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GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES

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GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES

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List of acronyms

MDD – Medical Devices Directive
MDR – Medical Devices Regulation
FSCA – Field Safety Corrective Action
FSN - Field Safety Notice
UDI - Unique Device Identifier
SRN - Single Registration Number
NB - Notified Body
ISO - International Organization for Standardization
IEC - International Electrotechnical Commission
CA – Competent Authority
PPE – Personal Protective Equipment
QMS - Quality Management System
Im – Class I devices with measuring function
Is – Class I sterile devices
Ir – Class I reusable surgical instruments
DI – Device Identifier
Eudamed - European database on medical devices
MD - Medical Device
CS - Common Specification
PMS – Post Market Surveillance
IFU – Instructions for use
PMCF - Post Market Clinical Follow-up

Foreword

These guidance notes do not aim to be a definitive interpretation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) and are intended for guidance purposes only.

Introduction

The purpose of this document is to provide guidance to manufacturers of Class I medical devices (other than custom made devices) who place on the Union market medical devices (from now on referred to as devices) under their name or trade mark, to help them meet the provisions of the MDR. This guidance should also be applicable for situations when an importer, distributor or any other legal person assumes the obligations incumbent on manufacturers, as per Article 16 (1), while not covering the exception indicated by Article 16 (2).

The MDR has changed the scope of the medical device legislation and it now extends its application to all economic operators in the supply chain (manufacturer, authorised representative, importer and distributor) as well as a broadened range of products such as those specifically intended for the cleaning, disinfection or sterilization of devices (Article 2 (1)) and products without an intended medical purpose (such as certain aesthetic products, as indicated in Annex XVI of the MDR). In addition, more emphasis is placed on a life-cycle approach to safety, backed up by clinical data and new requirements such as transparency and traceability[1].

Before placing a device on the market, the manufacturer will affix the CE mark in accordance with Annex V and draw up the EU declaration of conformity, including all the information required by Annex IV. Prior to that, the manufacturer will demonstrate conformity with the MDR and compliance with the applicable general safety and performance requirements laid out in Annex I.

In order to accomplish the abovementioned tasks, the manufacturer will carry out the following:

- Put in place a quality management system and a system for risk management according to Article 10(2) and 10(9).
- Conduct a clinical evaluation in accordance with Article 61, as established in Article 10(3) and Annex XV.
- Conduct a conformity assessment according to Article 52(7). In specific cases (*sterile devices, devices with measuring function, reusable surgical instruments*) defined in the referred Article, the manufacturer will request the involvement of a Notified Body (NB).
- Draw up and keep up-to-date technical documentation related to devices as set out in Annexes II and III, in accordance with Article 10(4).
- Draw up an EU declaration of conformity in accordance with Article 19.
- Submit the required information to the electronic system for registration of economic operators (Eudamed) and comply with the registration obligation. The manufacturer will use the Single Registration Number (SRN) when applying to a NB for conformity assessment, if applicable and for further accessing Eudamed[2] in order to fulfil its obligations related to registration of the devices.
- Register the device in Eudamed assigning the Basic UDI-DI to the device, as defined in Part C of Annex VI, and provide this to the UDI database together with the other core data elements referred in Part B of Annex VI related to that device.
- Assign to the device and, if applicable, to all higher levels of packaging, a UDI which will allow identification and traceability.

[1] More information can be found at https://ec.europa.eu/health/md_sector/overview

[2] Regarding all references to Eudamed in this document, please be advised that for the purposes of this guidance, obligations strictly related to Eudamed will only apply when it is fully functional and any updates will be published on the EU Commission webpage.

- Ensure that the device is accompanied by the information needed to identify it and its manufacturer, and any safety and performance information relevant to the user, or any other person, as appropriate (Article 10(11)). This information, set out according to Section 23 of Annex I, must be provided in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label will be indelible, easily legible and clearly comprehensible to the intended user or patient.
- Implement a post-market surveillance system in accordance with Article 83 (Article 10(10)) proportional to the risk class and appropriate for the type of device, this includes additional aspects to be taken into account in case of devices placed on the market in sterile condition, with a measuring function or that are reusable surgical instruments. This system will be an integral part of the manufacturer's quality management system based on a post-market surveillance plan (Article 84), which will be part of the technical documentation specified in Annex III.
- Implement a system for recording and reporting incidents and field safety corrective actions as described in Articles 87 and 88 (Article 10(13)).
- Put measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC[3], without prejudice to more protective measures under national law. These measures will be proportional to the risk class, type of device and the size of the enterprise (Article 10(16)).

Further detail on the aforementioned list of obligations is provided in the chapter "Placing Class I medical devices on the market ".

For devices placed on the market in a sterile condition, with a measuring function or which are reusable surgical instruments, the manufacturer will apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI which require a NB assessment, limited to critical aspects such as those concerning sterile condition, metrological requirements and the reuse of the device, as relevant, according with Article 52 (7 a, b and c).

