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| *Title* | **REGULATION FOR CONFORMITY ASSESSMENT OF MEDICAL DEVICES PURSUANT TO REGULATION (EU) No. 2017/745 FOR WHICH IMQ OPERATES AS NOTIFIED BODY No. 0051** |
| *Reference* | REG. IMQ/ON/MDR-E |
| *Revision and date of entry into force* | Rev. 4 of 2021-10-28<br>Changes from the revision no. 3 dated 2021/11/27 are highlighted in yellow. |
| *Approved by* | IMQ S.p.A. – Business Unit<br>"Product Conformity Assessment"(FP) |

*GENERAL NOTE: this document is a translation to English language based on the original document REG. IMQ/ON/MDR – rev. 4 (in Italian language). In case of discrepancy, the original document prevails.*

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# Art. 1. FOREWORD

This document is intended as applicable integrally unless the Parties expressly agree to waivers.

Any change or waiver will only be valid if previously agreed between the Parties in writing. In the case where one or more scheduled articles should be, for whatever reason, invalid or ineffective, this invalidity or ineffectiveness would not extend to other provisions in this Regulation.

Any expressly agreed waivers, will in no way affect conformity assessment procedures that IMQ is obliged operate as a Notified Body.

# Art. 2. SUBJECT MATTTER OF THE REGULATION

## 2.1. Conformity Assessment

This Regulation, approved by IMQ S.p.A. (hereinafter "IMQ"), establishes the requirements for the supply of one or more conformity assessment services (hereinafter "Service" or "Services") by IMQ pursuant to EU Regulation No. 2017/745 (hereinafter "MDR") for which IMQ operates as a Notified Body (hereinafter "NB").

This Regulation applies:

- to medical devices for human use and their accessories, and
- to products without an intended medical purpose that are listed in Annex XVI of the MDR,

as defined in article 1 of the MDR (hereinafter the "Device" or the "Devices"), for which IMQ is authorised to operate as a Notified Body.

## 2.2. EU Certification

The Manufacturer[1] entrusts IMQ with the relevant Service to issue the pertinent documents attesting conformity with the MDR (hereinafter, "EU Certification" or "EU Certifications").

This Regulation applies to the following EU Certifications:

- EU technical documentation assessment Certificate, according to Annex IX chapter II of the MDR;
- EU quality management system Certificate, according to Annex IX chapter I of the MDR;
- EU type-examination Certificate, according to Annex X of the MDR;
- EU quality assurance Certificate, according to Annex XI part A of the MDR;
- EU product verification Certificate, according to Annex XI part B of the MDR.

Each Certificate is issued exclusively to the applicant Manufacturer, shall refer to only one conformity assessment procedure and shall detail all individual Devices covered by EU Certification issued by IMQ; in case of a high number of

[1] "Manufacturer": a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Devices and/or trademarks, the Manufacturer is allowed to provide a Device list to be attached to the Certificate, drawn up using IMQ dedicated form, available on request.

The EU Certification issued by IMQ is valid for no longer than five (5) years; on the request of the Manufacturer or its Authorized Representative[2], it can be renewed for further periods of up to five (5) years each, on the basis of a new conformity assessment procedure (see also Art. 4.12 below).

The EU Certification issued by IMQ is drawn up in Italian and English; on the Manufacturer's request, if expressly included in the Service Quotation, and when the Manufacturer has made a sworn translation available, IMQ can issue the Certificate in an additional other official EU language and accepted by the competent Authority responsible of IMQ as NB.

The communications from IMQ to the Manufacturer and vice versa must be drawn up in Italian and/or English.

This Regulation does not apply to Certifications issued to Distributors and Importers pursuant to Art. 16 (4) of the MDR; for these Certifications, please refer to the dedicated IMQ Regulation.

# Art. 3. GENERAL CONDITIONS

### 3.1. Obtaining the certification

The EU Certification, and its maintenance, where applicable, depends on:

- the Manufacturer's availability to undergo the ordinary, extraordinary and supplementary and documentary assessments and at the Manufacturer's site and/or other sites involved (e.g. at the sites of the Manufacturer's critical suppliers and subcontractors), within the time limits expected and indicated by IMQ; these assessments include also unannounced audit and audit with little notice;
- the positive outcome of the above-mentioned compliance assessment activities, carried out by IMQ;
- payment of the amounts due to IMQ, for whatever reason (e.g. for release activities, maintenance and renewal of the certification, the variation/re-issuing of the Certificates, etc.).

### 3.2. Samples

If required, the samples must reach the laboratory indicated by IMQ, accompanied by a delivery document showing the reason “Technical Tests”. They must be adequately labelled with the order or quotation number.

Regardless of the outcome of the activity, if the Devices subjected to testing are returned, they are sent to the Manufacturer in their post-testing condition. IMQ reserves the right to request the Manufacturer to keep the samples subjected to testing, or a part of them, at its premises, duly marked or sealed.

[2] “Authorised Representative”: any natural or legal person established within the Union who has received and accepted a written mandate from a Manufacturer to act on the manufacturer's behalf in relation to specified tasks.

All transportation costs are borne by the Manufacturer. In the event of destructive testing, IMQ shall immediately dispose of the resulting materials, but the related costs shall be borne by the Manufacturer, except when the appeal procedure indicated at Art. 13.2 below is activated.

### 3.3. IMQ personnel, external experts and subcontractors

IMQ assigns the assessment activity to IMQ employees with specific competence, previously qualified according to dedicated procedures and in accordance with the applicable provisions.

After giving prior notice to the Manufacturer, IMQ reserves the right to assign specific and clearly defined parts of the requested Service to third parties. The Manufacturer, which shall be informed in detail of the activity assigned externally and of the external expert and/or subcontractors contacts, may reject such an assignment within five (5) working days from the date of the information, by sending written notice to the Medical Devices Certification Office at medicali@img.it.

In any case, IMQ takes full responsibility for all activities assigned externally and remains directly responsible for issuing, maintaining, extending, renewing, suspending or withdrawing the EU Certification.

IMQ guarantees that the external party to which the task is assigned is competent, conforms to the applicable provisions and is not involved in any activity/situation that could compromise the impartiality referred to in Art. 3.5 below.

### 3.4. Confidentiality

All the documents relating to the assessment activity (documentation, recordings, communications, assessment reports, etc.) are considered confidential, except for the provisions of mutual recognition agreements to which IMQ complies to and, in general, of legislative and/or the accreditation bodies and competent Authorities requirements.

Access to and consultation of the documents relating to the activities in hand is reserved to IMQ personnel, external experts and subcontractors involved in the conformity assessment process. In the event that any information must be communicated or disclosed due to legislative/accreditation provisions or at request of competent Authorities, IMQ will give communication to the Manufacturer of what has been communicated or disclosed.

The Manufacturer's documents related to the subject of this Regulation (e.g. technical documentation) that have been acquired by IMQ, are kept by IMQ for the whole period for which the Certification Contract is valid and for at least 15 years starting from the expiry date of the EU Certification.

### 3.5. Impartiality

In its role as an NB, IMQ must guarantee its own impartiality throughout the conformity assessment activity and avails of a process to assess and manage the risks of impartiality.

IMQ is not - and undertakes not to be - linked to any party that is directly involved in activities/situations of: design, implementation, supply, installation, purchasing, marketing, possession, use and maintenance of the Devices for which it is appointed.

IMQ does not perform - and undertakes not to perform - activities that could be in conflict with its own independence of judgement, integrity or objectivity regarding the assessment activities for which it is appointed.

As an NB, IMQ cannot in any way provide consultancy services regarding the design, manufacturing, marketing or maintenance of the Devices or processes under assessment.

### 3.6. IMQ code of ethics and Legislative Decree No. 231 of 8 June 2001

IMQ has adopted a Code of Ethics in compliance with Italian Legislative Decree No. 231 of 8 June 2001 regarding the responsibility of legal persons, companies and associations even without legal status, which is available at the website www.imq.it in the "About IMQ –Code of Ethical and Policy" section. Therefore, in conducting business with IMQ, the Manufacturer must read it and conduct itself according to the highest ethical standards.

By signing the Certification Contract, the Manufacturer declares that it has read, understood and accepted the content of the IMQ Ethics Code.

Furthermore, the Manufacturer declares that it is aware of the provisions of Italian Legislative Decree 231/01, to commit to respecting the IMQ Ethical Code and adhere to their contractual obligations in line with appropriate ways of preventing behaviour relevant to Italian Legislative Decree 231/01.

Specifically, failure of the Manufacturer to observe any of the expectations of the Ethical Code will lead to a serious failure to fulfil the obligations set out in the Certification Contract and would authorise IMQ to terminate this contract with immediate effect, pursuant to and in accordance with Article 1456 of the Italian Civil Code. To this end, IMQ must inform the Manufacturer via certified e-mail, registered letter with return receipt or other legally valid method, of its intention to apply the termination clause.

Furthermore, if IMQ somehow becomes aware of conduct by the Manufacturer, which sets in motion a legal process aimed at examining its relevance pursuant to Italian Legislative Decree 231/01, this would give IMQ just cause to terminate the Certification Contract.

### 3.7. IMQ accreditations and qualifications

#### 3.7.1. Obligations related to the designation

When carrying out the activity covered by this Regulation, IMQ operates as designated by the Authority responsible for NBs for the MDR.

Therefore, IMQ must operate in accordance with the MDR and its implementing provisions, considering the related guidance documents, which are to be considered expressly referenced by this document.

IMQ must notify the competent Authorities, the Authority responsible for NBs and the European Commission of all information referred to in Artt. 56 and 57 of the MDR (e.g. issued, suspended and withdrawn Certifications).

The Authority responsible for NBs may carry out audits at IMQ sites and/or at the sites of its Manufacturers (and relative critical suppliers and subcontractors), for the purpose of verifying IMQ's operation in relation to its authorisation.

*Note: Information about IMQ's notification status is available at the website http://ec.europa.eu/growth/tools-databases/nando/*

#### 3.7.2. Suspension, renunciation or revocation of IMQ's designation

If IMQ decides to cease the conformity assessment activities, it will inform the Manufacturer as soon as possible, and at least one (1) year before in the event of a planned cessation.

If IMQ's authorisation to operate is suspended, limited or revoked, it will inform the Manufacturer as soon as possible and within 10 days at the latest. The unduly EU Certifications issued will be suspended or withdrawn by a deadline established by the Authority responsible for NBs.

In all of the above cases, IMQ will support the Manufacturer in any transfer to another NB providing the Manufacturer with the required information pursuant to the Artt. 46 and 58 of the MDR.

Except in cases of fraud or gross negligence, IMQ is in no way liable for damage caused to the Manufacturer by the suspension, renunciation, limitation or revocation of its authorisation. In the aforementioned cases, the Manufacturer has the right to renounce to the EU Certification issued by IMQ, without the need to give prior warning and without additional obligations, in derogation to Art. 11.3 below.

## Art. 4. CONFORMITY ASSESSMENT PROCEDURE

### 4.1. Preliminary activity before submitting the Application

The Manufacturer may request a Service Quotation in advance, in which IMQ provides a detailed description of the activities performed as a NB and the corresponding Price list applied.

