Title	**REGULATION FOR CONFORMITY ASSESSMENT OF IN VITRO DIAGNOSTIC MEDICAL DEVICES PURSUANT TO REGULATION (EU) 2017/746 FOR WHICH IMQ OPERATES AS NOTIFIED BODY NO. 0051**
Reference	REG. IMQ/ON/IVDR-E
Revision and date of entry into force	Rev. 3 of 22/04/2025
Approved by	IMQ S.p.A. - Business Unit "Prodotto" (FP)

GENERAL NOTE: this document is a translation to English language based on the original document REG. IMQ/ON/IVDR – rev. 3 (in Italian language). In case of discrepancy, the original document prevails.

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Art. 1. FOREWORD

This document shall apply in its entirety unless the Parties expressly agree to derogations.

Any amendment or waiver shall be valid only if agreed in writing in advance between the Parties. If one or more of the articles provided for are for any reason null and void or ineffective, the nullity or ineffectiveness shall not extend to the other provisions of this Regulation.

Any expressly agreed exceptions may in no way affect the conformity assessment procedures according to which IMQ S.p.A. (hereinafter, "IMQ"), as Notified Body (hereinafter, "NB"), is required to operate.

1.1. Definitions

For the purposes of this Regulation, the definitions set out in Art. 2 of the IVDR apply and, in addition, the following definitions are introduced:

Supplier: natural or legal person (other than the Manufacturer) providing a product/service in connection with the Device.

Critical Supplier: natural or legal person (other than the Manufacturer) who supplies materials, components or services that could affect the safety or performance of the Device.

Critical Supplier on specification: natural or legal person (other than the Manufacturer) who supplies materials, components or services that could affect the safety or performance of the Device, made according to the Manufacturer's specifications.

Working days: days that can be legally worked according to the national calendar of the Italian state.

Nonconformity: failure to meet a requirement or deviation from the reference specification.

Major Nonconformity: Nonconformity related to the applicable legislative, regulatory and/or contractual requirements, which affects the safety and performance of the Device and/or the effectiveness of the quality management system. This type of finding may also be formulated in the case of a large number of Nonconformities classifiable as “Minor” and related to the same requirement/process.

Minor Nonconformity: Nonconformity related to the applicable legislative, regulatory and/or contractual requirements, which does not affect the safety and performance of the Device and the effectiveness of the quality management system.

Recommendation: an aspect that does not represent the non-fulfilment of legislative, regulatory and/or contractual requirements, but can be considered as an opportunity for improvement of the Manufacturer's quality management system

Subcontractor: natural or legal person (other than the Manufacturer) who performs, on behalf of the Manufacturer, a process in relation to the Device.

Crucial Subcontractor: natural or legal person (other than the Manufacturer) who performs, on behalf of the Manufacturer, a process that may affect the safety or performance of the Device.

Art. 2. SUBJECT OF THIS REGULATION

2.1. Conformity Assessment

This Regulation, approved by IMQ and available on the website https://www.imq.it/en in the section "Regulation (EU) No. 2017/746", sets out the requirements for the provision by IMQ of one or more conformity assessment services (hereinafter, the "Service" or the "Services") pursuant to Regulation (EU) 2017/746 (hereinafter, "IVDR").

This Regulation applies to in vitro diagnostic medical devices and their accessories (hereinafter, the "Device" or the "Devices"), as defined in Article 1 of the IVDR, for which IMQ is authorised to operate as a NB.

2.2. EU Certification

This Regulation applies to the following documents relating to the attestation of conformity under the IVDR:

- EU technical documentation assessment Certificate, according to Annex IX (chapter II) of the IVDR;
- EU quality management system Certificate, according to Annex IX (chapters I and III) of the IVDR;
- EU production quality assurance Certificate, according to Annex XI of the IVDR;

(hereinafter referred to as the 'Certification' or the 'Certificate' or the 'Certificates').

Each Certificate is issued to the applicant Manufacturer only, refers to a single conformity assessment procedure, details all the Devices covered by the Certification issued by IMQ and is drawn up bilingual in Italian and English.

The Certification issued by IMQ is valid for a maximum of five (5) years; upon the Manufacturer's request, this Certification may be renewed for further periods, each not exceeding five (5) years, based on the renewal procedure described in Art. 4.5 below.

This Regulation does not apply to Certifications issued to Distributors and Importers pursuant to Article 16 (4) of the IVDR.

Art. 3. GENERAL CONDITIONS

3.1. Obtaining the Certification

Obtaining the Certification and, where applicable, its maintenance, renewal and/or updating are subordinate to:

- the Manufacturer's compliance with the applicable requirements of the IVDR and of this Regulation;
- the availability of the Manufacturer to undergo ordinary, extraordinary and supplementary assessments of the documents and at the site of the Manufacturer itself and/or other involved sites (e.g. the premises of Suppliers and Subcontractors), within the timeframe envisaged and indicated by IMQ; such assessments also include unannounced audit and short notice audits;
- the positive outcome of the above conformity assessment activities, carried out by IMQ;
- the payment by the Manufacturer of the amounts due, for any reason whatsoever, to IMQ (e.g. for the issue, maintenance and renewal of the Certification, for the variation/update of the Certificates, etc.).

3.2. Documentation and Samples

The documentation submitted by the Manufacturer to IMQ as part of the conformity assessment procedure (including quality management system documents and technical documentation of the Device) must be in Italian or English and provided in non-editable electronic format, complete with date and (where applicable) signature.

Similarly, communications from the Manufacturer to IMQ (and vice versa) must be written in Italian or English.

If foreseen, the samples of the Devices and any further material (hereinafter referred to as "Test Samples") and/or equipment necessary to carry out the tests shall be sent to the laboratory indicated by IMQ accompanied by a delivery note bearing the reason for the delivery "Devices for evaluation", adequately labelled with the order or quotation number.

All transport costs are borne by the Manufacturer. It is the Manufacturer's responsibility to arrange for the collection of the Test Samples and/or equipment at the end of the tests, except when the appeal procedure referred to in Art. 13.2 below is activated or when different agreements have been made between IMQ and the Manufacturer.

When thirty (30) calendar days after the notification of the conclusion of the tests have elapsed without response:

- IMQ may, at its sole discretion, arrange for the disposal and/or return of the Test Samples at the Manufacturer's expense;
- if the Manufacturer has not taken back the equipment, IMQ will do so at the Manufacturer's expense.

It is understood that, in this case, IMQ declines all responsibility for the functionality and usability of the returned equipment.

3.3. IMQ personnel, external experts and subcontractors

IMQ assigns the assessment activities to IMQ employees with specific expertise, previously qualified according to specific procedures in compliance with the applicable provisions.

IMQ reserves the right to assign specific and clearly defined parts of the Service to external experts and subcontractors with specific expertise, previously qualified according to specific procedures, in compliance with the applicable provisions.

The Manufacturer, which will be informed in advance of the details of the activities outsourced and of the external expert and/or subcontractor contacts, has the right to refuse, for justified reasons, such outsourcing within five (5) working days from the date of the information notice, by sending written notice to the IMQ In Vitro Diagnostic Medical Devices Certification Office at the following address: medicali@imq.it

In any case, IMQ assumes full responsibility for any outsourced activity and retains direct responsibility for issuing, maintaining, extending, renewing, suspending, limiting or withdrawing the Certification.

3.4. Confidentiality

All documents relating to the assessment procedure (Manufacturer's documentation, records, communications, assessment reports, etc.) are considered confidential, except where otherwise provided for by the IVDR and applicable legal provisions.

Access to and consultation of the documents relating to the activities in question are restricted to IMQ staff and to any external experts/subcontractors involved in the conformity assessment process and may be made available to the Competent Authorities, to the European Commission, to the Authority responsible for the NBs or to other third parties by virtue of legal provisions, where requested by the provisions.

The documents owned by the Manufacturer acquired by IMQ and related to the subject matter of this Regulation (e.g. technical documentation) are kept by IMQ for the entire period of validity of the Certification Contract and for at least ten (10) years starting from the date of expiry of the Certification.

3.5. Impartiality

IMQ, in its role as NB, is required to ensure its impartiality during all conformity assessment activities and has a process for analysing, assessing and managing risks related to impartiality in accordance with applicable requirements.

IMQ is not - and undertakes not to be - connected to any party directly involved in activities/situations of: design, manufacture, supply, installation, acquisition, marketing, possession, use and maintenance of the Devices for which it is designated.

IMQ does not carry out - and undertakes not to carry out - activities that may conflict with its independence of judgement, integrity or objectivity regarding the assessment activities for which it is designated.

As a NB, IMQ is in no way allowed to provide consultancy services regarding the design, manufacture, marketing or maintenance of the devices or processes under evaluation.

3.6. IMQ Code of Ethics and Legislative Decree No. 231 of 8 June 2001

IMQ has adopted a Code of Ethics pursuant to Italian Legislative Decree no. 231 of 8 June 2001 on the liability of legal persons, companies and associations, including those without legal personality, which is available on the website https://www.imq.it/en in the section "About us - Code of Ethics and Policy". Therefore, the Manufacturer, in conducting business with IMQ, is required to read it and behave in accordance with the highest ethical standards.

By signing the Certification Contract, the Manufacturer declares to have read and understood the contents of the IMQ Code of Ethics and to have accepted its contents.

The Manufacturer also declares that it is aware of the provisions of Italian Legislative Decree 231/01, that it undertakes to comply with the IMQ Code of Ethics and to fulfil its contractual obligations in such a way as to avoid the occurrence of conducts relevant under Italian Legislative Decree 231/01.

In particular, failure by the Manufacturer to comply with any of the provisions of the Code of Ethics will constitute a serious breach of the obligations under the Certification Agreement and will entitle IMQ to terminate the same with immediate effect, pursuant to and for the purposes of article 1456 of the Italian Civil Code. To this end, IMQ must inform the Manufacturer, by registered letter with notification of receipt or other method valid for all purposes and effects of law, of the reasoned intention to make use of the termination clause.

Furthermore, any conduct on the part of the Manufacturer that leads to the initiation of legal proceedings aimed at ascertaining their relevance under Italian Legislative Decree 231/01, of which IMQ has become aware in any way, will entitle the latter to withdraw from the Certification Contract for just cause.

3.7. IMQ accreditations and authorizations

3.7.1. Obligations in relation to designation

When carrying out the activity covered by this Regulation, IMQ acts as designated by the Authority responsible for NBs for the IVDR and notified to the European Commission.

Therefore, IMQ must operate in accordance with the IVDR and the relevant national legislation[1], considering the relevant guidance documents, which are hereby expressly referred to.

IMQ is obliged to comply with its information and notification obligations established by the applicable legal provisions, including the obligation to notify in EUDAMED[2] the information related to Refused/Withdrawn Applications and Certifications withdrawn due to voluntary renunciation by the Manufacturer, as well as refused, issued, suspended, revoked or limited by IMQ.

The Authority responsible for NBs and the European Commission have the right to carry out audits at IMQ sites and/or at the sites of the Manufacturer (and its suppliers and subcontractors), in order to verify the work of IMQ within the scope of its authorization.

Note: Up-to-date information on IMQ's notification status is available at https://ec.europa.eu/growth/tools-databases/nando/.

3.7.2. Suspension, renunciation or revocation of IMQ designation and notification

In case IMQ decides to cease the Conformity Assessment Services covered by this Regulation, IMQ itself shall inform the Manufacturer as soon as possible and at least one year (1) before in case of planned termination.

If IMQ is suspended, limited or revoked the necessary authorisation to operate, IMQ will inform the Manufacturer as soon as possible and, the latest, within ten (10) days. Any Certifications unduly issued will be suspended or withdrawn within a time limit set by the Authority responsible for the NBs.

In all the above cases, IMQ will support the Manufacturer in the possible change to another NB, providing the necessary information pursuant to Articles 42 and 53 of the IVDR.

Except in cases of fraud and gross negligence, IMQ shall not be liable in any way for any damage caused to the Manufacturer by the suspension, waiver, limitation or revocation of its authorisation; in the aforementioned cases, the Manufacturer will have the right to withdraw, without the payment of penalties, from the Certification Contract in accordance with Art. 11.3 below.

