

HOW TO BE READY TO LAUNCH THE MEDICAL DEVICE CERTIFICATION PROCESS WITH AN EU NOTIFIED BODY

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1. What is my "medical device" (MD)?

- A Medical Device (MD)?
- An accessory?
- A product listed in Annex XVI?
- A system and/or a necessity?
- Parts and/or components?
- Customized DM?



1. What is my "medical device" (MD)?

Any instrument, apparatus, equipment, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, in humans for one or more of the following specific medical purposes:

- *diagnosis, prevention, control, prediction, prognosis, treatment or alleviation of a disease,*
- *diagnosis, control, treatment, alleviation of or compensation for injury or disability,*
- *investigation, replacement or modification of an anatomical structure or function, or of a physiological or pathological process or state,*
- *communication of information by means of in vitro examination of samples from the human body, including organ, blood and tissue donations,*

and whose principal intended action in or on the human body is not obtained by pharmacological or immunological means or by metabolism, but whose function can be assisted by such means. The following products are also deemed to be medical devices:

- *devices for design control or design assistance,*
- *products specifically intended for cleaning, disinfecting or sterilizing the devices referred to in Article 1(4) and those referred to in the first paragraph of this point;*

[Regulation \(EU\) 2017/745 \(art. 2\)](#)

1. What is my "medical device" (MD)?

An accessory

"Any article which, without itself being a medical device, is intended by its manufacturer to be used with a given medical device or devices to enable use of the latter in accordance with its or their intended purpose or to contribute specifically and directly to the medical function of the medical device or devices in accordance with its or their intended purpose." (Regulation (EU) 2017/745; art. 2)



Infusion pump holder

Devices not intended for medical use (Appendix XVI)

1. **Contact lenses** or other articles intended to be inserted into the eye or placed on the eye.
2. **Products intended to be totally or partially introduced into the human body by** invasive surgical means in order to **modify the anatomy or fix anatomical parts**, with the exception of tattooing products and piercings.
3. **Substances, combinations of substances or articles intended to fill the face, skin or mucous membranes** by subcutaneous, submucous or intradermal injection or any other method of introduction, except those intended for tattooing.
4. **Equipment intended for use in reducing, removing or destroying adipose tissue**, such as that used in liposuction, lipolysis and lipoplasty.
5. **Equipment emitting high-intensity electromagnetic radiation** (e.g. infrared, visible light, ultraviolet) and intended for use on the human body, including coherent and non-coherent, monochrome and broad-spectrum sources, such as lasers and intense pulsed light equipment used for skin resurfacing, tattoo removal, hair removal or other skin treatments.
6. **Equipment for transcranial brain stimulation** using electric currents or magnetic or electromagnetic fields to modify neuronal activity in the brain.

1. What is my "medical device" (MD)?

« System » (art.22)

a combination of products, whether or not packaged together, intended to be interconnected or combined for specific medical purposes



« Necessary » (art. 22)

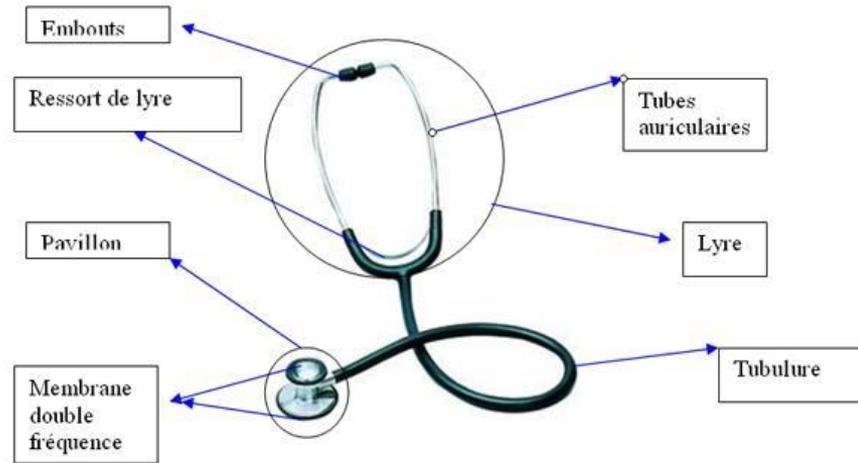
a combination of products packaged together and placed on the market to be used for specific medical purposes



1. What is my "medical device" (MD)?

Parts and components

Article specifically intended to replace an integral part or an identical or similar component of a failed or worn device in order to maintain or restore the device's function without altering its performance, safety features or purpose.



