Certification Scheme
Medical Devices Regulation EU 2017/745
SCPEMDR

05	18/01/2021	Update following the requests of JAT/ACCREDIA/MIN HEALTH	OPE	HEAD OF ISG	HEAD OF OPE
04	28/08/2020	Updated due to review of certain points of the MDR regulation	OPE	HEAD OF ISG	HEAD OF OPE
03	11/12/2019	SSCP changes and MDCG 2019-13 reception	OPE	ISG	HEAD OF OPE
02	04/11/2019	Reception of NBOG F 2017-5 findings	OPE	ISG	HEAD OF OPE
01	31/08/2019	Revision of general requirements	OPE	ISG	HEAD OF OPE
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Rev.	***Date***	***Description***	***Drawn up***	***Verified***	***Approved***
IDENTIFICATION: 0209CS_05_EN					

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PRODUCT/SERVICE DESCRIPTION

DEFINITION
The certification scheme applies to the assessment of conformity of the medical devices that fall under the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and which repeals Directives 90/385/EEC and 93/42/EEC of the Council, hereinafter referred to as the MDR. ***Device**: in this scheme, as in the MDR, the term "devices" applies to medical devices, the accessories for medical devices and the products listed in Annex XVI to the MDR.* ***Medical Device (MD):** any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:* - *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;* - *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;* - *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;* - *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations;* *and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.* *The following products shall also be deemed to be medical devices:* - *devices for the control or support of conception;* - *products specifically intended for the cleaning, disinfection or sterilisation of medical devices;* ***Accessory for a Medical Device:** means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).* ***Product**: in the context of this scheme the generic term "Product" is used, except in specific contexts, to define the term "Devices".* ***Manufacturer:** a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.*

REGULATORY REFERENCES

Standards and documents valid at the issue date of this document
ICIM 0001CR ICIM General regulation.
ICIM 0002CR Regulation for the certification of management systems.
ICIM 0003CR Regulation for the certification of products and services.
ICIM 0486BI - Monitoring of MDR guidance and best practices

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) no. 1223/2009 and repeals Directives 90/385/EEC and 93/42/EEC of the Council.
COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council.

UNI IEC EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purpose
APPLICABLE HARMONISED STANDARDS ref. website (pending specific harmonised standards for MDR and common specifications):http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/index_en.htm

MDCG AND NBOG GUIDELINES: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
COMMON SPECIFICATIONS (CS) APPLICABLE
MEDDEV DOCUMENTS: https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

Communications by the regulatory Authority, including the competent authorities and notifying authorities (ANNEX 4 to this regulation)

DESCRIPTION

The definitions of articles 1 and 2 of Regulation (EU) 2017/746 (MDR) apply to all types of Medical Device.
The MDR does not apply to the following products, as indicated in article 1 paragraph 6:

a) in vitro diagnostic medical devices covered by Regulation (EU) 2017/746;
b) medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/81/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product;
c) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;
d) to human blood, blood derivatives, plasma or blood cells of human origin. or to devices which, at the time of being placed on the market or put into service contain blood derivatives, plasma or blood cells, with the exception of devices which incorporate, as an integral part, a substance deriving from human blood or plasma as defined by Article 1 section 2 of directive 2001/83/EC, which, if used separately, may be considered as a constituent of a medicinal product or a medicinal product derived from human blood or plasma within the meaning of Article 1 of Directive 2001/83/EC and which expounds an action ancillary to that of the device, the latter is assessed and authorised in accordance with the MDR;
e) to cosmetic products covered by EC Regulation no. 1223/2009;
f) transplants, tissues or cells of animal origin, or their derivatives, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or are rendered non-viable;
g) transplants, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, or products containing or consisting of them; however this Regulation does apply to devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;
h) products, other than those referred to in points (d), (f) and (g), that contain or consist of viable biological material or viable organisms, including living micro-organisms, bacteria, fungi or viruses in order to achieve or support the intended purpose of the product;
i) *food covered by Regulation (EC) No 178/2002.*

GENERAL CERTIFICATION CONDITIONS

CERTIFICATION TYPE
REGULATED, it will bear the CE marking of the product. ICIM operates as notified body for Reg. (EU) no. 745/2017 - MDR

TYPE OF OPERATION

Introduction

ICIM and its personnel shall carry out conformity assessment activities on medical devices and accessories (MD) as defined in art. 1 paragraph 1 and 2 of the MDR with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. ICIM shall have the expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which it is designated. On its website (www.icim.it), ICIM makes available to the public the statements of its top management.

Type of operation

The classification uses Annex VIII to the MDR (see also ICIM doc. 0205BI) which divides medical devices and accessories in class I (with any variants), IIa, IIb, and III.

The operations intended by ICIM for MDR products are actuated, depending on the classes and choices of the Manufacturer or his representative, according to the procedures:

- ***Production quality assurance (annex XI part A)***
- ***Complete quality assurance system (annex IX)***

Conformity assessment method related to the class of MD:

MD class	***Applicable MDR annex***
Class III	*Annex IX – chapter I, II, III* *or* *Annex XI – part A (EU type-examination certificate required, as per Annex X)*
Class IIb implantable	*Annex IX – chapter I, II, III* *or* *Annex XI – part A (EU type-examination certificate required, as per Annex X)*
Class IIb	*Annex IX – chapter I, II section 4, III* *or* *Annex XI – part A (EU type-examination certificate required, as per Annex X)*
Class IIa	*Annex IX – chapter I, II section 4, III* *or* *Annex XI – part A*
Class I sterile	*Annex IX – chapter I, III (only for sterility aspects)* *or* *Annex XI – part A*
Class I with measuring function	*Annex IX – chapter I, III (only for metrological aspects)* *or* *Annex XI – part A*
Class I – reusable surgical instruments	*Annex IX – chapter I, III (only for aspects regarding reuse)* *or* *Annex XI – part A*
Devices consisting of substances intended to be introduced into the body or applied on the skin and which are absorbed by or locally dispersed in the human body	*One of the above, depending on class + section 5.4 of Annex IX* *or* *Annex XI – part A (EU type-examination certificate required, as per Annex X + section 6 to the latter)*

ICIM does not currently intervene on Annex X and Annex XI part B.

Specifically, the products on which the operation of ICIM is envisaged are as follows *(see also the NANDO website*: *https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34):*

1- ***Active non-implantable devices for images, monitoring and/or diagnosis:***
   - *MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters*
   - *MDA 0204 Active non-implantable devices for monitoring and/or diagnosis*

2- ***Active non-implantable therapeutic devices and active implantable devices in general:***
   - *MDA 0305 Active non-implantable devices for stimulation or inhibition*
   - *MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis*
   - *MDA 0307 Active non-implantable respiratory devices*
   - *MDA 0309 Active non-implantable ophthalmologic devices*
   - *MDA 0310 Active non-implantable devices for ear, nose and throat*
   - *MDA 0311 Active non-implantable dental devices*
   - *MDA 0312 Other active non-implantable surgical devices*
   - *MDA 0315 Software*
   - *MDA 0316 Medical gas supply systems and parts thereof*
   - *MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation*

3- ***Non-active implants and long term surgically invasive devices***
   - *MDN 1102 Non-active osteo- and orthopaedic implants*
   - *MDN 1103 Non-active dental implants and dental materials*

4- ***Non-active non-implantable devices***
   - *MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care*
   - *MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis*
   - *MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools*
   - *MDN 1204 Non-active non-implantable devices for wound and skin care*
   - *MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices*
   - *MDN 1206 Non-active non-implantable ophthalmologic devices*
   - *MDN 1207 Non-active non-implantable diagnostic devices*
   - *MDN 1208 Non-active non-implantable instruments*
   - *MDN 1209 Non-active non-implantable dental materials*
   - *MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing*
   - *MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route.*

5- ***Devices with specific characteristics***
   - *MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council*
   - *MDS 1005 Devices in sterile condition*
   - *MDS 1006 Reusable surgical instruments*
   - *MDS 1007 Devices that incorporate or consist in nanomaterials*
   - *MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices*
   - *MDS 1010 Devices with a measuring function*
   - *MDS 1011 Devices in systems or procedure packs*
   - *MDS 1012 Products without a medical intended use listed in Annex XVI to Regulation 2017/745.*

6- Devices for which specific technologies or processes have been used

- *MDT 2001 Devices which require metal processing*
- *MDT 2002 Devices which require plastic processing*
- *MDT 2003 Devices which require non-metal mineral processing such as glass, ceramics*
- *MDT 2004 Devices which require non-metal non-mineral processing such as textiles, rubber, leather, paper*
- *MDT 2006 Devices manufactured using chemical processing*
- *MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals*
- *MDT 2008 Devices which require clean room production*
- *MDT 2010 Devices which require manufacture or processing of electronic components including communication devices*
- *MDT 2011 Devices which require packaging, including labelling*
- *MDT 2012 Devices which require installation, refurbishment*

Performance of the activities

For the performance of the aforementioned activities, ICIM shall take account of the relevant requirements set out in Annexes IX to XI to the MDR, and in particular all of the following requirements:

- *appropriately plan the conduct of each individual project;*
- *ensure that the composition of the assessment teams is such that there is sufficient experience in relation to the technology concerned, and that there is continuous objectivity and independence, and to provide for rotation of the members of the assessment team at appropriate intervals,*
- *specify the rationale for fixing time limits for completion of conformity assessment activities,*
- *assess the manufacturer's technical documentation and the solutions adopted to meet the requirements laid down in Annex I to the MDR,*
- *review the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects,*
- *review the manufacturer's procedures and documentation relating to clinical evaluation,*
- *address the interface between the manufacturer's risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation and to evaluate their relevance for the demonstration of conformity with the relevant requirements in Annex I to the MDR,*
- *carry out the specific procedures referred to in Sections 5.2 to 5.4 of Annex IX to the MDR,*
- *in the case of class IIa or class IIb devices, assess the technical documentation of devices selected on a representative basis,*
- *plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,*
- *relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,*
- *evaluate and verify a manufacturer's compliance with relevant Annexes.*

NOTES

OFFER REQUEST
The Manufacturer shall send the Offer Request (OR) to ICIM providing all the technical data relating to the MD to be certified, the MED code, the class and the audit method selected. *When drafting the offer, the ICIM salesperson with the support of the Scheme Manager, defines the Audit Group (GI) and performs a first assessment regarding the existence of incompatibilities between the members of the GI and the Manufacturer in the past three years. (see also what is mentioned under the point "CERTIFICATION - Review of the Application - Audit group - Assessment of the incompatibility of GI inspectors").* *If ICIM has no qualified auditors for the type of product or such as to ensure the non-existence of incompatibility, the offer is not issued and the manufacturer is informed of the impossibility to proceed.* *At the same time any disputes arising between ICIM and the Manufacturer concerning the classification of the medical device, leads to the suspension of the procedure of the offer and sending of an official request for an opinion to the Ministry of Health. Depending on the opinion of the competent Ministry and the positive outcome of the aforementioned checks, ICIM issues a specific offer.* *The rates for the conformity assessment activities are available to the public in the condition and form dictated by the common guidelines.*
NOTES