[1] Legislative Decree of 5 August 2022, No. 138 "Disposizioni per l'adeguamento della normativa nazionale alle disposizioni del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medico-diagnostici in vitro [...]"

[2] The obligations and requirements relating to EUDAMED apply from the dates set out in Art. 113 of the IVDR. Until these dates, information on Applications and Certificates is notified to the Italian Ministry of Health.

Art. 4. CONFORMITY ASSESSMENT PROCEDURE

4.1. Initial certification

The following articles describe the procedure by which a Manufacturer can obtain from IMQ a Certification referred to in Art. 2.2 above.

4.1.1. Request for a Quotation

To request a service quotation (hereinafter, the "Quotation") for the initial Certification under the IVDR, the Manufacturer is requested to contact IMQ via the website https://www.imq.it/en (on the page: https://www.imq.it/en/contact-us) or by e-mail at: .medicali@imq.it

Upon such contact, IMQ makes available a specific form "Data Collection form - Regulation (EU) 2017/746 on in vitro diagnostic medical devices" (hereinafter, the "Data collection form"); such Data collection form, duly filled in all applicable parts and signed by the Manufacturer, shall be sent back to IMQ.

The Data collection form requires the Manufacturer to provide at least the following preliminary information:

- Data of the Manufacturer (company name, registered office, etc.) and, if applicable, its Authorised Representative,
- Data of the Device(s) being requested (identification, intended use, qualification of products as IVD Devices, classification, IVDR codes[3] assigned by the Manufacturer, Basic UDI-DI, EMDN code, etc.),
- Conformity assessment procedure chosen,
- Sites of the Manufacturer where processes related to the Device(s) in question are carried out, with information on the type of activity carried out, production shifts (if any) and the number of employees at each site,
- Any critical suppliers and/or crucial subcontractors related to the Device(s) in question, with information concerning the selection and control exercised by the Manufacturer over them and the product supplied,
- Any information for managing the transfer of Certification from another NB.

4.1.2. Formulation of the Quotation

IMQ examines the information provided by the Manufacturer in the Data collection form in order to verify, on a preliminary basis, that the products are covered by the IVDR, are classified according to Annex VIII of the IVDR and/or the relevant MDCGs, are included in the scope of IMQ's designation and that there are no aspects for which IMQ cannot guarantee the performance of the activity.

In the event of a positive outcome of this preliminary verification, IMQ will prepare, where applicable, a sampling plan for the assessment of the technical documentation (ref. Art. 48, pp. 7 and 9 of the IVDR) and formulate the Quotation, which will contain the following information:

- Description of the Service with details of the activities carried out by IMQ;
- References to this Regulation;

[3] Ref. Implementing Regulation (EU) 2017/2185 of 23/11/2017 (https://eur-lex.europa.eu/eli/reg_impl/2017/2185/oj) and document mdcg_2021-14

- Amount due, as per IMQ price list in force (hereinafter, the "IMQ Price List"), detailed for the individual activities required;
- Invoicing and payment methods;
- Expiry date of the Quotation.

If in the next steps (e.g. submission of the Application, Application review, Stage 1 Audit, etc.) inconsistencies emerge with respect to what is declared by the Manufacturer in the Data collection form, the Quotation may be subject to revision by IMQ.

In the event of a negative outcome of the preliminary verification, IMQ will inform the Manufacturer of the impossibility of issuing the requested Quotation with the related reasons.

4.1.3. Acceptance of the Quotation and Submission of the Application

If the Manufacturer decides to accept the Quotation and to submit a formal application (hereinafter, the "Application") to IMQ for initial Certification under the IVDR, the Manufacturer (or its Authorised Representative) shall send the following documents to IMQ within the validity period of the Quotation:

a) Quotation signed by the legal representative of the Manufacturer (or by an appropriately delegated person) for acceptance thereof and with evidence of full acceptance of this Regulation; if requested by the Manufacturer's administration, the relevant purchase order (containing an appropriate reference to the IMQ Quotation);
b) Application drawn up on the appropriate IMQ application form (made available by IMQ together with the Quotation), duly completed in all its applicable parts and signed by the legal representative (or by an appropriately delegated person) of the Manufacturer, containing:
   - Data of the Manufacturer (company name, registered office, etc.) and, if applicable, of its Authorised Representative;
   - Explicit reference to the Data collection form referred to in Art. 4.1.1 above, in which the purpose of the conformity assessment in question is defined. By signing the Application, the Manufacturer confirms the completeness and correctness of all information provided in the Data collection form, which becomes to all intents and purposes an integral and substantial part of the Application;
   - Information on any Applications for the same conformity assessment previously submitted to another NB but withdrawn by the Manufacturer before the final decision of that other NB, or rejected by that other NB, or whose assessment procedure ended in a refusal to certify;
   - Additional Manufacturer declarations / information relevant to the chosen conformity assessment procedure;
   - Documentation expressly requested in the aforementioned IMQ application form, in relation to the conformity assessment procedure chosen by the Manufacturer and the Device(s) in question.

Acceptance of the Quotation by the Manufacturer constitutes an irrevocable proposal.

The Application is considered as submitted - in accordance with section 4.3 (1st subparagraph) of Annex VII of the IVDR - upon receipt by IMQ of all the documents required under points a) and b) hereabove, attested by IMQ sending to the Manufacturer of a written confirmation of receipt thereof.

If the Application includes Devices with conformity assessment procedure according to Annex IX (only Chapters I and III) of the IVDR and/or Class A sterile Devices with conformity assessment procedure according to Annex XI of the IVDR,

the Manufacturer is required to propose, in the Application itself, the date when the technical documentation (including all the elements indicated in Annexes II and III of the IVDR) of such Devices will be available for IMQ.

The Manufacturer may delegate a person or company to act as consultant to assist it in all steps of the Certification process; IMQ must have evidence of such delegation, but the Application, contractual documents and all documentation must be signed by the Manufacturer.

It is understood that the Quotation will automatically expire if IMQ does not receive from the Manufacturer, by the end of validity date indicated in the Quotation, explicit acceptance of the same and/or all the documents required under point b) above.

4.1.4. Signing the Certification Contract

Upon receipt by IMQ of all the documents required under points a) and b) of Art. 4.1.3 above, IMQ and the Manufacturer shall sign - in accordance with section 4.3 (2nd subparagraph) of annex VII of the IVDR - the Certification Contract pursuant to the IVDR, drawn up on the appropriate IMQ form (the "Certification Contract").

The following documents form an integral and substantial part of the Certification Contract:

- this Regulation, accepted in full by the Manufacturer by signing the Quotation and the Certification Contract,
- the Quotation for the initial Certification and any subsequent revisions to it, formulated by IMQ and duly signed by the Manufacturer's legal representative (or by an appropriately delegated person),
- the Application for the initial Certification and any subsequent revisions to it, duly completed and signed by the legal representative (or by an appropriately delegated) of the Manufacturer.

4.1.5. Application Review and Order Confirmation

After the Certification Contract has been signed by both Parties, IMQ carries out the Application review - according to section 4.3 (3rd subparagraph) of Annex VII of the IVDR - by verifying:

- Consistency of information with the preliminary information provided by the Manufacturer in the Data collection form referred to in Article 4.1.1 above,
- Completeness of the Application with respect to the requirements of the chosen conformity assessment procedure, including the presence of all the documentation expressly requested in the IMQ application form,
- Qualification of the products covered by the Application as Devices and their respective classifications; if there is a disagreement between the Manufacturer and IMQ on the application of the classification rules, IMQ shall submit the dispute (reporting both its own opinion and the one of the Manufacturer) to the Competent Authority of the Manufacturer or (if the Manufacturer is based outside the EU) of its Authorized Representative, so that it can be resolved, in accordance with Art. 47 (2) of the IVDR. In this case, the review of the Application cannot be concluded until IMQ receives the answer from the Competent Authority,
- Applicability of conformity assessment procedures chosen by the Manufacturer,
- Title of IMQ to assess the Application according to its designation,
- Availability by IMQ of sufficient and adequate resources.

From this review, the need for clarifications, additions and/or corrections to the Application may emerge; such requests are communicated to the Manufacturer, who has ten (10) Working Days to send the modified/supplemented Application (updated also in revision and date) to IMQ.

In the absence of a response from the Manufacturer within the above-mentioned timeframe or if the modifications/additions implemented by the Manufacturer are not deemed adequate/sufficient, the initial review has a negative outcome and IMQ proceeds to reject the Application (either in full or limited to certain Devices), notifying the Manufacturer by registered letter with return receipt, or by other legally valid method, and notifying it in EUDAMED[2].

As from the date of the aforesaid communication of rejection, the Certification Contract ceases to produce its effects for the Devices subject to rejection of the Application and, unless the said Contract also covers Devices not subject to rejection, it is automatically terminated. In the case of complete rejection of the Application, the Manufacturer shall be required to pay IMQ only the amounts relating to the Application review activities carried out.

On the other hand, for Devices whose review has a positive outcome, the Application is accepted by IMQ; such acceptance is finalised by sending the Order Confirmation to the Manufacturer, containing information on the planning of the evaluation activity (including the list of sampled devices, if applicable).

If the Application includes Devices with conformity assessment procedure pursuant to annex IX (only chapters I and III) of the IVDR and/or Class A sterile Devices with conformity assessment procedure pursuant to annex XI of the IVDR, the Order Confirmation also contains the deadline by which the Manufacturer must send IMQ the technical documentation (including all the elements indicated in annexes II and III of the IVDR) of such Devices; this deadline is established by IMQ taking into account the date proposed by the Manufacturer in the Application and IMQ planning. In the case of non-receipt of the technical documentation by the deadline established in the Order Confirmation, IMQ will have the right to cancel the conformity assessment procedure and to decide the refusal of the Certification (for the methods of communication and the consequences of refusal, reference is made to and applied to the provisions of Art. 4.1.6.1 (2nd and 3rd subparagraphs) below).

IMQ does not guarantee and can in no way guarantee the positive outcome of the assessment procedure and, consequently, the issue of the relative Certification.

The Manufacturer is not allowed to advertise the in-progress Application until the relevant testing, verifications and evaluations have been successfully completed.

4.1.5.1. Withdrawal of the Application by the Manufacturer before IMQ final decision

If the Manufacturer intends to withdraw the Application (in whole or limited to certain Devices) prior to the final decision by IMQ (ref. Art. 4.1.6. below), it must give written notice thereof, signed by its legal representative (or by an appropriately delegated person), by registered letter with notification of receipt or other method valid for all purposes and effects of law.

Upon receipt of this communication, IMQ will cancel the conformity assessment procedure of the Devices subject to this withdrawal and notify it in EUDAMED[2].

Starting from the date of the aforesaid notice, the Certification Contract ceases to produce its effects for the Devices subject to such withdrawal.

The complete withdrawal of the Application by the Manufacturer shall entail the termination of the Certification Contract in accordance with Art. 11.3 below, unless the said Contract also includes Devices not covered by this

Application; in any case of complete withdrawal of the Application, the Manufacturer shall pay IMQ the amounts indicated in points a) to c) of Art. 11.3 below**.**

4.1.6. Assessment activity, final review and final decision - General

The purpose of IMQ assessment activity is to verify the conformity of the Device and, where applicable, of the quality management system to the relevant requirements of the IVDR. The individual activities performed by IMQ differ in relation to the assessment procedure chosen by the Manufacturer, in compliance with the IVDR requirements.

Within the scope of the assessment, IMQ - at its sole discretion - reserves the right to recognise any documents such as test reports, certificates etc. of the products and the quality management system, issued by other NBs, Certification Bodies, Testing Laboratories or other Bodies.

At the end of the assessment activity, the Manufacturer's documentation, the conformity assessment reports and their results (including any Non-Conformities found) are subject to final review by additional IMQ personnel. This final review may reveal the need for clarifications, additions and/or corrections to the Manufacturer's documentation; such requests are communicated to the Manufacturer, who is required to forward the modified/supplemented documentation.