[3] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

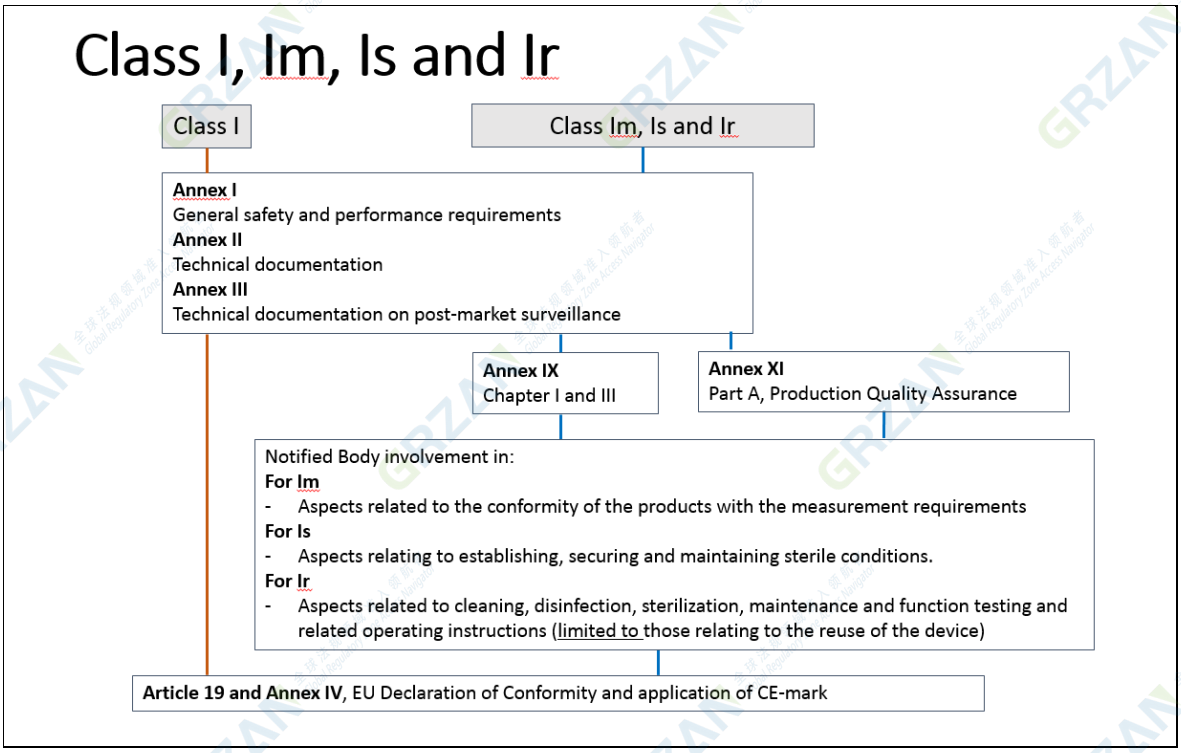


Figure 1. *Illustration of the conformity procedures for the assessment of Class I devices with and without NB involvement.*

For big and medium size enterprises, the manufacturer will have available within their organization at least one person responsible for regulatory compliance[4], as established by Article 15. Micro and small enterprises[5] are required to have such person permanently and continuously at their disposal.

A manufacturer with a registered place of business outside the Union will designate a sole authorised representative, at least per each generic device group, according to a written mandate. Such a mandate will establish the tasks to be performed by the authorised representative. To enable the fulfilment of these tasks, the manufacturer ensures that the authorised representative has the necessary documentation permanently available and up-to date. The mandate will require the authorised representative to perform at least the tasks described in Article 11(3), however the manufacturer cannot delegate its obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12). In case of the change of authorised representative, Article 12 establishes the minimum content of agreement to be addressed between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative.

Upon request, the manufacturer will provide all the information and documentation necessary to demonstrate conformity of the device to competent authorities and cooperate with them on any corrective action. If the manufacturer does not cooperate or does not provide the requested information or documentation, the competent authority (CA) can adopt restrictive measures.

The manufacturer should periodically verify whether *implementing and delegated acts, common specifications, technical standards and guidelines* might be available on the European Commission website[6]. Such documents might for example cover specific parts of legislation (e.g. classification of

[4] See the relevant MDCG guidance on Article 15 of MDR and IVDR regarding a "person responsible for regulatory compliance" (PRRC)
[5] See Commission Recommendation 2003/361/EC
[6] https://ec.europa.eu/health/md_sector/overview

medical devices, clinical evaluation) or specific requirements regarding certain medical device technologies (e.g. software, 3D printing) that can also be applicable for Class I devices.