On its website www.imq.it in the "Regulation (EU) No. 2017/745 (the "MDR")" section, IMQ provides a dedicated *Information Sheet* to be used by the Manufacturer to supply at least the following information when lodging a quotation request:

- the details of Manufacturer and, if applicable, its Authorised Representative;
- the Manufacturer's sites, with the information about the performed activity, eventual work shifts and number of employees;
- eventual critical suppliers and/or subcontractors;
- a description of the Device and its risk class;
- the chosen conformity assessment procedure.

IMQ can also receive the request in a form other than the dedicated sheet, as long as the Manufacturer provides all of the information listed above in writing.

After a preliminary verification that the product qualifies as a Device and ascertaining its classification, IMQ formulates the Service Quotation, containing the following information:

- a description of the Service;
- references to this Regulation (documentation available on the website www.imq.it in the "Regulation EU No. 2017/745" section);
- the methods of providing the service;
- the amount due, according to the current IMQ Price list, detailed for the individual activities requested;
- the billing and payment methods.

In case of acceptance of the quotation, the Manufacturer must send the following to IMQ:

- the quotation signed by the Legal representative by the Manufacturer (or by an appropriately delegated person), for its acceptance and with evidence of full acceptance of this Regulation;

- the purchase order, if required by the Manufacturer's administration;
- the certification Application and the related documentation explicitly requested in the Application itself (see Art. 4.2 below).

### 4.2. Application submission

The Manufacturer or its Authorised Representative requests to access the Service by submitting to IMQ the corresponding Application, containing at least the following information:

- the details (registered name, name, address, legal status, etc.) of the Manufacturer and, if applicable, of its Authorised Representatives;
- the unique registration number[3] of the Manufacturer and, if applicable, of its Authorised Representative;
- the Manufacturer's sites, the performed activity, the work shifts and number of employees;
- any critical supplier and/or subcontractors;
- a description of the Device to be certified;
- the basic UDI-DI[3] for the Device that require a EU technical documentation assessment Certificate or a EU type-examination Certificate;
- the Device classification pursuant to Art. 51 and according to the criteria defined in Annex VIII of the MDR;
- the assessment procedure required and/or chosen by the Manufacturer pursuant to Art. 52 of the MDR;
- a declaration that the same Application has not been submitted to any other NB, or information about any previous Applications for the same conformity assessment that have been rejected by another NB or withdrawn by the Manufacturer before the final decision of such other NB;
- a draft EU Declaration of Conformity for the device in question;
- the documentation required by the chosen conformity assessment procedure, allowing assessment of the conformity of the Device applied for and, if required, the quality management system to the applicable requirements of the MDR, included the relevant technical documentation as per Annexes II and III of the MDR[4];
- a summary of the safety and clinical performance of implantable Devices and class III Devices applied for;
- any information for managing a transfer of the EU Certification from another NB (see also Art. 4.14).

The Application must be drawn up and submitted using IMQ's dedicated Application form, which is available on request. It must be filled in fully and signed by a Legal representative (or by an appropriately delegated person) of the Manufacturer or of its Authorised Representative.

The Manufacturer may delegate a person or company to act as an agent to assist it in all stages of the certification process, in which case IMQ must have evidence of such delegation. However, the Application must be signed by the Manufacturer or by its Authorised Representative; the contractual documents and all the documentation must be signed by the Manufacturer.

[3] The requests of the unique registration number and of the basic UDI-DI apply from the date of 26/05/2021 or, if EUDAMED is not operational on that date, from the date corresponding to six months from the date of publication of the notice of full functionality referred to Art. 34 par. 3 of the MDR.

[4] The OBL (Own Brand Labelling) Manufacturer shall comply with all the requirements of the MDR applicable to the Devices Manufacturers. Consequently, the OBL Manufacturer shall draw up and keep updated the Device technical documentation for which it submits the certification Application; this technical documentation must refer to the Device subject to Certification and the Manufacturer applying and must include all the elements as per Annexes II and III of the MDR.

For class III Devices and IIb implantable[5] with conformity assessment procedure according to Annex IX of the MDR, the Manufacturer (or its Authorised Representative) must submit the Application for Annex IX chapter II and the Application for Annex IX chapter I.

The Application and related documentation (i.e., technical documentation, quality management system documentation, etc.) must be provided by the Manufacturer in Italian and/or English; any other language official of the European Union - and accepted by the competent Authority responsible of IMQ as NB - is acceptable only if stated in the quotation by IMQ.

Furthermore, technical documentation and quality management system documentation must be provided with date, signature and in a non-editable format.

### 4.3. Review and acceptance of the Application

IMQ's acceptance of the Application submitted by the Manufacturer (or its Authorised Representative) depends on a positive outcome of the Application review carried out by the competent IMQ personnel; IMQ perfects the Certification Contract by sending the order confirmation to the Manufacturer.

The Application review verifies the following aspects:

- that the Application is complete with respect to the requirements of the chosen conformity assessment procedure, including the presence of the full technical documentation;
- that the products covered by the Application qualify as Devices and their relative classifications; if there is disagreement between the Manufacturer and IMQ about application of the classification rules, IMQ will inform the Manufacturer and report the question to the competent Authority for resolution, in accordance with Art. 51, section 2, of the MDR;
- that the conformity assessment procedures chosen by the Manufacturer are applicable;
- that IMQ is qualified to assess the Application according to its designation, and
- that there are sufficient and suitable resources.

The need for clarification, additions and/or corrections to the Application may emerge from this review; these requests are communicated to the Manufacturer, who has ten (10) working days to transmit the modified / integrated Application to IMQ.

In the absence of a response from the Manufacturer within the aforementioned times and/or after a negative outcome of the review, IMQ will reject the Application.

If the Application is rejected, the Manufacturer will be informed by registered letter with return receipt, or by another legally valid method, and it will be reported in the European Database for Medical Devices (EUDAMED).

Following acceptance of the Application, IMQ plans the activity. This planning includes informing the Manufacturer of the methods, timing and dates of the activities that will be carried out, the names of the assessment group and any specific requests to be agreed.

[5] According to Art. 52 (4) of MDR, Annex IX chapter II is not applicable to the following implantable Devices: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

IMQ does not guarantee, nor can in any way guarantee, a positive outcome of the assessment activity, and subsequently that the relative EU Certification will be issued.

The Manufacturer is not allowed to advertise the Application while it is in progress, until there is a positive outcome for the related tests, verifications and assessments.

IMQ – at its sole discretion - reserves the right to recognise any document such as test reports, Certificates and/or conformity declarations of the Devices and of the quality management systems, etc. issued by other NBs, Certification Bodies, Testing Laboratories or other Bodies.

Minimum conditions necessary for the acceptance of the test reports included in the technical documentation are:

- Reports issued by Test Laboratories compliant with the requirements of EN ISO / IEC 17025 and / or by the Manufacturer, and
- Reports containing the minimum information required by EN ISO / IEC 17025 and the additional elements required by the MDR.

If the Device for which the EU Certification has been requested, already has a relevant voluntary IMQ certification, IMQ reserves the right to define criteria for possibly reducing the tests and verifications, depending on the suitability of the activities already carried out by IMQ on a voluntary basis. Any reductions, which in no case affect the assessment of the complete fulfilment of the requirements of the MDR, must be duly justified and registered by IMQ.

IMQ shall use EUDAMED to report if the Manufacturer withdraws the Application before the final decision.

### 4.4. Conformity assessment, final review and final decision

The purpose of IMQ's assessment is to verify conformity of the Device, and that of quality management system, to the relevant requirements of the MDR (for details of each assessment activity, see Artt. 4.5 to 4.9 below).

The conformity assessment procedure may find Non-Conformities, which are defined as a failure to satisfy a requirement or a deviation from the reference specifications, and are classified as:

- Major Non-Conformity: a non-conformity related to the requirements of the MDR and applicable standards, which prejudices safety of the Device and/or the efficacy of the quality management system.
  Non-Conformities found during the technical documentation evaluation and the Device tests/inspections are classified as Major Non-Conformities.
  This remark can also be formulated when there are a high number of Non-Conformities classifiable as “minor”, referable to the same requirement/process.

- Minor Non-Conformity: a non-conformity related to the requirements of the EU Regulation and applicable standards, which does not prejudice safety of the Device and the integrity of the Quality Management System.

IMQ may also formulate “Recommendations” to the Manufacturer, to highlight aspects that do not fail to satisfy the mandatory requirements and/or standards, but that could be considered opportunities for improving the Manufacturer's quality management system.

IMQ's qualified personnel subjects the Manufacturer's documentation, the conformity assessment reports and their outcomes and, if there are any non-conformities, the related corrective actions, to an additional final review and then IMQ's Approval Certification Committee analyses them.

Based on the outcome and any other relevant information, the Committee decides whether to issue the EU Certification or not.

If the EU Certification is approved, IMQ issues the EU Certification to the Manufacturer according to the assessment procedure performed; the Committee may impose restrictions (e.g. to the intended use) or request the Manufacturer to start specific post-market clinical follow-up studies (hereinafter "PMCF").

If the EU Certification is not approved, IMQ informs the Manufacturer of this decision in writing, giving the reasons and the minimum conditions to start the certification process from the beginning.

IMQ reports the issue or rejection of the EU Certification in EUDAMED.

#### 4.4.1. Interruption of the assessment procedure

If the Manufacturer has failed to demonstrate conformity after twelve (12) months since IMQ has accepted the Application, even with several additional assessment activities, the certification procedure is stopped and the Certification Contract with the Manufacturer is closed.
In this case, IMQ informs the Manufacturer of this decision in writing, giving the reasons and the minimum conditions to start the certification process from the beginning; IMQ reports the rejection of the EU Certification in EUDAMED.
In this case, the Manufacturer will be obliged to pay the amounts relating to the activities carried out by IMQ up to the date of cancellation of the Certification Contract.

### 4.5. EU technical documentation assessment

#### 4.5.1. Required documentation

If the conformity assessment procedure chosen by the Manufacturer requires EU technical documentation assessment according to Annex IX chapter II of the MDR, the Manufacturer must provide IMQ with a description of the design, manufacturing and performance of the Device in question. It consists of the technical documentation referred to in Annexes II and III of the MDR.

#### 4.5.2. Evaluation of the technical documentation

IMQ examines the technical documentation for the Device, including the pre-clinical and clinical evaluation, to assess conformity of the Device with the requirements of the MDR.

IMQ also validates the summary of safety and clinical performance provided by the Manufacturer.

IMQ can ask the Manufacturer to complete the Application with additional tests (physical or laboratory) or new elements.

#### 4.5.3. Assessment outcome

If the technical documentation assessment has a positive outcome, the procedure continues, and the EU technical documentation assessment Certificate is issued.

If however the documentation evaluation reveals Non-Conformities, the personnel involved informs the Manufacturer in writing and waits for the resolution of Non-Conformities.
The costs of performing additional verifications are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price list in force (see also Art. 6.1 below).

The Manufacturer has forty (40) working days to send to IMQ the updated (in date and revision) technical documentation, completed with the the missing or additional documentation related to the Non-Conformities; the EU Certification issue is depending on the positive result of this documentation additional verification.