APPLICATION FOR CERTIFICATION

ADDITIONAL DOCUMENTATION

The Manufacturer who intends on obtaining approval of the product according to one of the procedures described in Annexes IX (chapter I and chapter II) and XI (A) of the MDR, on accepting the offer issues ICIM with an Application for certification (Application), using the specific form.
Together with the Application, the Manufacturer sends ICIM the documentation required by the applicable annexes.
In particular, if a request under Annex IX is submitted, the following must be sent:

- *the name and the address of the registered office of the manufacturer and the address of all other manufacturing sites that form the subject of the quality management system, and, if the manufacturer's application is submitted by their authorised representative, the name and the address of the registered office of the latter, as well;*
- *where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;*
- *all relevant information on the device or group of devices covered by the quality management system;*
- *a written declaration to the effect that no application for the same quality management system relating to the device has been submitted to any other notified body, or information on any previous applications for the same device-related quality management system;*
- *a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure;*
- *the documentation on the quality management system:*
- *a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under MDR and the undertaking by the manufacturer in question to apply those procedures,*
- *a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,*
- *the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance,*
- *a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance, as well as the undertaking by the manufacturer to apply those procedures,*
- *documentation on the clinical evaluation plan,*
- *a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art*

moreover, it is necessary to submit an adequate description:

- *of the Manufacturer's quality objectives;*
- *of the Manufacturer's organisation:*
  - *the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority;*
  - *the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform;*
  - *where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party*
- *of the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:*
  - *the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,*
  - *identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account,*
  - *risk management as referred to in Section 3 of Annex I to the MDR,*
  - *the clinical evaluation, pursuant to Article 61 and Annex XIV, including post-market clinical follow-up,*
  - *solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,*
  - *solutions for fulfilling the applicable specific requirements regarding information to be supplied with the device, specifically the requirements of Chapter III of Annex I,*
  - *the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture,*
  - *management of design or quality management system changes;*
- *the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents,*
- *the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, the test equipment to be used and information on its calibration conditions.*

Lastly, the Technical documentation including procedures for surveillance and control of product design, the control and quality assurance techniques at the manufacturing stage, the tests and trials which will be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment used, which must include the information in the paragraph "TECHNICAL DOCUMENTATION".

TECHNICAL DOCUMENTATION

The documentation relating to the project to which the Application refers must be delivered to ICIM in Italian. Documentation in English is also accepted.
The Manufacturer's technical data must also include that of their subcontractors and/or critical suppliers and their quality system must also take account of these in the control procedures. The elements making up the technical documentation are listed below:

a) Device description and specification, including accessories and variants

- *product or trade name and a general description of the device including its intended purpose and intended users;*
- *the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;*
- *the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;*
- *principles of operation of the device and its mode of action, scientifically demonstrated if necessary;*
- *the rationale for the qualification of the product as a device;*
- *the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;*
- *an explanation of any novel features;*
- *a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;*
- *a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;*
- *a general description of the key functional elements, e.g. parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;*
- *a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;*
- *technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.*
- *an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;*
- *an overview of identified similar devices available on the Union or international markets, where such devices exist*

b) Information to be supplied by the Manufacturer:

- *the labelling design and*
- *the instructions for use*

c) Design and manufacturing information

- *information to allow the design stages applied to the device to be understood;*
- *complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;*
- *identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.*

d) General safety and performance requirements (the documentation shall contain information for the demonstration of conformity with the general safety and performance requirements that are applicable to the device taking into account its intended purpose), including:

- *the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;*
- *the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;*
- *the harmonised standards, CS or other solutions applied;*
- *the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance*

requirements.

e) Benefit-risk analysis and risk management:

- *the benefit-risk analysis referred to in Sections 1 and 8 of Annex I,*
- *the solutions adopted and the results of the risk management referred to in Section 3 of Annex I to the MDR*

f) Product verification and validation:

- *information regarding the pre-clinical safety of the device and its conformity with the specifications, e.g. laboratory, simulated use tests, and evaluation of published literature applicable to the device and to its intended purpose, and in particular the biocompatibility of the device, its physical, chemical and microbiological characterisation, electrical safety and electromagnetic compatibility, software verification and validation, stability, including shelf life, and performance and safety*
- *in the case of class III or implantable devices, other than custom-made or investigational devices, a summary of safety and clinical performance (SSCP); this summary, validated during assessment of the documentation before the certificate is issued, is made available through the electronic system put in place by the Commission.*
- *the clinical evaluation report, its updates and the clinical evaluation plan*
- *the PMCF plan and PMCF evaluation report (or, if not applicable, the reasons why)*
- *the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents;*
- *the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;*
- *any other documentation supporting the statements made in the FTC, if clarifying what has been stated.*

g) additional information in specific cases:

1) *devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:*
   - *absorption, distribution, metabolism and excretion,*
   - *possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions,*
   - *local tolerance,*
   - *toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device;*

   In the absence of such studies, a justification shall be provided;
2) *devices placed on the market in a sterile or defined microbiological condition:*
   - *a description of the environmental conditions for the relevant manufacturing steps,*
   - *a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues;*
3) *devices with a measuring function*
   - *a description of the methods used in order to ensure the accuracy as given in the specifications*
4) *reusable surgical instruments*
   - *a description of the allowed sterilisation methods and relative validations*
   - *a description of the allowed cleaning, decontamination and maintenance methods and relative validations*

NOTES

CERTIFICATION

APPLICATION ASSESSMENT

METHOD TO BE APPLIED

PERSON RESPONSIBLE FOR COORDINATING THE CONFORMITY ASSESSMENT ACTIVITIES

The Scheme Manager, taking into consideration the type of product for which the conformity assessment is requested and the reference MD code, choose the Project Leader (PL) who is best suited to assure that the assessment of the technical documentation conforms with the pertinent procedures and guarantee that adequate resources are used for each assessment task.

AUDIT GROUP

ICIM defines the Audit Group (GI), formed by auditor (AVI), technical expert auditor (if necessary) (TE), internal clinician (IC, perhaps assisted by one or more Clinical Specialists (CS)), among the auditors/experts registered in the special list, also considering the specific experience with respect to the MD to be certified and verifying that there is no incompatibility (see "Assessment of the incompatibility of the audit group (GI)") between them and the Manufacturer. In this phase ICIM also defines the Lead auditor (RGI) choosing the auditor under the scope of the GI who has more experience in the type of operation and the type of MD. ***The GI assigned for the assessment includes at least one person holding technology assessment experience of the MD.***

ICIM formalises the composition of the group and all pertinent changes in the first part of document 0602BM - CHECK LIST FOR FINAL REVIEWERS FOR CE MARKING AUTHORISATION.

ICIM communicates the name of the staff member assigned to conduct the audit to the Manufacturer. The Manufacturer has the right to request the replacement of the staff member assigned by ICIM if justified conflicts of interest exist, within five working days from the date of notification (see 0003CR par. 4.6).

Evaluation of incompatibility of the audit group (GI)

Members of the Audit Group who, before being hired by/starting to work with ICIM, were employed by a specific customer (as designers, in production, marketing, installation, maintenance and inspections) or who provided consultancy services in the medical devices segment for a specific customer, are not entrusted with any conformity assessment activities for this specific customer or for companies belonging to the same group of companies for a period of three years. Each member of the audit group must at least quarterly provide ICIM with a list of any extra ICIM actions of any kind carried out by these on Manufacturers, Authorised representative, Supplier or Commercial Competitor of the MD, so that ICIM can assess any incompatibilities.

The Scheme manager and Planning, to form the Audit Group, must evaluate that:

- *the auditor (including TE, IC and CS) has not had in the last three years consulting relationships with the Manufacturer, Authorised representative, Commercial Competitor or Supplier related to the design, manufacture, sale or maintenance activities. While it may have conducted for ICIM or for other NB third party operations,*
- *the auditor (also TE, IC and CS) has not had ongoing disputes that are not endorsed by objective technical problems with the Manufacturer,*
- *the auditor (also TE, IC and CS) has no obvious kinship with people in any way involved in the activities of the Manufacturer*
- *the auditor (also TE, IC and CS) has no investments in shares of the Manufacturer*

If there is clear incompatibility with one of the afore defined items the scheme Manager must replace the auditor (also TE, IC and CS) planned with another holding equal qualification.

REVIEW OF THE APPLICATION

Upon receipt of the Application and relative annexes, ICIM takes charge and reviews it as per par. 4.4 of ICIM Regulation 0003CR in order to verify:

a) *the completeness of the Application with regard to the requirements of the relevant conformity assessment, as per the respective annex to the MDR, in virtue of which the certification is requested;*
b) *the qualification of the products concerned by the Application as devices and the respective classifications;*
c) *the applicability of the conformity assessment procedures chosen by the Manufacturer to the device in question, in accordance with the MDR;*
d) *the right of ICIM to assess the Application based on its designation;*
e) *the availability at ICIM of sufficient and adequate resources.*

If the documentation submitted is in ICIM'S opinion incomplete and/or inadequate, the process is suspended until the Manufacturer meets the requests that ICIM has officially communicated.

Following positive outcome of the review, ICIM registers the Manufacturer in the Information System and communicates the acceptance of the Assessment Application.

The Manufacturer's Application, which makes specific mention of these Regulations, and related acceptance by ICIM contractually formalises the relationship between ICIM and the Manufacturer and the applicability of these Regulations.

If the Manufacturer withdraws the Certification Application, or if ICIM refuses the Certification Application, the latter notifies the competent authorities, as per art. 53 of the MDR. In the electronic system of art. 57, ICIM enters the information concerning the withdrawal or refusal of the Application, in any case by the aforementioned means. This information is available to the public.

If the electronic system EUDAMED is not operational, the notification is sent to the competent authority by certified e-mail.

SAMPLING OF THE TECHNICAL DOCUMENTATION

Initial assessment

No samples are taken; the entire technical documentation is audited.

If there are more than fifty technical documents, ICIM may, however, assess the possibility of adopting sampling criteria based on the procedures defined in art. 52, paragraph 4 and paragraph 6 of the MDR and, however, such as to guarantee the completeness of the evaluation of the devices presented. In any case, sampling will always be 100% for implantable class III, IIa and IIb MDs. Technical documentation that has not been audited during the initial phase must, in any case, all be reviewed in subsequent surveillance visits, distributed in such a way as to ensure that all technical documents are assessed before the certificate's expiry.

ICIM documents and makes the criteria used for the selection of the sample/representative samples available to the competent Authority. The sampling program is documented in the audit program.

