, to aspects relating to reuse of the device, particularly to cleaning, disinfection, sterilization, maintenance, functional testing and related instructions for use.

At the conclusion of the assessment activity, if the quality management system is found to comply with the requirements of the MDR, **MTIC** will issue the relevant Certification to the Client.

4.3. Conformity assessment based on type examination

Where EU type examination is required according to the procedure described in Annex X of the MDR, the Customer must submit a separate application for each type of device, i.e., for each representative specimen of a given production. The type may also include product variants, as long as these variants do not pose different types of risk to the general safety and performance requirements of the MDR.
Upon acceptance of an application, **MTIC** shall draw up a specific test plan and notify the Customer of the number of specimens of the type to be provided free of charge for conformity examination. On these specimens and the relevant documentation, **MTIC** shall carry out the appropriate tests and verifications as well as the necessary examinations, in accordance with point 3 of Annex X of the MDR.
At the conclusion of the evaluation activity, if the type is found to comply with the requirements of the MDR, **MTIC** shall issue the EU Type Examination Certificate to the Customer.
Whatever the outcome of the examination, **MTIC** shall retain a copy of the documentation attached to the application. Tested devices, if returned, shall be shipped to the Customer - at the Customer's expense - in the condition they are in after testing.
MTIC reserves the right to request that the Customer keep the tested samples, or parts thereof, duly marked or sealed, at its premises.

4.4. Conformity assessment based on the verification of product conformity

Where conformity assessment is required according to the procedure described in Annex XI of the MDR Regulations, the Client must specify whether it requires applying the production quality assurance procedure, Annex XI (Part A), or the product verification procedure, Annex XI (Part B).

4.4.1. Assurance of production quality

Where certification of the quality management system is required in accordance with the procedure described in Annex XI (Part A) of the MDR, it shall be carried out as described in Section 4.2 of these regulations.

4.4.2. Product verification

Upon acceptance of the application, **MTIC** plans to carry out the verification and defines the specific test plan.

On each device and its documentation, **MTIC** shall perform the appropriate testing and verification on each product, as required by Annex XI (Part B) of the MDR.

Unless otherwise agreed, product verification will be performed at the Customer's premises. However, **MTIC** has the right to request that some or all of the tests be performed at its own laboratories.

In this eventuality, the Customer agrees to deliver to **MTIC** the products concerned, free of charge; these products will then be returned, after the tests have been carried out, in the condition in which they are found after the tests, at the Customer's expense and risk.

At the conclusion of the evaluation activity, if the devices are found to comply with the requirements of the MDR and the technical documentation, **MTIC** will issue the EU Verification Certificate to the Customer, which will specify the products to which it refers.

If one or more of the tested devices are found to be non-compliant with the requirements of the MDR, **MTIC** shall inform the Customer in writing and take appropriate measures to prevent the same from being placed on the market.

4.5. Outcome of the certification activity

In carrying out certification activities, Nonconformities, defined as failure to meet a requirement or deviation from the reference specification and classified into:

- Major Nonconformity: nonconformity related to the requirements of the MDR Regulations and applicable legislation, which affects the safety of the device and/or the integrity of the Quality System;
- Minor Nonconformity: nonconformity related to the requirements of the MDR Regulations and applicable legislation, which does not affect the safety of the device and/or the integrity of the Quality System; and.

In addition, **MTIC** may detect opportunities for improvement, which, however, do not fall under the classification of Nonconformity described above.

MTIC shall inform the Customer about the Nonconformities found during the evaluation activity. The Customer shall submit, within the deadline specified by **MTIC**, the documentation and/or specimen with the appropriate changes to resolve these findings; the cost for the re-evaluation will be borne by the Customer.

In the event that the Customer fails to do so, the application will be deemed forfeited and **MTIC** will notify the competent authority by means of the Electronic System (Eudamed) provided by the MDR.