During the transitional period, manufacturers might be tempted to refer to guidance documents developed under the Directive 93/42/EC. However, the old guidance documents, unless otherwise updated in line with the MDR, may have only some limited indicative value under the MDR. For the purpose of the MDR, only the text of the Regulation is valid in law and sets out requirements not reflected in the old guidance. Hence, the MDR alone can be relied upon as a legal basis.

Definitions

For the complete list of definitions refer to Article 2 of the MDR. This is an excerpt of some definitions.

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) (Article 2(2)).

Authorised representative - means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the MDR (Article 2(32)). The designation of an authorised representative will be in compliance with Article 11 and effective at least for all devices of the same generic device group *(*Article 11(2)).

Adverse event - means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device (Article 2(57)).

Benefit-risk determination - means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer (Article 2(24)).

Class I medical devices with measuring function - are considered Class I medical devices which measure physiological parameters or anatomical parameter or energy, respectively, or volume of medicinal products, body liquids or other substances administered to or removed from the body and display or indicate its value in a unit of measurement (example: urine bags, non-active thermometers, measuring spoons).

Note: According to section 15.2 of Annex I, measurements made by devices with a measuring function will be expressed in legal units[7].

CE marking of conformity or CE marking - means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the MDR and other applicable Union harmonisation legislation providing for its affixing (Article 2(43)).

Note: CE marking will be made in accordance with Annex V.

Clinical evaluation - means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer. (Article 2(44)).

Clinical data - means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

- clinical investigation(s) of the device concerned,

[7] In conformance to the provisions of Council Directive 80/181/EEC

- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,
- reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up. (Article 2(48))

Conformity Assessment – The process demonstrating whether the requirements of the MDR relating to a device have been fulfilled. (Article 2(40)). This process depends on the medical device classification, according to the procedures described in the MDR, in particular Article 52 (7) applicable for class I devices.

Distributor - means any natural or legal person in the supply chain, other than the manufacturer or the importer that makes a device available on the market, up until the point of putting into service (Article 2(34)).

Economic operator - means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) (Article 2(35)).

Field safety corrective action - means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market (Article 2(68)).

Field safety notice - means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action (Article 2(69)).

Harmonised standard - means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) N° 1025/2012[8], (as referred on the Article 2(70)) – means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation.

Importer - means any natural or legal person established within the Union that places a device from a third country on the Union market (Article 2(33)).

Intended purpose/intended use - means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation (Article 2(12)).

Instructions for use - means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use, and of any precautions to be taken (Article 2(14)).

Label - means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices (Article 2(13)).

Medical device - means 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,

[8] Regulation (EU) No 1025/2012 of the European Parliament and of the Council, of 25 October 2012, on European standardization

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 devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. (Article 2(1))

Manufacturer - means 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; (Article 2(30)).

Notified Body - means a conformity assessment body designated in accordance with the MDR (Article 2(42)).

Placing on the market - means the first making available of a device, other than an investigational device, on the Union market (Article 2(28)).

Post-market surveillance - means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions (Article 2(60)).

Risk - means the combination of the probability of occurrence of harm and the severity of that harm (Article 2(23)).

Serious incident - means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat; ((Article 2(65))

Serious public health threat - means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time (Article 2(66)).

Unique Device Identifier (UDI) - means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market (Article 2(15)).

User - means any healthcare professional or lay person who uses a device (Article 2(37)).

Placing Class I medical devices on the market:

The necessary steps

Manufacturers that intend to place Class I medical devices on the market must guarantee compliance with all the requirements below. Please note that some of the described requirements are inter-dependent and can be performed in a different order than the one presented.

For Class I devices already placed on the market in accordance with the MDD, the manufacturer will conduct a gap analysis in order to guarantee that all the necessary requirements outlined below are fully completed at the date of the application of MDR.

0) Integrate MDR in the Quality Management System (QMS).

The applicable provisions of the MDR will be integrated into the QMS of the manufacturer. This will allow the correct assessment/decision to be made and the proper documented evidence to be created, ensuring compliance with the following requirements.

1) Confirm product as a medical device

Confirm that the product qualifies as a medical device as defined in Article 2(1) in accordance with its intended purpose and principal mode of action. If the manufacturer assigns several different intended purposes to their product, not all of which fall under the scope of the MDR, such a product qualifies as a medical device only with respect to those intended medical purposes which are covered by Article 2(1). This is applicable, for instance, for the case of examination gloves that are intended by the manufacturer to be used to protect the patient (medical purpose - MD) and also to protect the healthcare professional (protection purpose– PPE[9]). In that case the relevant requirements of both legislations will be applicable.

In the case of accessories to medical devices, despite not being medical devices per se, they are covered by MDR provisions and fall under the term "device" in the meaning of the MDR. However, accessories to devices covered by the MDR by virtue of its Annex XVI are not covered by the MDR.