Surveillance Audits

Following the issue of the certificate, during surveillance audits, the following conditions are guaranteed when defining the sampling plan:

A. *At least one technical document must be assessed every year*
B. *At least one device for each category (for Class IIa) and every device for generic category (for Class IIb) the relevant assessed technical documentation must be sampled*
C. *The samples envisaged must guarantee each year the assessment of different technical documents compared to the previous year. This does not apply if the technical documentation contains a limited number of documents.*

In choosing one or more representative technical documentation samples, ICIM takes into account:

- *risks related to the intended use*
- *innovation of the technology and/or the materials the MD is made of*
- *design and manufacturing complexity*
- *similarities in design, technology and manufacturing and sterilisation methods*
- *similarities in the intended use*
- *results of previous relevant assessments (e.g. with regard to physical, chemical or biological properties) and of market surveillance*

ICIM documents and makes the criteria used for the selection of the sample/representative samples available to the competent Authority. The sampling program is documented in the audit program.

SUITABILITY REVIEW (Technical review of the documentation)

The suitability review involves a thorough examination by ICIM of the documentation making up the file relating to the Manufacturer's Application, in order to assess suitability and make suitable arrangements for the next assessment visit.

Normally the technical documentation of all MDs with certification application is verified. If a 100% analysis is not possible, the rules set forth in the previous section apply.

ICIM assesses the Quality System documentation and the technical documentation (at ICIM's headquarters or the Manufacturer's headquarters) to determine whether it meets the requirements referred to in the relevant annexes to the MDR. During assessment of the documentation attached to the application using the Adequacy Review Report performed by the technical expert (TE), ICIM will verify that the Manufacturer, for each analysed and assessed risk, has taken measures for their elimination and if this proves impossible, how to control and reduce it to a level that would ensure the clinical benefit for the patient resulting from the use of the device (Risk Management).

Significant subsequent changes to the device will result in a new assessment.

ICIM may require the performance of integration tests of the documentation examined or to be planned on the next assessment visit.

PRE-CLINICAL EVALUATION ASSESSMENT

ICIM reviews and checks that the manufacturer's procedures and technical documentation suitably envisage:

- *the planning, the performance, the pre-clinical evaluation and the transmission of the pre-clinical evaluation, including the pre-clinical scientific literature review and the pre-clinical tests,*
- *the nature and the duration of the contact with the human body and the specific related biological risks,*
- *the links to the risk management process,*
- *the assessment and analysis of the available pre-clinical data and their suitability in proving the device's conformity with the general safety and performance requirements of the MDR (Annex I to the MDR).*

See also "Specific additional procedures - Annex 3".

CLINICAL EVALUATION ASSESSMENT

ICIM reviews, validates and checks that the manufacturer's procedures and documentation suitably envisage:

- *the planning, the performance, the assessment, the transmission, and the update of the clinical evaluation envisaged by Annex XIV to the MDR,*
- *the post-market surveillance and the PMCF,*
- *the links to the risk management process,*
- *the assessment and analysis of the available data and their usefulness in proving conformity with the general safety and performance requirements of the MDR (Annex I to the MDR),*
- *the conclusions drawn with regard to the clinical evidence and the drafting of the report on the clinical evaluation.*

See also "Specific additional procedures - Annex 3".

The preclinical and clinical evaluation assessment is performed by ICIM with the help of an Internal Clinician (IC), also assisted, if necessary, by one or more Clinical Specialists (CS). The assessment is carried out according to specific ICIM procedure.

The result of the assessment is the binding opinion for the purpose of continuation of the evaluation and the final certification decision. If passed, the IC will send the Scheme manager the respective opinion whether the MD can be certified.

Furthermore, for implantable devices and class III devices, other than custom-made or investigational devices, another element subject to the initial evaluation is the draft of the summary of safety and clinical performance (SSPC referred to in article 32 of MDR), see ANNEX 7 to this document.

REVIEW OF THE QUALITY MANAGEMENT SYSTEM DOCUMENTATION

ICIM reviews, validates and checks that the manufacturer's procedures and documentation suitably envisage:

- the manufacturer's quality objectives;

- the company's organisation;

- the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques;

- the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents;

- the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency

with which they are to take place and the test equipment to be used.

APPLICATION EXAMINATION REPORT

The verifications conducted are recorded on special forms (ICIM doc 0365CM - Suitability Review Report, and ICIM 1046CM - Verification of clinical data Evaluation and ICIM doc 1043CM - Quality Management Documentation Assessment Report) reporting, where necessary, recommendations or non-conformities and indicating for each applicable entry the suitability or otherwise of the same.
At the end of the analysis, the three documents are delivered to the Manufacturer.

Other

In the event that, during the analysis of the documentation submitted by the Manufacturer, a possible conflict arises on the application of the Classification Rules according to the intended use of the MD, the Ministry of Health will be consulted.

INITIAL AUDIT

METHOD TO BE APPLIED

The initial audit at the Manufacturer's site must be carried out after the positive result of the Suitability review (assessment of technical documentation), pre-clinical evaluation assessment and clinical evaluation assessment in order to complete the evaluation of the Quality System and to verify, on the field, application of that described in the documentation attached to the Application, making sure that the processes relative to design and development, to production and to the relative controls, to the product documentation, to the controls on purchases, to corrective and preventive actions (including those regarding post-market surveillance) are capable of guaranteeing that the MD complies with the provisions of the applicable requirements of the MDR.
Upon request of the Manufacturer, the initial audit can still be carried out even if the assessment of the technical documentation has not concluded. If NCs arise during completion of the documental verification following the initial audit, ICIM reserves the right to perform another audit when the previous one is completed.
The initial audit is preceded by an analysis of the documentation of the quality system after which ICIM drafts an audit program which clearly identifies the number and sequence of activities necessary to demonstrate that the quality management system is fully covered.
This documental assessment can be conducted off-site but, if the devices to be certified are high risk (Class III and Class IIb), the analysis must necessarily be conducted on-site.
ICIM, checks the Manufacturer's availability, officially announces the program of the assessment visit, specifying the names of the auditors, possibly also external to ICIM, which are to be used for said visit.
In duly justified cases, the initial audit can be extended to the headquarters of the suppliers and/or subcontractors (critical) to check the manufacturing processes.
During the audit the GI must assess:

- *if the Manufacturer's corporate organisation is appropriate to ensure conformity of the quality system and medical devices, therefore:*
  a) *the organisational structure,*
  b) *the qualifications of managerial staff and the related organisational independence,*
  c) *qualifications and training of the rest of the staff,*
  d) *internal controls, infrastructure and monitoring of the quality system in progress, even in relation to third parties involved such as suppliers and subcontractors.*
- *the existence of an unambiguous product identification system. Said system must ensure that the ICIM certificates, the manufacturer's declarations of conformity and the manufacturer's technical documentation can, together with the same system, unequivocally be attributed to certain devices and not to others.*
- *the Manufacturer's procedures comparing them with the product documentation. The procedures in terms of the product documentation must ensure that all products intended to be placed on the market or put into service have the necessary certificates, already issued or to be issued. The procedures relating to the product documentation must also ensure that all products intended to be placed on the market or put into service, regardless of their trade name, have the relevant conformity declarations of the Manufacturer and that these are annexed to the technical documentation and consistent with it.*
- *the Manufacturer's procedures, aimed at the fulfilment of the legal requirements relating to procedures, are up to date, complete, consistent and correct. In particular with reference to the determination of the appropriate*

class and the conformity assessment procedure.

- *the Manufacturer's procedures concerning pre-clinical and clinical evaluations and post-market clinical follow-up are complete, correct and properly conducted.*
- *the procedures for design and product development, including any change of control procedures, are adequate to ensure compliance of the devices.*
- *that the Manufacturer controls the environment and the manufacturing production processes, so as to ensure that the devices conform to the legal requirements. Particular attention should be given to critical processes, such as design control, the definition of material specifications, purchasing and control of materials or input components, assembly, validation of software, sterilisation, delivery of batches, packaging and the product quality control, regardless of whether they were subcontracted or not.*
- *the materials and components traceability system adopted by the Manufacturer, from entrance into the premises of the Manufacturer, suppliers or subcontractors to delivery of the final product. In particular, in cases where risks may arise due to exchange of raw materials the notified bodies check coherence between the amount of essential raw materials produced or acquired, or essential components approved for the design, and the quantity of finished products.*
- *the documentation and quality system records and that concerning its changes, the management review process and related control of the documentation is up to date, consistent, complete, correct and properly structured.*

In the case of a request in accordance with Annex IX

The application of the quality system must ensure conformity of the products with the provisions applicable to them of the MDR in all phases from design to final checking. All the elements, requirements and provisions adopted by the Manufacturer to ensure the quality system must be in documentation which is systematically updated and organised under strategies and written procedures such as programs, plans, manuals and quality records. It shall include in particular the documentation, data and corresponding records arising from the procedures referred to in the documentation attached to the Application.

The assessment procedure must include an assessment, on a representative basis, of the technical documentation of the selected devices, an audit on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

If necessary ICIM reserves the right to have partial or total tests conducted by the Manufacturer on the products according to the harmonised standards of reference of the MDR.

When choosing one or more representative samples, take into account the sampling methods defined previously in the section SAMPLING OF THE TECHNICAL DOCUMENTATION.

In the case of a request in accordance with Annex XI part A

The application of the quality system must guarantee conformity of the MD to the type described in the EU Declaration of Conformity. All the elements, requirements and provisions adopted by the Manufacturer for the quality system must be in documentation which is systematically updated and organised under strategies and written procedures. The quality system documentation annexed to the Application must permit uniform interpretation of the strategies and procedures followed regarding quality, for example programs, plans, manuals and quality records.

The assessment procedure must include an audit visit at the Manufacturer's premises and, in duly substantiated cases, on the premises of the Manufacturer's supplier to inspect the manufacturing processes.

If necessary ICIM reserves the right to have partial or total tests conducted by the Manufacturer on the products according to the harmonised standards of reference of the MDR.

ICIM ascertains conformity of the technical documentation required by the MDR with the provisions of the MDR itself, the devices selected on a representative basis, taking account of the sampling methods defined previously in section SAMPLING OF TECHNICAL DOCUMENTATION.