In case of lack of feedback from the Manufacturer within the established timeframe, or after three (3) additional verifications, without the Manufacturer provided evidence that all Non-Conformities have been closed, IMQ is allowed to decide to stop the evaluation procedure, to deliberate the rejection of the EU Certification (see also Art. 4.4 above) and to request payment for the activity performed up to that point.

### 4.6. EU Type-Examination

#### 4.6.1. Required documentation

If the conformity assessment procedure chosen by the Manufacturer requires the EU Type-Examination according to Annex X of the MDR, the Manufacturer must provide IMQ with the technical documentation referred to in Annexes II and III of the MDR.

#### 4.6.2. Evaluation of the technical documentation

IMQ verifies that the technical documentation, including the pre-clinical and clinical evaluation, conforms to the applicable requirements of the MDR.

Moreover, for implantable and class III Devices, IMQ validates the summary of safety and clinical performance.

If the technical documentation examination has a positive outcome, the assessment procedure continues with tests and controls on the Device (see also Art. 4.6.3 below).

If however the technical documentation evaluation reveals Non-Conformities, the personnel involved informs the Manufacturer in writing and waits for their resolution.
The costs of performing additional verifications are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price list in force (see also Art. 6.1 below).

The Manufacturer has forty (40) working days to send to IMQ the updated (in date and revision) technical documentation, completed with the missing or additional documentation related to the Non-Conformities; the execution of tests and verifications is depending on the positive result of this documentation additional verification.

In case of lack of feedback from the Manufacturer within the established timeframe, or after three (3) additional verifications, without the Manufacturer provided evidence that all Non-Conformities have been closed, IMQ is allowed to decide to stop the evaluation procedure, to deliberate the rejection of the EU Certification (see also Art. 4.4 above) and to request payment for the activity performed up to that point.

#### 4.6.3. Tests and inspections

If the technical documentation assessment has a positive outcome, IMQ draws up a specific test protocol.
IMQ only considers test reports submitted by the Manufacturer if they have been drawn up by competent conformity assessment Bodies that are independent of the Manufacturer.

IMQ notifies the Manufacturer of the location where the testing will take place, and the number of type examples that are representative of the production to be provided free of charge for the conformity examination. IMQ can request other samples of the same type, if needed to perform the test schedule. The Manufacturer must send the samples for testing, accompanied by the documents prescribed by the laws in force, according to Art. 3.2 above.

The examination consists of the following activities:

- verification that the type has been manufactured in conformity with the evaluated technical documentation;
- identification of the elements that have been designed in conformity with the applicable provisions of the harmonised standards or the Common Specification (CS), as well as the elements whose design is not based on applicable provisions of the aforementioned standards;
- if the harmonised standards or the CS have not been applied, performing inspections, measurements and testing to verify if the solutions adopted meet the general safety and effectiveness requirements of Annex I of the MDR;
- if the harmonised standards or the CS have been applied, performing inspections and testing to verify if the application has been effective.

#### 4.6.4. Assessment outcome

If the tests and inspections have a positive outcome, the procedure continues with EU type-examination Certificate issue.
If however the tests and inspections reveal Non-Conformities, the personnel involved informs the Manufacturer in writing and waits for their resolution. The costs of performing additional testing are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price list in force (see also Art. 6.1 below).

The Manufacturer has forty (40) working days to send IMQ the modified type to repeat the tests related to the Non-Conformities; the EU Certification issue is depending on the positive result of this additional tests.

In case of lack of feedback from the Manufacturer within the established timeframe, or after three (3) additional tests and controls, without the Manufacturer provided evidence that all Non-Conformities have been closed, IMQ is allowed to decide to stop the evaluation procedure, to deliberate the rejection of the EU Certification (see also Art. 4.4 above) and to request payment for the activity performed up to that point.

### 4.7. EU product verification

#### 4.7.1. Required documentation

If the conformity assessment procedure chosen by the Manufacturer requires EU product Verification according to Annex XI part B of the MDR, the Manufacturer must provide IMQ:

- the technical documentation referred to in Annexes II and III of the MDR;
- for class III and IIb Devices, a copy of the EU type-examination Certificate (or reference to it, if the Certificate was issued by IMQ);
- time schedule for implementation of the verifications.

#### 4.7.2. Verification of the technical documentation

For class IIa Devices, IMQ verifies the technical documentation and applies Art. 4.6.2 above.

#### 4.7.3. Verification through examination and testing of every single product

IMQ draws up a specific test protocol. IMQ only considers test reports submitted by the Manufacturer if they have been drawn up by competent conformity assessment Bodies that are independent of the Manufacturer.
IMQ notifies the Manufacturer of the location where the testing will take place and any modifications/additions to the time schedule proposed by the Manufacturer itself.

The Manufacturer must send the samples for testing at the IMQ laboratories free of charge, accompanied by the documents prescribed by the laws in force, according to Art. 3.2 above.

Each Device is examined individually and subjected to inspections, measurements and tests to:

- verify, for class III and IIb Devices, that the Device conforms to the type described in the EU type-examination Certificate and the requirements of the MDR;
- verify, for class IIa Devices, that the Device conforms to the technical documentation and the requirements of the MDR.

In case of devices placed on the market in sterile condition, IMQ performs a quality management system audit in which verifies the manufacturing aspects, related to the securing and maintaining of the sterile state.

#### 4.7.4. Assessment outcome

If the Devices subjected to testing conform to the requirement of the MDR and the type described in the EU type-examination Certificate or the technical documentation, the procedure continues with the EU product verification Certificate issue.

If one or more of the Devices tested is found not compliant, IMQ informs the Manufacturer in writing and takes appropriate measures to prevent them from being placed on the market.

### 4.8. Assessment of the quality management system

#### 4.8.1. Required documentation

If the conformity assessment procedure chosen by the Manufacturer requires assessment of the quality management system according to Annex IX chapter I (full quality management system) or Annex XI part A (production quality assurance) of the MDR, the Manufacturer must provide:

the technical documentation referred to in Annexes II and III of the MDR;

- the elements of the quality management system documentation referred to in Annex IX point 2.1 of the MDR;
- for class III and IIb Devices with the procedure in Annex XI part A, a copy of the EU type-examination Certificate (or reference to it if the Certificate was issued by IMQ).

For class I sterile devices, class I measurement devices and class I reusable surgical instruments, the assessment procedure is respectively related only to:

- aspects relating to establishing, securing and maintaining sterile conditions;
- aspects relating to the conformity of the device with the metrological requirements;
- aspects relating to the reuse of the device (cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use).

For class III or implantable IIb Devices (for exemptions, see article 52, section 4, second paragraph of the MDR) the procedure in Annex IX chapter I could be performed only when the assessment procedure according to Annex IX chapter II will be concluded with positive result.

### 4.8.2. Evaluation of the technical documentation

IMQ verifies the technical documentation, including the pre-clinical and clinical assessment, for all of the Devices covered by the quality management system for which the Manufacturer has submitted an Application.

The technical documentation verification is not provided for Devices with an EU type-examination Certificate (see also Art. 4.6 above) or an EU technical documentation assessment Certificate (see also Art. 4.5 above), unless otherwise indicated by IMQ and adequately motivated.

If the technical documentation examination has a positive outcome, the assessment procedure continues with the quality management system audit (see Art. 4.8.3 below).

If, instead, the documentation evaluation reveals Non-Conformities, the personnel involved informs the Manufacturer in writing and waits for the resolution of Non-Conformities.
The costs of performing additional verifications are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price list in force (see also Art. 6.1 below).

The Manufacturer has forty (40) working days to send to IMQ the updated (in date and revision) technical documentation, completed with the missing or additional documentation related to the Non-Conformities; the audit is dependent on the positive additional verification of the documentation.

In case of lack of feedback from the Manufacturer within the established timeframe, or after three (3) additional verifications, without the Manufacturer provided evidence that all Non-Conformities have been closed, IMQ is allowed to decide to stop the evaluation procedure, to deliberate the rejection of the EU Certification (see also Art. 4.4 above) and to request payment for the activity performed up to that point.

### 4.8.3.Assigning the audit team and planning the audit activities

If the technical documentation assessment has a positive outcome, IMQ assigns the certification audit to an audit team made up of one of more parties, guaranteed to be capable of carrying out the required activity.

The Manufacturer is entitled to request replacement of one team member; such request must be made in writing within five (5) days after the Manufacturer receives the information and must be adequately motivated.

IMQ – at its sole discretion - reserves the right to confirm or substitute the person in question, depending on the importance of the motivations expressed by the applicant.

IMQ contacts the Manufacturer to set the dates of audit; after confirmation of such dates, the “Lead site auditor”, the responsible of the audit team, sends to the organization the audit plan.

If the Manufacturer requests a change of date of an audit in the ten (10) working days before the planned date, IMQ reserves the right to charge an amount for the resulting costs, equal to ten percent (10%) of the total amount of the offer.

### 4.8.4. Performing the audit activity

The audit activity consists of assessing if the Manufacturer's quality management system conforms with the requirements of the MDR; this verification is performed according to the sampling method and is based on interviews with personnel, direct observation of the activities and processes, examination of places, documents and records.

The impossibility of verification of activities in progress (production, service delivery) during the audit and, later on, during the certification period, may result – depending on the cases – in a refusal to issue the Certificate, in suspension, in withdrawal or reduction of the scope indicated in the EU Certificate.

During the audit, evaluators of the audit team (and any accompanying persons) must be assisted by the Manufacturer's staff, and if necessary, accompanied by interpreters and translators whose costs are borne by the Manufacturer.
The Manufacturer must permit safe access to the audit team (and any accompanying persons) to all areas where activities relevant for the object of Certification are carried out and, in addition, must allow to interview the staff involved in such activities and, in general, must put at disposal all necessary information for audit conducting.

The initial certification audit is divided into two stages, named Phase 1 and Phase 2 (or "Stage 1" and "Stage 2").

**a) Stage 1 audit**

The Stage 1 audit is generally carried out at the Manufacturer site[6] in case of class IIb and III Devices, or at IMQ itself in case of Devices with a lower risk class, unless otherwise indicated by IMQ.

The main aims of this verification are as follows:

- examine the quality management system documentation;
- gather or confirm the required information about the field of application of the system, including the sites, suppliers, subcontractors, processes, applicable mandatory requirements and inspections defined by the Manufacturer;
- establish the level of preparation for Stage 2, identifying any weaknesses that would be classified as Non-Conformities for this Stage (for the classification, see Art. 4.4 above);
- acquire sufficient knowledge of the system and the activities carried out at each site to proceed with Stage 2 planning, agree all of the details with the Manufacturer and verify that the allocated resources are suitable to execute it.

At the end of the Stage 1 activity, the Lead site auditor identifies any situations that block continuing with the certification procedure, i.e. the critical areas that must be solved before continuing with the Stage 2 audit.

If, during the Stage 1 activities, information acquired about the Manufacturer (e.g. number of employees, sites, suppliers, processes) is in contrast with that previously provided by the Manufacturer, it may be necessary to vary the commitment previously established for carrying out the Stage 2 audit.

**b) Stage 2 audit**

The Stage 2 audit must take place at the Manufacturer's site(s)[6] and at its critical suppliers or subcontractors, if applicable. This audit must be performed within and not later than six (6) months from the Stage 1 audit.