For *borderline* products where such a determination could be difficult, please consult primarily the information[10] available on the European Commission website. Your CA may be able to provide guidance on where to find published information and regulatory requirements.

2) Confirm product as a Class I medical device

Consult Annex VIII of the MDR to confirm that the product is correctly classified as Class I. It should be noted that some Class I devices according to MDD will be reclassified under the MDR considering the new classification rules of that annex, this is the case for most software (rule 11) and devices that are composed of substances or of combination of substances (rule 21).

For devices that were reclassified from Class I to higher risk classes by application of the MDR, the present guideline cannot be applied.

The application of the classification rules will be governed by the intended purpose of the device and

[9] Directive 89/686/EEC is repealed with effect from 21 April 2018 by Regulation (EU) 2016/425

[10] Guidelines available on https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

their inherent risks linked to the duration of use, part of the body, whether it is active or not, whether it is invasive or non-invasive.

If more than one rule according to Annex VIII applies to the intended purposes of the device, the highest classification applies to the device, i.e. it must be classified on the basis of the most critical specified use.

For classification issues, please primarily consult the information[11] available on the European Commission website. Your CA may be able to provide guidance on where to find published information and regulatory requirements.

3) Procedures before placing on the market

a) Meet the general safety and performance requirements

The devices will meet the general safety and performance requirements set out in Annex I of the MDR which apply to them, taking into account the purposes intended by their manufacturers.

Particular attention will be given to devices that are also machinery, within the meaning of Article 2(2), point (a), Machinery Directive 2006/42/EC[12], where the relevant requirements of that directive will also be covered given their specificity (according to Article 1(12)).

The manufacturer will establish and implement a risk management system, which will allow for the identification and analysis of the hazards associated with each device, estimation and evaluation of the associated risks, elimination or control of residual risks and evaluation of the adopted measures based on the information collected from the post-market surveillance system.

The risk management will be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. To carry out this process the manufacturer can find solutions in common specifications, or in harmonised standards, published in the Official Journal of the European Union, or in other referential materials. Where a harmonised standard exists but the manufacturer is following other referential, the application of that referential should guarantee at least the same level of safety and performance. Conformity with the relevant harmonized standards will provide presumption of conformity with the requirements of the MDR covered by those standards or parts thereof. Where common specifications are available the manufacturer is obliged to follow them unless they can duly justify that they have adopted a solution at least with the same level of safety and performance.

The risk management, clinical evaluation processes and PMS will be inter-dependent and will be periodically updated.

b) Conduct clinical evaluation

All devices, regardless of risk classification, require a clinical evaluation as part of the technical documentation requirements of the MDR[13].

The manufacturer will specify and justify the level of clinical evidence necessary to demonstrate

[11] Guidelines available on https://ec.europa.eu/health/md_sector/new_regulations/guidance_en%20

[12] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24)

[13] For further, see Annex II of the MDR

conformity with the relevant general safety and performance requirements described in Annex I. That level of clinical evidence will be appropriate in view of the characteristics of the device and its intended purpose. In order to do that, manufacturers will plan, conduct and document a clinical evaluation in accordance with Article 61 and Part A of Annex XIV.

Guidance on the process of conducting clinical evaluation is also available on the Commission website.[14]

Conformity to Annex I requirements can only be assumed when the following items are aligned with each other:

- Risk management;
- The information materials supplied by the manufacturer, including:
  - labelling,
  - instructions for use (where required),
  - available promotional materials,
  - any accompanying documents foreseen by the manufacturer;
- The clinical evaluation (the device description used for the clinical evaluation, other contents of the clinical evaluation report);
- The available clinical data (such as results of clinical investigations, publications, Post Market Surveillance studies, clinical registries, etc.).

The MDR reinforces the need to consider the following aspects when carrying out a clinical evaluation:

- **Consideration of available alternative treatment options** is required as part of clinical evaluation for the MDR[15]. Whilst the existence of better alternative treatment options does not influence the compliance of the device with the MDR, the manufacturer needs to be able to justify the clinical benefit of using their device if alternatives are available.
- **The incorporation of clinical data** obtained throughout the life cycle of the device from the manufacturers post-market clinical follow-up plan and post-market surveillance plan to update the clinical evaluation and documentation[16].
- **The acceptability of the benefit-risk ratio** must be based upon sufficient clinical data and will be continuously monitored and reassessed from clinical data collected through the post-market surveillance phase. The post-market surveillance plan should incorporate suitable indicators and threshold values to be used in this reassessment [17].

If available clinical data are not sufficient to demonstrate compliance with the MDR, further clinical data will be obtained or generated by clinical investigations.

For devices which are currently certified with respect to the Directive 93/42/EC, and for which the available clinical data are not sufficient to demonstrate compliance with MDR, additional clinical data may be obtained by post-market clinical follow-up studies of the device. Sometimes, even data from the general post-market follow-up might suffice to close the gap[18].