Certification procedure for systems and procedure packs

See ANNEX 2 to this regulation

IA REPORT
The audit performed is reported on the Assessment Report specifying the conclusions of the audit and a reasoned assessment and reporting, where appropriate, the recommendations or nonconformities, defining for each applicable entry the suitability or non-suitability thereof. *Copy of the report and, if tests have been carried out, the test report is given to the Manufacturer as a notification of the operation.*
Other

INITIAL TESTS (ITT)
METHOD TO BE APPLIED
ITT are not required for the Annexes in which ICIM operates.
ITT TEST REPORT
Other
NOTES

OUTCOME OF THE TECHNICAL, CLINICAL EVALUATION AND AUDIT OF THE MANUFACTURER
METHOD TO BE APPLIED
The outcome of the assessment is documented in specific Assessment Reports prepared by the GI, which highlight any deviations from the QMS requirements applicable to the type of Medical Device in question and any Non Conformities, Observations and Recommendations formulated for improvement purposes. These reports are officially delivered to the Manufacturer by the GI. After receiving the Assessment Reports from the GI, ICIM (PL) has fifteen days to make any justified amendments in agreement with the GI, in which case they notify the Manufacturer in writing. *The findings are defined as follows:* ▪ *Non-Conformities (NC)* *Non-conformity formulated to the Manufacturer with reference to the General safety and performance requirements of the MDR or the requirements of the specific reference standard or the requirements of a common specification or of the ICIM Regulations and Certification Scheme, if some of these requirements are not met. An NC blocks the certification sequence at the initial assessment stage or may entail the suspension of the Certificate under surveillance, until the non-conformity is duly resolved. ICIM's verification of implementation of the corrective action could require additional auditing documentation assessments and/or audits to the Manufacturer.* ▪ *Observation (OBS)* *Observation formulated to the Manufacturer with reference to the General safety and performance requirements of the MDR or the requirements of the specific reference standard or the requirements of a common specification or of the ICIM Regulations and Certification Scheme, if some of these requirements are only met partially. Also, the said requirements must not compromise the conformity of the products that the Certification refers to. The corrective measures, proposed by the Manufacturer, must be considered easily implementable according to the*

proposed methods and timescale. One or more OSS do not block the certification sequence and ICIM's verification of implementation of the corrective action by the Manufacturer is usually carried out during the next auditing visit.

- *Recommendation (REC)*

Instruction for improvement formulated to the Manufacturer, with reference to the MDR or the specific reference standard or a common specifications or the ICIM Regulations and Certification Scheme. One or more recommendations do not pose any variation to the final assessment expressed by the GI, nor the requirement of the Manufacturer to implement corrective action.

ICIM assesses the corrective actions proposed by the Manufacturer and if ICIM does not accept the proposals for resolution of the non conformities detected in relation to the times and ways of performing them, ICIM shall inform the Manufacturer in writing who must propose time and action plans
In the case of NC, the Manufacturer must undertake to correct such NC within the time limit as proposed and accepted by ICIM. Based on the documentation received on the indicated deadline, ICIM decides whether another assessment or audit are required or whether said documentation is sufficient.
In the event that the Manufacturer fails to take appropriate action in the agreed time to respond to the NC found, the application will be considered lapsed and ICIM will inform the competent Authorities (Ministry of Health) and the other Notified bodies.

CONFORMITY ASSESSMENT ACTIVITY MANAGEMENT TIMES	
Notification of initial audit/surveillance visit/unscheduled/re-certification audit (except surprise audits)	*ICIM notifies at least ten (10) business days before the agreed date and the Manufacturer has five (5) business days from receipt of the notification to recuse one or more members of the audit group or request that the audit is postponed. If that is not the case, the Manufacturer will pay the cost of the audit, which, in any case, will be rescheduled, except in situations where it is not possible to foresee an adverse event.*
Initial certification	*In the presence of discrepancies found during the audit of the documentation (ARR), clinical audit (Questionnaire) and on-site audit (Report), the Manufacturer has a maximum of six (6) months from the first comment in each one of these phases to take action to rectify the comments. At the end of this period, the application is forfeited and the assessment procedure must begin anew.*
Initial certification	*In the presence of discrepancies found during the approval/final review, the Manufacturer has a maximum of six (6) months to take action to rectify the comments. At the end of this period, the application is forfeited and the assessment procedure must begin anew.*
Annual surveillance Visit	• *It is possible to exceed by thirty (30) days the periodic date of twelve (12) months from approval for the performance of the annual surveillance without specific justification.* • *For delays ranging from thirty (30) days to three (3) months, the company must provide due written justification for the delay, which must be approved by ICIM.* • *If the three (3) months are exceeded, the certificate is suspended.*
Annual surveillance Tests	*In case of negative outcome of the tests and of a subsequent second tranche, the certificate is suspended for a maximum period of six (6) months.* *After the six (6) months the certificate is withdrawn.*
Re-certification (Renewal)	*If, within six (6) months from the expiry, the Manufacturer does not request the cancellation from ICIM, the latter will start planning re-certification operations.*
Re-certification (Renewal)	*If the Manufacturer does not fulfil the obligations required for re-certification (acceptance of the re-certification offer, dispatch of documentation, planning of operations, etc.), such inaction will be deemed a surrender after ten (10) days.*
Re-certification (Renewal) Re-certification Visit	*It must be scheduled by ICIM and be performed at least sixty (60) business days before the certificate's expiry. If the Manufacturer does not make the visit possible within this deadline, ICIM does not guarantee the closure of the re-certification procedure, which may entail the revocation of the certificate on its expiry with the obligation to repeat the entire certification procedure.*

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Suspension of the CE Certificate	*ICIM may suspend a product certificate for a maximum of twelve (12) months, which, if no action is taken (if the Manufacturer does not submit any request to ICIM for the restoration of the certificate) entails the withdrawal of said certificate.*
Surrender or withdrawal of the CE Certificate	*In both cases, the Manufacturer has fifteen (15) days to notify ICIM of the stocks of products in its warehouse.*
Surrender or withdrawal of the CE Certificate	*In case payment becomes overdue. following official notice by ICIM, the Manufacturer has one (1) months to make the payment. If that is not the case, the certificate is withdrawn.*
Appeals	*The Manufacturer has thirty (30) days from the communication by ICIM to lodge an appeal. ICIM has fifteen (15) days to confirm receipt of the appeal and ninety (90) days to formulate an opinion.*
Complaint	*ICIM has fifteen (15) days to confirm receipt of the complaint which will be followed by the launch of the assessment procedure. Following the procedure, ICIM issues the Manufacturer with a written opinion, which must be appealed against in the subsequent five (5) days. If ICIM does not receive further instructions, the complaint will be deemed closed.*
Complaint *For loss or damage*	*The Manufacturer must lodge a complaint for loss or damage within six (6) months from the date on which the service was provided. If that is not the case, the complaint is not taken into account.*
Modifications *To the certification scheme (regulation, standards, rates).*	*The Manufacturer has thirty (30) days to notify acceptance thereof. If ICIM receives nothing, the Manufacturer will be deemed to have accepted the modification.*
Modifications Of the Manufacturer's organisation	*ICIM has thirty (30) days from receipt of the notification by the Manufacturer of changes to its organisation to inform the Manufacturer of the consequences thereof (documentation audit, audit, etc.).*

Other
NOTES

ISSUING THE CERTIFICATION

OUTCOME

FINAL REVIEW

The final Review is performed by the Final Reviewer (an internal ICIM employee), possibly assisted by a TE: neither of them will have participated in the certification procedure.

The Final Reviewer:

- *checks that the report(s) and supporting documentation needed for decision-making, also with regard to the resolution of the non-conformities found during the assessment, are complete and sufficient for the purpose of the application, and*
- *checks that there are no unresolved non-conformities that prevent the issue of a certificate.*

If the outcome is positive, all documentation on the MD's certification is submitted to the Approval Committee, as per the procedure.

The ICIM scheme relating to the MDR Regulation Directive provides for the issue of different certificates depending on the applicable procedures of the MDR and/or the Manufacturer's choices.

APPROVAL

The approval is made by the Decision Maker (an internal employee of ICIM), possibly assisted by a TE. Neither of them will have participated in the certification procedure.

The Decision maker must:

- *decide based on the documentation relating to the assessment and on the additional information available whether the requirements of the MDR have been met;*
- *decide based on the results of their clinical evaluation and of the management of risk, whether the post-market surveillance plan, including the PMCF, is adequate,*
- *decide based on the specific stages of the additional review by the notified body of the updated clinical evaluation;*
- *decided whether specific conditions or provisions for the certification must be defined;*
- *decide, based on the new features on the risk classification, on the clinical evaluation and on the conclusions of the device risk analysis, a certification period that may not exceed five years;*
- *clearly document the decision-making stage and the approval stage by signing the specific form.*

Where as a result of the Decision Maker's inspection, the MD results to be nonconforming to all or part of the requirements defined in the relevant annexes to the MDR, to the applicable harmonised standards and to common specifications, ICIM issues a ***negative*** *outcome.*

ICIM, through the scheme manager, within fifteen (15) days of the refusal, formalises and justifies the reasons for the refusal to the applicant of the certificate providing all details with a letter to the Manufacturer or Authorised representative, and informs the Competent Authorities (Ministry of Health), Italian notified bodies and other European notified bodies via the electronic system set up by the European Commission.

The Manufacturer can however initiate a review procedure following the procedure described in Regulation 0001CR.

If the outcome of the operation is ***positive*** *and therefore complies with the requirements defined in the relevant annexes to the MDR and that which is declared by the Manufacturer, or Authorised representative, ICIM submits the product to the Approval Committee that technically checks the work and if no problems exist shall decide on certification. The Approval Committee may also decide, on a proposal or independently, to certify the product with limitations that will subsequently be stated in the CE certificate.*

Following the issue of the certification, ICIM enters in the electronic system of article 57 of the MDR the information relating to the certificate issued. If the EUDAMED system is not operational, ICIM sends the communications to the competent authority and registers the Manufacturer in the database of the (It.) Ministry of Health in accordance with the Decree of the (It.) Ministry of Health of 21/4/2011, as amended and supplemented.

At the written request of any party, ICIM provides the means to confirm the validity of the certification.

APPROVAL COMMITTEE
The Approval Committee consists of the Decision Maker(s), possibly a TE and/or an IC (when an external opinion is necessary), and the Final Reviewer. The Committee assesses the submissions and if there are no objections, grants certification. The Decision Maker is internal and employed by ICIM and is responsible for the final approval. The Decision Maker takes the opinion of the IC into due consideration, representing a "veto power" for the approval of the certification. *The Decision Maker, before assessing the contract documents of a medical device, checks the non-existence of incompatibility by the TE and/or IC with the same procedure defined in the section "CERTIFICATION - Examination of the Application - Audit group - Incompatibility assessment of the GI inspectors". In the event of existence of incompatibility, requests another TE (or IC) in order to approve the decision.*
CERTIFICATE
If the result of this assessment is positive, ICIM draws up an EU certificate for Annexes IX and XI part A (different for each annex) which is sent to the applicant and records on the "ICIM Register of EC Certified Companies and Products" (Register) the device, Manufacturer or Authorised representative data and all data required by the Register. *The EC Certificate contains as a minimum:* ▪ *Name, address and ICIM identification number* ▪ *Name and address of the Manufacturer or Authorised representative* ▪ *Certificate number made up as follows 0425/MDR/XXXXXX* ▪ *Unique registration number of the manufacturer, if already issued* ▪ *Starting date of issue and expiration date of the certification* ▪ *The data necessary for the unambiguous identification of the approved device(s).* ▪ *Any references to previous certificates if the certificate is issued integrating or modifying them, including identification of the modifications* ▪ *The reference to the MDR Regulation and to the relevant conformity assessment annex used* ▪ *The tests and trials carried out, for example referring to CS, harmonised standards, test reports and relevant audit reports* ▪ *For class IIb implantable devices and class III devices, a reference to the relevant parts of the technical documentation or other certificates necessary* ▪ *Conclusions of the conformity assessment, relative to the respective Annex, performed by ICIM* ▪ *Certificate validity conditions or restrictions* ▪ *Juridically binding signature of ICIM* *The Certificate is sent to the Manufacturer or Authorised representative, after verification of complete payment of the operations carried out by ICIM.*
MARK
The voluntary ICIM Mark is not applicable as it is a regulated product. ***The appropriate CE marking must be applied, as per MDR***
Other