[6] In the event of emergency situations (e.g. health emergency from COVID-19, manufacturer's production sites located in an area subject to serious natural disaster, etc.), IMQ reserves the right to adopt extraordinary alternative measures (e.g. remote audits). In any case, the application of these extraordinary alternative measures must take place in compliance with the relevant regulatory provisions, laws, regulations and related guidelines and is subject to a preliminary assessment by IMQ about the suitability and effectiveness of such measures.

The main goals are as follows:

- verify that the Manufacturer's quality management system complies with the requirements of the MDR;
- verify that this system guarantees the Devices conformity with the relevant requirements of the MDR;
- for class III and IIb Devices – with the procedure according to Annex XI part A - verify that this system guarantees the Devices conformity with the type described in the EU type-examination Certificate.

If the audit is stopped following a Manufacturer's request before the activities indicated in the plan are completed, the Manufacturer must still pay the amounts for the entire planned audit activity.

#### 4.8.5. Audit outcomes

a) Audit Report

At the end of Stage 2, the audit team must analyse all the information and the gathered evidences during Stage 1 and Stage 2, in order to review the audit results and define the conclusions.

The audit team draws up a specific audit Report (hereinafter the "Report"), which also highlights any Non-Conformity and Recommendations (for the classification, see Art. 4.4 above).

The Lead site auditor presents the audit conclusions and the Manufacturer has the opportunity to discuss the Report contents to clear up any doubts, express any reservations about the contents of the audit documentation, recording the reasons.
Subsequently, a Manufacturer's Representative signs for acceptance the Report issued by IMQ and the eventually found Non-Conformities and receives a copy.
If IMQ does not send the Manufacturer written notification of amendments to the outcomes in the Report within thirty (30) calendar days after audit closure, it will be considered confirmed.

b) Audit outcome

If no Non-Conformities are found during the audit the procedure continues and an EU quality management system Certificate (for procedure according to Annex IX chapter I) or an EU quality assurance Certificate (for procedure according to Annex XI-part A) is issued.

If Non-Conformities are found during the audit, the relevant EU Certification issue is depending on the positive resolution of these Non-Conformities and is applied the procedure as for points c) and d) below.

c) Corrections and Corrective Action plan

The Manufacturer must undertake to eliminate all the Non-Conformities eventually found during the audit by identifying their causes and adopting and implementing adequate Corrections and Corrective Actions.

The causes of the Non-Conformities and the Corrections and Corrective Action plan must be sent to IMQ within seven (7) working days from the audit closure date, specifying the implementation times and relative responsibilities.
The action plan proposed by the Manufacturer is considered accepted if IMQ does not send to the Manufacturer, within thirty (30) calendar days from the date of receipt of the same, specific request for integration or modification.

If the Manufacturer fails to send IMQ an adequate Corrections and Corrective Action plan in the abovementioned timeframe, IMQ may decide to stop the evaluation procedure, to deliberate the rejection of the EU Certification and to request payment for the activity performed up to that point.

For the Recommendations, there is no need to send action plan to IMQ; during the next audit, the Manufacturer is requested to provide evidence that these Recommendations have been taken into consideration, or to justify any decision to not take any action.

d) Verification of Corrections and Corrective Actions

The verification of the implementation and effectiveness of the Corrections and Corrective Actions for resolution of all found (Major and minor) Non-Conformities is carried out on the basis of documented evidences or with an additional audit; the EU Certification issue is depending on the positive result of this documentation additional verification. The costs of performing additional activities are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price List in force (see Art. 6.1 below).

In case of lack of feedback from the Manufacturer within the established timeframe, or if it has not been possible to obtain adequate evidence of the implementation and the effectiveness of the Corrections and Corrective Actions, IMQ is allowed to decide to stop the evaluation procedure, to deliberate the rejection of the EU Certification (see also Art. 4.4 above) and to request payment for the activity performed up to that point.

### 4.9. Specific procedures

#### 4.9.1. Clinical evaluation consultation procedure

The clinical evaluation consultation procedure is required for class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product (for exclusions, see Art. 54 of the MDR).

IMQ sends the clinical evaluation drawn up by the Manufacturer and the corresponding analysis report prepared by IMQ to the European Commission using EUDAMED and examined by an expert panel (ref. Art. 54 of the MDR).

If the group of experts expresses a scientific opinion, IMQ duly considers it. IMQ reserves the right to:

- request the Manufacturer to modify/add to the clinical evaluation with further clinical evidence,
- restrict the intended use of the Device to a certain group of patients or medical conditions,
- impose a limit to the duration of the Certificate validity,
- impose other restrictions in its conformity assessment report.

### 4.10. Procedure for assessing the PSUR

The Manufacturer must draw up the Periodic Safety Update Report (hereinafter “PSUR”) with the following frequency:

- at least one (1) time per year for class III and IIb Devices and,
- where necessary, and at least every two (2) years for class IIa Devices.

This report is an integral part of the technical documentation and contains:

- a summary of the outcomes and the conclusions of the analyses of the post-market surveillance data gathered;
- the reasons for and a description of any preventive and corrective actions adopted by the Manufacturer;

Each year, the Manufacturer must send to IMQ - using EUDAMED[7]- the PSUR for all class III Devices and implantable Devices for which IMQ has issued an EU Certification.
IMQ verifies this report, draws up the related assessment report and enters it into EUDAMED.

The costs of assessing the PSUR are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price list in force.

For devices other than those abovementioned, the Manufacturer must make available the PSUR to IMQ and the competent Authority. Annually IMQ verifies the PSUR for at least one Device for which it issued an EU Certification and draw up its assessment report. This verification can be performed during the periodic surveillance and the EU Certification renewal activity. If the conformity assessment procedure does not include surveillance, IMQ and the Manufacturer define appropriate deadlines and methods for sending the PSUR.

### 4.11. Surveillance of an approved quality management system

To maintain the EU quality management system Certificate (Annex IX, chapter I) and the EU quality assurance Certificate (Annex XI, part A), the Manufacturer must be available to undergo periodic surveillance and unannounced audits, and the outcomes of these visits conducted by IMQ must be positive.

The main objectives of surveillance activity are the following:

- To verify that the Quality Management System is compliant and ensures compliance of the Devices it contemplates, with the requirements applicable in accordance with the provisions of Annex IX pt. 3 and Annex XI (A) pt. 7 of MDR;
- To verify compliance with the applicable provisions of this Regulation.

#### 4.11.1. Periodic surveillance of an approved quality management system

IMQ performs periodic surveillance audits to ensure that the Manufacturer maintains and effectively applies the approved quality management system.

The first surveillance audit must be done within and not later than twelve (12) months after the EU Certification has been issued, unless IMQ considers a shorter period more appropriate.

After the first one, surveillance audits are generally performed within and not later than twelve (12) months after the previous audit.

The Manufacturer is notified in advance of these visits, - generally at least fifteen (15) days from the proposed audit date. As far as assigning the audit team and planning the audit activities, see requirements in Art. 4.8.3 here above.

The Manufacturer undertakes to allow IMQ to perform all required inspections, both at its own premises[6] and at those[6] of its subcontractors and critical suppliers, where considered necessary to guarantee effective inspection; the Manufacturer also undertakes to make all useful information available to the audit team, specifically:

- documentation related to the quality management system;

[7] Until the date from which the obligation to transmit via EUDAMED takes effect, the Manufacturer shall make the PSUR available to IMQ during the periodic surveillance.

- documentation related to any outcomes and conclusions arising from application of the post-market surveillance plan, including the PMCF;
- documentation related to any outcomes and conclusions arising from application of the vigilance provisions (e.g. the trend report);
- design and manufacturing data and the related records;
- technical documentation related to Devices covered by the approved quality management system.

During these audits, IMQ assesses the technical documentation of at least one Device covered by the approved quality management system and carry out test in order to check that this system is working properly.

For class III Devices, the surveillance also includes a test on the approved parts and/or materials that are essential for the integrity of the Device, including - if necessary - a verification that the quantities of parts and/or materials produced or purchased correspond to the quantities present in the finished Devices.

In case of Manufacturer's unavailability to undergo the surveillance audit in the abovementioned timeframe, IMQ is authorised to suspend the EU Certification validity.

#### 4.11.2. Unannounced audit

At least once every five (5) years, IMQ performs unannounced audits at each Manufacturer. This frequency may be increased if the medical Devices covered by the certification have a potential high risk (e.g. class III medical Devices), if there are frequent Non-Conformities or if specific information leads to the belief that they or the related quality management system have Non-Conformities.

Normally, unannounced audits last, at least, one (1) day, are performed by at least two (2) auditors and are conducted at the Manufacturer's premises; in alternative or in addition to these, unannounced audits may be conducted at the premises of subcontractors and critical suppliers, if this can guarantee that the inspection is more effective. If a visa is required to visit the country in which the Manufacturer is located, an invitation must be provided, with the signature date and visit date left open. The subcontractors and critical suppliers must issue similar invitations.

The Manufacturer must have documented procedures to manage the unannounced audit. To ensure that this visit is effective, the Manufacturer must inform IMQ, with the required frequency, of the periods in the year in which the Devices covered by the certification are not in production, with special attention to company closures, holidays, etc.

During the unannounced audits, IMQ test an adequate sample of the Devices produced or an adequate sample from the manufacturing process to verify that the manufactured Device is in conformity with the technical documentation. Instead of, or in addition to, IMQ shall take samples of Devices from the market to verify that the manufactured Device is in conformity with the technical documentation.
The tests may also be performed by the Manufacturer, by a subcontractor or by a critical supplier, under the supervision of IMQ.

The following are at the Manufacturer's expense, according to IMQ rates:

- the costs of unannounced audits, including those for the Device acquisition activity or for testing it and the safety measures;
- the costs of any unannounced audits that IMQ was unable to perform due to failure of the Manufacturer to provide the information described above.

Moreover, if it is not possible to provide unannounced access to the Manufacturer's premises, or those of its subcontracts or critical suppliers, IMQ is authorised to suspend the EU Certification validity.

#### 4.11.3. Outcome of periodic surveillance and unannounced audits

Following periodic surveillance audits and unannounced visits, IMQ issues to the Manufacturer the Report, which highlights any Non-Conformities and Recommendations (for the classification, see Art. 4.4 above).

Relatively to the Report and to the corrections and corrective actions plan, see the requirements of Art. 4.8.5 points a) and c) here above.

Audit result

a) If no Non-Conformities are found during the audit, or if only a few minor Non-Conformities are found - which combined do not prejudice Device safety and performance and the effectiveness of the quality management system – IMQ proceeds with the maintenance of the issued EU Certificate.
The verification of the implementation and effectiveness of the corrections and corrective actions, related to any minor Non-Conformity, is normally verified during the next audit. If considered necessary, IMQ can request documentary evidence or perform extraordinary audits; in this case, refer to point b) herein below.

b) If minor Non-Conformities are found during the audit - which combined could prejudice Device safety and performance and/or the effectiveness of the quality management system - IMQ requests documentary evidence and/or performs extraordinary audits to verify the implementation and the effectiveness of the corrections and corrective actions; the maintenance of the EU Certification is subject to the positive outcome of these supplementary activities. The costs of this supplementary activity are to be borne by the Manufacturer and communicated through an appropriate quotation as per the IMQ Price List in force (see also Art. 6.1 below).
If the Manufacturer fails to respond within the timeframe established by IMQ, or if it has not been possible to obtain adequate evidence of the implementation and the effectiveness of the corrections and corrective actions, IMQ can decide to suspend the validity of the issued EU Certification (for suspension, see Art. 8.2 here below).

c) If during the audit minor Non-Conformities - which combined could prejudice Device safety and performance and/or the effectiveness of the quality management system - and/or Major Non-Conformities are found, IMQ suspends the EU Certification validity and warns the Manufacturer not to continue the production and the placing on the market of the Devices covered by it.
IMQ assesses the need to suspend any linked EU Certifications, coordinating with the other NB that issued them, if they were not issued by IMQ.
The suspension will be annulled only after IMQ has verified the solutions to guarantee conformity have been adopted (for restoring the EU Certification, see Art. 8.2.4 here below).

