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Rev.	Date/Data	Issued by Emesso da	Verified and approved by Verificato ed Approvato da	Description of changes Descrizione delle modifiche
0.0	15.02.2021	DM Scheme Manager	Quality Manager	First issue
0.1	25.02.2022	DM Scheme Manager	Quality Manager	Revision for JAT NCs closure
0.2	01.07.2022	DM Scheme Manager	Quality Manager	Revision for JAT NCs closure
0.3	13.12.2022	DM Scheme Manager	Quality Manager	Revision for JAT NCs closure
0.4	11.05.2023	DM Scheme Manager	Quality Manager	Revision for JAT NCs closure
0.5	24.09.2024	DM Scheme Manager	Quality Manager	Adding chapter 12-Legacy medical devices
0.6	15.09.2025	DM Scheme Manager	Quality Manager	Changes of parapraghs 3.2, 4, 4.5 e 10
0.7	30.10.2025	DM Scheme Manager	Quality Manager	Changes of parapraghs 4.4.1, 4.5, 4.6, 4.7 and 6.4 Adding of paragraphs 4.2.1, 4.2.2 and Annex 1

Contents

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:

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- Scope of application
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- Certification contract
- Duration of the contract - termination
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- Rights and obligations of the client
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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 recognise, at its sole discretion, documents such as certificates, declarations of approval, test reports, reports certifying the conformity of devices or quality systems, issued by other Notified Bodies pursuant to the MDR, Certification Bodies, Test Laboratories or other Bodies.
Documents relating to preclinical and clinical data and test reports are also subject to evaluation. The results of tests carried out by the manufacturer and included in the technical documentation must be carried out at external laboratories accredited to ISO 17025 for the tests in question, or at test centres authorised for Good Laboratory Practice (GLP), or at test centres recognised by scientific bodies of proven authority (such as IECEE CB, university centres of excellence). The use of other laboratories, or the manufacturer's internal laboratories, is accepted if the laboratory has been adequately qualified by **MTIC** on the basis of the requirements of ISO 17025 and produces a test report containing the minimum information required by ISO 17025. **MTIC** also reserves the right to request additional tests if deemed necessary for the conformity assessment. These additional activities or tests will be at the Customer's expense.

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.
The customer must submit the technical documentation and all documentation required for the certification application within six months of the date of order confirmation by **MTIC**. Failure to do so will result in the process being interrupted and the Certification Agreement with the Customer being cancelled, except for any extensions granted by **MTIC** on the basis of justified reasons.
The MDR conformity assessment process usually shall be completed within eighteen (18) months since the receiving date of technical documentation from the manufacturer.

4.2. Conformity assessment based on the quality management system and assessment of technical documentation

4.2.1. Quality management system

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 to the Client the quality management system UE Certificate.

4.2.2. Technical documentation review

For class III devices and class IIb devices referred to in Article 52(4), second paragraph of the MDR, where the Client requests certification of the quality management system in accordance with the procedure described in Annex IX (Chapter I) of the MDR, a request for assessment of the technical documentation relating to the device covered by the quality management system must also be submitted, in accordance with the procedure set out in Annex IX (Chapter II) of the MDR.

The request includes a description of the design, manufacturing and performances of the subjected device and its technical documentation.

MTIC could ask that application shall be presented including additional performed tests or asking additional evidences. **MTIC** performs appropriated physical or laboratory test referred to the device or asks to Client to perform them.

At the end of evaluation assessment, if the device is found to comply with the requirements of the MDR, **MTIC** will issue to the Client the assessment of the technical documentation EU certificate

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 4.2.1 of these regulations.

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 to the Client the quality assurance EU Certificate

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 Product Verification EU Certificate to the Client, 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.
Each conformity assessment step (technical and clinical evaluation, certification audit, final reviewer), the manufacturer shall providence evidences of resolution of all non-conformity within three (3) months since the date of the receipt of the first evaluation report, except specific extensions allowed by MTIC on justified reason.
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:

- If non-conformities (major or minor) are detected as a consequence of the review of the technical documentation, the Client must submit evidences of resolutions of the same within three (3) months since the receipt of the non-conformity review report.
- If opportunities of improvement are detected as a consequence of the review of the technical documentation, the Client must submit evidences of their managing, and the justification of the decision of no-action facing them.
- Only when the result of the technical documentation review is found as compliance, **MTIC** will plan the certification audit, when it is required
- If non-conformities (major or minor) are detected as a result of audit, the Client 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 working days from the date of their receipt, specific request for supplementation or modification.
- If minor non-conformities are detected as a result of audit, 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 non-conformities or Minor on-conformities are detected as a result of audit 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 three (3) 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 as a result of an a audit 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.
- Upon completion of the assessment activities, **MTIC** proceeds with a final review of the manufacturer's documentation and conformity assessment reports with the relevant results (including any findings) by additional internal personnel (*final reviewers*) who did not participate in the assessment activities. Following this review, the *final reviewer* has the right to reclassify the findings issued following the assessment of the technical documentation or by the audit team, and/or request additional evidence to that already provided. In this case, the client and the personnel who

carried out the conformity assessment activities are notified. This may also occur if the client has already submitted proposals to **MTIC** for the treatment and corrective actions of the findings.
If new non-conformities are resulting and addressed to the manufacturer, they shall be solved within three (3) months from the date of detecting them