INFORMATION ON THE CERTIFICATION
ICIM supplies all the information on the issued, modified, integrated, suspended, withdrawn or refused certificates via the electronic system set up by the Commission. *ICIM enters in the electronic system of article 57 the information concerning the certificates issued, including amendments and supplementations, as well as the suspended certificates, those that are valid once more, withdrawn or refused certificates and the restrictions imposed on the certificates, and, in any case, by the means defined above. This information is available to the public.* *In addition ICIM makes available to the Ministry of Health, the Commission and Member States, upon reasoned request, all additional relevant information (copy of the EU Certification, a copy of part of or all the documentation and/or audit reports and/or reports on the examinations and tests carried out, etc.).* *As per its own procedures, ICIM keeps a copy of the technical documentation, copies of the reports, a copy of the EC Certification and all related documentation. Said documentation is strictly confidential and access to the archive is limited to personnel authorised by ICIM only.* *In any case, ICIM personnel keeps the related documentation fully confidential, except on a valid request by the national competent authority for notified bodies ((It.) Ministry of Health), by the same competent authorities of the member States or by the Commission. Property rights must be protected. ICIM has documented procedures in place with regard to the provisions of the previous point.* *The technical documentation and all important documents as per above that concern it must be archived by ICIM for ten (10) years from the certificate's issue (Certificate issue date), as per a specific document management procedure, except for implantable MDs for which the documentation is filed for fifteen (15) years from the date the certificate was issued. On expiry of this date if the Manufacturer or Authorised representative does not request return, said documentation is destroyed.*
NOTES

ANNUAL AUDIT (VS)

METHOD TO BE APPLIED
ICIM conducts an audit surveillance visit (VS) at the Manufacturer's premises (or their suppliers and/or critical subcontractors) every 12 months starting from the date of the certification [1]to assess the maintenance of all the obligations arising from the approved Quality System and ensure that the MD is manufactured in accordance with technical documentation and the MPC as per paragraphs c), d) and e) of section 2.2 of Annex IX and section 2.3 of Annex XI to the MDR *ICIM will also take into account the information coming from the assessment of scientific and clinical data and the post-market information in its possession or in possession of the Manufacturer both for scheduling and executing the audits and for implementing specific actions (e.g. specific product/process assessment, intensification of audit activities, etc.) if compliance with the requirements of the MDR are not fully guaranteed. Furthermore, ICIM, when planning and carrying out the audits, must also consider the legal, technical and scientific information available on the market (ANNEX 4, 5, 6).* *The Manufacturer will allow access to ICIM for auditing purposes at the premises of the manufacture, inspection, testing and storage and to their suppliers and/or critical subcontractors providing all necessary information, in particular:* ▪ *the documentation and quality system records, technical documentation, its changes (technical and quality) the management review process and related control of the documentation (must be up to date, consistent, complete, correct and properly structured)* ▪ *the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, the solutions adopted, pre-clinical and clinical evaluation, post-market clinical follow-up plan (PMCF) and the results of the post-market clinical follow-up, if applicable, etc.;* ▪ *the data stipulated in the part of the quality system relating to manufacture, such as audit reports and test data, calibration data, qualification reports of the personnel concerned, etc.* ▪ *incidents or complaints by the user (ANNEX 5 to this regulation);* ▪ *information collected during the pre-marketing and marketing, for own experiences of the Manufacturer and the experience gained in the post-production phase, in particular the complaints received from the users and the supervisory data are systematically collected and assessed with reference to devices referred to in the manufacturer's application and that the necessary improvements of the devices or of their production have been started. In particular they ensure that the Manufacturer has adopted specific business processes with regard to the distributors, users or patients, such as to identify the possible need to review the design of the device, its manufacture or quality system (ANNEX 5 and 6 to this regulation).* *During the audit the GI must check that:* *1) The Quality Manual has remained in the revision held by ICIM since the last audit,* *2) The quality procedures have remained in the revision held by ICIM since the last audit,* *3) The technical documentation of the medical device is in the revision in possession of ICIM since the last audit, based on the schedule issued during the certification audit phase and anyhow applying the rules referred to in section SAMPLING OF TECHNICAL DOCUMENTATION* *4) The MD is consistent with the documentation referred to in section 3)* *5) The manufacturing and control plan has remained in the revision held by ICIM since the last audit,* *6) Production structures or cycles have not been changed since the last audit.* *Furthermore, in its audit, the GI also takes into account the PMS (post-market surveillance) plan, the PSUR, the PMCF plan and its assessment.* *In the event of a variation of the previous points of which the Manufacturer has not previously informed ICIM as per par. "Changes to the certification requirements", the GI must assess deviations encountered from pre-set requirements, due to quality system elements or incorrect application. In the event that the deviations referred to in sections 3) and 4), influence compliance with the general safety and performance requirements referred to in Annex I to the MDR, the Audit Group informs ICIM who suspends the use of CE Certificate until successful completion of all*

1 Any delays not beyond 30 calendar days respect to the deadline of the 365th day from the date of approval of the certificate will not require a written request by the company, while for delays beyond 30 calendar days, a written request with appropriate grounds must be submitted to ICIM by the manufacturer. The latter must be approved by the Technical Manager of the Medical Device Competence Area for the site or by the Territorial Areas Operating Supervision Manager. Postponements beyond 3 months are not acceptable, barring serious situations making it impossible If upon expiration of the postponement requested by the company, it still does not respect the date to carry out the audit, the certificate will immediately be suspended for a maximum of 3 months

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the necessary checks (ICIM, via the electronic system, shall also inform the Ministry of Health of the suspension of the CE Certificate and the reasons for the suspension, as per the procedure described in this scheme), charging the costs to the Manufacturer. In case of a negative outcome of the audits, the CE Certificate is revoked and the information is entered in the electronic system, as per procedure.

For sections 1), 2), 5) and 6), (and for sections 3) and 4) if the deviations do not affect compliance with the general safety and performance requirements referred to in Annex I to the MDR, ICIM informs the Manufacturer in writing, inviting them to eliminate the deficiencies detected. Otherwise, ICIM shall take appropriate measures (NC management, limitation of the field of application, suspension or withdrawal of the CE Certificate, etc.) foreseen by the Regulations 0001CR and 0003CR.
The audit may be replaced or supplemented by visits to subcontractors and/or critical suppliers; the audit may also include tests on the devices conducted by their Manufacturer to ensure the proper operation of the quality system.

The reports received from the market or nonconformities identified during surveillance of the system that may compromise the performance of the MD are assessed by ICIM and, if necessary, even by the IC (perhaps assisted by CS) (ANNEX 5 to this regulation).
In addition ICIM can however perform unannounced visits at the Manufacturer's premises, depending on the particular evidence of criticality received from the market or from the scheduled visits.
If the audit group discovers elements which can raise doubts as to the maintenance of the conformity of the devices, ICIM can perform relevant tests on the devices, on the materials or on the parts, to check that they correspond with that defined in the approved technical documentation. Having identified the device(s) (code, batch, serial number), ICIM may ask the manufacturer to perform these tests or may entrust them to independent laboratories identified in the list of laboratories 1109BM.
For class III devices, the evaluation of the audit also includes testing the approved parts and/or materials which are essential for the integrity of the device, including, if applicable, a verification that the amount of parts and/or materials produced or purchased correspond to the amounts present in the finished devices. Having identified the device(s) (code, batch, serial number), ICIM may ask the Manufacturer to perform these tests or may entrust them to independent qualified laboratories identified in the list of laboratories 1109BM.
The Manufacturer must be understood to be responsible for the tests performed.
ICIM envisages a rotation of the members of the assessment group every at least three years. Usually, persons responsible for audits do not lead or participate in the audits performed at the same Manufacturer for more than three consecutive years.
If ICIM withdraws or suspend a CE Certificate with justification, it informs the Manufacturer or their Authorised Representative.
The Manufacturer can however initiate a review procedure following the procedure described in Regulation 0001CR.
ICIM enters in the EUDAMED electronic system of article 57 the information concerning the certificates issued, including amendments and supplementations, as well as the suspended certificates, those that are valid once more, withdrawn or refused certificates and the restrictions imposed on the certificates, and, in any case, by the means defined above. This information is available to the public.

UNANNOUNCED AUDIT (ANNEX 1 to this regulation)
Unannounced audits included in the five-year audit program, are held at least once every 5 (five) years. This frequency is increased for devices with a high risk potential, with frequent nonconformities or specific information from interested parties.
Unannounced audits must have an unforeseeable date.

SV REPORT

The audit performed is reported on the Assessment Report specifying the conclusions of the audit and a reasoned assessment and reporting, where appropriate, the recommendations or nonconformities, defining for each applicable entry the suitability or non-suitability thereof.
Copy of the report and, if tests have been carried out, the test report is given to the Manufacturer as a notification of the operation.

Other

NOTES

CERTIFICATION VALIDITY

METHOD TO BE APPLIED
ICIM is responsible for ensuring that the CE Certificate issued remains valid by performing at least one surveillance visit per year and unannounced audits (see ANNEX 1 to this regulation), otherwise it withdraws certificates which are no longer valid. *The CE Certificates issued by ICIM for ann. IX and XI part A have a maximum duration of 5 (five) years and can be renewed if no problems exist (product no longer manufactured, substantial change, etc.)* *If ICIM notes, during the five-year period of validity of the CE certificate:* ▪ *any nonconformities surfaced from reports coming from the market (ANNEX 5 to this regulation), from findings from scheduled or unannounced audits which affect compliance with the essential requirements set forth in Annex I to the MDR,* ▪ *that the requirements of the MDR were not or are no longer met by the Manufacturer* ▪ *that a CE Certificate couldn't have been issued,* *suspends, withdraws or limits the issued CE Certificate, taking account of the principle of proportionality, unless conformity with these requirements is assured by applying appropriate corrective measures by the Manufacturer. In this case, the scheme manager sends the Approval Committee what has been assessed and proposes the possible action to be taken, the Committee, through the Decision-Maker, indicates the actions to be taken (suspension, limitation or revocation).* *In case of suspension, revocation or restrictions of the certificate or in situations where the intervention of the Competent Authority (Ministry of Health) is necessary, ICIM will inform the Ministry of Health through the foreseen channels (electronic system).* *The CE certificate may be revoked or suspended in case of unduly affixed marking. ICIM shall inform the Competent Authorities (Ministry of Health) for appropriate action.* *If the validity of the CE Certificate is not extended, the Manufacturer shall cease the marketing of the MD in question.*
Other *If ICIM does not extend the duration of the CE Certificate, it informs the Manufacturer, the competent Authority and other notified bodies through the electronic system.* *The Manufacturer can however initiate a review procedure following the procedure described in Regulation 0001CR.*
NOTES
In case of significant changes in its structure or other events that may compromise its conformity with the MDR Regulation, ICIM acts as indicated in ANNEX 8 (Monitoring and re-assessment of notified bodies and Change of designation and notification) [art. 44 and 46]

RECERTIFICATION (RENEWAL)

METHOD TO BE APPLIED

The CE Certificates issued by ICIM are valid for a maximum of five years and may be renewed for periods of up to five years.