At the end of the final review, the results of the assessment and final review activities and any other relevant information are analysed by the Certification Committee operating at IMQ for the final decision on the granting or refusal of Certification.

If a Certification is granted, IMQ will issue the Certificate foreseen by the evaluation procedure applied; the Committee may impose limitations (e.g. on the intended use) or define specific conditions or provisions for the Certification.

If a Certification is refused, IMQ will inform the Manufacturer of this decision in writing, stating the relative reasons and the minimum conditions for starting the Certification process from scratch.
As from the date of the aforesaid communication of refusal, the Certification Contract shall cease to produce its effects for the Devices subject to refusal of Certification and, unless the said Contract also covers Devices not subject to refusal, it shall be automatically terminated. In any case, the Manufacturer shall be required to pay IMQ all amounts due for activities performed up to the date of the aforementioned communication.

IMQ notifies the granting and/or refusal of Certification in EUDAMED[2].

In the remainder of this Regulation, details are provided for each conformity assessment procedure as follows:

- Art. 4.1.7: EU technical documentation assessment - Annex IX (Chapter II) of the IVDR;
- Art. 4.1.8: EU Quality Management System assessment - Annex IX (Chapters I and III) and XI of the IVDR;
- Art. 4.1.9: Additional specific procedures (performance evaluation procedure for class D Devices; consultation procedure for companion diagnostics).

4.1.6.1. Interruption of the assessment procedure

After twenty-four (24) months from the date on which IMQ sends the first results of the assessment activity (i.e. the first non-conformity report), without the Manufacturer having been able to demonstrate compliance with the IVDR, IMQ has the right to cancel the conformity assessment procedure and to decide the refusal of the Certification.

In such a case, IMQ will inform the Manufacturer in writing of this decision, stating the relative reasons and the minimum conditions for starting the Certification process from scratch; IMQ shall notify the refusal of Certification in EUDAMED[2].

As from the date of the aforesaid communication of refusal, the Certification Contract shall cease to produce its effects for the Devices subject to refusal of Certification and, unless the said Contract also covers Devices not subject to refusal, it shall be automatically terminated. In any case, the Manufacturer shall be required to pay IMQ all amounts due for activities performed up to the date of the aforementioned communication.

4.1.7. EU technical documentation assessment - All. IX (Chapter II) of the IVDR

4.1.7.1. Evaluation of the documentation

IMQ examines the technical documentation of the Device and, for Class C or D Devices, validates the summary of safety and performance (hereinafter, "SSP"), to assess the conformity of the Device with the IVDR requirements.

In addition, the respective additional procedures set out in Art. 4.1.9 below also apply to Class D Devices and Accompanying Diagnostic Devices (CDx).

IMQ may request the Manufacturer to integrate the Application with further tests (physical or laboratory) or with new elements

4.1.7.2. Assessment Outcome

If the evaluation of the documentation (including, as far as applicable, the supplementary procedures referred to in Art. 4.1.9.1(a) and 4.1.9.2 below) and, as far as applicable, the supplementary procedure referred to in Art. 4.1.9.1(b) below are successful, the process continues with the final review and final decision on the issue of an EU technical documentation assessment Certificate (see also Art. 4.1.6 above).

If, on the other hand, the evaluation of the documentation reveals Non-Conformities, the IMQ personnel in charge shall communicate them in writing to the Manufacturer and wait for their resolution.

The costs for carrying out additional verifications are intended to be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 below).

The Manufacturer has forty (40) Working days to send IMQ the technical documentation and/or the summary of safety and performance updated (also in revision and date) and complete with the missing or supplementary documentation relating to the Non-Conformities. For Class D Devices, the application of the supplementary procedure as per Art. 4.1.9.1 (b) is subject to the positive outcome of the assessment of such documentation.

The Certification issue is subject to the positive outcome of supplementary verifications of documentation and, for class D Devices, to the positive outcome of the supplementary procedure referred to in Art. 4.1.9.1 (b)

In the absence of such feedback from the Manufacturer within the established time limits, or after three (3) additional verifications of the documentation without the Manufacturer having provided evidence of the resolution of all the Nonconformities, IMQ may decide to block the assessment process, to decide the refusal of Certification (see also Art. 4.1.6 above) and to request payment for the work performed up to that point.

4.1.8. EU quality management system assessment- Ann. IX (chapters I and III) and XI of the IVDR

4.1.8.1. General information

For class D Devices, for self-testing devices (ST) and for companion diagnostic Devices (CDx), the procedure of Annex IX (chapters I and III) of the IVDR can only be carried out upon successful conclusion of the assessment procedure pursuant to Annex IX (chapter II) of the IVDR.

4.1.8.2. Evaluation of the documentation

IMQ examines the documentation of the Devices included in the Application lodged by the Manufacturer as follows:

- evaluation of the technical documentation for all class A sterile Devices covered by the Application, limited to the aspects relating to establishing, securing and maintaining sterile conditions,
- evaluation of technical documentation for class C and B Devices selected on a representative basis, according to the relevant sampling plan (ref. Art. 4.1.5. above),
- validation of the SSP for all class C Devices included in the Application, for which a sampling plan is applicable.

The evaluation of the documentation is not foreseen for Devices with an EU technical documentation assessment Certificate per Annex IX (Chapter II) of the IVDR, as this activity is already carried out under this procedure (see also Art. 4.1.7 above).

If the documentation evaluation has a positive outcome, the process continues with the quality management system audit (see Art. 4.1.8.3 below).

If, on the other hand, the assessment of the documentation leads to Nonconformities, the personnel in charge report them in writing to the Manufacturer and wait for their resolution.
The costs for carrying out additional evaluation are intended to be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 below).
The Manufacturer has forty (40) working days to send IMQ the technical documentation and (where applicable) the SSP updated (also in the revision and date) and complete with the missing or supplementary documentation related to the Nonconformities; the execution of the audit is subject to the positive outcome of this additional verification of the documentation.
In the absence of such feedback from the Manufacturer within the established timeframe or after three (3) additional verifications without the Manufacturer having provided evidence of the resolution of all the Nonconformities, IMQ may decide to block the assessment process, to refuse Certification (see also Art. 4.1.6 above) and to request payment for the activity performed up to that point.

4.1.8.3. Assignment of the audit team and planning of audit activities

If the assessment of the documentation has given a positive outcome, IMQ assigns the certification audit to an audit team, composed of one or more persons, who guarantee a competence appropriate to the activity to be performed.

The manufacturer is entitled to request the replacement of a member of the audit team; such request must be made in writing, within five (5) days of receipt of the information, and must be duly motivated.
IMQ - at its sole discretion - reserves the right to confirm or replace the person in question, depending on the relevance of the reasons put forward by the Manufacturer.

IMQ contacts the Manufacturer in order to define the dates of the audit; once these dates are confirmed, the "Lead site auditor" (responsible for the audit team) sends the audit plan to the Manufacturer.

If the Manufacturer requests the postponement of an audit during the ten (10) working days prior to the scheduled date, IMQ reserves the right to charge an amount for the resulting costs equal to ten per cent (10%) of the amounts relating to the audit activities indicated in the Quotation, except in the case of force majeure.

4.1.8.4. Conduct of the audit activity

The audit activity consists in assessing the conformity of the Manufacturer's quality management system with the requirements of the IVDR and is carried out partly remotely using information and communication technologies (ITC) and partly at the sites of the Manufacturer and, if deemed necessary by IMQ, of critical Suppliers and/or crucial Subcontractors, unless otherwise indicated by IMQ[4].

This verification is carried out according to the sampling method and is based on interviews with personnel, direct observation of activities and processes, examination of places, documents and records.

The initial certification audit is divided into two stages, named 'Stage 1' and 'Stage 2'.

a) Stage 1 audit

The main objectives of the Stage 1 audit are as follows:

- To review the documentation of the quality management system;
- To gather or confirm the necessary information regarding the scope of the system, including sites, suppliers and subcontractors, processes, applicable regulatory requirements, controls defined by the Manufacturer;
- To acquire sufficient knowledge of the system and the activities carried out at each site to proceed to Stage 2 planning, agreeing all the details with the Manufacturer and verifying the adequacy of the resources allocated for its execution.

At the end of the Stage 1 audit, the audit team identifies any situations that preclude the continuation of the Certification process, i.e. critical areas that must be resolved before proceeding to the Stage 2 audit and issues a Stage 1 Audit Report to the Manufacturer.

If, during the Stage 1 audit, information relating to the Manufacturer (e.g. number of employees, sites, suppliers/subcontractors, processes) is acquired which differs from that previously provided by the Manufacturer itself, the previously determined Stage 2 audit commitment may be subject to change, and the Quotation may be revised (see Art. 4.1.2 above).

b) Stage 2 audits

The Stage 2 audit must be carried out no later than six (6) months after the Stage 1 audit.

[4] In the event of emergency situations (e.g. health emergency, Manufacturer's production sites located in areas subject to serious natural disaster or war, etc.), IMQ reserves the right to adopt extraordinary alternative measures (e.g. fully remote audits). In any case, the application of these extraordinary alternative measures must comply with the relevant regulatory and legislative provisions, regulations and relative guidelines and is subject to a preliminary assessment by IMQ of the suitability and effectiveness of these measures.

The main objectives are as follows:

- To verify that the Manufacturer's quality management system meets the requirements of the IVDR and is actually and efficiently implemented by the Manufacturer;
- To verify that such system ensures the devices compliance with the relevant requirements of the IVDR.

If, following a request from the Manufacturer, the audit is interrupted before the completion of the activities indicated in the plan, the Manufacturer must anyway pay the amounts stipulated for the entire audit activity.

4.1.8.5. Audit outcome

a) Audit Report

At the end of the Stage 2 audit, the audit team analyses all the information and evidence gathered during Stage 1 and Stage 2 in order to review the audit outcome and to define conclusions.

The audit team then draws up an Audit Report (hereinafter, the 'Report'), that also highlights any Nonconformity and Recommendations (for classification, see Art. 1.1 above).

The Lead site auditor presents the conclusions of the audit and the Manufacturer has the opportunity to discuss the contents of the Report, clarifying any doubts, and to express reservations on said contents, recording the reasons for them. Subsequently, a Representative of the Manufacturer signs for acceptance the Report issued by IMQ and any Nonconformities found and receives a copy of it.

If IMQ does not send the Manufacturer, within thirty (30) calendar days from the date of closure of the audit, a written communication rectifying the findings contained in the Report, the Report shall be deemed to be confirmed.

(b) Audit results

If no Nonconformities are found in the audit, the process continues with the final review and final decision on the issue of an EU quality management system Certificate (according to Annex IX, chapters I and III of the IVDR) or an EU production quality assurance Certificate (according to Annex XI of the IVDR) (see also Art. 4.1.6 above).

If, on the other hand, Nonconformities are found during the audit, the issue of the relevant Certification is subject to the resolution of those Nonconformities and the procedure described in points c) and d) below applies.

c) Corrections and corrective action plan

The Manufacturer must undertake to eliminate all Nonconformities found during the audit through the identification of their causes and the adoption and implementation of appropriate corrections and corrective actions.

The causes of the Nonconformities and the plan of corrections and corrective actions must be sent to IMQ within seven (7) working days from the closing date of the audit, specifying the timeframe for implementation.

The plan proposed by the Manufacturer shall be deemed accepted if IMQ does not send the Manufacturer a specific request for integration or modification within thirty (30) calendar days from the date of receipt thereof.

If the Manufacturer fails to send IMQ an adequate corrections and corrective actions plan within the above-mentioned timeframe, IMQ will be entitled to decide the block of the assessment procedure, to decide the refusal of Certification and to request payment for the work carried out up to that point.

For Recommendations, it is not necessary to forward an action plan to IMQ; during the next audit, the Manufacturer is requested to provide evidence that such Recommendations have been addressed, or to justify any decision not to implement any action.

d) Verification of the implementation and effectiveness of corrections and corrective actions

Verification of the implementation and effectiveness of the corrections and corrective actions aimed at resolving all the Nonconformities found during the audit (both minor and Major ones) is carried out by IMQ by means of (i) documentary review of the evidence provided by the Manufacturer in accordance with the plan referred to in point c) above or (ii) supplementary audit performed within the terms established by IMQ; in any case, the issue of Certification is subject to the positive outcome of such supplementary verification, the costs of which are to be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 below).