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

- In the absence of Nonconformities, **MTIC** will deliberate the issuance of certification.
- If nonconformities (major or minor) are detected, the Customer must submit to **MTIC** the analysis of the causes and the planning of treatments and corrective actions, with an indication of the expected timeframe for resolution, within 15 working days.
- The proposed actions are deemed accepted if **MTIC** does not send the Customer, within 30 calendar days from the date of their receipt, specific request for supplementation or modification.
- If Minor Nonconformities are detected, the combination of which does not affect the safety of the device and the integrity of the Quality System, the Customer shall submit, within the established timeframe, the plan of treatments and corrective actions to be taken with an indication of the expected timeframe for resolution. Thereafter, the Client submits evidence of the treatments of nonconformities within the proposed timeframe. **MTIC** suspends the decision on certification until the outcome of additional assessment activities of the treatments to be completed within 6 months from the date of detection of nonconformitieswithin 15 working days, the plan of corrective actions to be taken for any Minor Nonconformities not yet resolved, with an indication of the expected timeframe for resolution.
- If Major Nonconformities or Minor Nonconformities are detected whose combination could jeopardize the safety of the device and/or the integrity of the Quality System, **MTIC** suspends the decision on certification until the outcome of a further activity of integrative assessment of treatments and corrective actions, to be completed within 6 months from the date of detection of nonconformities.
- If the Client fails to submit an adequate treatment and corrective action plan to **MTIC** within the timeframe described above, **MTIC** may decide to halt the evaluation process, resolving to deny EU Certification and require the administrative balance of the activity performed.
- If the Client provides evidence of resolution of Nonconformities and demonstrates compliance with MDR requirements, **MTIC** takes this into account when deciding on the issuance of certification. Otherwise, it deliberates the refusal to certify by providing information to the Competent Authority.
- If opportunities for improvement are formulated, it is not necessary for the Client to forward the relevant corrections, corrective and/or preventive actions to **MTIC**; during the subsequent audit, the Client will be asked to provide evidence that these reports have been taken into account, or to justify any decision not to implement any action.
- **MTIC**'s Deliberation Committee has the right to reclassify the findings issued by the audit team, or request additional evidence to that already provided; in this case, the Client and the audit team are notified within 30 working days of the date of conclusion of the audit. This may also be the case if the client has already submitted to **MTIC** proposed treatment and corrective actions of the findings. After the deadlines have passed, if **MTIC** does not send the manufacturer a written communication rectifying the findings contained in the Report, the same shall be deemed confirmed.

4.6. Discontinuation of the certification process

After twelve months (12) have elapsed from the acceptance of the application, without the Customer having been able to demonstrate compliance, possibly even in more than one supplementary evaluation activity, the process is discontinued and the Certification Contract with the Customer is cancelled, unless an extension is granted by **MTIC** based on justified reasons.
In the case of non-issuance of Certification, the reasons are communicated to the Customer and the minimum time deemed necessary before a new evaluation can be carried out is indicated.

4.7. Duration of validity of Certificates

The Certificates issued by **MTIC** have the maximum time validity indicated in the table below, which is confirmed following successful completion of the surveillance required by the individual conformity assessment procedures requested by the Manufacturer when submitting the application.

Certificate	Duration Validity	Surveillance
Quality Management System (Annex IX)	5 (five) years	- Annual - Unannounced par. 6.3
EU Type Examination (Annex X)	5 (five) years	No surveillance
Assurance of production quality (Annex XI Part A)	5 (five) years	- Annual - Without notice par. 6.3
Product Verification (Annex XI Part B)	No deadline	- Annual - Without notice par. 6.3

5. Accomplishments to be borne by the client

5.1. Obligations of the Client

The Client agrees to:

- Ensure continued compliance of the device and/or quality management system with the requirements of the MDR Regulations;
- Undergo the ordinary/ordinary audits required for the maintenance/renewal of certification, within the terms specified by **MTIC**;
- Inform the body without delay of substantial changes related to:
  - Approved quality management system or product range covered,
  - Of the approved design for the device,
  - Of the intended use of the device or the statements made about the device,
  - Of the approved type of the device,
  - Of any substance included in or used for the manufacture of a device and subject to the specific procedures set forth in Section 4.5.6 of the MDR Regulations.
- Wait for **MTIC**'s evaluation of the changes before making them operational and provide procedures for managing the changes.

MTIC may arrange for one or more additional audits (the cost of which is borne by the Customer) to be conducted, proceeding if necessary to formulate an updated offer.
With respect to the above, **MTIC** follows the NBOG guideline BPG 2014-3;

- not make any statement or publicize its certification in a way that could be considered misleading or unauthorized, nor use its certification in a way that brings discredit to **MTIC**;
- as part of the Management System, where applicable, keep records of complaints and corrective actions and, where requested by **MTIC**, give evidence of their management;
- in relation to **MTIC**'s enabling status, allow access to inspectors of the Competent Authority to perform the verification activities required by the applicable provisions;
- immediately notify **MTIC** of all dissimilar situations detected by the Control Authorities, as well as any suspensions or revocations of authorizations, concessions, etc.; and
- immediately notify **MTIC** of any ongoing judicial/administrative proceedings related to the subject of certification, subject to the limits imposed by the provisions;
- notify **MTIC** at the beginning of each year of the periods of the year when production of the devices subject to certification is not expected to take place.