Regulation (EU) 2017/745 (art. 23)

1. What is my "medical device" (MD)?

Custom-made devices are:

- manufactured expressly according to the written prescription of any person authorized by national legislation by virtue of his professional qualifications, indicating, under his responsibility, the specific design characteristics, and
- intended for use on a specific patient only, and
- exclusively in response to the patient's needs and state of health



The following are not considered custom-made devices:

- mass-produced devices that need to be adapted to meet the specific requirements of any professional user, or
- devices that are mass-produced by industrial manufacturing processes in accordance with the written specifications of any authorized person



1. What is my "medical device" (MD)?

Medical Devices
Medical Device Coordination Group Document MDCG 2021-3

MDCG 2021-3
Questions and Answers on Custom-Made Devices
& considerations on Adaptable medical devices and Patient-matched medical devices

March 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

- What is a custom-made device?
- What is an adaptable medical device?
- What is a patient-matched medical device?

2. What is my role ?

- Legal manufacturer?
- European representative?
- Importer?
- Distributor?
- Importer or distributor becoming a legal manufacturer?
- MD assembler for system and/or necessary?
- Subcontractor or supplier of a legal manufacturer?



2. What is my role ?



Manufacturer

- manufactures or refurbishes a device OR has a device designed, manufactured or refurbished
- markets this device under its own name OR under its own brand name



EU representative

- established in the EU
- receives and accepts a written mandate from a manufacturer located outside the EU,
- to act on its behalf in carrying out specific tasks related to its obligations



Importer

- established in the EU
- places a device from a third country on the EU market



Distributor

- makes a device available on the market, right up to the commissioning stage



2. What is my role ?



Art. 16 RDM

Importer or distributor becoming a legal manufacturer (=OBL)

- makes a device available on the market under its own name, trade name or registered trademark;
- changes the purpose of a device already on the market or in service;



Art. 22 RDM

DM assembler

- Any natural or legal person shall draw up a declaration if they combine CE-marked devices with [...] with a view to placing them on the market in the form of a system or kit.
- Where the system or kit incorporates devices which do not bear the CE marking [...] the natural or legal person assumes the obligations incumbent on manufacturers.



Subcontractor or supplier

- Supplies (raw materials, components, sub-assemblies, etc.)
- Services (sterilization, calibration services, maintenance services, transport services, consulting services, packaging services, etc.)

3. Regulatory Vs Quality?



- › Legal manufacturers
- › « OBL » (art. 16)
- › Assemblers (if at least 1 non-CE-marked DM)



- › EU reps
- › Importers
- › Distributors
- › Subcontractors and suppliers
- › Assemblers (for all CE-marked DMs)



3. Regulatory Vs Quality?



Chapter 2

› Placing devices on the market and putting them into service, obligations of economic operators, reprocessing, CE marking and free circulation



Chapter 3

› Device identification and traceability, registration of devices and economic operators, summary of safety characteristics and clinical performance, and European medical device database.



Chapter 4

› Notified bodies



Chapter 5

› Classification and conformity assessment



Chapter 6

› Clinical assessment and investigations



Chapter 7

› Post-market surveillance, vigilance and market monitoring



... And do not forget requirements set out in Appendices I to XVI!

4. MDR => Impacts for critical suppliers?

Article 10 "General obligations of manufacturers"

Section 9: "The quality management system covers at least the following aspects:

d) resource management, including **the selection and control of suppliers and subcontractors**".



Article 30 & Annex VI (part A, section 1, 2.13) "EUDAMED"

in the case of **devices designed and manufactured by another natural or legal person as** referred to in Article 10(15), the name, address and contact details of that natural or legal person