Note: if a clinical investigation is required, then the Member State requires advance notification of the proposal and the provisions of Article 62 and Annex XV will be applicable.

[14] https://ec.europa.eu/health/md_sector/new_regulations/guidance_en
[15] MDR, Article 61(3)(c)
[16] MDR, Article 61(11)
[17] MDR, Article 61(1) and Annex III 1.1b
[18] An MDCG guidance is intended to be published on this matter including 'sufficient clinical data' in 2020 and will be available at the EU Commission webpage

In duly justified and substantiated cases, some Class I devices manufacturers may exceptionally demonstrate that the conformity with general safety and performance requirements based on clinical data is not deemed appropriate. Such a justification by the manufacturer must be based upon an evaluation of evidence in accordance with Article 61(10).

The clinical evaluation, risk management processes and PMS will be inter-dependent and will be periodically updated.

c) Prepare technical documentation

The manufacturer will draw up and keep up to date the technical documentation that demonstrates the conformity of their devices with the technical requirements of the MDR. This technical documentation must be prepared according to Annex II and III and prior to drawing up the EU declaration of conformity.

The technical documentation and, if applicable, its summary, will be drawn up and presented by the manufacturer in a clear, organised, readily searchable and unambiguous manner.

The manufacturer must make the technical documentation available to the CA, the authorised representative (when applicable) and NB (when applicable).

The technical documentation will be prepared following review of the general safety and performance requirements and relevant technical provisions of the MDR and, if applicable, of the Machinery Directive[19] and will cover all the relevant aspects from Annex II and III, such as:

- Rationale for the *qualification* as a medical device and *the risk class* attributed.

- *Description and specification* - A general description of the device, including its intended purpose and intended users/patient population and, if applicable, accessories and variants of the product (for example trade names, model numbers, references, sizes). In addition, the Basic UDI-DI as per Part C of Annex VI will be provided.

- *Technical Specifications* of the device - Specifications including details of raw materials, drawings of components and/or master patterns and any quality control procedures.

- *Information to be supplied by the manufacturer* - Labels on the device and packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions and instruction for use (if applicable), in the languages determined by the Member States where the device is envisaged to be sold.

- *Reference to previous generations of the device and to similar devices* - Provide an overview of previous generation(s) of the device and similar devices available on the market as applicable

- *Design and manufacturing information* – Information that allows the understanding of the design and manufacturing of a device, including the results of qualifications tests and design calculations relevant to the intended use of the product, including connections to other devices in order for it to operate as intended. If the manufacturer can provide information showing that a safe design has been established for a number of years and that product has been performing as intended during that time such information is likely to be sufficient to cover this

[19] According to Article 1 (12)

requirement. The identification of all sites, suppliers and sub-contractors, where design and manufacturing activities are performed will also be included.

- *General safety and performance requirements* – information for the demonstration of conformity with the general safety and performance requirements, set out in Annex I. In order to do this, the manufacturer will refer to all the methods and solutions used for conformity demonstration with each safety and performance requirement, including harmonised standards and/or common specifications (CS). The same applies for the requirements contained in the Machinery Directive.

- *Demonstration of conformity* with the requirements set out in Annex I should typically be presented in the form of a checklist. This should list all requirements referred to in Annex I and specify:

  (1) the applicability of each requirement to the device,
  (2) the solution adopted by the manufacturer to comply with each applicable requirement,
  (3) the reference to any possible CS or harmonized standards applied in full or in part and
  (4) the reference to where to find evidence of the solution adopted in the technical documentation.

  Manufacturers will list the relevant harmonised standards (concerning for example sterilisation, labelling and information to be supplied with the device, biocompatibility, specific groups of products) which have been applied in full or in part. If harmonised standards have not been applied in full, additional data will be required and provided detailing remaining solutions adopted to meet the concerned requirements.

  Information on standards harmonised under the MDR will be made available in the Official Journal of the European Union.

  Changes on the harmonised standards used to demonstrate the conformity of device will be adequately taken into account in a timely manner.

  Please note that no standard harmonized under the Directive 93/42/EC, has ever covered all the requirements of the Annex I to that Directive. Hence, it is not likely that any one standard harmonized under the MDR will cover all the requirements of the Annex I to the MDR. The scope of coverage is indicated in the so-called Annex Z to the European "EN" standard. The scope of coverage is never to be found in the ISO or IEC standard text.

- *Benefit-risk analysis (sections 1 and 8 of Annex I) and Risk management (section 3 of Annex I).*

- *Pre-clinical and Clinical evaluation data* – Information to be provided on the results from pre-clinical and clinical evaluation.