If the Manufacturer does not reply within the established time limits, or if it has not been possible to obtain adequate evidence of the implementation and effectiveness of the corrections and corrective actions to resolve all the Nonconformities, IMQ may decide to block the assessment procedure, decide to refuse Certification (see also Art. 4.1.6 above) and request payment for the activities performed up to that point.

4.1.9. Additional specific procedures

4.1.9.1. Class D Devices performance evaluation procedure

The performance evaluation procedure pursuant to Annex IX, p. 4.9 of the IVDR is required for class D devices, for the issuing of the EU technical documentation assessment Certificate (see also Art. 4.1.7 above).

According to this procedure:

a) In the context of the evaluation of the technical documentation, IMQ requests the consultation of relevant experts (ref. Art. 106 of Regulation (EU) 2017/745 concerning medical devices) on the performance evaluation report of the Manufacturer, where no Common Specifications (SC) are available and where it is also the first Certification for the type of Device under evaluation (ref. Art. 48 p.6 of the IVDR). To this end, IMQ shall provide the expert panel with the performance evaluation report of the Manufacturer within five (5) days of receiving it from the Manufacturer.
The relevant experts shall provide their opinions to IMQ within sixty (60) days of receipt of the aforementioned documentation.

b) At the end of the evaluation of the technical documentation, IMQ requests one of the EU reference laboratories (ref. Art. 100 of IVDR) to verify the performance claimed by the Manufacturer. The verification must be performed through laboratory tests on test samples of the Device and concerns the performance claimed by the Manufacturer and the compliance of the Device with the applicable CS or other solutions chosen by the Manufacturer (ref. Art. 48 p. 5 of the IVDR).

Any equipment and reference materials required for carrying out the tests must be provided, free of charge (see also Art. 3.2 above), by the Manufacturer to the EU Reference Laboratory, if the laboratory itself does not already have such equipment.
In addition, the Manufacturer, at its own expense, shall provide the personnel of the EU reference laboratory with training in the use of the above equipment, if the laboratory considers it necessary for the performance of its activities.

The EU Reference Laboratory shall provide a scientific opinion to IMQ within sixty (60) days of receiving the sample of the device under evaluation and associated documentation.

The costs of the verification activity by the EU reference laboratory are borne by the Manufacturer, according to the fees set by the laboratory.

When making its decision, IMQ shall take due account of the opinions of the EU Reference Laboratory and, where applicable, of the experts consulted and reserves the right to ask the Manufacturer to modify/supplement the performance assessment and to proceed with a new evaluation request.

IMQ will not issue the EU technical documentation assessment Certificate in case the scientific opinion of the EU Reference Laboratory is unfavourable.

4.1.9.2. Consultation Procedure for Companion Diagnostics

The consultation procedure pursuant to Annex IX (5.2), p. c) to e), of the IVDR is required for Companion Diagnostics for the issuing of the EU technical documentation assessment Certificate (see also Art. 4.1.7 above).

According to this procedure, IMQ requests a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA (hereinafter referred to as 'the medicinal products authority consulted'), regarding the suitability of the device in relation to the medicinal product concerned.

The medicinal products authority consulted shall provide its opinion within sixty (60) days of receipt of all the necessary documentation; this period may be extended once for a further sixty (60) days for justified reasons. The costs of such consultation shall be borne by the Manufacturer in accordance with the fees of the medicinal products authority consulted.

When making its decision, IMQ shall give due consideration to the scientific opinion of the medicinal products authority consulted and convey the final decision to that authority.

IMQ also reserves the right to ask the Manufacturer to modify/integrate the technical documentation and to proceed with a new assessment request (see also Art. 4.1.7.2 above).

4.2. Batch verification procedure for class D Devices

The batch verification procedure pursuant to Annex IX, pp. 4.12 and 4.13 of the IVDR is requested for class D Devices for which the relevant certificates pursuant to the IVDR have been issued, for the purpose of placing on the market each batch manufactured.

The Manufacturer must request IMQ to verify the batch for a specific class D Device by sending the appropriate form (made available by IMQ upon request), duly completed and signed by the Manufacturer.

IMQ, with the support of the EU reference laboratory, shall draw up a specific test plan for the testing of samples or batches of the Device subject of the Application.

IMQ defines, in agreement with the Manufacturer, the logistics of supplying samples and any other material/equipment needed for carrying out the tests.

This information, together with the test plan approved by the Laboratory and any further conditions useful for the correct performance of the tests, becomes an integral part of the Quotation that IMQ sends to the Manufacturer and which contains:

- Description of the Service with details of the planned activities,
- References to this Regulation (document available on website https://www.imq.it/en in the section "Regulation (EU) 2017/746"),
- Amount due, as per IMQ Price List, detailed for the individual activities foreseen,
- Invoicing and payment methods,
- Expiry date of the Quotation.

The Manufacturer sends IMQ the Quotation signed by the legal representative (or by an appropriately delegated person) of the Manufacturer, for acceptance thereof and with evidence of full acceptance of this Regulation, and (if requested by the Manufacturer's administration) the relevant purchase order.

Acceptance of the Quotation by the Manufacturer constitutes an irrevocable proposal.

The Manufacturer shall carry out control tests on each batch of the Device manufactured and, based on the provisions of the aforementioned Quotation, shall send IMQ the reports of such tests and make the samples or batches under examination available.

IMQ requests the EU reference laboratory to carry out batch testing on those samples, in accordance with the plan established for the device in question.

Samples to be tested must be sent to the laboratory at the Manufacturer's expense, accompanied by the delivery documents required by current legislation, in accordance with Article 3.2 above.

The equipment and reference materials required for carrying out the tests must be provided, free of charge, by the Manufacturer to the EU reference laboratory, if the laboratory itself does not already have such equipment.
In addition, the Manufacturer shall, at its own expense, provide the staff of the EU reference laboratory with training on the use of such equipment, where the laboratory deems it necessary in order to operate the equipment.

The costs of the verification activity by the EU reference laboratory are borne by the Manufacturer, according to the fees set by the laboratory.

The laboratory shall inform IMQ about its outcome and IMQ shall communicate to the Manufacturer its decision as to whether or not to place the batch on the market.

The Manufacturer will be allowed to place the devices on the market unless IMQ, within the agreed timeframe but not later than thirty (30) days from receipt of the samples, communicates to the Manufacturer any other decision, including any conditions to be applied to the certificates issued.

4.3. PSUR assessment

For class C and D devices, the Manufacturer shall draw up and update, at least once (1) a year, the periodic safety update report - hereinafter "PSUR" (ref. art. 81 of the IVDR).

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

- A summary of the results and conclusions of the analysis of the post-market surveillance data collected;

- The justification and description of any preventive and corrective actions taken by the manufacturer.

Annually, the Manufacturer shall submit to IMQ - by means of EUDAMED[5] - the PSUR of all class D Devices for which IMQ has issued a Certification.

IMQ will review this report and add the relevant evaluation to EUDAMED[5].

The costs for PSUR evaluation are intended to be borne by the Manufacturer and communicated through an appropriate Quotation.

For class C devices, the Manufacturer shall make the PSUR available to IMQ and to the Competent Authority. IMQ verifies this report annually, on a representative basis (ref. Annex VII, p. 4.10 of the IVDR), during the annual surveillance audit.

4.4. Surveillance of the approved quality management system

Maintenance of the validity of the EU quality management system Certificate of Annex IX (chapters I and III) and of the EU production quality assurance Certificate of Annex XI is subject to the Manufacturer's availability to undergo annual surveillance audits, unannounced audits, any extraordinary verifications (including short-notice audits) and assessment of the technical documentation on a representative basis, where applicable (ref. Annex IX, p. 3.5, of the IVDR), as well as the actual carrying out of such activities by IMQ and their positive outcome.

4.4.1. Annual surveillance

4.4.1.1. Surveillance audit

IMQ carries out surveillance audits at least once every twelve (12) months from the date of issue of the Certification (this date of issue being the "Target Date").

The first annual surveillance audit must be carried out twelve (12) months after the Target Date.

In order to take into account the need for contingent scheduling adjustments, surveillance audits can be anticipated (up to a maximum of three (3) months) or postponed (up to a maximum of three (3) months) with respect to the theoretical dates - every twelve (12) months - calculated based on the Target Date.

Such surveillance visits shall be announced to the Manufacturer at least fifteen (15) days before the proposed audit date.

With regard to the assignment of the audit team and the planning of the audit activities, the provisions of Art. 4.1.8.3 above are referred to and applied.

In the absence of Manufacturer's availability to undergo the annual surveillance audit within the above-mentioned deadlines, IMQ is authorised to suspend the validity of the Certification.

[5] Until the date from which the obligation to transmit via EUDAMED takes effect, the Manufacturer shall make the PSUR available to IMQ during the annual surveillance audit and Certification renewal. IMQ shall make its assessment available to the Competent Authorities, the European Commission and the Italian Ministry of Health (as the Authority responsible for IMQ as ON), if requested by them.

The main objectives of the annual surveillance audit are as follows:

- To verify that the quality management system continues to comply and ensure the conformity of the devices it covers with the applicable requirements of the IVDR, in accordance with Annex IX p.3 and Annex XI p. 4 of the IVDR;
- To verify that the quality management system is effectively and efficiently applied by the Manufacturer;
- To verify compliance with the applicable requirements of this Regulation.

These verifications are carried out by IMQ through the examination of the documents and records of the quality management system (including the technical documentation of the Devices, where applicable), inspections**Errore. Il segnalibro non è definito.** at the Manufacturer's sites and, where deemed necessary by IMQ itself, at the sites of critical Suppliers and crucial Subcontractors, with direct observation of premises, processes/activities and interviews with personnel and possible tests to verify that this system works properly.

Audit outcome:

At the end of the annual surveillance audit, IMQ issues the Manufacturer with the audit Report that also highlights any situation of Nonconformity and Recommendations (for classification, see Art. 1.1 above).

Regarding the Report and the corrections and corrective actions plan, the provisions of Art. 4.1.8.5 (a) and (c) above are recalled and applied.

Concerning the outcome of the audit:

a) If during the audit no Nonconformities are found, or minor Nonconformities are found that, combined, do not compromise the safety and performance of the Device and the effectiveness of the quality management system, IMQ will confirm the Certification validity (as indicated in Art. 4.4 above), subject to acceptance of the corrections and corrective actions plan for all the Nonconformities found during the audit.
   The verification of the implementation and effectiveness of the proposed actions is normally carried out during the next audit. However, IMQ is allowed to request documentary evidence or to perform extraordinary audits, where deemed necessary; in this case, refer to point b) below.

b) If during the audit Major Nonconformities not affecting the safety of the device are found, with or without minor Nonconformities, IMQ will confirm the Certification validity (as indicated in Art. 4.4 above).
   The maintenance of the Certification validity is subject to: (i) acceptance by IMQ of the corrections and corrective actions plan proposed by the Manufacturer for all Nonconformities and (ii) verification of the implementation and effectiveness of the corrections and corrective actions for all Major Nonconformities. This verification will be carried out by IMQ within three (3) months from the date of closure of the surveillance audit by means of a supplementary activity (document review or audit depending on the problems found). The costs of such additional verification shall be borne by the Manufacturer and communicated through an appropriate Quotation (see also Art. 6.1 below).
   In the absence of feedback from the Manufacturer within the time limits established by IMQ, or if it has not been possible to obtain adequate evidence of the implementation and effectiveness of the corrections and corrective actions to resolve all Major Nonconformities, IMQ may decide to suspend the validity of the Certification (for suspension, see Art. 8.2 below).

c) If during the audit at least one (1) Major Nonconformity affecting the safety of the Device is found, with or without Minor Nonconformities, IMQ will suspend the validity of the Certification (for suspension, see Art. 8.2 below).