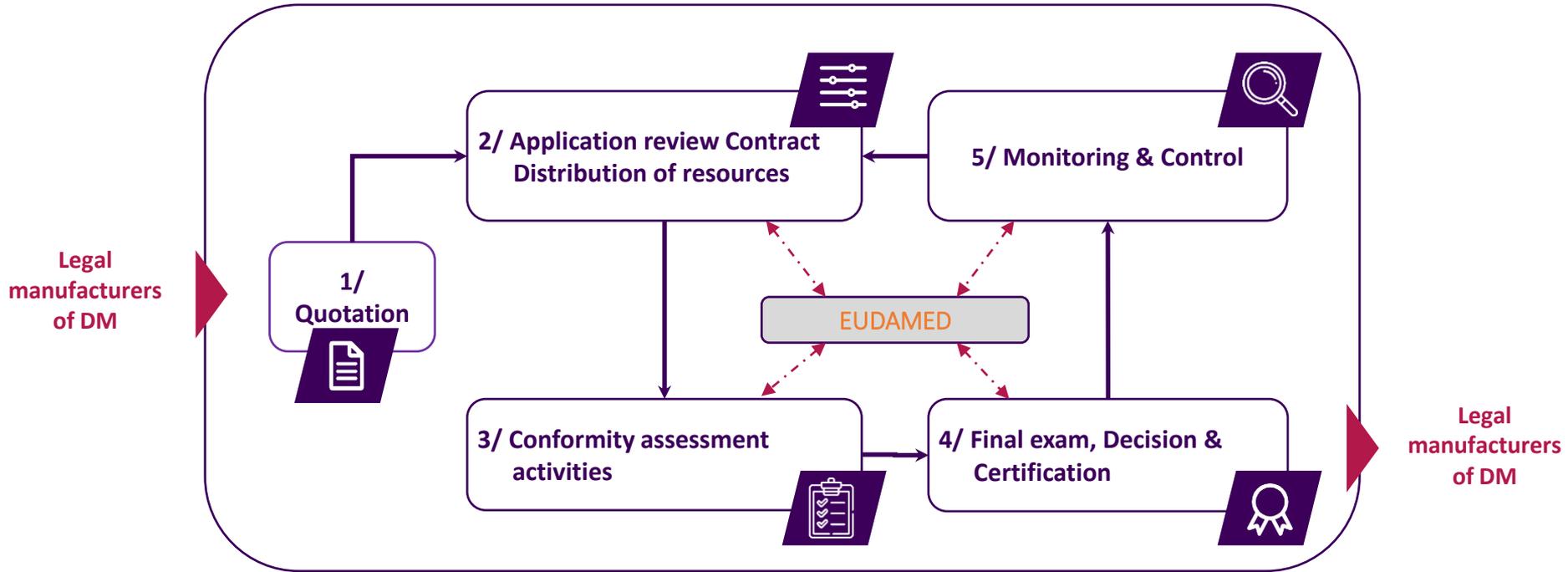
Appendix II "Technical Documentation"

Section 3. c) "Identification of all sites, **including those of suppliers and subcontractors**, where design and manufacturing activities take place."

Annex VII "Requirements to be met by NBs".

Section 4.10 "NBs have documented procedures specifying how and when surveillance activities with manufacturers should be carried out. These procedures include arrangements for **unannounced on-site audits of manufacturers and, as appropriate, subcontractors and suppliers**, for product testing and for monitoring compliance with any conditions imposed on manufacturers and relevant to certification decisions."

5. Certificate issuance process?



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Application

- **List of DM covered by your future MDR certification:**
 - Codes (see (EU) 2017/2185)?
 - Classification?
 - Justification?
 - List of related technical documentation?
 - Specificities: sterility? medicinal substances? nanomaterials, AI, etc.
- **Conformity assessment routes:**
 - Quality management system + Technical documentation (Annex IX)?
 - Type examination (Annex X)?
 - Verification of product conformity (Annex XI)?

5. Certificate issuance process?

Common pitfalls

- Unjustified classification of DM / accessories
- More than one MDAXXX or MDNXXX code for a DM
- Incomplete list of MDS/MDT codes
- Distribution of DMs in technical files
- ...

5. Certificate issuance process?

Completeness of submissions



*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

5. Certificate issuance process?



This International Standard specifies the requirements of a quality management system that may be used by an **organization involved in one or more stages of the life cycle of a medical device**, including :

- › design and development,
- › production,
- › storage and distribution,
- › installation,
- › related services,
- › decommissioning and disposal of medical devices
- › design, development and provision of related activities (e.g. technical support)

5. Certificate issuance process?

Chapter 0.1 General information

Many jurisdictions have regulatory requirements for the application of quality management systems by organizations playing various roles in the medical device supply chain. Accordingly, this International Standard requires the organization :

- › identifies its **role(s)** under current regulatory requirements;
- › identifies the **regulatory requirements applicable** to its activities in these roles;
- › integrates these applicable regulatory requirements into its quality management system.

Chapter 0.2 Clarifying concepts

When used, the term "**regulatory requirements**" includes requirements contained in any law applicable to the user of this International Standard (e.g. laws, regulations, ordinances or directives).

The application of the term "**regulatory requirements**" is limited:

- › quality management system requirements,
- › the safety or performance of the medical device.

For manufacturers

RDM Art. 10 (section 9)

"The QMS covers at least the following elements..."

RDM Annex 1 (« GSPR »)

Requirements 1 to 23

6. Timelines?

Regulation (EU) 2023/607 amending the MDR – new timelines



* For devices that did not require involvement of a NB under MDD (e.g. Ir)

6. Timelines?

Message to Manufacturers...