The Customer must comply with the post-marketing surveillance requirements of the DM Regulations.
The Customer shall allow personnel assigned by **MTIC** access to the production, control and testing premises and warehouses, accompanied, where appropriate, by officials of the competent Authority.
In connection with the fulfillment of the obligations provided for in this point, **MTIC** may carry out extraordinary inspection visits for a fee, and possibly take measures to suspend or revoke the certification, depending on the seriousness of the situation and/or the impact of the event occurred.

6. Continuous surveillance

6.1. General

Maintenance of Certifications issued by **MTIC** under Annexes IX and XI (Part A) of the MDR is subject to the Client's willingness to undergo continuous surveillance and the successful outcome of such monitoring activities performed by **MTIC**.

6.2. Periodic Surveillance of the Quality Management System

MTIC periodically conducts surveillance audits to ensure that the Client maintains and implements the Quality Management System.
Surveillance audits must be conducted every 12 months, always calculated from the date of certification (e.g. first surveillance at 12 months, second at 24 months, etc.).
Failure to conduct surveillance audits will result in suspension of certification for up to 6 months. Late performance of a surveillance audit has no effect in calculating the date of the next audit activity (always calculated from the date of certification).
If there are serious and justified reasons, it is possible to postpone the surveillance audit by 30 days.
Such visits shall be announced in advance to the Client, which undertakes to allow **MTIC** all necessary inspections, both at its own premises and at those of its subcontractors and critical suppliers, when deemed necessary to ensure effective control; the Client also undertakes to make available to the evaluators all

relevant information, in particular technical documentation, documents related to the Quality Management System and records made on quality.

6.3. Unannounced audits

MTIC also conducts, at least once every five (5) years, unannounced audits at each Client. This frequency may be increased if the medical devices subject to certification present a high potential risk (e.g., Class III medical devices), are frequently found to be noncompliant, or if specific information suggests that the devices or the related Quality Management System have nonconformities.

In general, unannounced audits last at least one day, are conducted by at least two assessors, and are conducted at the Client's premises; in lieu of or in addition to these, they may be conducted at the premises of subcontractors or critical suppliers if this would ensure more effective auditing. If a visa is required to visit the country where the Client is located, an invitation must be provided with the date of signature and the date of the visit open, to enable the audit to be conducted without prior notice. Similar invitations should be issued by subcontractors and critical suppliers.

In order for the visit to be effective, the Client must notify **MTIC** as frequently as necessary of the periods of the year when the medical devices subject to certification are not scheduled to be manufactured, with particular attention to company closures, holidays, etc.

The Client must have documented practices or procedures in place to handle unannounced audits in accordance with the MDR.

During unannounced visits, **MTIC** performs checks on an appropriate sample of recent manufacture, preferably a device taken from the current manufacturing process, in order to ascertain by testing its compliance with the technical documentation and legal requirements. Said tests may also be performed by the Customer, a subcontractor, or a critical supplier, under the supervision of **MTIC**.

They are charged according to **MTIC** rates:

- the costs of unannounced audits-including, if necessary, those for the activity of acquiring the device and for the tests performed on it and the security arrangements;
- the costs of any unannounced audits that **MTIC** was unable to perform due to deficiencies in the above communications from the Customer.

In addition, in the event that permanent access to the premises of the Client, 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 audits in 6.2 and 6.3, **MTIC** issues appropriate documentation (audit report) with the findings of the activities carried out and the conclusions reached.

MTIC determines the outcome of surveillance activities by applying the principles set forth below:

- In the absence of Nonconformities, **MTIC** deliberates the maintenance of the certification.
- If non-conformities (major or minor) are detected in the approved Quality Management System, i.e., in a device covered by EU certification, the Customer must submit within 15 working days to **MTIC** the root cause analysis and treatment and corrective action planning, with an indication of the expected time frame for resolution.