- At the conclusion of the final review, the results of the assessment and final review, along with any other relevant information, are analysed by the **MTIC** Deliberation Committee for a final decision on whether to issue or refuse the certification.
- In the absence of Nonconformities, **MTIC** will deliberate the issuance of certification.

4.6. Discontinuation of the certification process

After eighteen (18) months since the sending from the client of technical documentation, 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) EU-certificate	5 (five) years	- Annual - Unannounced par. 6.3
Assessment Of The Technical Documentation EU-certificate (Annex IX chapter II)	5 (five) years	No surveillance
EU Type Examination (Annex X) certificate	5 (five) years	No surveillance
Production Quality Assurance EU-Certificate (Annex XI Part A)	5 (five) years	- Annual - Without notice par. 6.3
Product Verification EU-Certificate (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 three (3) 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 three (3) months 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 of withdrawal of the valid certificate and its acceptance by the original Notified Body
- Copy of the report related to the documentary evaluation performed by the outgoing NB
- Copy of the sampling plane issued by the outgoing NB
- 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

The following types of certificates are not recognised by **MTIC** as suitable for transfer:

- Type EU examination certificate (MDR Annex X);
- Product EU conformity verification certificate (MDR Annex XI part B).

If the client voluntarily requests **MTIC** to take over as the new Notified Body (voluntary change), **MTIC** may decide not to apply the entire conformity assessment procedure as required for initial certification, provided that it has sufficient information on the conformity activities carried out by the outgoing NB. In this case, the assessment activities are described in §§ 10.1 and 10.2. If **MTIC** does not have sufficient information regarding the conformity activities performed by the outgoing NB, or in the case of innovative high-risk devices, **MTIC** decides to carry out the entire conformity assessment procedure as indicated in §4 at its sole discretion.

10.1 Transfer of an EU quality system management certificate issued according to Annex IX(I+III) of MDR, or EU quality assurance certificate issued according to Annex XI(A) of MDR

For the transfer of an EU certificate issued in accordance with Annex IX(I+III) of the MDR, or an EU quality assurance certificate issued in accordance with Annex XI (A) of the MDR, **MTIC** must perform:

1) An examination of the results of the assessment of the technical documentation carried out by the outgoing NB together with a partial assessment of the technical documentation corresponding to the devices for which such assessment has already been carried out by the outgoing NB in accordance with the sampling plan drawn up by the latter. **MTIC** will decide which documents will be sampled based on

the type, intended use and risk class of the device to confirm the results of the outgoing NB's assessment. A non-exhaustive example of the documents to be assessed could be: risk analysis, validation of sterilisation processes, pre-clinical tests, clinical evaluation reports, etc.

2) A surveillance audit to ensure that the manufacturer is implementing the approved QMS and post-market surveillance plan.

With regard to the transfer of certificates relating to devices whose technical documentation assessment is based on sampling, **MTIC** reviews the results of the previous assessment together with an assessment of the technical documentation of at least one device not sampled by the outgoing body and draws up or modifies the sampling plan.

The above activities must be carried out before any certificate is issued, including the assessment of the closure of any non-conformities.

If the above assessment activities reveal non-compliance issues that could cast doubt on the results of the assessments carried out by the outgoing ON, **MTIC** will refuse to transfer the certificate and decide to conduct a full assessment process as described in §4.

10.2 Transfer of an EU technical documentation evaluation certificate di valutazione della documentazione tecnica emesso secondo Allegato IX(II) of MDR

For the transfer of EU certificates issued in accordance with Annex IX(II) of the MDR, **MTIC** must review the results of the technical documentation assessment carried out by the outgoing NB together with a partial assessment of the corresponding technical documentation. **MTIC** will decide which documents will be spot-checked based on the type, intended use and risk class of the device to confirm the results of the outgoing NB's assessment. A non-exhaustive example of the documents to be assessed could be: risk analysis, validation of sterilisation processes, pre-clinical tests, clinical evaluation reports, etc. This assessment must be carried out before the certificate is issued, including the assessment of the closure of any non-conformities.

In case of non-compliance issues arise that could cast doubt on the results of the assessments carried out by the outgoing ON, **MTIC** will refuse to transfer the certificate and decide to conduct a full assessment process as described in §4.