#### 4.11.4. Extraordinary audit and audit with short notice

On the basis of the results of the performed verifications, after incidents reporting or other reporting coming from the market or competent Authorities and – in general – in all the cases in which IMQ considers that the issued EU Certification may be at risk, IMQ can perform extraordinary verifications, included audit with short notice. The costs of these activities are to be borne by the Manufacturer and communicated through an appropriate quotation as per the IMQ Price List in force (see also Art. 6.1 below).

The audits with short notice are preformed within five (5) working days from the date of the notice to the Manufacturer. For these audits, the Manufacturer must not recuse the audit team; IMQ is committed to choosing the audit team in order to reduce the potential risks linked to the impossibility of the Manufacturer to exercise this right.

### 4.12. Renewal of the EU Certification

The Manufacturer must submit the request for renewal of the EU Certification validity with IMQ no later than eight (8) months before the expiry date of the Certification itself, providing the Devices data for which wants to obtain the renewal. This deadline also applies when the EU Certification is suspended.

For submitting the Application and reviewing it, Artt. 4.2 and 4.3 above apply.
In addition to the documentation requested during the initial certification, the Manufacturer must provide IMQ with a summary of changes and scientific findings of the Device(s), containing at least the following elements:

- all changes to the originally approved Device;
- experience gained from post-market surveillance;
- experience from risk management;
- experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I;
- experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF;
- changes to the requirements, to components of the device or to the scientific or regulatory environment;
- changes to applied or new harmonised standards, CS or equivalent documents;
- changes in medical, scientific and technical knowledge, such as:
    - new treatments,
    - changes in test methods,
    - new scientific findings on materials and components, including findings on their biocompatibility,
    - experience from studies on comparable devices,
    - data from registers and registries,
    - experience from clinical investigations with comparable devices.

IMQ will analyse this document in detail during the Device(s) technical documentation evaluation.

For conformity assessment, for the final review and for the decision on the renewal of the Certification, IMQ applies the same methods and principles used in the initial certification (see Art. 4.4 above).

Where renewal of the *EU technical documentation assessment Certificate* *(Annex IX c. II)* is required, IMQ evaluates the technical documentation for the Device to assess if the Device continues to conform to the requirements of the EU Regulation. Relatively to modalities and outcomes of evaluation, see Art. 4.5 above.

Where renewal of the *EU type-examination Certificate* *(Annex X)* is required, IMQ examines the type technical documentation and repeats the tests and inspections performed during the initial certification to assess if the type continues to conform to the requirements of the MDR. Relatively to modalities and outcomes of evaluation, see Art. 4.6 above.

Where renewal of the *EU product verification Certificate* *(Annex XI p. B)* is required, IMQ applies the same procedure as per initial certification (see Art. 4.7 above).

Where renewal of the *EU quality management system Certificate* (Annex IX c. I) or the *EU quality assurance Certificate (Annex XI p. A)* is required, IMQ evaluates the technical documentation for all of the Devices covered by the quality management system (where applicable, see Art. 4.8 above) and performs the audit at[6] the Manufacturer and, if applicable, at its critical suppliers and subcontractors to verify all of the requirements/processes.
The main aims are as follows:

- verify that the quality management system continues to conform to the requirements of the MDR;
- verify that the quality management system continues to guarantee the Device conformity with the relevant requirements of the MDR and – where applicable - to the type described in the EU type-examination Certificate.

Relatively to modalities and outcomes of evaluation, see Art. 4.8 above (with exception of Stage 1 audit, which is not performed).

Following a positive outcome of the renewal activity, the EU Certification is renewed for a further period not exceeding five (5) years. The costs of each renewal activity are to be borne by the Manufacturer and communicated through an appropriate economic offer, as per the IMQ Price List in force (see also Art. 6.1 below)

If the renewal activities are not performed and/or completed and/or does not have a positive outcome within the expiry date of the EU Certification, it loses its validity. The Certification Contract is annulled from the day after the EU Certification validity expires.
If the Manufacturer intends to reacquire the EU Certification, it must start the certification process from the beginning.

### 4.13. Extension and Changes to the EU Certification

**a) For the EU technical documentation assessment Certificate according to Annex IX (II) of MDR**:

The Manufacturer is required to communicate in advance to IMQ any plan for change to the Device approved pursuant to Annex IX chapter II of the MDR, affecting the safety and performance or the conditions of use of this Device, and to its intended purpose or claims made for it. IMQ evaluates the changes and any approval is issued in the form of an update of the EU technical documentation assessment Certificate (see also Art. 4.13.2 below).

The approval of a new trademark and/or trade name of the approved Device is an *EU Certification Extension for addition of a new trademark and/or trade name.* IMQ carries out a partial evaluation of the technical documentation and any approval is issued in the form of an update of the EU technical documentation assessment Certificate (see also Art. 4.13.1 below).

The approval of a further Device with the same intended use and the same conditions of use as the approved Device is an *EU Certification Extension for addition of a new model.* IMQ carries out a full evaluation of the technical documentation and any approval is issued as an update of the EU technical documentation assessment Certificate (see also Art. 4.13.1 below).

The approval of a further Device with intended use and/or conditions of use different from the approved Device is configured as an *initial Certification* according to Annex IX (II) of MDR and the provisions of Art. 4.2 above apply.

**b) For EU Type Examination Certificate according to Annex X of MDR:**

The Manufacturer is required to communicate in advance to IMQ any plan for change to the Type approved pursuant to Annex X of the MDR, to its conditions of use and or its intended purpose or claims made for it. IMQ evaluates the

changes affecting the safety and performance or the conditions of use of the Type and any approval of these changes is issued in the form of an update of the EU type-examination Certificate (see also Art. 4.13.2 below).
Changes to the intended purpose and conditions of use of the approved Device, with the exception of limitations, shall necessitate a new application for a conformity assessment.

The approval of a new trademark and/or trade name of the approved Type is an *EU Certification Extension for addition of a new trademark and/or trade name.* IMQ carries out a partial evaluation of the technical documentation and any approval is issued in the form of an update of the EU type-examination Certificate (see also Art. 4.13.1 below).

The approval of a further Type with the same intended use and the same conditions of use as the approved Type is an *EU Certification Extension for addition of a new model.* IMQ carries out a full evaluation of the technical documentation and performers the necessary tests; any approval is issued as an update of the EU type-examination Certificate (see also Art. 4.13.1 below).

The approval of a further Type with intended use and/or conditions of use different from the approved Type is configured as an *initial Certification* according to Annex X of MDR and the provisions of Art. 4.2 above apply.

**c) For EU quality management system Certificate according to Annex IX (I) or EU quality assurance Certificate according to Annex XI (A) of MDR.**

The Manufacturer is required to communicate in advance to IMQ:

I. any plan for significant change to the quality management system approved pursuant to Annex IX chapter I or Annex XI part A of the MDR, as:
   - changes to the sites of the Manufacturer and to manufacturing site of its subcontractors,
   - modifications to the Manufacturer's organization structure, to the process interaction and/or to the structure of the Manufacturer's quality management system,
   - internalisation / outsourcing of a process (or part of it),
   - elimination and addition of critical suppliers / subcontractors as well as changes to the activities entrusted to them,
   - changes to the production process (e.g. production technology, equipment, clean room and controlled environment, sterilization process, etc.) and to the approved design process (e.g. tasks of design verification and validation, etc.), which affects the compliance of the quality management system and the Devices - covered by this system - with the MDR applicable requirements (general safety and performance requirements of Annex I of the MDR included),
   - changes to the design specifications which affects compliance of the Device with the safety and performance requirements of Annex I of the MDR,
   - changes to the intended use of the Device, to its conditions of use or claims made for it, and
   - any other modification affecting the compliance of the quality management system and the Devices - covered by this system - with the MDR applicable requirements (general safety and performance requirements of Annex I of the MDR included).

   In order to clarify which changes constitute "*significant changes to the quality management system*", IMQ applies the document NBOG 2014-03 "*Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System*" and any other relevant documents that may be available (e.g. MDCG documents).
   The approval of these changes is issued as an update of the EU quality management system Certificate or of the EU quality assurance Certificate (see also Art. 4.13.2 below);

II. any plan for significant change to Device range covered by the quality management system approved pursuant to Annex IX chapter I or Annex XI part A of the MDR. These changes are divided into:

- Enlargement of the Device-range which is an *Extension of the EU Certification* whose approval is issued as an update of the EU quality management system Certificate or of the EU quality assurance Certificate (see also Art. 4.13.1 below). In this case, the extensions are classified into the following types:
  - *approval of a new tradename and/or a new trademark of an already approved Device*, for which IMQ carries out a partial evaluation of the technical documentation;
  - *approval of a new model with the same intended use and the same conditions of use as the approved Devices (as belonging to an already approved product category)*, for which IMQ carries out a complete evaluation of the technical documentation;
  - *approval of further Devices with the intended use and the conditions of use different from the approved Devices (as belonging to a new product category),* for which IMQ carries out a complete evaluation of the technical documentation and a Quality Management System audit;
- Changes to the model name, commercial name and tradename of the Device, for which IMQ evaluates the modification and any approval is issued as an update of the relevant EU certificate (see also Art. 4.13.2 below);
- Limitation of the Device-range covered by the quality management system and of the EU Certificate, which requires an update of the relevant EU Certificate (see also Arts. 4.13.2 and 8.1 below).

**For all types of EU Certification issued according to MDR**, in addition to the above, the Manufacturer is required to communicate in advance to IMQ also:

- the change of Authorised Representative in accordance with the provisions of Art. 12 of the MDR;
- the administrative changes, such as changes of the registered name of the Manufacturer, (where present) of the Authorised Representative and of the critical suppliers / subcontractors, changes of the registered office of the Manufacturer and (where present) of the Authorised Representative, etc.
- the corporate changes of the Manufacturer, such as sell-off, transformation, merger, split, transfer or rental, etc. of a company or a company branch (see also Art. 7.2 below).

IMQ evaluates the above-mentioned changes and any approval is issued as an update of the relevant EU certificate (see also Art. 4.13.2 below).

### 4.13.1. Extension of the EU Certification

On request, IMQ provides a dedicated Application to be used to submit a request for Extension of the EU Certification established in the Art. 4.13 above. All parts of this form must be filled in, providing the data of the Devices subject to the extension; it must be signed by the Legal representative (or by an appropriately delegated person) of the Manufacturer or of its Authorised Representative.
The Application for extension must be sent to IMQ with the documentation expressly requested in the Application itself (including the technical documentation of the Devices subject to the extension).