The suspension will be cancelled only following (i) acceptance by IMQ of the corrections and corrective actions plan proposed by the Manufacturer for all the Nonconformities and (ii) verification (documentary and/or by extraordinary audit) of the implementation and effectiveness of the corrections and corrective actions for all the Major Nonconformities. This verification will be carried out by IMQ within one (1) month from the date of closure of the surveillance audit by means of a supplementary activity (documental review or audit depending on the problems found). The costs of such additional verification shall be borne by the Manufacturer and communicated through an appropriate Quotation (see also Art. 6.1 below).

4.4.1.2. Assessment of technical documentation on a representative basis

In the case of class B and C devices for which a sampling plan is foreseen (ref. Art. 4.1.8.2 above), the annual surveillance activity also includes an assessment of the technical documentation of further representative samples of the devices covered by the Certificate in question (ref. Annex IX, p. 3.5 of the IVDR).

The costs for carrying out this assessment are intended to be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 below), sent by IMQ to the Manufacturer approximately four (4) months before the end of the relevant surveillance year.

If the review of the documentation has a positive outcome, IMQ will confirm the Certification validity (as indicated in Art. 4.4 above).

If, on the other hand, verification of the documentation reveals Nonconformities, the personnel in charge will communicate them in writing to the Manufacturer and await their resolution.
The costs for carrying out additional assessments are intended to be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 below).
The Manufacturer has forty (40) Working Days to send IMQ the Technical Documentation and (where applicable) the SSP updated (also in revision and date) and complete with the missing or supplementary documentation related to the Nonconformities.

In the absence of such feedback from the Manufacturer within the established time limits or after three (3) supplementary verifications without the Manufacturer having provided evidence of the resolution of all the Nonconformities, IMQ may decide to suspend or revoke the validity of the Certification for that specific Device or for the entire category/ generic device group and request the payment for the activity performed up to that point (for suspension and revocation, see Articles 8.2 and 8.3 below respectively).

4.4.2. Unannounced audits

In addition, at least once every five (5) years, IMQ carries out unannounced audits at each Manufacturer. This frequency may be increased if the Devices covered by the Certification have a high potential risk (e.g. class D Devices), if there are frequent Nonconformities or if specific information leads to the belief that they or the related quality management system present Nonconformities.

Generally, unannounced audits have a duration of at least one (1) day, are carried out by at least two (2) auditors and are conducted at the Manufacturer's premises; in their substitution or addition, unannounced audits may be conducted at the premises of critical Suppliers and of crucial Subcontractors, where this may ensure more effective control. If a visa is required to visit the country where the Manufacturer is located, an invitation must be provided with the signature date and visit date left open. Similar invitations must be issued by Critical Suppliers and Crucial Subcontractors.

The Manufacturer must have documented procedures to manage unannounced audits. To guarantee the possibility of effectively carrying out this type of audit, the Manufacturer must inform IMQ, with the necessary frequency, of the periods of the year in which production of the Devices covered by the Certification is not expected, with particular attention to company closures, holidays, etc.

During unannounced audits, IMQ tests an appropriate sample of the Devices manufactured or an appropriate sample taken from the ongoing manufacturing process to verify that the Device manufactured complies with the technical documentation. Alternatively or additionally, IMQ tests samples of the Devices taken from the market to verify that the Device manufactured complies with the technical documentation.

These tests may also be carried out by the Manufacturer, its Supplier or a Subcontractor, under the monitoring of IMQ.

The following expenses are borne by the Manufacturer, according to IMQ fees:

- The costs of unannounced audits - including, if necessary, those for the purchase of the Device and for the tests performed on it and the safety measures;
- The costs of any unannounced audits that IMQ was unable to carry out due to the failure of the Manufacturer to provide the above mentioned information.

If unannounced access to the premises of the Manufacturer, critical Suppliers or crucial Subcontractors is not allowed, IMQ will be authorised to suspend the validity of the Certification.

Regarding the outcome of the audit, the provisions of Article 4.4.1 above are recalled and applied.

4.4.3. Extraordinary verifications, including audits with short notice

Based on the results of the performed verifications, following incidents reporting or other reporting from the market or from the Competent Authorities and, in general, in all cases where IMQ considers that the Certification issued may be at risk, IMQ is allowed to perform (i) extraordinary audits, including audits with short notice, at the Manufacturer's premises and, in substitution or in addition to these, at the premises of Suppliers and Subcontractors and/or (ii) documentary assessments; the costs of these activities shall be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 below).

Short notice audits shall be carried out within five (5) Working Days from the date of notification to the Manufacturer; for such audits, the Manufacturer shall not have the right to recuse the audit team.

4.5. Renewal of Certification

The Manufacturer shall ask IMQ for a new Quotation for the renewal of the validity of the Certification at least nine (9) months before the expiry date of the Certification itself, according to the procedures established in Art. 4.1.1 above. This deadline shall also apply in cases where the Certification is suspended.

IMQ performs a preliminary review of the information provided by the Manufacturer in the Data collection form, in order to determine the activities necessary for the renewal of the Certificate and issues the relevant Quotation.

If the Manufacturer intends to proceed with the renewal of the Certification, he must accept the Quotation and submit the Application for Renewal referred to in the previous Art. 4.1.3 at least eight (8) months before its expiry.

As for the initial Certification, the Application for renewal shall be deemed to have been lodged upon receipt by IMQ of all the documents specifically requested in the Application form, attested by IMQ sending written confirmation of receipt to the Manufacturer.

The Quotation for renewal of Certification (formulated by IMQ and signed for acceptance by the Manufacturer) and the relative Application (signed by the Manufacturer and submitted to IMQ) are an integral and substantial part of the Certification Contract in force between the Parties as from the date of the aforementioned confirmation of receipt by IMQ. The Certification Contract regulates the renewal activities in question only as from that date.

It is understood that the Quotation will automatically expire if IMQ does not receive from the Manufacturer, by the end of validity date indicated in the Quotation, explicit acceptance of the same and/or all the required documents.

IMQ performs the Renewal Application review by verifying:

- the completeness of the Application,
- the availability of sufficient and adequate resources,
- the correct implementation, up to that point, of the audit activities program and, where applicable, of the sampling plan of the technical documentation relating to the Certification cycle in question, identifying any gaps to be filled.

IMQ identifies the specific activities necessary for the renewal of the Certificate, assigns the resources, issues the project and sends the order confirmation to the Manufacturer. In particular:

a) For EU technical documentation assessment Certificate according to Annex IX (Chapter II) of the IVDR

IMQ assesses the summary of changes and scientific findings relating to the device submitted by the Manufacturer with the Application (ref. Annex VII, p. 4.11 of the IVDR), paying particular attention to the clinical data deriving from post-market surveillance and post-market performance follow-up activities carried out since the previous Certification or recertification, including appropriate updates to the Manufacturer's performance evaluation reports. Any Nonconformities found are communicated to the Manufacturer.

b) EU quality management system Certificate pursuant to Annex IX (Chapters I and III) and EU production quality assurance Certificate pursuant to Annex XI of the IVDR

IMQ ensures that all the regulatory requirements relevant to the performance of audits (ref. Annex VII, sect. 4.5.2 and Annex IX, sect. 2.2 and 2.3) are assessed in their entirety at least once after issuing the Certificate and before its expiry date.
Furthermore, IMQ reviews the results of all surveillance activities carried out during the Certification cycle (ref. Annex VII, sect. 4.10) and the outcome of the technical documentation assessments, in order to verify whether the approved quality management system still conforms with the relevant provisions of the IVDR.

Any additional verification activities aimed at ensuring compliance with the aforementioned requirements shall be managed as part of the fifth surveillance audit, to be performed at least three (3) months before the expiry of the Certificate, applying the rules envisaged for surveillance audits as per Art. 4.4.1 above. Any Nonconformities found shall be communicated to the Manufacturer.

In both cases, before renewing the Certification IMQ ensures that all identified Nonconformities are closed or followed up by an appropriate and accepted corrective and preventive actions plan with appropriate timelines, applying the same

rules provided for surveillance audits (ref. Art. 4.4.1 above). Furthermore, IMQ verifies the adequacy of the scope of the Certification or the possible need for modifications, in particular possible limitations or new conditions.

For the final review activity and the decision on the renewal of the Certification, IMQ uses the same methods and principles used in the initial Certification (see Art. 4.1.6 above).

Following a positive outcome of the renewal activities (including final review and final decision), the validity of the Certification is renewed for a further period not exceeding five (5) years.

If the renewal activities (including final review and final decision) are not performed and/or not completed and/or do not have a positive outcome by the expiry date of the Certification, the Certification will lose its validity upon expiry and the Manufacturer must:

- Refrain from advertising and using the expired Certification, by removing references to IMQ as NB from the documentation (including advertising material) of the Devices referable to this Certification,
- Cease to affix the CE0051 marking to Devices referable to this expired Certification and, consequently, cease their production and placing on the market with this marking,
- Communicate, by email to medicali@imq.it within three (3) working days following the expiry date of the Certificate, the last batch/registration number placed on the market of each Device referable to this Certification; any stocks bearing the CE0051 marking must be run out within the expiry date of the Certification,
- Pay all amounts due to IMQ for maintaining the Certification until the expiry of the Certificate.

As from the day following the day on which the Certificate ceases to be valid, the Certification Contract shall cease to have effect in respect of the Devices covered by the expired Certificate and, unless the Contract covers other Devices with a valid Certificate, shall be automatically terminated.

A Manufacturer intending to regain Certification must restart the initial Certification process (see Art. 4.1 above).

4.6. Extensions and Changes to Certification

a) For EU technical documentation assessment Certificate according to Annex IX (chapter II) of the IVDR

The Manufacturer is required to communicate IMQ in advance:

- ❖ Any plan for change to the Device approved in accordance with Annex IX (Chapter II) of the IVDR, which may affect the safety and performance, or conditions of use of this Device, including changes in the intended purpose or claims made about it. IMQ assesses such changes, and any approval is issued as an update of the relevant Certificate;

- ❖ Any plan to extend the Devices range, identified as a *Certification Extension*; extensions are classified in the following types:
  - approval of a new trade name and/or a new trademark of a Device already included in the Certificate; in this case, IMQ carries out a partial assessment of the technical documentation and the SSP and any approval is issued in the form of an update of the relevant Certificate,
  - approval of a new Device with the same intended use and the same conditions of use as the Devices already approved (i.e. belonging to the technical documentation already approved); in this case, IMQ shall carry out all the assessments referred to in Art. 4.1.7 above and any approval shall be issued in the form of an update of the relevant Certificate,

- approval of a Device with a different intended use and/or conditions of use from the Devices already approved (i.e. belonging to a new technical documentation); in this case, IMQ shall perform all the assessments referred to in Art. 4.1.7 above and any approval shall be issued in the form of a new EU technical documentation assessment Certificate , which shall have the same expiry date as the related EU quality management system Certificate.

b) EU quality management system Certificate according to Annex IX (chapters I and III) and EU production quality assurance Certificate according to Annex XI of the IVDR

The Manufacturer is required to communicate IMQ in advance:

- Any plans for substantial changes to the quality management system approved pursuant to Annex IX (chapters I and III) or Annex XI of the IVDR, such as:
  - changes to the sites of the Manufacturer and to manufacturing sites of crucial subcontractors,
  - changes to the structure of the Manufacturer's organisation, the interaction between processes and/or the structure of the quality management system,
  - internalisation / outsourcing of a process (or part of it),
  - elimination and addition of critical suppliers/crucial subcontractors as well as changes to the activities entrusted to them,
  - changes to the sterilisation of the Device (e.g. change of terminal sterilisation method, changes to the sterilisation process, equipment or cycle parameters, etc.),
  - changes to the production process (e.g. to production technology, equipment, clean rooms and controlled environments, etc.) and to the approved design process (e.g. to the design verification and validation stages, etc.), which may affect the conformity of the quality management system and the Devices - covered by this system - with the applicable IVDR requirements (including the general safety and performance requirements of Annex I of the IVDR),
  - changes to the design of the Device (e.g. to the test principle, control systems/materials, power sources, design specifications, software, user interface, materials/components, labelling, primary packaging, shelf-life, etc.) that may affect the compliance of the Device with the safety and performance requirements of Annex I of the IVDR,
  - changes to the intended use of the Device, to its intended conditions of use or to statements made about it,
  - any other changes that affect the compliance of the quality management system and the Devices - covered by that system - with the applicable IVDR requirements (including the general safety and performance requirements of Annex I of the IVDR).