- The proposed actions shall be deemed accepted if **MTIC** does not, within 30 calendar days from the date of their receipt, send the Customer a specific request for supplementation or modification.
- If the Client fails to send **MTIC** an appropriate treatment and corrective action plan within the timeframe described above, **MTIC** may decide to suspend EU Certification and demand the administrative balance of the work performed.
- If Minor Nonconformities are detected, the combination of which does not affect the safety of the device and the integrity of the Quality System, the Customer submits, within the proposed timeframe, the plan of treatments and corrective actions to be taken with an indication of the expected timeframe for resolution. Subsequently, the Customer submits evidence of the treatments of nonconformities within the proposed timeframe and **MTIC** evaluates their effectiveness. Evidence of treatments of minor nonconformities must be submitted within the timeframe proposed and accepted by **MTIC**, which in any case may not exceed 6 months from the date of surveillance. In the event that the treatments are considered unsatisfactory, or the timelines exceed the time agreed with **MTIC** or the 6-month limit, **MTIC** may decide to halt the existing certification, ruling the suspension or limitation of the EU Certification, until the outcome of the further supplementary evaluation activity of the treatments. The assessment of corrective actions, however, will be carried out by **MTIC** in the subsequent surveillance/renewal audit.
- If Major Nonconformities or Minor Nonconformities are detected, the combination of which could affect the safety of the device and/or the integrity of the Quality System, the Client submits within the proposed timeframe the plan of treatments and corrective actions to be taken with an indication of the expected timeframe for resolution. Subsequently, the Client submits evidence of the treatments and corrective actions of nonconformities within the proposed timeframe and **MTIC** schedules a supplementary audit in order to verify their effectiveness. **MTIC** may decide to halt the existing certification, deliberating the suspension, limitation or revocation of the EU Certification until the outcome of the additional supplementary assessment activity of the treatments and corrective actions to be completed within 6 months from the date of detection of nonconformities. In this case **MTIC** will warn the Customer to continue production and supply to the market of all products covered by it. The Customer will also be requested to communicate to **MTIC** information regarding the marketed products, data on stock in the warehouse, analysis of the causes of unmanaged nonconformities that caused the outstanding measure, in order not to jeopardize the safety of the product, the manner of treatment, and the timeframe within which the manufacturer, in a short time, will demonstrate compliance with reference to the findings. The suspension will be lifted only after **MTIC** has been able to establish that technical measures have been taken to ensure future compliance. If the suspension cannot be lifted within 6 months, **MTIC** shall proceed to revoke or restrict the affected certificates. **MTIC** shall also inform the Competent Authority of what has been implemented in accordance with the MDR. Failure to address the findings, necessary to restore product compliance, which could compromise the safety of the device, devices, models and variants referred to in the certificate subject to suspension, could result in the manufacturer's responsibility to: send information on potential risks to users and end users, as well as to commercial operators (importers distributors, retailers etc.), recall devices from the market.
- If opportunities for improvement are formulated, it is not necessary for the Customer to forward the relevant corrections, corrective and/or preventive actions to **MTIC**; during the subsequent audit, the

Customer will be asked to provide evidence that these reports have been taken care of, or to justify any decision not to implement any action.
MTIC's Deliberation Committee has the authority to reclassify the findings issued by the audit team, or request additional evidence to that already provided; in such a case, the client and the audit team are notified within 30 working days from the date of completion of the audit. This may also be the case if the client has already submitted to **MTIC** proposed treatment and corrective actions of the findings. After the deadlines have passed, if **MTIC** does not send the manufacturer a written communication rectifying the findings contained in the Report, the same shall be deemed confirmed.

7. Renewal of certification

The client must submit to **MTIC** an application for renewal of certification within 12 months of the expiration on the certificate. In cases where the certification is for a Class IIb active device intended to administer to the body and/or take from the body a drug, the application for recertification must be submitted to **MTIC** within 18 months of the expiration of the certificate.

7.1. Submission of application for renewal

The Customer must apply for renewal by completing the appropriate form available at www.mtic-group.org or upon request from **MTIC** and provide the necessary documentation as indicated on the form.

Upon receipt of the application, **MTIC** shall review the application for acceptance.
Failure to perform the renewal activities within the validity period of the certification shall result in the termination of the Certification Contract as of the day following the expiration of the certificate.

7.2. Renewal of Management System Certification

Where renewal of Certification is required, **MTIC** will review the technical product documentation based on representative samples (where applicable) and the approved quality management system to verify that they continue to comply with the requirements of the MDR Regulations.
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 scope of certification;
- the effectiveness of the management system with reference to the achievement of the Organization's objectives and expected results;
- the demonstrated commitment to maintaining effectiveness and improvement.

If the Quality Management System is found to comply with the requirements of the MDR, **MTIC** renews the relevant Certification to the Client.