The costs of performing the verification to be performed for the EU Certification extension are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price list in force (see also Art. 6.1 below).

For the review and acceptance of the Application, conformity assessment, final review and final decision, IMQ uses the same methods and principles as for the initial certification (see Arts. 4.3, 4.4, 4.5, 4.6 and 4.8 above).

It is understood that any kind of extension mentioned above requires prior approval from IMQ in written form before being implemented by the Manufacturer.

#### 4.13.2. Changes to the EU Certification

On request, IMQ provides a dedicated form to be used to communicate proposals of changes established in the Art. 4.13 above. All parts of this form must be filled in, providing the data of the Devices subject to the change, and it must be signed by the Legal representative (or by an appropriately delegated person) of the Manufacturer or of its Authorised Representative.

Upon receipt of the communication with the proposal of modification, IMQ assesses the proposed changes and indisputably establishes the extent of the verification to be performed.
The costs of performing these verifications are borne by the Manufacturer and notified through a dedicated quotation, according to the IMQ Price List in force (see also Art. 6.1 below).

Upon acceptance of the quotation, the Manufacturer is required to transmit to IMQ the necessary documentation for the evaluation of the proposed changes (including technical documentation if the change has an impact on it).

For the review and acceptance of the notice, the conformity assessment, final review and final decision, IMQ uses the same methods and principles as for the initial certification (see Art. 4.3, 4.4, 4.5, 4.6 and 4.8 above).

It is understood that any type of modification indicated above requires prior approval by IMQ before being implemented by the Manufacturer.

### 4.14. Transfer of the EU Certification from another NB

If the Manufacturer has already obtained one or more EU Certifications from another NB (herein below “outgoing NB”), and requests IMQ to step in as a new NB, the Manufacturer must provide IMQ with the following documentation in addition to that listed in Art. 4.2 above:

- a copy of the currently valid EU Certifications issued by the outgoing NB;
- a copy of the audit reports for the last certification period, drawn up by the outgoing NB;
- if the designation of the outgoing NB was suspended, limited or revoked, confirmation from the Authorities responsible for NBs (in case of designation suspension or limitation) or competent Authority (in case of designation revocation) that there are no safety issues related to the Device in question.

Moreover, on request, IMQ provides a dedicated form to be used to communicate the following information:

- the date from which the Certifications of the outgoing NB are no longer valid;
- the date up to which the identification number of the outgoing NB can be indicated in the information provided by the Manufacturer, including its promotional material;
- the last serial number or lot number for which the outgoing NB is responsible.

All parts of this form must be filled in, and it must be signed by the Legal representative (or by an appropriately delegated person) of the Manufacturer or of its Authorised Representative.

In any case, IMQ does not assume responsibility for the following EU Certifications: EU technical documentation assessment Certificate (Annex IX chapter II of the MDR) and related EU quality management system Certificate (Annex IX chapter I of the MDR); EU type-examination Certificate (Annex X of the MDR); EU product verification Certificate (Annex XI Part B of the MDR).

#### 4.14.1. Forced transfer of the EU Certification from another NB

Except for the exclusion listed in Art. 4.14 above, if the Manufacturer requires to transfer the EU Certification from another NB following the renunciation, suspension, limitation or revocation of the designation of this other NB (forced transfer), IMQ reviews the Application (see also Art 4.3 above).

With adequate/complete technical documentation and the confirmation that there are no safety issues related to the Device in question and that the outgoing NB's Certificate is not unduly issued, IMQ takes responsibility for the EU Certification and informs the Manufacturer and the Authority responsible for NBs in writing. In particular:

- In the event of suspension or limitation of the designation of the outgoing NB, IMQ takes responsibility for the EU Certification surveillance activities for the suspension/restriction period established by the Authorities responsible for NBs.
- In the event of voluntary renunciation or revocation of the designation of the outgoing NB, IMQ takes responsibility for the EU Certification for a maximum period of 9 months, during which IMQ conducts the whole conformity assessment procedure. As far as the evaluation procedure, see the requirements in Art. 4.8 here above.
  If the outcome of the assessment is positive, IMQ issues the Manufacturer with the required EU Certification.
  If the outcome is negative, IMQ issues the Manufacturer with a dedicated communication containing a description of the Non-Conformities found.

#### 4.14.2. Voluntary transfer of the EU Certification from another NB

If the Manufacturer voluntarily requests IMQ to step in as a new NB (voluntary transfer), IMQ applies the whole conformity assessment procedure established for the initial certification (see Art. 4.8 above).

The day after which IMQ is assigned the assessment tasks of the outgoing NB coincides with the date of EU Certification issue by IMQ.

## Art. 5. OBLIGATIONS OF THE MANUFACTURER

### 5.1. Obligations of the Manufacturer

The Manufacturer undertakes to:

- Satisfy the general obligations of Manufacturers established in Art. 10 of the MDR;
- Guarantee the conformity of the Device (subject to the EU Certification) to the general safety and performance requirements of Annex I of the MDR, taking into account the generally acknowledged state of the art;
- Draw up the documentation referred to in Annexes II and III of the EU Regulation for each Device subject to EU Certification and keep it up to date. This documentation includes, inter alia, a clinical evaluation, a post-market surveillance plan and a PMSR/PSUR compliant with the requirements of the MDR and of the relevant available guidelines (e.g. MDCG documents);
- Establish, document, apply, maintain, update and continuously improve a quality management system compliant with the requirements of the Art. 10 (9) and Annex IX (I) or XI (A) of the MDR and which assures the conformity of the Device with the applicable requirements of the MDR.
  This quality management system includes, inter alia, a risk management system, a post-market surveillance system, a vigilance system (including the recording and reporting of incident and safety corrective actions), a system for managing complaints, withdrawals and recalls, a system for the registration of Manufacturer and Devices, a UDI system, compliant with the MDR requirements;
- Notify IMQ in advance of changes to the issued EU Certification, in accordance with the procedures defined in Art. 4.13 of this Regulation;
- Not to insert in or not to use to manufacture the Device any substance subject to the specific procedures referred to in Annex IX points 5 and 6, Annex X point 6, and Annex XI point 16 of MDR;
- Guarantee that IMQ personnel has access to the design, manufacturing, inspection, testing and warehouse locations of the Device in question, and provide the required means and aids so that IMQ can perform the required Service, including access to the related documentation and complaints received. In this regard, the inability to carry out the activities for fact and/or cause imputable to the Manufacturer (for example, inability to access to such places, lack of documentation), such as to prejudice the fulfilment of obligations by IMQ, will constitute cause for termination of Certification Contract;
- Guarantee that IMQ personnel can perform periodic surveillance audits and unannounced audits, according to the terms of the relevant assessment procedure of the MDR (see also Art. 4.11 above) and, where necessary, extraordinary verifications;
- Guarantee that the Authorities responsible for NBs and the European Commission can access the above locations, accompanied by IMQ personnel. These visits, which are for surveillance of the operation of IMQ's personnel and not that of the Manufacturer, are normally suitable notified in advance;
- Notify IMQ of the periods of the year in which the Manufacturer's activities are suspended (e.g. company closures, holidays, etc.);
- Notify IMQ of any incident related to its Devices and any safety corrective actions within the times defined in Art. 87 of the MDR;
- Immediately inform IMQ of all non-compliant situations found by the vigilance Authorities, as well as any suspensions or revocations of authorisations, concessions, etc.;
- Immediately inform IMQ of any legal/administrative proceedings in progress related to the subject of the EU Certification, with the exception of the limits set by the provisions;

- Make no declaration nor publish its certification in a way that could be considered misleading, unauthorised, or inconsistent with the field of application of the Certification itself, nor use its Certification in a way that could discredit IMQ;
- If the EU Certification is suspended, revoked or has expired, stop the use of advertising material that contains references to it;
- When providing copies of the documentation regarding the Certification to third parties (EU Certificate included), reproduce the documents in full.

The communications referred to above must be sent to IMQ by registered mail with return receipt or by certified email to this address: prodotto.imq@legalmail.it.

In relation to fulfilment of the obligations described in this paragraph, on payment, IMQ can perform extraordinary verification and, if necessary, suspend or revoke the Certification, depending on the severity of the situation and/or the impact of the event that occurred.

### 5.2. Safety at work – Obligation of notice

The Manufacturer, according to the legislation in force on safety and accident prevention at work, undertakes to provide IMQ personnel and any accompanying persons with a full and detailed notice on the specific existing risks in the environment in which they will work.

The Manufacturer also undertakes to promote, through its own person empowered for that purpose, the cooperation and coordination to implement the measures and actions of protection and prevention from risks at work, which affect the work activities of the auditors appointed by IMQ, and which require the protection of workers and of all other subjects who work or in any case are present in the same work environment.

The Manufacturer, according to any specific existing risks, will provide IMQ personnel and any accompanying persons with the appropriate personal protection equipment and will put in place any protection to allow the activities to be carried out in total safety.

## Art. 6. FINANCIAL TERMS AND CONDITIONS

### 6.1. Amounts due for Certification

The amounts due for the initial Certification and, where specified, for the maintenance activities (unannounced audit included), together with the relevant payment conditions, are indicated in the quotation as accepted by the Manufacturer; this quotation is formulated according to the fees indicated in the IMQ Price List in force and on the basis of the information provided by the Manufacturer (number of staff, operative sites, technical documentation, etc.).
The Manufacturer is required to correctly communicate all the information requested during the quotation formulation phase, in order to issue it, as well as update IMQ on any modifications; on the basis of the updated data, IMQ assesses if it is necessary to modify the financial terms and conditions agreed.

Any changes to the maintenance costs of the Certification determined following changes in the number of employees, sites, evaluation procedure, etc. will be properly communicated by IMQ to the Manufacturer.

On request from the Manufacturer, IMQ draws up a quotation for the renewal of the EU Certification (see also Art. 4.12 above). On receiving acceptance of this quotation, IMQ plans and execute the EU Certification renewal activities.

If the Manufacturer fails to accept the quotation, at least six (6) months prior to the Certificate expiry date, the Certification Contract will be terminated as of the date following expiry of the Certificate itself. The Manufacturer must pay the amounts due for EU Certification maintenance up to its expiry date.

On request from the Manufacturer, IMQ draws up a quotation for the extension and/or for the approval of changes to EU Certification (see also Art. 4.13 above). On receiving acceptance of this quotation, IMQ plans and carries out the activities aimed at updating the EU Certification; if the Manufacturer fails to accept the quotation, IMQ will not be able to perform the verifications.

Where IMQ considers necessary to perform supplementary/extraordinary verifications (for example aiming at Non-Conformities solution), IMQ draws up a dedicated quotation according to the IMQ Price List in force. On receiving acceptance of this quotation, IMQ plans and carries out those verifications; if the Manufacturer fails to accept the quotation, IMQ will not be able to perform the verifications.

For anything not specifically set out in the quotation, as well as any absence of the same, the amounts indicated in the IMQ Price List in force, which is intended as specifically referred to, are applied.

The payments due for the Service requested are subject to VAT as required by law (article 3. Pres. Dec. No. 633 dated October 26, 1972).