- *The post-market surveillance system* - The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 85 will be presented in a clear, organized, readily searchable and unambiguous manner. It shall address and cover the elements of point 1.1 of Annex III. The plan will cover the post-market clinical follow up plan as referred to in part B of Annex XIV or a justification as to why it is not applicable. The PMS report of article 85 shall be part of the technical documentation on post-market surveillance.

- *Records* - Manufacturers will keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market (Article 10(8)).

Availability of documentation – In case of request by the CA, the manufacturer will provide the required technical documentation in an official Union language determined by the Member State concerned (Article 10(14)).

d) Request Notified Body involvement

In the case of devices placed on the market in sterile condition, having a measuring function or being reusable surgical instruments, the manufacturer will apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI of MDR. This requires the involvement of a NB. In all other cases the intervention of a NB is not required for Class I devices. If involvement of the NB is needed it is limited:

- In the case of devices placed on the market in sterile condition, to the aspects of manufacture concerned with securing and maintaining sterile conditions;
- In the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements;
- In the case of reusable surgical instruments[20], to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

Manufacturers can choose any NB designated according to the MDR for the relevant codes and corresponding types of devices as established by Regulation (EU) 2017/2185 (code MDS 1005 for "Devices in sterile condition", code MDS 1006 for "Reusable surgical instruments" and code MDS 1010 for "Devices with a measuring function"). The list of designated NBs is available in the NANDO database at the following link: http://ec.europa.eu/growth/tools-databases/nando/

Please note that notification under the Directive 93/42/EC, becomes void after the application of the MDR on the 26 May 2021. Hence, it is necessary to consult the NANDO database for the MDR.

e) Prepare Instructions for Use and Labelling

Each device must be accompanied by any safety and performance information needed to use it safely and to identify the device as well as the manufacturer and/or the authorised representative, taking account of the training and knowledge of the potential users. This information comprises the label, device packaging and the data in the instructions for use. By way of derogation to the general principles, no instructions for use are required for Class I devices if they can be used properly and safely without such instruction. An exception is most likely posed for Class Ir devices as reprocessing (cleaning and sterilization) will require an instruction.

The requirements regarding the information to be supplied with the device will be found in Annex I, Chapter III (23). In the labelling and instructions for use as well as in promotional materials of the device, the manufacturer may not (Article 7):

[20] Please also note that involvement of a Notified Body in the case of reusable surgical instruments is a new requirement under the MDR, which did not exist under the MDD. Manufacturers of such products are advised to take this into consideration for their plans to meet the provisions of the MDR before its application on the 26 May 2021.

- Ascribe functions and properties to the device which the device does not have;
- Create a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
- Fail to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;
- Suggest uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

National language requirements must be taken into account in relation to the labelling and instructions for use. Versions of labelling and IFU (in each of the relevant national languages) will be included in the technical documentation.

Note: According to Article 16(2), a distributor or importer may provide a translation of the information provided according to Section 23 of Annex I. The manufacturer will be informed about the intended translation and receive a copy 28 days prior to the date of making the device available in the respective country. It is advisable to perform a review of the translation, as a wrong or misleading translation can cause harm to patients or others, leading to possible liability of the manufacturer.

Where appropriate, the information supplied by the manufacturer will take the form of internationally recognised symbols. Any symbol or identification colour used will conform to harmonised standards or common specifications (CS). In areas for which no harmonised standards or CS exist, the symbols and colours will be described in the documentation supplied with the device.

The label should have the indication that the product is a "medical device".

4) Check compliance with general obligations for manufacturers

Before placing a device on the market, the manufacturer will make sure to comply with the general obligations for manufacturers as established in Article 10.

Special attention will be given to the establishment of an appropriate QMS that will ensure compliance with the MDR in the most effective manner, for example by means of an internal audit. The QMS will be documented, implemented, maintained, kept up to date and continually improved and will cover at least the following aspects:

a) a strategy for regulatory compliance;
b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;
c) responsibility of the management;
d) resource management, including selection and control of suppliers and sub-contractors;
e) risk management;
f) clinical evaluation, including post market clinical follow-up (PMCF);
g) product realisation, including planning, design, development, production and service provision;
h) verification of the UDI assignments;
i) setting-up, implementation and maintenance of a post-market surveillance system;
j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
l) management of corrective and preventive actions and verification of their effectiveness;
m) processes for monitoring and measurement of output, data analysis and product improvement.

The QMS will be established at least in parallel, if not prior to chapter 3 a) and 3 b) as described in this guidance note.

Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Therefore, manufacturers shall, in a manner that is proportionate to the risk class, type of device and size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

5) Draw-up the EU Declaration of Conformity

The EU declaration of conformity, referred to in Article 19, is the procedure whereby the manufacturer, who fulfils the obligations imposed by Article 52(7), declares that the devices concerned fulfil the requirements of the MDR which apply to them. The declaration of conformity will contain as a minimum all information referred to in Annex IV and will be available to the CA.