  In order to clarify what changes constitute *"substantial 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 document that may be available (e.g. MDCG documents).
  IMQ evaluates these changes, and any approval is issued as an update of the relevant Certificate.

- Any plan for substantial changes to the range of Devices covered by the quality management system approved in accordance with Annex IX (chapters I and III) or Annex XI of the IVDR, such as:
  - Extension of the Device range, identified as a Certification Extension, the approval of which is issued as an update of the relevant Certificate. In this case, extensions are classified into the following types:

- approval of a new trade name and/or a new brand name of a Device already included in the Certificate, for which IMQ carries out, if appropriate, an update of the sampling plan;
- approval of a new Device with the same intended use and same conditions of use as the Devices already approved (i.e. belonging to a category/ generic device group already present in the Certificate), for which IMQ performs:
  - ✓ an update of the sampling plan and, if applicable, an evaluation of the SSP (only for Annex IX of the IVDR);
  - ✓ a complete evaluation of the technical documentation (only for Annex XI of the IVDR);
- approval of a Device with different intended use and/or conditions of use from already approved Devices (i.e. belonging to a new category/generic device group), for which IMQ performs an update of the sampling plan (only for Annex IX of the IVDR), a complete evaluation of the technical documentation and, if applicable, of the SSP, plus a quality management system audit.

▪ Limitation of the Device range covered by the quality management system and the Certificate, which requires an update of the relevant Certificate; in this case the provisions of Art. 8.1 below are recalled and applied).

c) For all types of Certifications issued according to the IVDR

In addition to the above, the Manufacturer shall also communicate to IMQ in advance:

❖ the change of Authorised Representative as provided for in Art. 12 of the IVDR;
❖ administrative changes, such as: changes to the registered name of the Manufacturer and (if any) of the Authorised Representative, changes to the registered office of the Manufacturer and (if any) of the Authorised Representative, changes to the legal representative of the Manufacturer, etc.;
❖ corporate changes of the Manufacturer, such as: sell-off, transformation, merger, demerger, transfer, leasing of a company or a branch of a company, etc. (see also Art. 7.2 below).

IMQ evaluates these changes, and any approval is issued in the form of an update of the relevant Certificate.

The procedure by which the Manufacturer may obtain such extensions of Certification is described in Art. 4.6.1 below; the procedure by which the Manufacturer may obtain approval of such changes is described in Art. 4.6.2 below.

4.6.1. Procedure for obtaining extension

The Manufacturer is required to ask IMQ for a new Quotation for the extension of the Certification, according to the procedures established in Art. 4.1.1 above.

The provisions of Articles 4.1.2 and 4.1.3 above shall apply to the formulation of the new Quotation by IMQ as well as its acceptance and submission of the Application for Extension by the Manufacturer

As for the Initial Certification, the Application for Extension shall be deemed to have been lodged - in accordance with section 4.3 (1st subparagraph) of Annex VII of the IVDR - upon receipt by IMQ of all the documents indicated in points a) to b) of Art. 4.1.3. above, attested by sending written confirmation of receipt by IMQ to the Manufacturer.

The Quotation for the extension of Certification (issued by IMQ and signed for acceptance by the Manufacturer) and the relative Application (signed by the Manufacturer and submitted to IMQ) are an integral and substantial part of the Certification Contract in force between the Parties as from the date of the aforementioned confirmation of receipt by IMQ. The Certification Contract regulates the Devices subject to extension only as from that date.

It is understood that the Quotation will automatically expire if IMQ does not receive from the Manufacturer, by the expiry date indicated in the Quotation, explicit acceptance thereof and/or all the documents indicated in point b) of Art. 4.1.3 above.

For the Application review and the Order Confirmation as well as for the assessment activity, the final review and the final decision on the extension, IMQ uses the same methods and principles as for the initial certification (refer to Articles 4.1.5 to 4.1.9 above).
Rejection of the Application for Extension by IMQ, withdrawal of the same by the Manufacturer prior to the final decision by IMQ, as well as refusal of the extension of Certification, do not cause the termination of the Certification Contract in force between the Parties; in such cases, the Certification Contract ceases to produce its effects for the Devices subject to such refusals or withdrawals.
It is understood that any type of extension indicated in Art. 4.6 above shall require prior approval by IMQ before being implemented by the Manufacturer and will in no case determine a change in the expiry date of the relevant Certificate.

4.6.2. Procedure for approving changes

To notify intended changes referred to in Article 4.6 above, IMQ shall make available, upon request of the Manufacturer, a specific form "Notice of changes to the Certification - Regulation (EU) 2017/746 (IVDR)" (hereinafter, the "Notice"). Such Notice must be completed in all its applicable parts and signed by the legal representative (or by an appropriately delegated person) of the Manufacturer and sent back to IMQ.

Upon receipt of the Notice, IMQ shall determine, at its sole discretion, the assessments to be carried out, the costs of which are intended to be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 below).

Upon acceptance of the Quotation, the Manufacturer shall forward the following documents to IMQ within the period of validity of the Quotation itself:

a) Quotation issued by IMQ, signed by the legal representative (or by an appropriately delegated person) of the Manufacturer, for acceptance thereof and (if requested by the Manufacturer's administration) the relevant purchase order,
b) Documentation required for the evaluation of the proposed changes (including technical documentation if the change has an impact on it).

Acceptance of the Quotation by the Manufacturer constitutes an irrevocable proposal.

The Notice shall be deemed to have been lodged upon receipt by IMQ of all the documents indicated in points a) to b) above, attested by sending a written confirmation of receipt by IMQ to the Manufacturer.

The Quotation for approval of the changes to the Certification (formulated by IMQ and signed for acceptance by the Manufacturer) and the relative Notice (signed by the Manufacturer and submitted to IMQ) are an integral and substantial part of the Certification Contract in force between the Parties as from the date of the aforementioned confirmation of receipt by IMQ. The Certification Contract regulates the approval activities in question only as from that date.

It is understood that the Quotation will automatically expire if IMQ does not receive from the Manufacturer, by the expiry date indicated in the Quotation, explicit acceptance of the same and/or the documents necessary for the assessment of the proposed changes.

For the review of the Notice and order confirmation as well as for the assessment activity, the final review and the final decision, IMQ uses, as far as applicable, the same methods and principles used in the initial Certification (refer to Articles 4.1.5 to 4.1.9 above).

IMQ rejection of the Notice, the withdrawal of the same by the Manufacturer prior to the final decision by IMQ, as well as the refusal to approve the modification of the Certification do not cause the termination of the Certification Contract in force between the Parties.

It is understood that any type of change indicated in Art. 4.6 above shall require prior approval by IMQ before being implemented by the Manufacturer and shall in no case determine a modification in the expiry date of the relevant Certificate.

4.7. Transfer of Certification from another NB

If the Manufacturer has already obtained one or more Certifications from another NB (hereinafter, "outgoing NB") and requests IMQ to step in as a new NB, in addition to the provisions of Art. 4.1 above, IMQ will make available a dedicated form to be used for the communication of the following information:

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

This form must be submitted completed in full and signed by the legal representative (or by an appropriately delegated person) of the Manufacturer.

In no case IMQ recognises and takes responsibility for the following Certifications: EU technical documentation assessment Certificate (Annex IX (chapter II) of the IVDR) and related EU quality management system Certificate (Annex IX (chapters I and III) of the IVDR), and EU production quality assurance Certificate (Annex XI of the IVDR).

4.7.1. Forced transfer of the Certification from another NB

Without prejudice to the exclusions indicated in Art. 4.7 above, if the Manufacturer requests the transfer of the EU Certification from another NB following the renunciation, suspension, limitation or revocation of the designation of such other NB (forced transfer), IMQ shall review the Application in accordance with the procedures defined in Art. 4.1.5 above.

In the presence of adequate/complete documentation and of confirmation by the Authority that there are no safety issues related to the Device in question and that the Certificate of the outgoing NB has not been unduly issued, IMQ will assume responsibility for the Certification, notifying the Manufacturer and the Authority responsible for NBs in writing. In particular:

- In the case of suspension or limitation of the designation of the outgoing NB, IMQ takes responsibility for the Certification surveillance activities for the period of suspension/limitation established by the Authority responsible for NBs;
- In the case of voluntary renunciation or revocation of the designation of the outgoing NB, IMQ will take responsibility for Certification for a maximum period of nine (9) months, during which it will apply the entire conformity assessment procedure, in accordance with Articles 4.1.6 to 4.1.9 above. If the outcome of the assessment is positive, IMQ will issue the Manufacturer with the requested Certification. In the event of a negative outcome, IMQ will not issue the Certification and will inform the Manufacturer and the Authority responsible for NBs of the refusal of Certification.

4.7.2. Voluntary transfer of the Certification from another NB

If the Manufacturer voluntarily requests IMQ to step in as a new NB (voluntary transfer), IMQ will apply the entire conformity assessment procedure established for the initial certification (see Art. 4.1 above).

The date from which IMQ takes over the tasks previously in charge of the outgoing NB coincides with the date of the Certificate issued by IMQ itself as NB.

Art. 5. OBLIGATIONS TO BE FULFILLED BY MANUFACTURER

5.1. Obligations of the Manufacturer

The Manufacturer undertakes to:

- Meet the requirements of this Regulation,
- Satisfy the general obligations of Manufacturers set out in Art. 10 of the IVDR and any relevant national legislative provisions,
- Ensure the conformity of the Device (subject of the Certification) with the IVDR, taking into account the generally acknowledged state of the art,
- Draw up and keep up-to-date technical documentation for each Device subject to Certification, in accordance with the requirements of the IVDR and relevant available guidelines (e.g. MDCG documents); this documentation must refer to the Device(s) (subject to Certification) of the Manufacturer submitting the Application,
- Draw up and keep up to date the SSP for Class C and D devices, in accordance with the requirements of the IVDR and relevant available guidelines (e.g. MDCG documents),
- Establish, document, apply, maintain, update and continuously improve a quality management system that complies with the requirements of Article 10.8 and Annex IX or XI of the IVDR and ensures the conformity of the Devices covered by this system,
- Guarantee IMQ personnel and its external experts/subcontractors access (under safe conditions) to all the design, manufacture, inspection, testing and storage locations of the Devices subject to Certification and to the relevant documents (including the technical documentation), as well as provide the information, means and indispensable aids (including any interpreters/translators made available at the Manufacturer's expense) so that IMQ can perform the requested Service. In this regard, the impossibility to perform the activities due to facts and/or causes attributable to the Manufacturer and/or Suppliers/Subcontractors (e.g. impossibility to access the aforementioned sites, lack of documentation, impossibility to interview personnel, etc.), such as to

compromise the fulfilment of the obligations by IMQ, will constitute cause for termination of the Certification Contract,

- Guarantee inspectors from the Authority responsible for NBs and the European Commission have access to the aforementioned places, accompanied by IMQ personnel (see also Art. 3.7.1 above),
- Notify IMQ of the periods of the year when the Manufacturer's activities are suspended (e.g. company closures, public holidays, etc.)
- Notify IMQ of any incidents relating to its Devices and any safety corrective actions within the timeframe provided for in Art. 82 of the IVDR (at least until the use of EUDAMED is mandatory),
- Immediately inform IMQ of all non-compliant situations detected 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 relating to the subject of the Certification, without prejudice to the limits imposed by law,
- Do not make any statement or advertise your Certification in such a way that could be considered misleading or unauthorised, or inconsistent with the scope of the Certification itself, nor use your Certification in such a way as to bring IMQ into disrepute,
- Reproduce the certification documents (including the Certificate) in their entirety if copies are provided to third parties,
- Accept any supplementary activities and/or requests for changes resulting from any decisions of the Authority responsible for NBs, from the competent Authorities and from the European Commission.