7.3. Renewal of the certificate EU Type Examination

Where renewal of the EU Type Examination certificate is required, **MTIC** verifies that the certified type continues to comply with the requirements of the MDR.
The renewal activity includes a general review of the product's technical documentation and a repetition of all tests and checks performed on the device during initial certification.

If the type is found to comply with the requirements of the MDR Regulations, **MTIC** renews the EU Type Examination Certificate to the Client.

7.4. Outcome of certification renewal activity

MTIC determines the outcome of the certification renewal activities by applying the same principles assumed for the issuance of the initial certification (ref. Section 4.5).
Following the successful outcome of the renewal activities, the certificate is reissued; the costs of any reissuance of the certificate are borne by the Client.
Following the negative outcome of the certification renewal activity or if this activity is not completed by the expiration date of the certificate, the certificate loses its validity.

8. Use of EU certifications

8.1. General

On devices that have obtained EU certifications from **MTIC** according to the procedures below:

- Conformity assessment based on quality management system and technical documentation evaluation (Annex IX);
- Conformity assessment based on product conformity verification-Product quality assurance (Annex XI Part A);
- Conformity assessment based on product conformity verification-Product verification (XI Part B);

the CE marking is affixed, by the Client, in the manner provided for in Article 20 of the MDR Regulations.
Said marking must be followed by the number 0068, identifying **MTIC** as Notified Body, attesting to **MTIC** 's intervention in the continuous surveillance phase.
For devices that have obtained EU certification from **MTIC** according to the procedure provided in Annex X of the MDR (EU Type Examination), the Client shall subsequently obtain further certification according to one of the procedures in Annex XI (Part A) or XI (Part B) before affixing the CE marking.
The affixing of the CE marking and the use of EU certifications are improper when they are likely to mislead the purchaser as to the nature, quality, or origin of the device and in particular when the Customer has not fulfilled the obligations specified in these Regulations.
It is prohibited to affix marks or inscriptions on the devices that may be confused with the CE marking.
The Customer shall unambiguously distinguish its devices provided with the CE marking from those that do not have it.

9. Suspension, limitation, revocation and surrender of certification

9.1. Suspension of certification

CE certificates may be suspended by **MTIC** as a result of the Customer's default, and in particular:

- in the case of non-observance, involving gross negligence, of the commitments made regarding the maintenance of the conformity of the product and the quality management system;
- non-fulfillment, by the Customer, of the obligations stipulated in the general contractual conditions;
- in the cases provided for in 4.5, 6.4 and 7.4 above;

- in the case of undue affixing of the CE marking (ref. point 8.1).

The suspension measure will take into account the principle of proportionality and may be cancelled as soon as the Customer demonstrates that it has satisfactorily taken appropriate corrective measures, or in the event that the situation that had given rise to the suspension measure ceases to exist. The certification suspension measure and any reinstatement measure shall be communicated to the Customer by registered letter with return receipt or other valid method for the purposes of the law.
During the period of suspension:

- **MTIC** may suspend the surveillance activity referred to in Section 6 above, except as provided in Section 6.3;
- **MTIC** shall notify the Competent Authority of the suspension measure by means of the Electronic System (Eudamed) provided for in the MDR Regulations;
- the Customer may not use the certificate(s) obtained and the marks referred to in item 8, unless otherwise indicated by **MTIC**, nor qualify as a Certified Organization;
- the Client is still required to pay the amounts for maintaining the certification.

Before proceeding with the reinstatement of the certification, **MTIC** may carry out documentary checks and/or visits to the Customer in order to ascertain the actual resolution of the issues previously encountered; all expenses related to such additional checks shall be borne by the Customer.
The duration of the suspension, which may not exceed six (6) months, is indicated in the communication sent by **MTIC** to the Customer; after this period has elapsed without the suspension having been able to be lifted, the certification is revoked.

9.2. Limitation and/or revocation of certification

EU certificates may be revoked or restricted by **MTIC** as a result of Customer default, and in particular:

- in case of bankruptcy of the Client or cessation of business;
- serious non-compliance with the commitments made with respect to the general contractual conditions and point 6 hereof;
- in case of non-payment of amounts due to **MTIC**. In this case, before proceeding to revocation, **MTIC** shall send the Customer a warning notice; one month after such notice without the Customer having paid the balance of the amounts due, the certificate shall be revoked. During this notice period, all verification activities are suspended, similarly to the case of suspension;
- in the case of non-compliance, involving gross negligence, with the commitments made regarding the maintenance of compliance of the device and/or the quality management system;
- serious irregularities or abuse in the use of the certificate and/or CE marking;
- failure of the Client to adapt to changes in laws and/or regulations;
- suspension of certification that exceeds six (6) months.