Recertification or renewal, carried out on ICIM renewal proposal or upon request of the Manufacturer or Authorised representative, for acceptance of the offer related to the following period of validity of the certification and submission of the Renewal Application (it is the Certification Application with specification that it regards the renewal) is subject to the completion by ICIM of a full review of the reference technical documentation and audit visit where the technical data and the certified management system are subjected to checks according to the requirements of the MDR.

The Manufacturer is obliged to submit a summary of the modifications, including changes/modifications that have not yet been notified, made to the MD being certified and of the scientific results relative:

- *to the experience acquired with post-market surveillance,*
- *to the experience resulting from risk management,*
- *to the experience resulting from updating the demonstration of conformity to the general safety and performance requirements set forth by Annex I to the MDR,*
- *to the experience resulting from clinical evaluation assessments, including the results of clinical investigations and of PMCF,*
- *to modifications of the requirements, of the components of the device and of the scientific or normative context,*
- *to modifications of applied harmonised standards (or of new ones), of the CS or of equivalent documents.*
- *to changes in medical, scientific and technical know-how:*
  - new treatments,
  - changes in testing methods,
  - new scientific results on materials and components, including biocompatibility-related matters,
  - experience obtained from studies on similar devices,
  - register data,
  - experience deriving from clinical investigations on similar devices.

During review of the documentation the GI must check that:

1) *The Quality Manual has remained in the revision held by ICIM since the last audit,*
2) *The quality procedures have remained in the revision held by ICIM since the last audit,*
3) *The technical documentation of the medical device is in the revision held by ICIM since the last inspection,*
4) *The MD is consistent with the documentation referred to in section 3)*
5) *The manufacturing and control plan has remained in the revision held by ICIM since the last audit,*
6) *Production structures or cycles have not been changed since the last audit.*

In the event of a variation of the previous points of which the Manufacturer has not previously informed ICIM as per par. "Changes to the certification requirements", the GI must assess deviations encountered from pre-set requirements, due to quality system elements or incorrect application.

In the event that the deviations referred to in sections 3) and 4), influence compliance with the general safety and performance requirements referred to in Annex I to the MDR, the Audit Group informs ICIM who, following an analysis by the Final Reviewer, suspends the use of CE Certificate until successful completion of all the necessary checks (ICIM shall also inform the competent Authority of the suspension of the CE Certificate and the reasons for the suspension, as per the procedure described in this scheme), charging the costs to the Manufacturer. In the event of negative outcome of the checks, following an analysis by the Final Reviewer, the CE Certificate is revoked and the Ministry of Health is notified as per the procedure.

For points 1), 2), 5) and 6), (and for points 3) and 4) if the deviations do not affect compliance with the general safety and performance requirements referred to in Annex I to the MDR, ICIM informs the Manufacturer in writing, inviting them to eliminate the deficiencies detected. Otherwise, ICIM shall take appropriate measures (NC management, suspension or withdrawal of the CE Certificate, etc.) foreseen by the Regulations 0001CR and 0003CR.

The recertification visit is carried out with the same methods as the initial audit.

In the case of any nonconformity found during the recertification verification, the Manufacturer must send ICIM on the appropriate form, the proposal relating to the corrections and corrective actions established (as a result of analysis and formalisation of the causes that generated them), with a timetable for implementation. The application cannot be analysed for approval until receipt of the proposals for a resolution and corrective actions. In addition in

the event of nonconformities before the certification renewal, the resolution of all nonconformities must be checked, according to the assessment procedures established by ICIM (audit at the customer's premises and/or through documentary evidence where possible). Based on the renewal audit results and any subsequent actions to be completed by the expiration date of the certificate, this is confirmed for another 5 (five) years.
Certification renewal is also subject to meeting the requirements of Regulations 0001CR and 0003CR.
If ICIM does not certify the duration of the CE Certificate, it will notify the Manufacturer, the Competent authority and the other Notified Bodies through the electronic system.
The Manufacturer can however initiate a review procedure following the procedure described in Regulation 0001CR.

ISSUING RENEWED CERTIFICATE
With a positive outcome, ICIM issues the new certificate, maintaining the reference dates of the cycle (the date of issue of the first certificate is a reference for future cycles).
ICIM enters in the EUDAMED electronic system of article 57 the information concerning the re-certified certificates, including amendments and supplementations, as well as the suspended certificates, those that are valid once more, withdrawn or refused certificates and the restrictions imposed on the certificates, and, in any case, by the means defined above. This information is available to the public.

DELAY IN COMPLETION OF THE RENEWAL STAGE
If the renewal stage is not completed within the expiration date, the certificate expires at the date indicated on it. From that moment the Manufacturer or his Representative can no longer market the product, even if manufactured before the expiration date of the certificate (products in the Manufacturer's warehouse).
ICIM notifies the Competent authority through the intended channels (electronic system) of the absence of re-certification. ICIM enters the information concerning the non-re-certified certificates in the EUDAMED electronic system of article 57. This information is available to the public.

Other

NOTES

CHANGES TO CERTIFICATION CONDITIONS

METHOD TO BE APPLIED
The Manufacturer must submit to ICIM any adaptation and/or modification design relating to: ▪ *quality management system approved or product range under the CE Certificate;* ▪ *design approved for the device;* ▪ *intended use of the device and/or of statements made regarding the device;* ▪ *approved type of the device;* ▪ *any substance inserted or used to manufacture a device that is composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body,* *providing adequate modification designs and the pertinent information, which ICIM ensures is complete. ICIM assesses the proposed modifications and verifies whether the modified quality system or the modified product meets the requirements of the relevant annexes to the MDR. The Manufacturer must wait to receive a notification by ICIM of the decisions regarding the modification and the corresponding final report and authorisation by ICIM to go ahead.* *ICIM, after having assessed these changes, decides that:* *a) (simplified procedure) the change is not significant, in which case the Application is accepted without the need for additional inspections or tests; therefore it informs the Manufacturer or Authorised representative that the EC Certificate is valid with a supplement of the original examination document. Non-significant changes are, by way of example but not limited to:* *i. Addition or modification of trade name* *ii. Modifications of the manufacturer's address (not of the production units)* *iii. Variation of the manufacturer's business name* *iv. Reduction of the certification scope (number of products/families)* *b) (partial procedure) the change is significant but not such to produce a new product, in which case verifications or additional tests; are required; therefore the Manufacturer or Authorised representative is informed that the EC Certificate remains valid with a supplement of the original examination document issued on positive outcome of the additional verifications or tests.* *c) (full procedure) the change is significant and such to produce a completely new product, in which case the Manufacturer or Authorised representative is informed that the operations for the EC certification must be done in their entirety. Significant changes are, by way of example but not limited to:* *i. Changes of the approved design* *ii. Modification or replacement of components and/or materials and/or raw materials and substances* *iii. Modification of primary packaging* *iv. Modification of special processes subject to validation* *v. Modification following application of new standards, harmonised standard or revised common specifications* *vi. Change of the intended use* *d) (full procedure) the variation is significant and affects application of the quality management system. Significant changes to the quality system are, by way of example but not limited to:* *i. Modifications to the production processes* *ii. Modifications to critical suppliers which affect the validations of the special processes* *Having verified the above and having assessed that the change to the quality management system and/or to the device still meets the requirements of the MDR, approves the modification requested by the Manufacturer and notifies such approval by using form 1133CM.* *These changes may, in ICIM's opinion may cause a new assessment visit to be carried out under the responsibility of the manufacturer in order to reach a decision. The final decision shall contain the conclusions of the inspection and a reasoned written assessment is sent to the Manufacturer.* *In the event of a negative decision the Manufacturer can however initiate a review procedure following the procedure described in Regulation 0001CR.*
Other
NOTES

AUDITOR REQUIREMENTS

ADDITIONAL QUALIFICATIONS
The qualifications for the MDR defined in the specific procedure to qualify ICIM auditors are taken as a reference. Additionally, each auditor and ET (every three months) and each ECI and SC (annually) is required to send ICIM at least a list of any extra ICIM operations performed on or for MD manufacturing companies. ICIM will verify the incompatibility of any operations carried out with their own requirements, as defined in section "CERTIFICATION - Examination of the Application - Audit Group - Assessment of incompatibility of the auditors of the GI".
ADDITIONAL CHARACTERISTICS
Other
NOTES

VOLUNTARY CHANGE OF NOTIFIED BODY

METHOD TO BE APPLIED
If the manufacturer terminates its contract with ICIM to appoint conformity assessment of the same device to another notified body or if the manufacturer appoints ICIM with the conformity assessment of a device certified with another notified body, in accordance with article 58 the change methods are defined in a written agreement with the manufacturer. *This agreement at least touches the following aspects:* *a) the date from which the certificates of the outgoing body are no longer valid;* *b) the date until which the identification number of the outgoing notified body can be indicated in the information supplied by the manufacturer, including advertising material;* *c) the transfer of documents, including confidentiality-related aspects;* *d) the date after which the tasks of conformity assessment of the outgoing notified body are assigned to the new notified body;* *e) the last serial number or batch number the outgoing notified body is responsible for.* *ICIM, if configured as outgoing notified body, withdraws the certificates issued for the devices in question from the date on which they have become invalid.* *In case ICIM is the incoming notified body, it is envisaged that, on completion of the certification procedure of voluntary Change in Notified Body, an audit of the Manufacturer is performed.*
Other
NOTES