The manufacturer will continuously update the EU declaration of conformity and will translate it into an official union language or languages required by Member States in which the device is made available.

If, in addition to the MDR, a device is covered by other Union legislation which also requires an EU declaration of conformity, the manufacturers will elaborate a single EU declaration of conformity where all the Union legislation applied to the product are referred to.

By drawing up the EU declaration of conformity the manufacturer assumes the responsibility for the regulatory compliance of the device with all Union legislation applicable to it.

Before affixing a CE mark, for class Ir, Im and Is devices, the manufacturer will have an EC certificate issued by NB according to the Annex IX, Chapter I and III, or to Annex XI, Part A.

6) Affix the CE marking

All Class I medical devices placed on the market will bear the CE marking of conformity, which will be affixed in a visible, legible and indelible form on the device or on its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear on the instructions for use, as well as on any sales packaging.

In the case of Class I medical devices placed on the market in a sterile condition and/or devices with measuring function and/or reusable surgical instruments, the CE marking will be accompanied by the identification number of the relevant NB.

It is prohibited to affix marks which are likely to mislead third parties with regard to the meaning of the CE marking. Other additional marks may be affixed to the device, to the packaging or the instructions for use, but must not impair the visibility or legibility of the CE marking.

The CE marking format will be in compliance with Annex V. Where the device is very small the minimum dimensions of the CE mark may be waived.

7) Registration of devices and manufacturers in Eudamed

Before placing a device on the market, the manufacturer of a Class I medical device will register the device in Eudamed.

In order to register the device, the manufacturer will submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI, provided that they have not already been registered in accordance with Article 31. In cases where the conformity assessment procedure requires the involvement of a NB pursuant to Article 52, the information referred to in Section 1 of Part A of Annex VI will be provided to that electronic system before applying to the NB.

After having verified the data about the manufacturer, the CA will validate it in Eudamed and the manufacturer will obtain a SRN from said electronic system.

The manufacturer will use the SRN when applying to a NB for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 29.

Note: Authorised representatives and importers are also required to register to get an SRN in order to access Eudamed and provide data, as appropriate

The registration of a device in Eudamed by the manufacturer includes:

- Assignment of a UDI-DI (with a Basic UDI-DI) as defined in Part C of Annex VI to the device (in accordance with the rules of the issuing entity referred to in Article 27(2) and introduction of the UDI-DI (with a Basic UDI-DI) to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

- Entering, or if already provided, verifying in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and thereafter keeping the information updated.

If the manufacturer has its devices designed or manufactured by another legal or natural person, the information on the identity of that person will be part of the information (Section 2.13 of Part A of Annex VI) to be submitted to Eudamed before the registration of the device.

Note 1 – The Unique Device Identification system will allow the identification and facilitate the traceability of devices (as referred on Article 27). [Special attention will be given to point 11 of Article 27].

Note 2 – The Basic UDI-DI as defined in Part C of Annex VI is the primary identifier of a device model. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity[21].

Note 3 – For Class I devices placed on the market according to MDD, after the date of application of MDR manufacturers will have in consideration the guidance documents applicable to legacy devices timelines[22] and registration in Eudamed[23].

[21] For more information on the Basic UDI-DI, please refer to https://ec.europa.eu/docsroom/documents/28667

[22] See at EU Commission webpage the relevant guidance on timelines for registration of device data elements in EUDAMED[23] See at EU Commission webpage the relevant guidance on the registration of legacy devices in EUDAMED

[23] See at EU Commission webpage the relevant guidance on the registration of legacy devices in EUDAMED

All devices including legacy devices of the manufacturer portfolio which are placed on the market or put into service will have to be registered in Eudamed. However, until Eudamed is fully functional the manufacturer of a Class I medical device, or, where the manufacturer has no place of business in the EU, its authorised representative must inform the CA of the country in which they have their registered place of business and provide a description of the device that is sufficient to identify it. The manufacturer or its authorised representative will contact their relevant CA for the required procedures and forms required for such notifications. A fee might be applicable.

8) Post Market Surveillance (PMS)

After placing the Class I device on the market, the manufacturer will follow the next PMS steps:

a) Review experience gained from Post-Market Surveillance

The manufacturer will put in place the required post market surveillance (PMS) system and actively keep this PMS up to date in accordance with Article 83 of MDR. This includes actively and regularly collecting the user experience from devices on the market, reviewing these and ensuring timely implementation of any necessary corrective action, taking account of the nature and risks in relation to the product. In addition, there should be an evaluation of whether the intended benefits are achieved and whether the benefit-risk profile stays positive. The manufacturer will involve the distributors of the device and where applicable, the authorised representative and importers of the device in this system, in order to obtain the relevant information from the market.