10.3 Forced change of the Notified Body

If the client requests the transfer of EU certification from the outgoing NB following the withdrawal, suspension, restriction or revocation of the designation of that Notified Body (forced change), **MTIC** will review the application.

If the documentation is complete, there are no issues with the safety of the device, and the EU certificate has not been issued improperly, **MTIC** will take over the existing certification, assuming responsibility for the EU Certification and notifying the customer and the Authority responsible for Notified Bodies in writing.

The conditions for takeover, established by **MTIC**, are as follows:

- in case of provision of suspension or restriction of the outgoing NB's designation, the responsibility for EU Certification surveillance activities is equal to the duration of the suspension/restriction period established by the Authority responsible for Notified Bodies.
- In case of voluntary withdrawal or revocation of the outgoing NB's designation, the responsibility for EU Certification is equal to a maximum period of 9 months during which to conduct the entire conformity assessment process (as described in §4).

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.

12. Legacy medical devices

Regulation (EU) 2017/745 (MDR), which will be fully applicable from 26 May 2021, allows, by virtue of Article 120, the continued placing on the market of devices with a valid certificate issued in accordance with Directive 93/42/EEC (MDD), provided that the following conditions are met:

a) the devices concerned continues to comply with the MDD
b) no significant changes in design and use have been introduced.

These devices are identified as *"legacy devices"*.
For ***"legacy devices"***, the MDR requirements on post-market surveillance, market surveillance, vigilance, registration of operators and devices and certification notifications apply from 26 May 2021, replacing the corresponding MDD requirements.

On 23/03/2023, Regulation (EU) 2023/607 was adopted, which under certain conditions extends the period of validity of certificates issued under the MDD until 31 December 2028 at the latest, provided that the manufacturer submits a formal application to a Notified Body by 26 May 2024 and that a contract concerning conformity assessment procedures is signed by 26 September 2024.

12.1. Management of the transition period

In accordance with the provisions of Regulation (EU) 2023/607, MDD certificates issued by **MTIC** on 25/05/2017 and still valid on 26/05/2021, and not subsequently revoked, will be considered valid after the expiry of the period indicated on the certificate, until the date indicated below, depending on the risk class of the devices. The risk class is determined according to the rules set out in Annex VIII of the MDR.

a) **31 december 2027**, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

b) **31 december 2028**, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

Devices may only be placed on the market or put into service up to the above-mentioned dates if the following conditions are met:

1) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
2) there are no significant changes in design and intended purpose (see **§6.3.9**);
3) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
4) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10, paragraph 9;
5) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of MDR for conformity assessment of a legacy device, or a device intended to replace such a device, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of MDR.

If a manufacturer decides not to submit the above application, the validity of the certificate for the ***legacy device*** is extended beyond the expiry date of the MDD certificate until **26 May 2024**.

MDD certificates issued by MTIC on or after 25 May 2017 that were still valid on 26 May 2021 and **expired before 20 March 2023** shall only be considered valid until the dates specified in (a) and (b) above if either of the following conditions is met:

i. prior to the expiry date of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Annex VII, Section 4.3, second subparagraph, of the MDR for conformity

assessment of the legacy device covered by the expired certificate, or of a device intended to replace such a device;

ii. a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59, paragraph 1, of the MDR or has required the manufacturer to carry out the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR.

If any of the above conditions are not met, MDD certificates issued with an expiry date prior to 20 March 2023 will be deemed to have expired on that date.

12.2. Surveillance activities

MTIC will continue to be responsible for the appropriate surveillance of all MDD certificates issued before 26 May 2021 until 26 September 2024. **MTIC** will therefore plan and carry out surveillance activities on a regular basis, including on-site surveillance, with and without prior notice, and monitoring of significant changes. After 26 September 2024, the responsibility for the appropriate surveillance of MDD certificates that benefit from the extension of the transitional period in accordance with the previous paragraph shall shift to the Notified Body that has signed the written agreement for the conformity assessment of legacy products according to the MDR.

It is also possible that a manufacturer has agreed with a Notified Body designated under the MDR that the latter will also carry out the appropriate surveillance before 26 September 2024. In this case, **MTIC** will consider whether to transfer responsibility for the appropriate surveillance to the new body by entering into a tripartite agreement with it and the manufacturer.

In October 2021, the MDCG approved the document MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC providing guidance for the identification of MDR pipelines applicable to CE marked devices under the MDD.