### 6.2. Variation to IMQ Price List

Any variations to the IMQ Price List are communicated by IMQ to the Manufacturers if the same imply a significant modification to the existing financial conditions applied.

The Manufacturer has, in any case, the right to renounce the EU Certification within one (1) month from the receipt date of the first invoice updated to the new fees.

During the period of prior notice, the Manufacturer who avails of the aforementioned right to renunciation will be charged the fees prior to the variations.

### 6.3. Payment of amount due

Upon conclusion of the Service, IMQ issues to the Manufacturer the document set out at Art. 2.2 above, only on condition that all the fees due to IMQ have been paid.

In case of failure to pay the amounts and/or related interests, or in the event of non-fulfilment of the Certification Contract, IMQ has the right to interrupt the Services at any moment, until the Manufacturer has paid and/or remedied to its non-fulfilment.

# Art. 7. USE OF CERTIFICATIONS AND CE MARKING

## 7.1. CE Marking

For the devices that have attained the relevant EU Certifications from IMQ, the Manufacturer must draw up a dedicated declaration of conformity and affix the CE marking according to the requirements of the MDR.

Before affixing the CE marking for Devices that have attained the EU type-examination Certificate from IMQ, the Manufacturer must attain a further EU Certification according to the conformity assessment procedure based on Annex XI part A (guarantee of production quality) or according to the procedure of Annex XI part B (product verification) of the MDR.

Before affixing the CE marking for Devices that have attained the EU technical documentation assessment Certificate from IMQ, referred to in Annex IX chapter II of the MDR, the Manufacturer must attain by IMQ the EU quality management system Certificate referred to in Annex IX chapter I of the MDR.

The CE marking must be followed by the number 0051 - IMQ's identification number as the NB engaged for the conformity assessment procedure.
The Manufacturer must unequivocally distinguish its Devices with CE0051 marking from those without.

In the labelling, instructions for use and advertising of Devices ("Declarations"), the Manufacturer must not make use of texts, names, trademarks, pictures and figurative or other signs that could induce the user or patient to mistake the intended use, safety or performance of the Device, as prescribed in Art. 7 of the MDR.

## 7.2. Transferability of the Certification EU – Modification in the organizational structure

The use of EU Certifications issued by IMQ is strictly reserved to the Manufacturer and it is not transferable, without prejudice to cases of sell-off, transformation, merger, split, transfer or rental of the company or a branch of the company involved.

In these cases, the outgoing Manufacturer[8] must send a communication to IMQ in a timely manner and in any case no later than fifteen (15) days from the entry of the registration into the Business Register, where required; failure to observe this term can cause the application of the provision to suspend or revoke the Certification.

The ingoing Manufacturer[9] must also forward to IMQ a written request for maintenance of the Certification of the outgoing Manufacturer, with copy of the relevant Certificate of registration in the Chamber of Commerce, written declaration of absence of changes or communication of substantial changes and of any further documents, if these are considered necessary.

IMQ reviews the request of EU Certification transfer, in order to verify that the conformity of quality management system and of the Devices - covered by it - to the applicable requirements of the MDR.

IMQ at its sole discretion assesses the need to carry out additional documentary verification activities.

[8] The subject whose certification has been transferred following the change in its organizational structure.
[9] The subject resulting from the event modifying the organizational structure of the outgoing Manufacturer.

The EU Certification update and any supplementary verifications' costs are borne by the ingoing Manufacturer and communicated Manufacturer with a dedicated quotation formulated by IMQ, according to the Price List in force.

The transfer of the EU Certification depends on the positive result of the assessments carried out, as well as payment of the balance of all the amounts due by the outgoing Manufacturer.

## Art. 8. RENUNCIATION, SUSPENSION AND REVOCATION OF THE CERTIFICATION

### 8.1. Renunciation of the EU Certification

If the Manufacturer intends to renounce an EU Certification issued by IMQ, it must give written communication signed by the Legal representative (or by an appropriately delegated person) of the Manufacturer.

This communication must be sent to IMQ by registered mail with return receipt or by certified email to this address: prodotto.imq@legalmail.it, or other modality valid for all purposes and effects of law.

In case of renunciation, the Manufacturer must:

- Cease affixing the CE marking with the identification number IMQ (0051) on the Devices subject to the renunciation and referring to IMQ as NB for these Devices;
- Communicate, in the same date of the renunciation, the serial number or batch number of the last Devices placed on the market and any the stock in the production sites and warehouses of the Devices which show reference to IMQ as NB (identification number 0051); IMQ - at its sole discretion - reserves the right to authorize any stock;
- Use up abovementioned Devices in own production sites or warehouses within the term which will be indicated by IMQ.

In relation to the obligations provided in this Article, IMQ will be allowed to perform verification checks; all expenses related to these additional checks are the responsibility of the Manufacturer.

In case of renunciation, IMQ, in turn:

- Cancels EU Certification, which will cease to produce its effects starting from the date of receipt of the related communication by IMQ;
- Inserts the renunciation notification in EUDAMED;
- Cancels the surveillance activity of EU Certification, see Art. 4.11 above, if conducted by IMQ.

If the Certification Contract covers more EU Certificates, the renunciation of an EU Certificate will not result in the termination of the Certification Contract.

## 8.2. Suspension of validity of the EU Certification

### 8.2.1. Justification for suspension

The validity of the EU Certification issued by IMQ is allowed to be suspended in the event of failure to fulfil the obligations, and specifically:

- Failure to pay the amounts due to IMQ;
- Failure of the Manufacturer's business;
- Failure of the Manufacturer to fulfil the obligations referred to in Art. 5 above;
- A Major Non-Conformity or minor Non-Conformities that, when combined, prejudice Device safety and performances and/or the effectiveness of the quality management system; failure to adopt corrections and corrective actions and, generally, a negative outcome of the surveillance audits, including the unannounced audits; in case of failure to meet the commitments to maintain conformity of the Devices and the quality management system;
- Notifications from the market and/or competent Authorities, prior to investigation into their severity;
- Implementation of substantial changes to the Device and/or to the quality management system by the Manufacturer without prior IMQ's approval;
- Conviction for facts surrounding failure to comply with the mandatory requirements related to the certified Device;
- Undue use of CE marking (see Art. 7 above).

### 8.2.2. Communication of the suspension

The suspension of the Certification and any restoration of it are communicated to the Manufacturer by registered letter with notification of receipt or by certified email or other modality valid for all purposes and effects of law. The communication shows the reason for the suspension and deadlines by which the Manufacturer must implement the corrections and corrective actions requested. The Manufacturer must communicate to IMQ of having taken charge of the provision, adaptation to requirements and any other useful information on the solution of the findings disputed. The communication must occur in written form. The suspension will consider the principle of proportionality.

### 8.2.3. Consequences of the suspension

Following the suspension, the Manufacturer must interrupt the use of the EU Certifications and abstain from publicising them until the end of the suspension period.

The suspension implies the impossibility of affixing the CE marking with the identification number IMQ (0051) and the consequent impossibility to put the related Devices on the market, starting from the suspension date.

In the most serious cases, IMQ reserves the right to request the Manufacturer to recall the Devices from the market.

IMQ is allowed to suspend the surveillance activity, except for unannounced audits. In any case, the Manufacturer must pay the amounts due for EU Certification maintenance.

IMQ notifies the suspension in EUDAMED.

### 8.2.4. Restoring the Certification

The suspension can be cancelled only when the Manufacturer has satisfactorily resolved the Non-Conformities found or when the situation having given way to the suspension provision has been resolved.

Before proceeding to restore the Certification, IMQ performs verification to ascertain the actual resolution of the issues previously found; all the costs for these additional verification activities are borne by the Manufacturer and communicated to the Manufacturer with a dedicated quotation formulated by IMQ, according to the Price List in force (see also Art. 6.1 above).

IMQ notifies the restoring of the Certification also in EUDAMED.

#### 8.2.5. Suspension period duration

The suspension period duration, which is not allowed to exceed six (6) months, is indicated in the communication set out at Art. 8.2.2 above; if the suspension is not cancelled within this period established by IMQ, the EU Certificate is revoked.

### 8.3. Revocation of the EU Certification

#### 8.3.1. Justification for revocation

The EU Certification issued can be integrally or partially revoked by IMQ in case of failure by the Manufacturer to fulfil the obligations, and especially in case of:

- Failure to cancel the suspension as set out at Art 8.2 above, within the period indicated by IMQ (see also Art. 8.2.5 above);
- Serious non-observance of the obligations of the Manufacturer, set out in Art. 5 above;
- Fraudulent or illegitimate use of the EU Certification;
- Misleading use of the EU Certification, such to damage or discredit IMQ;
- Significant and systematic Non-Conformities; failure to adopt corrective actions and, generally, negative outcomes of the supplementary/extraordinary verifications; failure to fulfil the commitments to maintain conformity of the Devices and quality management system, which constitutes serious negligence;
- Differences between the sample taken and the Devices manufactured or from the market and the specification laid down in the technical documentation or in the approved design;
- Failure to adapt the Device and/or quality management system to the requirements imposed by the applicable new revisions of the MDR and applicable standards or CS;
- Failure to pay the amounts due to IMQ, for any reason. In this case, before proceeding with the revocation, IMQ sends a communication to the Manufacturer entitled “prior notification of revocation”; after fifteen (15) days have elapsed from the date of this communication without the Manufacturer having paid the amounts due, the Certificate will be revoked. During this period of prior warning, all verification activities are suspended, similarly to what occurs in the hypothesis of suspension;
- Conviction for facts surrounding failure to comply with the mandatory requirements related to the certified Device;
- Failure or final termination of the Manufacturer’s business.

#### 8.3.2. Communication of the revocation

The decision of integral or partial revocation is communicated to the Manufacturer by registered letter with notification of receipt or by certified email or other modality valid for all purposes and effects of law.

#### 8.3.3. Consequences of the revocation

In the case of revocation of the EU Certification, the Manufacturer immediately undertakes to:

- Abstain from publicising and using the EU revoked Certificates, removing the logo and the references to IMQ from the documentation in use;
- Cease affixing the CE marking with the identification number IMQ (0051) to Devices referable to the EU Certificate revoked and, consequently, stop their production and placing on the market with that marking;
- Pay the balance of all the amounts due to IMQ.

IMQ also interrupts the surveillance activity and communicates the revocation in EUDAMED.

If the EU Certification was revoked due to defects potentially hazardous for users and/or patients, IMQ is allowed to invite the Manufacturer to withdraw all units of the Device from the market and, in any case, informing the competent Authority.

If the Certification Contract covers more EU Certificates, the revocation of an EU Certificate will not result in the termination of the Certification Contract.

## Art. 9. LEGISLATIVE AND REGULATORY VARIATIONS

### 9.1. Modifications to the legislative provisions

If the legal provisions applicable to the single Service in question undergo significant variations that affect the validity of the issued EU Certification, IMQ informs the Manufacturer, which can adapt its Devices, or its quality management system, within the term that will be indicated by IMQ, or to renounce the EU Certification.

In case the Manufacturer intends to adapt to the new provisions, IMQ will be entitled to repeat the tests and verification activities on the Devices or the quality management system assessment, as also to request new documentation. The expenses for said activities will be charged to the Manufacturer, according to a new quotation.