Measures to limit or revoke certification are communicated to the Client by registered letter with return receipt or other valid method for the purposes of the law.

In case of revocation, the Client is required to immediately cease the application of the CE marking for the devices concerned and to remove all references to the relevant attestations in catalogs and advertisements in general.
MTIC shall provide appropriate information of what has been implemented, in particular to the Competent Authority and - upon request - the other Notified Bodies by means of the Electronic System (Eudamed) provided by the MDR.
In the case of the presence on the market of a device for which the CE certification has been revoked due to defects that may pose a danger to users, **MTIC** may invite the Customer to withdraw from the market all the units of the said device, informing in each case the Competent Authority and the other Notified Bodies by means of the Electronic System (Eudamed) provided for by the MDR.

9.3. Withdrawal

Should the Customer wish to withdraw from permanent monitoring by **MTIC** (quality management system surveillance), he/she shall give at least one (1) month's written notice, also undertaking to:

- To cease to affix the CE marking accompanied with the **MTIC** identification number (0068) and otherwise refer to **MTIC** as the Notified Body;
- To exhaust in its factories or warehouses the devices concerned within the period of time to be indicated to it by **MTIC**;
- To notify, three (3) days before the date of last validity of the issued CE Certificate, the serial number or batch of the last devices sold.

If the Customer wishes to cancel an EU Type Examination Certificate issued by **MTIC**, it shall give written notice thereof. Such notice shall automatically result in the cancellation of the relevant surveillance activity, if conducted by **MTIC**; in this eventuality, the provisions of the preceding paragraph shall apply.
MTIC shall provide for the cancellation of the EU Certifications issued, informing the Competent Authority and - upon request - the other Notified Bodies of the renunciation, in accordance with the MDR Regulations.
MTIC shall also remove the name of the relevant types from the list of EU certified devices.

10. Change of notified body

The Customer must apply by completing the appropriate form available at www.mtic-group.org or upon request from **MTIC**, explicitly indicating that he/she is requesting a voluntary change of Notified Body.
In such a case, a written agreement must be made between the manufacturer, **MTIC** and, where possible, the outgoing Notified Body; this agreement must explicitly state at least the following aspects in accordance with Article 58 of the MDR:

- The date from which the certificates of the outgoing body are no longer valid;
- The date until which the identification number of the outgoing notified body may be indicated in the information provided by the manufacturer, including promotional material;
- The transfer of documents, including aspects of confidentiality and ownership rights;
- The date after which the conformity assessment tasks of the outgoing notified body are assigned to the new notified body;

- The last serial number or batch number for which the outgoing notified body is responsible; and.

In addition to the documentation normally required, the manufacturer is requested to provide the following:

- Copy of the outstanding certificate
- The request for revocation of the outstanding certificate and its acceptance by the original Notified Body
- Copy of the last certification or renewal audit report and related surveillance audits
- Any Nonconformities found in the last audits received and related corrective actions taken or planned

We then proceed with the same procedure as in use for new certifications.

11. Extraordinary audits

The client, in the event that the assessment results require extraordinary audits/tests, or other extraordinary assessment activities to:

a) Verifications as a result of reports or complaints received that are considered particularly significant relating to the subject matter of the certificate and its compliance with applicable reference standards and regulations, or
b) Verification of changes made by the client to the subject matter of the certificate and considered relevant by **MTIC**, or
c) As a consequential action against clients whose certification has been suspended, o
d) Verification of the implementation and effectiveness of nonconformity treatments and corrective actions implemented by the client, o
e) In response to needs that arose during the issuance of the certificate, o
f) The reinstatement of the validity of the certificate following a suspension,
g) Where provided for in the legislative instrument applied.

It declares itself as of now available for the same to be carried out in order to allow for the proper performance of the service.
In cases a), b), c) above, **MTIC** reserves the right to carry out the extraordinary audits even without, or on short notice excluding, or limiting, the possibility of recusing the evaluators appointed by **MTIC**.
In the event of rejection of the extraordinary audits, without valid reasons, by the customer, **MTIC** may halt the certification process or initiate the process of suspension/withdrawal of the issued certification as stipulated in the applicable contract conditions.
All expenses related to any extraordinary audits are to be borne by the customer; exceptions are extraordinary audits as a result of reports or complaints, which will be borne by the customer only if the same are deemed justified by **MTIC**.
The rate applied will be that contractually defined for ordinary activity.