CRITICAL SUPPLIER

METHOD TO BE APPLIED FOR THE ASSESSMENT OF CRITICAL SUPPLIERS
DEFINITION *The critical supplier is the supplier of materials, components of services which can affect the safety and performance of the overall medical device and that cannot be controlled by the manufacturer. By way of example but not limited to, suppliers of the design, production processes whose output cannot be verified by the manufacturer, of special processes (sterilisation, packaging, etc.), of software, are considered critical.* *INITIAL CERTIFICATION* *In the initial certification and renewal stage, the ICIM marketing department meets the technical coordinator in order to define whether an inspection is necessary at the critical suppliers' promises, the data of which are found in the doc. 0355CM (Offer Request) filled out by the Manufacturer, who assumes the responsibility of the truthfulness of the communications transmitted.* *The critical suppliers of devices with innovative elements (by way of example but not limited to: new production technologies, devices where the existence of equivalent devices cannot be demonstrated, etc.) are always subject to audits, unless they are already certified by ICIM (according to the diagram ISO 13485 or pursuant to Directive 93/42/EEC or Regulation 2017/745).* *Audits can be avoided if the following conditions are met simultaneously:* *1) the supplier has a quality management system which fulfils one of the following requirements:* *i. certified according to the ISO 13485 or ISO 9001 scheme by an accredited Certification Body, with the purpose of certification referring to the activities/processes/products supplied;* *ii. certified pursuant to annexes II or V to Directive 93/42/EC or to Regulation 2017/745 by a Notified Body and if the purpose of certification refers to the supplied products;* *iii. compliant with the accreditation standards for ISO 17025 laboratory or with GMP guidelines.* *2) the Manufacturer controls the work of the supplier through appropriate second party audits, scheduled appropriately in relation to the risk related to the medical device in question.* *The suppliers of sterilisation or surface treatment services who operate according to harmonised standards, with a quality management system certified by an accredited Certification Body and whose work is widely consolidated are not subject to audits.* *SURVEILLANCE* *The critical suppliers of class IIb or III devices are usually audited every year. It is possible to audit such suppliers every two years if they meet the requirements of points 1 and 2 above.* *The critical suppliers of class IIa devices are usually audited every two years.* *During surveillance audits, the Lead Auditor in charge assesses the list of critical suppliers and establishes from time to time the need to perform audits, indicating it in the schedule and notifying it to ICIM.* *The assessment of the relationship between Manufacturer and critical supplier (and subcontractors, if any) must also verify:* ▪ *technical contracts which contain at least, and if applicable:* - *the possibility of the Manufacturer or ICIM performing audits at the supplier's premises, even unannounced;* - *the possibility of the Manufacturer, ICIM or the Competent Authorities of accessing, on demand, the technical documentation;* ▪ *presence, in the Manufacturer's documentation, of the technical documentation of the supplier relevant to the object of the supply or, if not possible, a precise reference to it.*
Other
NOTES

ANNEX 1 (Unannounced audits)

METHOD TO BE APPLIED
Unannounced audits included in the five-year audit program are held at least once every 5 (five) years. *In the presence of devices with a high risk potential, or when frequent nonconformities are detected on the devices during the periodic surveillance audits, or if criticalities are reported by the interested parties (see ANNEX 5 and 6), ICIM can increase the frequency of surveillance visits or perform audits on short notice.* *The unannounced audits must have an unforeseeable date and can be combined to the periodical surveillance assessment. ICIM drafts the audit and sampling plan before the unannounced audits, but does not communicate it to the manufacturer.* *Unannounced audits are included in the contractual arrangements with the Manufacturer and may also include subcontractors and/or critical suppliers, if conformity of the devices is significantly affected by their activity; if carried out in countries where a visa is necessary, an invitation with open visa must be provided.* *The manufacturer must constantly inform ICIM regarding the periods in which production of the certified devices is not carried out. ICIM shall terminate the contract and withdraw the certificate as soon as permanent access for unannounced audits of the manufacturer's or critical subcontractors or critical suppliers is denied.* *The duration of unannounced audits may not be less than one day and must be conducted by at least two auditors.* *In particular, during the audit, ICIM checks the compliance of manufacturing activities in progress with the Manufacturer procedures and applicable legal provisions (MDR), identifying at least two critical processes chosen among:* ▪ *design control,* ▪ *Preparation of specifications of materials,* ▪ *purchase and control of materials or input components,* ▪ *assembly,* ▪ *sterilisation,* ▪ *the inspection and/or revalidation of clinical data,* ▪ *batch delivery,* ▪ *packaging and product quality control.* *One of the processes must have a high probability of non conformity, and one must be particularly relevant from a safety point of view.* *The unannounced audit must also be carried out at the subcontractor's and/or critical supplier's premises, mainly if the design, manufacture, tests or other fundamental processes are carried out to a great extent at the subcontractor's or the supplier's premises.* *Reports on unannounced audits are drafted using the Assessment Report form, a copy of which is delivered to the Manufacturer at the end of the audit in question.* *If the unannounced audit finds non-conforming situations (documents, audits, tests), ICIM adopts the appropriate measures (management of NC, suspension or withdrawal of the CE certificate, etc.) envisaged by Regulations 0001CR, 0003CR and this document.* *ICIM enters in the EUDAMED electronic system of article 57 the information concerning the certificates, including amendments and supplementations, as well as the suspended certificates, those that are valid once more, withdrawn or refused certificates and the restrictions imposed on the certificates, and, in any case, by the means defined above. This information is available to the public.* *<u>TEST</u>* *In the context of such unannounced on-site audits, ICIM tests a suitable sample of the devices produced or a suitable sample obtained from the (ongoing) manufacturing process to check if the device manufactured complies with the technical documentation, with the exception of custom-made class III devices (art. 52, par. 8).* *Otherwise, or in addition to the sampling above, ICIM tests device samples taken from the market to verify that the manufactured device complies with the technical documentation, with the exception of custom-made class III devices (art. 52, par. 8).* *Before the sample tests, the Audit Team Manager (RGVI) specifies the sampling criteria, taking into account the innovation of the technology, similarities in design, technology and manufacturing and sterilisation methods, intended use and the results of any previous relevant assessments (for e.g. with regard to physical, chemical or biological properties) conducted in accordance with the technical documentation.* *At the same time, before the unannounced on-site audit, the Audit Team Manager defines the control procedure*

which envisages checking the traceability and the appropriate tests (as defined by the harmonised standards or equivalent tests in accordance with the procedure indicated by the Manufacturer in the technical documentation that has been validated by ICIM). *The test may also be performed at the premises of the Manufacturer, a sub-contractor or critical supplier under the supervision of ICIM.* *ICIM documents and makes the criteria used for the selection of the sample/samples available to the competent Authority. During the certificate's period of validity (i.e. for a maximum of five years) the sampling plan must be designed to ensure that every device category among those specified in said certificate is subject to sampling.* *If one or more of the samples do not comply, ICIM shall take appropriate measures (NC management, suspension or withdrawal of the EC Certificate, etc.) provided by the Regulations 0001CR and 0003CR.*
Other
NOTES

ANNEX 2 (Certification procedure for systems and procedure packs)

METHOD TO BE APPLIED
The systems and procedure packs referred to in Art. 22 of MDR consists of a group of devices bearing the CE marking and of: ▪ *other devices bearing the CE marking in compliance with the MDR* ▪ *in vitro diagnostic medical devices bearing the CE marking in conformity with Regulation 746/2017* ▪ *other products not marked CE which are in conformity with legislation that applies to them where they are used within a medical procedure (or their presence in the system or procedure pack is justified)* *In this case the assembly constitutes a device in its own right and as such should be labelled as normal procedure.* *If the assembly is sterilised by the assembler, he must follow one of the procedures described in annexes IX or XI part A to the MDR. In the latter case the ICIM operation is limited to the verification of the aspects linked to the sterilisation process as indicated by the Manufacturer.*
Other
NOTES

ANNEX 3 (Additional procedures)

METHOD TO BE APPLIED
Class III implantable devices and class IIb active devices intended to administer and/or remove medicinal substances (Annex IX chap.5.1 MDR). *In these cases, ICIM must send to the competent Authority/Commission, having checked the quality of the clinical data supporting the manufacturer's clinical evaluation report, an assessment report of the clinical evaluation with conclusions on the clinical evidence provided by the manufacturer, especially with regard to the establishment of the benefit/risk ratio and the consistency of such evidence with the intended use, including the medical indications and the PMCF plan. At the same time as this report, ICIM provides the documentation relating to the Manufacturer's clinical evaluation, so that they may be subjected to the scientific opinion of the group of experts appointed by the European Commission.* *The group fo experts may ask ICIM to present its conclusions on the aforementioned documentation.* *If within 21 days from receipt of the aforementioned documentation, the Commission notifies that the group of experts will give no opinion, the certification process can continue. Otherwise they must wait 60 days to receive the*

scientific opinion. *If no opinion has still been received after 60 days, the certification process can proceed.* *If the opinion requests specific interventions ICIM evaluates the relevant actions to be taken (follow the group of experts or justify failed reception and continue with the certification).* *This procedure does not apply in the following situations:* ▪ *in case of renewal of a certificate issued pursuant to MDR;* ▪ *if the device was designed making changes to a device already marketed by the same manufacturer for the same intended use, after ICIM has verified that the changes do not jeopardise the benefit-risk ratio of the device;* ▪ *if the principles of the clinical evaluation of the type or category of device are defined in a common specification and if this condition is confirmed by the IC/CS;* *If the issue of the certificate has been granted, ICIM loads the instructions for use and the opinion of the group of experts, including justification of ICIM, if any, onto the EUDAMED database.* ***Devices consisting of substances systemically absorbed by the human body in order to achieve the intended purpose (Annex IX chap.5.4 MDR).*** *For devices consisting of substances absorbed by the human body or locally dispersed therein, ICIM must check the additional requirements of directive 2001/83/EC in reference to absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices/medicinal products/substances and potential adverse reactions.* *In the specific case of devices consisting of substances or the products of their metabolism which are absorbed at systemic level by the human body for the purpose of pursuing the intended use, ICIM requests the scientific opinion of the medicinal products Authority consulted concerning the conformity of the device with the pertinent provisions of Annex I to Directive 2001/83/EC.* *The competent authority drafts the opinion within 150 days from reception of the documentation.* *The scientific opinion of the medicinal products authority consulted and any amendment thereto are entered in the ICIM documentation on the product. In adopting its decision, ICIM duly takes into account the opinions expressed in the scientific opinion and sends its final decision to the medicinal products authority consulted.*
Other
NOTES

ANNEX 4 (Management procedure of the communications by the regulatory authorities, including the competent authorities and notifying authorities)

METHOD TO BE APPLIED
All incoming communications to ICIM by regulatory authorities, including the competent authorities and notifying authorities are managed by ICIM ISG (Innovation, Development and Governance), that: ▪ *provides the information to the Head of OPERATIONS (OPE) and the scheme manager for relevant management (impact on existing contracts or in process, impact on the technical documentation, information to auditors, etc.),* ▪ *assess the impact on the documents of the ICIM Management System.* *Within 15 (fifteen) days, unless otherwise requested by the communication, ICIM ISG checks that the consequent actions to the communications have been initiated and/or completed by the OPE and by itself. Where applicable or if requested, ISG communicates to the authority issuing the communication the actions taken or execution thereof.*
Other
NOTES

ANNEX 5 (Communication procedure and analysis of the impact of reports on supervision of the certification of medical devices)