In case the Manufacturer does not intend to adapt and does not send a communication of renunciation of the EU Certification within the time of application of the new provisions, IMQ will revoke the EU Certification issued according to Art. 8.3.1 above.
In case of revocation of the EU Certification, the provisions of Art. 8.3 above are applied.

### 9.2. Modifications to IMQ Regulation

In case the requirements applicable to the certification activity are subject to variations, IMQ may update the conformity assessment procedure to transpose the new provisions.

IMQ also reserves the right to make modifications and integrations to this Regulation without the preventive agreement of the Manufacturer; in this case, IMQ will communicate the change of the Regulation by a notice to the Manufacturers or, if these changes do not affect the work carried out for the specific Manufacturer, by publishing them on the website www.imq.it in the section "UE Directives and Regulations -> Medical Device (MDR) – Regulation 2017/745/EU".

If these changes do affect the Manufacturer and have a significant impact on the activity carried out for the specific Manufacturer (e.g. variation of the frequency or duration of visits, etc.), IMQ will inform it, by formulating a new quotation, where necessary.
The Manufacturer will have the right to renounce the EU Certification within thirty (30) days following the IMQ's communication; in this case the provisions of Art. 8.1 above are recalled and applied.
If the assessment process for obtaining the Certification is still in progress, the Manufacturer will have the right to withdraw from the Certification Contract within thirty (30) days following IMQ's communication, renouncing the conformity assessment and without prejudice to payment of the amount due to IMQ for the activities carried out by the same until receipt of the notice of withdrawal.

### 9.3. Supplementary assessments following modifications

Any costs incurred for the documental assessment form and/or on site, deriving from the changes to the standards or regulations referred to above are, in any case, borne by the Manufacturer.

## Art. 10. LIMITS TO CERTIFICATION AND RESPONSIBILITY

### 10.1. Liability of Manufacturer – Hold Harmless

The Manufacturer undertakes to comply with and maintaining compliance with mandatory requirements, such as laws, regulations, etc., of an international, national or local level, with particular regard to the products, processes and services inside the scope of Certification.

The issue and maintenance of the EU Certification do not constitute attestation nor guarantee by IMQ of conformity to the compulsory requirements that weigh on the Manufacturer and, in general, of the legislative conformity of the latter.

Therefore, the Manufacturer is and remains the only responsible party towards itself and towards third parties of the correct activity and conformity of the same, and of its products/services, to the applicable standards as well as to the expectations of the Manufacturers and third parties in general**.**

The Manufacturer also undertakes to hold harmless IMQ and its employees, external experts and subcontractors against any complaint, action and/or claim of third parties connected with activities performed by IMQ according to this Regulation.

### 10.2. IMQ breach – Limits of responsibility

Except in cases of fraud or gross negligence, the responsibility of IMQ towards the Manufacturer for any damage deriving from the total or partial execution or non-fulfilment of its obligations subject matter of the Certification Contract will be limited to a sum which cannot exceed a total amount equal to three (3) times the sum of the amount paid for the activities carried out by IMQ in relation to the performed evaluation activity, starting from the verification of the event which has determined the responsibility of IMQ.

### 10.3. Forfeiture clause

Any complaint or claim for damages against IMQ must be brought by the Manufacturer, on pain of forfeiture, within and no later than one (1) year from the event which has given way to the claim or to the complaint.

### 10.4. Exclusion of IMQ from liability

Except in cases of fraud or gross negligence, even in cases of proven failure by IMQ, it remains excluded compensation in favor of the Manufacturer for any loss of profit, such as business activity interruption, loss of profits, loss of business opportunities, of revenue, business start-up or of expected profits.

## Art. 11. DURATION OF CONTRACT, RIGHT TO WITHDRAW AND PENALTIES

### 11.1. Contract entry into force

The Certification Contract is considered to be in force and legally binding as long as the Manufacturer has accepted in writing the IMQ quotation within the time of validity, has submitted the Application for Certification, has signed the "EU Certification Contract - Regulation (EU) No. 2017/745 on medical devices" with full acceptance of this Regulation and IMQ has confirmed in writing the Manufacturer's order.

Acceptance of the quotation by the Manufacturer constitutes an irrevocable Offer.

### 11.2. Duration of the contract

With exception of the hypotheses set out at Art. 11.3 below, the Certification Contract, of which this Regulation constitutes an integral and substantive part, is entered into force for an indefinite time period, starting from the date of entry into force set out at Art. 11.1 above.

### 11.3. Right to withdrawal and penalties

Each contracting party has the right to withdraw from the Certification Contract at any time by registered letter with notification of receipt, or other modality valid for all purposes and effects of law, signed by the Legal representative or by an appropriately delegated person.

This communication, if sent to IMQ by certified email, must be sent to the address: prodotto.imq@legalmail.it.

The withdrawal by the Manufacturer entails the renunciation of the EU Certification which will cease to produce its effects starting from the date of receipt of the related communication by IMQ. Referring to the obligations for the withdrawal, see Art. 8.1 above.

The Manufacturer is allowed to withdraw from the Certification Contract before obtaining the EU Certification. However, in this hypothesis:

- If the notice of withdrawal arrives to IMQ before the start of the activities, the Manufacturer shall be required to pay a penalty equal to ten percent (10%) of the total amount of the offer;
- If the notice of withdrawal arrives to IMQ after the start of the assessment activities, but before the completion of the assessment process, the Manufacturer shall be required to pay the amount relating to the activities carried out by IMQ until the time of receipt of the notice of withdrawal and, in addition, an amount equal to ten percent (10%) of the total amount of the offer;
- If the notice of withdrawal arrives to IMQ after the completion of the assessment process, the Manufacturer shall be obliged to pay the total amount of the offer.

The Manufacturer who withdraws after having obtained the Certification, is required to the payment of all the amounts invoiced by IMQ, according to the terms and frequency indicated in the offer, up to the date of receipt of the withdrawal notice. The Manufacturer shall also be obliged to pay IMQ the maintenance amounts for the period in progress at the date of withdrawal and, if the relative communication is not received by IMQ at least 15 (fifteen) days before the deadline for invoicing the amounts for the following period, the Manufacturer shall also be obliged to pay IMQ the maintenance amounts for that period. In no case will IMQ be obliged to refund the amounts already paid at the date of receipt of the notice of withdrawal from the Manufacturer for Certification and Maintenance.

In any case, the failure to perform the renewal activities within the validity period of the Certification involves the termination of the Certification Contract from the day following the expiration date of the Certificate (see Art. 4.12 above).

The withdrawal by IMQ - before and/or during the assessment activity - determines the cancellation of the evaluation process and the related offer, with the return to the Manufacturer of any amounts already paid to IMQ; after this restitution, nothing else can be claimed for any reason, cause or cause whatsoever by the Manufacturer against IMQ.

The withdrawal by IMQ – after the Certification issue - determines the revocation of the EU Certification for all the certified Devices, which will therefore cease to produce its effects starting from the date of receipt of the relevant communication by the Manufacturer, unless otherwise indicated by IMQ. In the event of withdrawal by IMQ after the certification issue, the Manufacturer shall not be entitled to receive any sum by way of compensation or for any other reason from IMQ.

## Art. 12. PROTECTION OF PERSONAL DATA

### 12.1. Processing of personal data

Pursuant to Regulation (EU) No. 2016/679 on the protection of natural persons with regard to the processing of personal data ("General Data Protection Regulation"), personal data provided directly by the Manufacturer or via third parties are and will be processed by IMQ - and, in particular, recorded and stored in a database - in order to ensure proper execution of the contractual relations with the Manufacturer. Special categories of personal data and personal data relating to criminal convictions and offences, pursuant to Arts. 9 and 10 respectively of the General Data Protection Regulation may be requested as a mandatory condition for the issue of certification. These data will be processed solely for the purpose of providing the service requested, applying appropriate, strengthened technical and organisational security measures.

For the above purposes, the data requested ("Data") will be processed using IT, manual and ICT tools, applying logic strictly correlated with the purposes of the processing and, in any case, in a manner that guarantees the security and confidentiality of the Data.

Proper execution of the contractual relations with IMQ therefore depends on provision of the Data by the Manufacturer, with the consequence that refusal to provide the Data will prevent IMQ from continuing these contractual relations.

The Data will be processed for the time strictly necessary for execution of the contractual relations with the Manufacturer, subject to a further period for which the Data will be stored of 10 years (dependent on whether specific

EU regulations or directives require retention for a longer period) from completion of the last service provided, in order to comply with the established legal and regulatory obligations.

IMQ may disclosure the Data to accreditation and certification Bodies, Administrations, Institutions, Associations, Judicial Authorities and Public Security Authorities, for use to the extent of their respective specific responsibilities, as well as to all other relevant competent Authorities and, in general, to all public and private entities to which disclosure is required by law or necessary for execution of the services provided by IMQ. These parties will process the Data as independent Data controllers.

The Data are disseminated solely to guarantee institutions and consumers with regard to the issue, existence, waiver, suspension or withdrawal of the certification.

### 12.2. Data controller

The "Data controller" is IMQ S.p.A. with headquarters at Via Quintiliano No. 43 - 20138 Milan – Italy.

Pursuant to Arts. 15-21 of the General Data Protection Regulation, the Manufacturer may at any time exercise the rights of access, rectification or erasure (so-called "right to be forgotten"), restriction of processing and to data portability by sending a specific request to the Data Protection Officer (DPO): dpo@imqgroup.it.

The Data may be disclosed and processed by third-party companies and other parties (including but not limited to suppliers of IT services, banks, professional firms, consultants) that perform activities outsourced by the Data controller in their roles as Data processors.

The list of specifically authorised Data processors is available from the Data controller.

### 12.3. Consent to processing personal data

By signing this Regulation, the Manufacturer gives consent to the processing of the Data for the purposes stated above and, also, to be disclosed and disseminated in that context.

## Art. 13. COMPLAINTS AND APPEALS

### 13.1. Complaints

The Manufacturer, like anyone who is interested in doing so, is allowed to present a complaint regarding the work of IMQ or IMQ certified Organizations, stating and motivating the reasons of the complaint, using the methods referred to in the IMQ's website at following https://www.imq.it/en/contact-us. IMQ will process the complaint according to its procedures, described in the specific section of the aforementioned website.

### 13.2. Appeals

The Manufacturer is allowed to lodge an appeal against the decisions taken by IMQ regarding the result of the conformity assessment within thirty (30) days from receipt of the relevant communication, stating and motivating the reasons for the objection, following the procedures laid down on IMQ's website at following https://www.imq.it/en/contact-us.

IMQ will take care to manage the appeal according to its own procedures, described in a dedicated section of the aforementioned website. The decision on the appeal - taken by a Committee composed by persons not involved in the conformity assessment activities subject to appeal - will be communicated to the Manufacturer by IMQ within four (4) months from the date of receipt of the appeal.

## Art. 14. APPLICABLE LAW AND COMPETENT COURT

### 14.1. Applicable law

The Certification Contract, of which this Regulation is an integral and substantive part, is governed by Italian law.

### 14.2. Competent court

Any dispute regarding the application or interpretation of the Certification Contract, including those on its validity, performance and termination, will be subject to the exclusive jurisdiction of the Court of Milan (Italy).