This system will be part of the QMS, and be supported by the manufacturer's PMS plan, which must address a range of information (Annex III), such as information from the vigilance context, information from trending and trend reporting, information and data on any undesirable side-effects, information from reports, complaints and incidents, provided by users and economic operators, related to the device. Moreover, the manufacturer will gather and assess the relevant information such as technical literature, databases, registers review and public information for the device itself as well as for similar devices already present on the market.

A PMS report will be prepared according to Article 85, summarizing the results and conclusions of the analysis of all of the data from the market. This report will be updated when necessary, for example the intended benefits are not achieved or there is a change in the benefit-risk balance. The report can be requested by the CA at any time.

Data gathered from PMS system must be used to actively update the clinical evaluation, benefit-risk determination, improve risk management, as well as other technical documentation on a regular basis.

b) Vigilance

The manufacturer is responsible for reporting all serious incidents and field safety corrective actions (FSCA) to the relevant CAs, according to Article 87 (1) of the MDR. After serious incident notification, the manufacturer is obliged to make investigations, according to Article 89, which will include a risk assessment of the incident. If needed, a FSCA will be implemented in order to reduce the risk associated with the use of the device.

The manufacturer will involve the distributors of the device and, where applicable, the authorised representative and importers in the system, in order to obtain the information needed from the market, especially for FSCA and issued field safety notices (FSN) to ensure that required actions are followed and completed in a timely manner.

When Eudamed is available, serious incidents and FSCAs will be submitted via this electronic system only.

Manufacturers will report any serious incident immediately after they have established the causal relationship between that incident and their device or that such a causal relationship is reasonably possible.

The timeframe to report serious incidents must not exceed the following upper limits:

- In the event of a serious public health threat, a report will be submitted not later than 2 days after becoming aware of the threat. (Article 87 (4))
- In the event of death or an unanticipated deterioration in a person's state of health a report will be submitted not later than 10 days after becoming aware of the serious incident. (Article 87 (5))
- In all other cases not later than 15 days after becoming aware of the serious incident (Article 87 (3))

Where necessary to ensure timely reporting of serious incidents, the manufacturer may submit an initial report that is incomplete followed up by a complete report. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report. Serious incidents will be reported only to the competent authority of the country in which the serious incident occurred via Eudamed.

The manufacturer will provide a final report to that competent authority via Eudamed setting out its findings from the investigation. The report will set out conclusions and - where relevant - indicate corrective actions to be taken.

When the competent authority notifies a manufacturer of a suspected serious incident, communicated to the competent authority by a healthcare professional, patient or user, the manufacturer is obliged to:

- submit a report of this serious incident to the notifying competent authority via Eudamed within the timeframes described above;
- submit an explanatory statement, to the competent authority, if the manufacturer believes the suspected serious incident does not fulfil the reporting criteria.

In case the competent authority disagrees with the explanatory statement provided by the manufacturer a report of the serious incident may be required to be provided to the competent authority that does not agree via Eudamed by the manufacturer.

If a FSCA is undertaken, manufacturers will without unnecessary delay report the field safety corrective action via Eudamed in advance of the carrying out of the FSCA unless urgency demands the manufacturer to undertake the actions immediately.

Manufacturers will ensure that the information related to the FSCA is brought without delay to the attention of users of the device in question by means of a FSN. Except in cases of urgency, the content of the draft FSN will be submitted to the evaluating competent authority or to the coordinating competent authority to allow it to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice will be consistent in all Member States. Manufacturers will also report the FSN(s) to Eudamed.

The FSN will allow the correct identification of the manufacturer (by including the, if issued, SRN), the device or devices affected (by including the relevant UDIs) and the FSN will explain, in a clear manner, without understating the level of risk, the reasons for the FSCA. This includes a clear reference to the device deficiency and the associated risks for patients, users or other persons and will clearly indicate all action to be taken by the users.

Manufacturers will report by the means of a trend report to Eudamed any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects, when it could have a significant impact on the benefit-risk analysis and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

Manufacturers will, if they exist, follow national provisions in the field of vigilance specifically in but not limited to the case of field safety corrective actions:

- The allowed languages used to communicate with users by means of the Field Safety Notice.

Manufacturers are asked to check if templates exist (on European Commission website) on any of the reportable forms and make sure that all the necessary information according to these templates is provided. This will be only applicable until Eudamed is available.

Manufacturers should keep concerned economic operators informed of reported serious incidents and FSCA activities.

c) Non-conforming products

If a manufacturer has reasons to believe that a device which they have placed on the market or put into service is not in conformity with the MDR they will immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. The manufacturer will inform the distributors of the device in question and, if applicable, the authorised representative and importers. If the device presents a serious risk, the manufacturer will immediately inform the competent authorities of the Member States in which the manufacturer made the device available and, where applicable, the notified body that issued a certificate for the device, in particular, of the non-compliance and of any corrective action taken.