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

In relation to the fulfilment of the obligations envisaged in this article, IMQ may carry out extraordinary verification against payment and, if necessary, suspend or revoke the Certification, depending on the severity of the situation and/or the impact of the event occurred.

5.2. Safety at Work - Obligation of notice

The Manufacturer, in accordance with current legislation on safety and accident prevention at work, undertakes to provide IMQ personnel and any accompanying persons with complete and detailed information on the specific risks existing in the working environment in which they will have to operate.

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

Based on any specific existing risks, the Manufacturer shall provide IMQ personnel and any accompanying persons with the appropriate personal protective equipment and put in place all the protections to allow the activity to be carried out in complete safety.

Art. 6. FINANCIAL TERMS AND CONDITIONS

6.1. Amounts due for Certification

The amounts due for the initial Certification activities, (where applicable) for the maintenance of the Certification issued (such as annual surveillance audits, assessment of technical documentation on a representative basis and activities related to the administrative management of the Certification) and for unannounced audits as well as for renewal, extension and change approval activities, together with the relevant payment conditions, are indicated in the relevant Quotations as accepted by the Manufacturer; such Quotations are 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 employees, sites, suppliers/subcontractors, technical documentation, etc.).

The Manufacturer is required to correctly communicate all the information requested during the formulation of the Quotation, for the purpose of its issuance, as well as to update IMQ on any changes; based on the updated data, IMQ shall assess whether it is necessary to revise the economic conditions.

Any changes to the Certification Maintenance costs determined as a result of changes to the number of employees, sites, etc. will be duly communicated by IMQ to the Manufacturer.

If IMQ considers necessary to carry out supplementary / extraordinary verifications (e.g. aimed at resolving Nonconformities) and/or additional verifications (e.g. assessment of PSUR for certain Devices), IMQ will prepare a dedicated Quotation according to the IMQ Price List in force. On receipt of acceptance of this Quotation, IMQ will plan and perform these verifications; if the Manufacturer doesn't accept the Quotation, IMQ will not be able to perform these verifications and, where necessary, will be entitled to suspend the Certification validity.

For anything not expressly provided for in the Quotation, as well as in its absence, the amounts indicated in the IMQ Price List in force, which is hereby expressly referred to, shall apply.

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

6.2. Variation of the IMQ Price List

Any changes to the IMQ Price List shall be communicated by IMQ to the Manufacturer in writing.

In this case, the Manufacturer shall have the right to withdraw from the Certification Contract within thirty (30) calendar days from the date of receipt of the communication from IMQ, in accordance with Art. 11.3 below, without prejudice to the payment of the amounts due to IMQ for the activities carried out up to receipt of the withdrawal communication, including any amounts relating to the maintenance of the Certification in accordance with the terms and frequency indicated in the Quotation; the application of penalties shall be excluded.

During the aforementioned thirty (30) days, the Manufacturer who avails himself of the aforementioned right of withdrawal will be subject to the fees prior to the changes.

If a Certification Contract is not yet in place between the Parties, the Manufacturer has the right to withdraw from the accepted Quotation, within the aforementioned thirty (30) days; such withdrawal entails the automatic withdrawal of the Application by the Manufacturer.

6.3. Payment of due amounts

Upon conclusion of the Service, IMQ shall issue the Manufacturer with the Certification referred to in Art.2.2 above only on condition that all fees due to IMQ have been paid.

Without prejudice to the provisions of Art. 8.3.1 below, in case of failure to pay the fees and/or related interest within the terms set out in the Quotation, IMQ will have the right to suspend the Services at any time until the Manufacturer has paid and remedied its non-fulfillment.

If the breach continues beyond six (6) months, the relevant Manufacturer's Application will be deemed withdrawn by the Manufacturer himself.

Art. 7. USE OF CERTIFICATIONS AND CE MARKING

7.1. CE marking

The Manufacturer affixes the CE marking followed by the number 0051 (identification number of IMQ as the NB in charge of the conformity assessment procedure) on the Devices covered by the relevant Certification issued by IMQ and valid, in compliance with the IVDR requirements.

This CE0051 marking must not be affixed to Devices whose relevant Certification has been refused, withdrawn due to voluntary renunciation by the Manufacturer, suspended, revoked or has expired.

In order to affix the CE marking, for Devices with assessment procedure according to Annex IX (complete) of the IVDR, the Manufacturer must have obtained the EU technical documentation assessment Certificate according to Annex IX (Chapter II) of the IVDR and the EU quality management system Certificate according to Annex IX (Chapters I and III) of the IVDR.

The Manufacturer shall unambiguously distinguish its Devices bearing the CE0051 marking from those not bearing it.

7.2. Transferability of Certification

The use of the Certifications issued by IMQ is strictly reserved to the Manufacturer and is not transferable, except in cases of transfer, transformation, merger, demerger, transfer, leasing of a company or a company branch of the company concerned.

In these cases, the outgoing Manufacturer[6] must send a communication to IMQ in a timely manner, in any case no later than fifteen (15) days from the date of registration in the Business Register (or other equivalent register); failure to meet this deadline may result in the suspension or revocation of the Certification.

The incoming Manufacturer[7] shall also send IMQ a written request to maintain the Certification of the outgoing Manufacturer, accompanied by a copy of the relative certificate of registration at the Chamber of Commerce, a written

[6] The entity whose certification has been transferred as a result of a change in its organisational structure.

[7] The entity resulting from the event modifying the organisational structure of the outgoing Manufacturer.

declaration of the absence of changes or communication of substantial changes and any further documents considered necessary.

IMQ reviews the request for transfer of Certification in order to ensure that the conformity of the Devices and the quality management system with the applicable requirements of the IVDR is guaranteed.

IMQ determines, at its sole discretion, whether supplementary verifications are necessary and to what extent.

The costs of updating the Certification and any supplementary verifications shall be borne by the incoming Manufacturer and communicated by means of an appropriate Quotation as per the IMQ Price List in force.

The transfer of the Certification and the related Certification Contract is subject to the positive outcome of the evaluations carried out, as well as the balance of the payment of all amounts due by the outgoing Manufacturer.

Art. 8. RENUNCIATION, SUSPENSION AND REVOCATION OF CERTIFICATION

8.1. Renunciation of Certification

If the Manufacturer decides to renounce a Certification issued by IMQ, it shall give written notice thereof, signed by the legal representative (or by an appropriately delegated person) of the Manufacturer, indicating the effective date of the renunciation.

This communication must be sent to IMQ by registered mail with return receipt or by any other method valid for all purposes and effects of law.

In case of Certification renunciation, the Manufacturer must:

- Refrain from advertising and using the Certification in question by removing references to IMQ as an NB from the documentation (including advertising material) of the Devices referable to such renunciation,
- Cease to affix the CE0051 marking to Devices referable to this renunciation and, consequently, cease their production and placing on the market with this marking,
- Communicate, at the same time as the renunciation, the last batch/serial number placed on the market of each Device subject to renunciation; any stocks bearing the CE0051 marking must be run out within the effective date of the renunciation,
- Pay all amounts due to IMQ.

In relation to the obligations set out in this Article, IMQ may carry out verifications; all costs relating to such additional checks shall be borne by the Manufacturer.

IMQ shall in its turn:

- Withdraw the Certificate, which will therefore cease to produce its effects as from the effective date of renunciation;

- Notify the renunciation of Certification in EUDAMED[2];
- Cancel the surveillance activity of the Certification referred to in Art. 4.4 above, if conducted by IMQ.

Starting from the effective date of the renunciation, the Certification Contract shall cease to produce its effects for the Devices subject to the renunciation and shall be automatically terminated, unless this Contract also covers Devices not subject to the renunciation.

8.2. Suspension of validity of Certification

8.2.1. Reasons for the suspension measure

The validity of the issued Certification may be suspended by IMQ in case of:

- Non-payment of amounts due to IMQ (see also Art. 8.3.1 below);
- Judicial liquidation of the Manufacturer's business;
- Non-fulfilment of the Manufacturer's obligations underArt. 5 above;
- Major Nonconformities affecting the safety of the Device, with or without Minor Nonconformities; in cases of failure to take corrections and corrective action and, in general, negative results of surveillance audits, including unannounced audits; in cases of non-compliance with commitments undertaken to maintain the conformity of Devices and the quality management system;
- Reports from the market and/or the competent Authorities, after ascertaining the relative seriousness.

8.2.2. Communication of the suspension measure

The decision to suspend the validity of the Certification and any restoration measure will be communicated to the Manufacturer by registered letter with advice of receipt or any other method valid for all purposes and effects of law. The communication states the reason for the suspension and the deadlines by which the Manufacturer must implement the corrections and corrective actions required. The Manufacturer must notify IMQ of the acceptance of the measure, the compliance with the requirements and any other useful information on how the contested findings will be resolved. The communication must be in written form. The suspension measure shall take into account the principle of proportionality.

8.2.3. Consequences of the suspension measure

From the date of communication of the suspension measure until the date of communication of the of the Certification restoring, the Manufacturer must:

- refrain from advertising and using the suspended Certificate,
- not affix the CE0051 marking to Devices referring to this suspension,
- not place on the market the Devices subject to the suspension measure.

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 activities, except for unannounced audits. The Manufacturer is in any case obliged to pay the amounts due for maintaining the Certification.

IMQ notifies the suspension measure in EUDAMED[2].

8.2.4. Restoring the validity of the Certification

The suspension may only be cancelled when the Manufacturer has satisfactorily resolved the Nonconformities found, or when the situation that originated the suspension measure no longer exists. Before proceeding with the restoring of the Certification, IMQ shall carry out verifications to ascertain the effective resolution of the issued previously found; the costs for carrying out these additional verifications shall be borne by the Manufacturer and communicated by means of an appropriate Quotation (see also Art. 6.1 above).

IMQ notifies the restoring of the validity of the Certification in EUDAMED[2].

8.2.5. Duration of the suspension period

The duration of the suspension, which shall not exceed six (6) months, shall be indicated in the communication referred to in Art.8.2.2 above; if the suspension is not cancelled within the terms established by IMQ, the Certification shall be revoked.

8.3. Revocation of Certification Validity

8.3.1. Reasons for the revocation measure

The validity of the Certification issued may be revoked, in whole or in part, by IMQ in case of:

- Failure to cancel the suspension measure referred to in Art.8.2 above, within the period set by IMQ (see also Art. 8.2.5 above);
- Serious breach of the Manufacturer's obligations Art. 5 above;
- Fraudulent, misleading or unlawful use of the Certification (see Art. 7 above);
- Significant and systematic Nonconformities; failure to take corrections and corrective actions and, in general, negative results of supplementary/ extraordinary verifications; failure to comply, involving serious negligence, with the commitments undertaken regarding the maintenance of conformity of the Devices and the quality management system;
- Divergence between the sample taken from the manufactured Devices and/or from the current manufacturing process and/or from the market and the specifications contained in the technical documentation;
- Failure to adapt the Device and/or the quality management system to the requirements of new revisions of the IVDR, applicable standards or CS;
- Failure to pay the amounts due, whatever the reason, to IMQ for maintaining the Certification. In this case, before proceeding to revocation, IMQ will send the Manufacturer a notice called "prior notification of revocation"; fifteen (15) days after such notice, without the Manufacturer having paid the balance of the amounts due, the Certificate will be revoked. During this notice period, the validity of the Certificate and all verifications are suspended, as is foreseen in the case of suspension;
- Conviction for facts concerning failure to comply with the mandatory requirements relating to the Device being certified;
- Judicial liquidation or definitive cessation of the Manufacturer's business.

8.3.2. Communication of the revocation measure

The decision of withdrawal, in whole or in part, shall be communicated to the Manufacturer by registered letter with notification of receipt or other means valid for all purposes and effects of law.

8.3.3. Consequences of the revocation measure

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

- Refrain from advertising and using the revoked Certificate by removing references to IMQ as an NB from the documentation in use (including advertising material) of the Devices referring to such revocation;
- Cease to affix the CE0051 marking to Devices referable to this revocation and, consequently, cease their production and placing on the market with this marking;
- Pay all amounts due to IMQ.