METHOD TO BE APPLIED
INCIDENT REPORTS BY MANUFACTURER *The Manufacturer must communicate to ICIM any incident reports concerning medical devices object of certification and the relevant corrective and preventive actions taken for them. As it is an MDR request, in addition to a contract-related request, ICIM verifies during the audits that the Manufacturer has complied with that requested and if situations of reports of incidents surface, which ICIM has not been informed about, it issues an NC or an OBS (depending on the seriousness of the incident and the possible frequency).* *For conformity assessment procedures containing a quality system analysis,, ICIM verifies:* ▪ *that the vigilance procedures established by the Manufacturer comply with the applicable normative requirements* ▪ *that the procedures regard starting corrective and preventive actions (CAPA), including adoption of field safety correction actions (FSCA) and publishing Notifications (FSN),* ▪ *that the procedures are fully implemented by the Manufacturer and, if appropriate, through contractual agreements, also known and actuated by the authorised representative of the manufacturer and by national distributors,* ▪ *that the Manufacturer has adequate resources to manage vigilance issues.* *During each of its audits, ICIM verifies actuation of these procedures. When verifying the system, ICIM assesses a series of examples of incidents recorded by the Manufacturer, verifies that the procedures have been respected, confirms that all significant incidents have been identified and reported to be Ministry of Health and to ICIM within an adequate period of time and confirms that all the corrective and preventive actions necessary have been taken. ICIM pays special attention to any adverse events or incidents not reported by the Manufacturer in the vigilance system in which it is considered that these events or incidents were effectively reported as incidents. ICIM assesses the justification provided by the Manufacturer when a problem is not reported.* *If the ICIM audit team observes that incidents or FSCA have not been managed in compliance with the regulatory requirements, it point out a nonconformity and asks the Manufacturer to adopt corrective actions. If the Manufacturer agrees with ICIM's assessment, the Manufacturer must report the incident to the Ministry of Health, examine the issue as usual and take any corrective actions necessary. In this case, ICIM does not request any particular action, other than verifying the implementation of any corrective action plan. Whereas if the Manufacturer does not agree, ICIM reports the event to the Ministry of Health. The impact on the continual validity of any issued certificate should be taken into consideration. Among the inspections, ICIM examines the determinations made by the Manufacturer regarding which incidents and reports can affect the certification of the device and are therefore reported to ICIM. Deviations and inappropriate determinations are considered as a serious nonconformity.* *The scheme manager must analyse the report and assess its impact on the Manufacturers and on the technical documentation, with the help of ICIM ISG and the auditors if required (TE, IC).* *The scheme manager shall inform for the part under the authority of internal personnel working on the MD and all the auditors of the contents of the report and any consequences, so that account can be taken during their operation.* *ICIM ISG assesses the impact of the reports on the documents of the ICIM Management System and acts if necessary on the same.* *ICIM considers the information in these reports when it plans its future revision activities of the Manufacturer and when it approves or renews the certificates. In extreme situations, ICIM could need to consider the withdrawal or suspension of the conformity certificate with regards to certain devices.* *REPORTING INCIDENTS BY THE MINISTRY OF HEALTH* *Furthermore, all the incoming incident communications regarding the medical devices subject to the certification in ICIM by the Ministry of Health are managed by ICIM ISG (Innovation, Development and Governance), which provides the information to the Head of OPE and the scheme Manager for the management of the case.* *The project leader or contract coordinator informs and takes appropriate action on Manufacturers with ICIM certifications concerned in the reports made by the Ministry.*

Within 15 (fifteen) days, ICIM ISG checks that the consequent actions to the communications have been initiated and/or completed by ICIM OPE. Where applicable or if requested, ICIM ISG communicates to the Ministry of Health the actions taken or execution thereof.
Other
NOTES

ANNEX 6 (Surveillance and control procedure following the certification)

METHOD TO BE APPLIED
The planning and execution of the surveillance activities must also take account of the results of the surveillance inspections relative to the assessment of the relevant clinical and scientific data, as defined in the procedure 0268BP – Clinical data evaluation, § 5.3. *The auditors (AVI/RGVI), the inspectors (TE) and the internal clinicians (IC) who perform surveillance activities on certified products must, before the activity, take into account the sources of scientific and clinical data and the post-market information to obtain information with regard to possible issues related to the use of the aforementioned products.* *Furthermore, the persons involved as per above must review the data relating to vigilance that can be found on the EUDAMED system in order to assess to what extent they may affect the certificates' validity.* *This task makes it possible to confirm compliance of the devices subject to the certification with the general safety and performance requirements set forth by the MDR and consequently to maintain the certification or, if compliance with these requirements is not fully guaranteed, to implement actions to restore them.* *Upon receipt of information about vigilance cases from a manufacturer or from the competent authority, ICIM decides which of the following options to apply:* ▪ *not to take action on the basis that the vigilance case is clearly not related to the certification granted;* ▪ *observe the manufacturer's and competent authority's activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken;* ▪ *perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and product testing, where it is likely that the certification granted is at risk;* ▪ *increase the frequency of surveillance audits;* ▪ *review specific products or processes on the occasion of the next audit of the manufacturer;* ▪ *take any other relevant measure.* *The results of the assessment and any decisions adopted are documented in the specific surveillance reports.*
Other
NOTES

ANNEX 7 (SSCP - Summary of Safety and Clinical Performance / PSUR - Periodic Safety Update Report)

METHOD TO BE APPLIED
SSCP - SUMMARY OF SAFETY AND CLINICAL PERFORMANCE *The summary of safety and clinical performance includes at least the following aspects (MDCG2019-09):* 1. *the identification of the device and of the manufacturer, including the Basic UDI-DI, and, if already issued, the single registration number (SRN);* 2. *the intended purpose of the device and any indications, contraindications and target populations;* 3. *a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and*

products, which are intended to be used in combination with the device;
4. *possible diagnostic or therapeutic alternatives;*
5. *reference to any harmonised standards and CS applied;*
6. *the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up;*
7. *suggested profile and training for users;*
8. *information on any residual risks and any undesirable effects, warnings and precautions;*
9. *chronology and description of revisions.*

The draft summary that forms part of the technical documentation is assessed and validated by ICIM and becomes the final document.
The SSCP is uploaded in EUDAMED[2] by ICIM, at the same time as the certificate's issue. ICIM is the only party that can manage the SSCP in EUDAMED (assessment of the draft summary, update, renewal).

The deadline for the validation of the SSCP may depend on the device's class and on the conformity assessment paths:

- *For class III devices and implantable class IIb devices, with the exception of stitches and metal staples, etc., the validation is performed when a draft SSCP, as part of the application documents, is presented to ICIM before the certificate is issued.*
- *For implantable class IIa and IIb devices (e.g. suture thread, staples, etc.), ICIM must upload the SSCP of all devices covered by the certificate issued when the certificate is issued, even if some SSCP have not yet been validated. The latter will be assessed and validated during the certificate's validity period.*

ICIM must upload the SSCP (re-issued by the Manufacturer) each time that it has been validated in case of updates of and amendments to the pertinent documents of the technical documentation, thus replacing the SSCP uploaded on issue of the certificate.

The SSCP must be supplied in Italian and in English, with a document confirming the correctness of the translation. For manufacturers based outside of Italy, only the English version is accepted. In the draft validated by ICIM is written in Italian, the English translation must be sent to ICIM within 90 days from when the draft was loaded onto EUDAMED.

The Manufacturer decides when to have the "master" of the initial SSCP translated in other languages of the member states depending on when and whether they intend to place the product on that market. The translation into English and any translations in other languages provided by the Manufacturer are uploaded by ICIM within 15 days from receipt.

PSUR - PERIODIC SAFETY UPDATE REPORT
During the period in which the certificate is valid, the manufacturer is obliged to draft and update the periodical safety update report (PSUR) with methods and timetables depending on the type of the device. The PSUR forms an integral part of the Technical Documentation of Annexes II and III.
The manufacturers of class IIB and III devices must update the PSUR at least once per year. The manufacturers of class IIa devices must update the PSUR when needed and at least every two years.

For class III devices or implantable devices, the manufacturers must send the PSUR, through the electronic system of art. 92 of the MDR, to ICIM, who reviews the report and enters its assessment in the electronic system, specifying any actions adopted[3]. The manufacturer must make this document available every year by the day and month mentioned in the certificate's issue date (e.g. issue 10/10/2020 → PSUR available annually by 10/10/21, then 10/10/2022, then 10/10/2023, then 10/10/24, then 10/10/25). The PSUR and the ICIM assessment are made available to the Competent Authority through the EUDAMED electronic system.

[2] In case EUDAMED is not operational or if the specific section is not available, ICIM will store the draft summary in the order's folder to be uploaded later and will send the document, together with the approval of the PSUR, to the Competent Authority (Ministry of Health).
[3] If the electronic system of article 92 of the MDR is not operational, the manufacturer will send the PSUR to ICIM. The document's assessment will be kept in the order's folder to be uploaded later. Said document will be made available to the Competent Authority, on request.

For devices other than those mentioned above (art. 86 MDR), the Manufacturers make the PSUR available to ICIM, depending on the periodicity of updates. During Surveillance and Re-certification, ICIM will check the content and draft a report on its assessment, specifying any actions adopted. ***FOR BOTH DOCUMENTS (SSCP AND PSUR)*** *If the update of the PSUR requires a revision of the SSCP, this document must be subject to validation by ICIM which will load the revised document into EUDAMED within 15 days from its validation.* *If the Manufacturer is not able to make the PSUR and SSCP documents available to ICIM within the deadlines set forth by the MDR, ICIM may exercise its right to suspend the certificate until it has received and assessed such documents.*
Other
NOTES

ANNEX 8 (Monitoring and re-assessment of notified bodies and Change of designation and notification) [art. 44 and 46]

METHOD TO BE APPLIED
ICIM informs as soon as possible and within 15 days at the latest the competent authority (Ministry of Health) of any significant change that could compromise its conformity with the requirements of Annex VII or its ability to perform the conformity assessment procedures with regard to the devices for which it has been designated. *On request of the competent authority, ICIM provides all pertinent information and documents required to make it possible for the authority, the Commission and the other member States to check their conformity.* *If the Commission or the authority of a member State other than Italy presents ICIM with a request regarding the conformity assessment performed thereby. ICIM sends a copy of said request to the competent authority. ICIM replies to said request within 15 days. The competent authority ensures that requests submitted by the authorities of all other member States or by the Commission are received by ICIM, unless there is a legitimate reason for not doing so, in which case the question may be submitted to the MDCG.* *If ICIM decides to cease the conformity assessment activity, it informs the competent authority and the manufacturers concerned as soon as possible and one year before ceasing the activities, if said cessation was scheduled. The certificate may remain valid for a limited period of nine months following the cessation of the activity by ICIM, on the condition that another notified body has confirmed in writing that it will assume the responsibility for the devices covered by the certificate in question. The new notified body completes a full assessment of the devices involved by the end of the period indicated, before issuing new certificates for the devices in question.* *If ICIM's designation is suspended, restricted or revoked in whole or in part, the manufacturers concerned will be informed within ten days at the latest.*
Other
NOTES