Below are listed all applicable MDR requirements that must be assessed during appropriate surveillance for legacy devices:

- all the requirements of Chapter VII on post-market surveillance and supervision;

- articles 85 and 86 on post-market surveillance report and PSUR depending on the risk class of the device;

- registration of economic operators and devices (in the absence of full functionality of EUDAMED, the transitional provisions of Articles 122 and 123 apply);

- article 10, points 10, 12 – 15;

- article 31;

- articles 83 (except SSCP referred to in point 3 d), 84 and PMS plan (Annex III);

- articles from 87 to 100.

From 26 May 2024, the requirements relating to the quality management system in accordance with Article 10, paragraph 9, will also apply.

12.3. Change management

The document MDCG 2020-3 “Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD”, specifies that from 26 May 2021, no changes will be allowed to MDD certificates issued before that date. Therefore, limitations of the scope of the certificate, including cases resulting from partial and voluntary surrender by the manufacturer for certain products, as well as cases of detected non-compliance, or modifications of a certificate resulting from non-substantial changes to the products, such as changes of an administrative nature, such as the name of the manufacturer, the address of the registered office, or a change of the authorised representative, be confirmed by MTIC by means of a written declaration in order to correct or integrate the information of an existing certificate .

In the event of a modification on a legacy device, the Customer is required to inform MTIC of any modification deemed not significant and request a conformity assessment of the same. MTIC evaluates the feasibility of the modification according to the MDCG 2020-3 guideline in the latest revision and if this is deemed not significant, it proceeds to evaluate compliance with the essential requirements of the MDD and the state of the art. Once the activity is concluded, MTIC will insert a single file in PDF format into the Medical Device Database containing the certificate, as issued before 26 May 2021, and a written declaration relating to the changes or additions to the information in the existing certificate, appropriately indicating the specific causes "limitation" or "non-significant changes".

12.4. Management of contracts and issuing of confirmation letter

On the expiry date indicated on the certificates issued by MTIC, in the event that these enjoy the conditions for the extension of the transitional period by virtue of Regulation (EU) 2023/745, MTIC signs a written agreement with the manufacturer for the performance of appropriate surveillance. This contract integrates the one previously signed for the conformity assessment according to MDD. In the event that MTIC is not the notified body to which the manufacturer has submitted the application for certification in MDR of legacy devices reported in the MDD certificate, the responsibility for the appropriate surveillance reported in the agreement is indicated until 26 September 2024.

In the event that a manufacturer decides not to sign this contract for the performance of appropriate surveillance, MTIC communicates this situation to the Ministry of Health.

In the event of an application for the assessment according to Regulation (EU) 2017/745 of “legacy” devices, the agreement for the performance of appropriate surveillance is included in that for the conformity assessment according to MDR. When signing contracts for the conformity assessment according to MDR for legacy devices, MTIC signs the confirmation letter with the manufacturer.

Annex 1

The following table resumes the management of the remarks pointed out by **MTIC.**

Type of assessment	Grade of the remark	Time for presenting cause analysis and proposal of treatment and corrective actions	Methods for verifying resolutions	Time within the manufacturer shall demonstrate the conformity	Report
Technical documentation	Major non-conformity	---	Documentary review within three (3) months since the date of receiving the evidences of solving remarks	Within three (3) months from the date of sending the first non-conformity report	F-PC-MDR-06-01
Technical documentation	Minor non-conformity	---	Documentary review within three (3) months since the date of receiving the evidences of solving remarks	Within three (3) months from the date of sending the first non-conformity report	F-PC-MDR-06-01
Technical documentation	Opportunity of improvement	---	Documentary review within three (3) months since the date of receiving the evidences of solving remarks	Within three (3) months from the date of sending the first non-conformity report	F-PC-MDR-06-01
Clinical documentation	Non-conformity	---	Documentary review within three (3) months since the date of receiving the evidences of solving remarks	Within three (3) months from the date of sending the first non-conformity report	F-PC-MDR-06-02
Clinical documentation	Opportunity of improvement	---	Documentary review within three (3) months since the date of receiving the evidences of solving remarks	Within three (3) months from the date of sending the first non-conformity report	F-PC-MDR-06-02

Certification audit / surveillance / renewal	Major non-conformity	Within 15 working days since the audit date	Documentary review or supplementary audit to check the proposed treatment or the efficacy of corrective actions within three (3) months since the date of receiving the evidences of solving remarks	Within three (3) months from the date of sending the first non-conformity report	F-PC-MDR-11-01
Certification audit / surveillance / renewal	Minor non-conformity	Within 15 working days since the audit date	Documentary review or supplementary audit to check the proposed treatment or the efficacy of corrective actions within three (3) months since the date of receiving the evidences of solving remarks	Within three (3) months from the date of sending the first non-conformity report	F-PC-MDR-11-01
Certification audit / surveillance / renewal	Opportunity of improvement	Within 15 working days since the audit date	During next surveillance audit	Before the performing of next surveillance audit	F-PC-MDR-10-01