In case of revocation, IMQ shall in turn:

- Withdraw the revoked Certification, which will therefore cease to produce its effects from the date of the revocation notice,
- Notify revocation in EUDAMED[2],
- Cancel the Certification Surveillance activity referred to in Art. 4.4 above, if conducted by IMQ.

If the Certification has been revoked due to defects that may compromise the clinical condition or safety of patients, the safety and health of users and possibly other persons (ref. Annex I, p. 1 of the IVDR), IMQ is allowed to invite the Manufacturer to withdraw all the units of the Device from the market, informing the competent Authority in any case.

Starting from the date of the aforesaid notice of revocation, the Certification Contract shall cease to produce its effects in respect of the Devices subject to revocation and, unless this Contract also covers Devices not subject to revocation, it shall be automatically terminated.

Art. 9. LEGISLATIVE AND REGULATORY CHANGES

9.1. Amendments to legislative provisions

If the legislative provisions applicable to the individual Service in question undergo significant changes affecting the validity of the Certification issued, IMQ will inform the Manufacturer, who will have the right to adapt its Devices and/or its quality management system, within the deadline specified by IMQ, or to renounce the Certification.

If the Manufacturer intends to comply with the new provisions, IMQ will be entitled to repeat the tests and verifications on the Devices and/or the assessment of the quality management system, as well as to request new documentation. The costs for said activities will be borne by the Manufacturer, according to a new Quotation.

If the Manufacturer does not intend to comply and does not send communication of renunciation of the Certification within the application times of the new provisions, IMQ will revoke the validity of the Certification in accordance with Art. 8.3.1 above.

In the case of revocation of the Certification validity, the provisions of Art. 8.3 above shall be recalled and applied.

9.2. Amendments to the IMQ Regulation

If the requirements applicable to conformity assessment activities change, IMQ may update the conformity assessment procedures described in this Regulation to transpose the new legal provisions.

IMQ also reserves the right to make amendments and integrations to this Regulation without the prior consent of the Manufacturer; in this case, IMQ will make the new revision of this Regulation available by publishing it on its website www.imq.it/en in the section "EU Directives and Regulations -> In Vitro Diagnostic Medical Devices (IVDR) - 2017/746/EU" and will inform the Manufacturer of the amendment in writing.

In this case, the Manufacturer shall have the right to withdraw from the Certification Contract within thirty (30) calendar days from the date of receipt of the aforesaid communication from IMQ, in accordance with Art. 11.3 below, without prejudice to the payment of the amounts due to IMQ for the activities carried out by IMQ up to receipt of the notice of withdrawal, including any amounts relating to the maintenance of the Certification in accordance with the terms and frequency indicated in the Quotation; the payment of amounts as compensation for exercising the right of withdrawal shall be excluded.

If a Certification Contract is not yet in force between the Parties, the Manufacturer has the right to withdraw from the accepted Quotation, within the aforementioned thirty (30) days; such withdrawal entails the automatic withdrawal of the Application by the Manufacturer.

9.3. Supplementary assessments following changes

Any costs for documentary and/or on-site assessment, resulting from the aforementioned changes to the legislative provisions or to this Regulation, shall in any case be borne by the Manufacturer.

Art. 10. LIMITS OF CERTIFICATION AND RESPONSIBILITY

10.1. Manufacturer's Liability - Hold Harmless

The Manufacturer undertakes to comply and maintain itself in conformity with the mandatory requirements, such as laws, regulations, etc., whether international, national or local, with particular regard to the products, processes and services falling within the scope of Certification.

The issuing and maintenance of the Certification do not constitute an attestation or guarantee by IMQ of compliance with all the mandatory requirements that concern the Manufacturer and, in general, of its legislative compliance.

Therefore, the Manufacturer is - and remains - solely responsible, both to itself and to third parties, for the proper conduct of its business and the conformity of the same, and of its products/services, with applicable regulations, as well as with the expectations of customers and third parties in general.

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

10.2. IMQ breach - Limits of responsibility

Except in cases of wilful misconduct or gross negligence, the responsibility of IMQ towards the Manufacturer for any damage deriving from the performance or non-performance, in whole or in part, of its obligations under the Certification Contract shall be limited to a maximum amount of three (3) times the fee due for the assessment activity carried out at the time of the error or omission that caused the damage.

10.3. Forfeiture clause

Any complaint or request for compensation against IMQ shall be made by the Manufacturer, under penalty of forfeiture, within and no later than one (1) year from the event that gave rise to the claim or complaint.

10.4. IMQ disclaimer

Except in cases of wilful misconduct or gross negligence, even in cases of ascertained non-fulfilment by IMQ, compensation in favour of the Manufacturer for any loss of profit, such as, for example, interruption of business activities, loss of profit, business opportunities, turnover, goodwill or expected profits, shall be excluded.

Art. 11. DURATION OF THE CONTRACT, RIGHT OF WITHDRAWAL AND PENALTIES

11.1. Entry into force of Contract

The Certification Contract shall be considered entered into force and binding for all legal purposes from the date on which it is signed by a legal representative (or by an appropriately delegated person) of IMQ and the Manufacturer.

11.2. Duration of the Contract

The Certification Contract is stipulated for an indefinite period, starting from the date of entry into force referred to in Art.11.1 above.

11.3. Right of withdrawal and penalties

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

Withdrawal by the Manufacturer before obtaining Certification entails withdrawal of the Application on the date of receipt of the relative communication by IMQ. However, in this case:

a) If the Manufacturer's communication is received by IMQ before the order confirmation, the Manufacturer shall be obliged to pay a sum equal to fifty percent (50%) of the amount relating to the Application Review indicated in the Quotation, as a lump-sum compensation for the expenses incurred for the preliminary verifications carried out by IMQ pursuant to Art. 4.1.2 above;
b) If the Manufacturer's communication is received by IMQ after the order confirmation but before the start of the assessment activity, the Manufacturer shall be required to pay the amount relating to the Application review and, in addition, a sum equal to ten percent (10%) of the total amount of the Quotation;
c) If the Manufacturer's communication is received by IMQ after the start of the assessment activity, but before the issue/update of the Certification, the Manufacturer shall be obliged to pay the amount related to the activities carried out by IMQ up to the time of receipt of the withdrawal communication and, in addition, a sum equal to ten percent (10%) of the total amount of the Quotation.

Withdrawal by the Manufacturer after obtaining the Certification implies the renunciation of the Certification, which will therefore cease to produce its effects from the date of receipt of the relative communication by IMQ.

In this case, the Manufacturer shall pay all amounts due to IMQ, according to the terms and periodicity indicated in the Quotation, up to the date of receipt of the withdrawal notice.
The Manufacturer will also be obliged to pay IMQ the amounts for maintenance relative to the period in progress at the date of withdrawal and, if the relevant communication is not received by IMQ at least 15 (fifteen) days before the deadline set for invoicing the amounts relating to the subsequent period, the Manufacturer will also be required to pay IMQ the maintenance amounts relating to that period. In no case will IMQ be obliged to refund the amounts for Certification and maintenance already paid on the date of receipt of the notice of withdrawal from the Manufacturer.
With regard to further obligations resulting from withdrawal, the provisions of Art. 8.1 above shall be recalled and applied.

Withdrawal by IMQ - before issuing the Certification - entails the cancellation of the assessment process and the relevant Quotation, with the return to the Manufacturer of any amounts already paid to IMQ; after this refund, nothing else may be claimed by the Manufacturer against IMQ for any reason or cause whatsoever.

Without prejudice to the provisions of Art. 3.7.2 above, withdrawal by IMQ - after issuing the Certification - shall be communicated to the Manufacturer with at least a three (3) months prior notice; such withdrawal shall entail the (full) revocation of the Certification itself, which shall therefore cease to produce its effects from the effective date of the withdrawal, unless otherwise indicated by IMQ. In the event of withdrawal by IMQ after the issue of the Certification, 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

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 directly provided by the Manufacturer or through third parties will be processed by IMQ - and in particular recorded and stored in a database - in order to ensure the proper performance of the contractual relationship with the Manufacturer (the "Personal Data").

The "Data Controller" of Personal Data is IMQ S.p.A., a sole shareholder company, subject to the direction and coordination of IMQ Group S.r.l., with registered office in Via Quintiliano, 43 - 20138 Milan (Italy). The contact address of the appointed Data Protection Officer (hereinafter, the "DPO") is: dpo@imqgroup.it

Personal Data will be processed for the provision of the Service. The legal basis of the processing is the performance of the Certification Contract to which the Manufacturer is a party, the execution of pre-contractual measures taken at the request of the Manufacturer, the need to comply with legal, regulatory or accreditation obligations to which the Data Controller is subject and, in certain cases, the legitimate interest of the Data Controller in managing relations with its customers. Due to the latter legal basis, the Data Controller processes the Personal Data (typically personal and/or contact details) of contact persons and legal representatives of the legal entities with which it has business relations. In the absence of such data, the Data Controller will not be able to guarantee the requested Service.

In relation to the aforementioned purposes, Personal Data is processed by means of manual and telematic tools, with logics strictly related to the purposes themselves and, in any case, in such a way as to guarantee the security and confidentiality of Personal Data.

Personal data shall be processed for the time strictly necessary for the performance of contractual relations, without prejudice to the retention of data for a further period of ten (10) years after the expiry of the last Service provided, in order to comply with legal and regulatory obligations.

Personal Data may be disclosed to personnel authorised to process them and may be communicated by IMQ, within the limits of their respective and specific competence, to Accreditation Bodies, Certification Bodies, Administrations, Institutions, Associations, Judicial Authorities and Public Security Authorities as well as to any other competent Authority and, in general, to any public or private subject whose communication is mandatory by law or necessary for the performance of the Service. These subjects will process Personal Data in their capacity as autonomous data controllers.

Personal Data may also be disclosed to third party companies or other entities (by way of example only, IT service providers, credit recovery companies) performing outsourcing activities on behalf of the Data Controller, in their capacity as data processors. The list of specifically appointed data processors who process Personal Data is available from the Data Controller.

Personal Data may also be communicated for the purposes of the performance of the Service to companies of the IMQ Group as well as to Accreditation Bodies and/or Certification Bodies located outside the European Union.

Pursuant to Articles 15-21 of the General Data Protection Regulation, the Manufacturer may at any time exercise its rights of access, rectification or erasure, restriction of processing, and portability of its data by sending a request to the address of DPO: .dpo@imqgroup.it

The Manufacturer has the right to lodge a complaint with a competent Supervisory Authority pursuant to Article 77 of the GDPR, which for the Italian territory is the *Garante per la protezione dei dati personali* (Italian Data Protection Authority) in accordance with the procedures set out on the website https://www.garanteprivacy.it/ .

Art. 13. COMPLAINTS AND APPEALS

13.1. Complaints

The Manufacturer, as well as anyone who has an interest, may submit complaints about the work of IMQ, or about the Devices certified by IMQ, setting out and explaining the reasons for the complaint, according to the procedures provided on the IMQ website at https://www.img.it/en/contact-us. IMQ will deal with the complaint according to its own procedures, within the handling times commensurate with the level of complexity of the complaint.

13.2. Appeals

The Manufacturer may lodge an appeal against the decisions taken by IMQ on the outcome of the conformity assessment, within thirty (30) days from receipt of the relevant communication, setting out and justifying the reasons for the appeal, according to the procedures provided on the IMQ website at https://www.img.it/en/contact-us.

IMQ will process the appeal according to its own procedures, described in the relevant section of the above mentioned website. The decision on the appeal, taken by a Committee made up of persons not involved in the conformity assessment activities subject of the 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 COURT OF COMPETENT JURISDICTION

14.1. Applicable law

The Certification Contract is governed by Italian law.

14.2. Place of jurisdiction

Any dispute relating to the application or interpretation of the Certification Contract, including those concerning its validity, performance and termination, shall be submitted to the exclusive jurisdiction of the Court of Milan (Italy).