Medical Devices
Medical Device Coordination Group Document MDCG 2022-11 Rev.1

MDCG 2022-11 Rev.1
MDCG Position Paper
Notice to manufacturers and notified bodies to ensure timely compliance with MDR and IVDR requirements

November 2023

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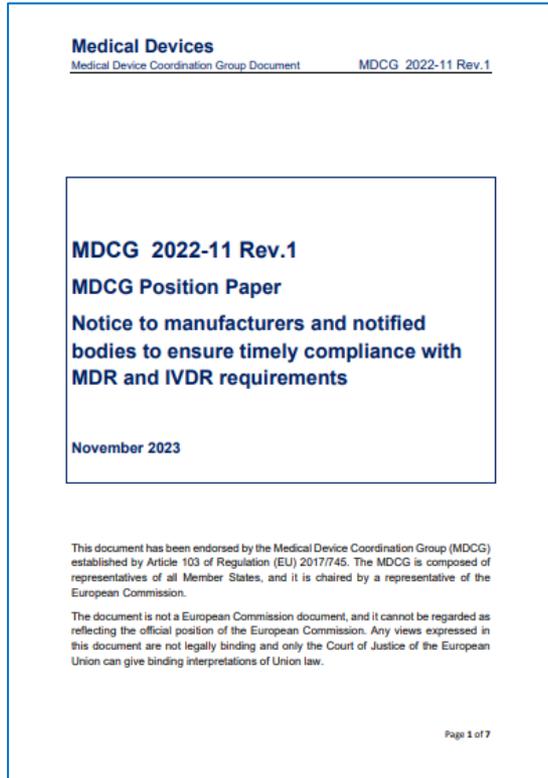
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- Considering the deadlines established by the Regulations, manufacturers are thus **urged to strengthen their efforts to transition as soon as possible** and not to delay submissions further, as this could lead to bottlenecks in the work of notified bodies and possible shortages of products in the market.
- This is particularly true for manufacturers of class D IVD devices, which must transition to IVDR by May 2025.

6. Timelines?

Message to Notified Bodies...



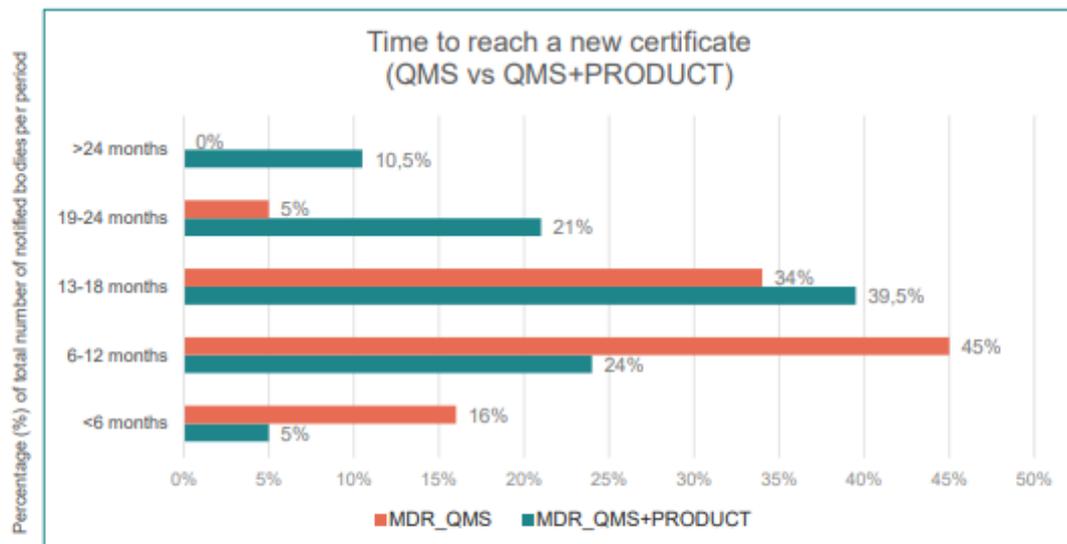
- It is essential that notified bodies streamline their procedures and **make all needed efforts to improve their conformity assessment activities** in terms of transparency, timelines, predictability and consistency. Notified bodies are reminded to operate in accordance with consistent, fair, and reasonable terms and conditions, taking into account in particular the interests of SMEs in relation to fees
- **A proper assistance** to manufacturers with regulatory guidance and technical information on how to apply for the conformity assessment procedure is key for a smoother and faster process and to avoid incomplete applications, which have been identified as an important cause of the delays. Such assistance is particularly relevant for SMEs
- The MDCG reminds notified bodies to organize **structured dialogues** with manufacturers, which is expected to be part of the normal pre-application and conformity assessment activities and therefore not to be a separated service to be charged for

Time to reach a new certificate (QMS vs QMS+Product)

June 2023

MDR Applications: 13.177

MDR Certificates: 3.899



MDR QMS certificates:

- For 45 % of NBs: **6-12 months** to issue a new QMS certificate
- For 39 % of NBs: ≥ 13 months (max: 24 months)

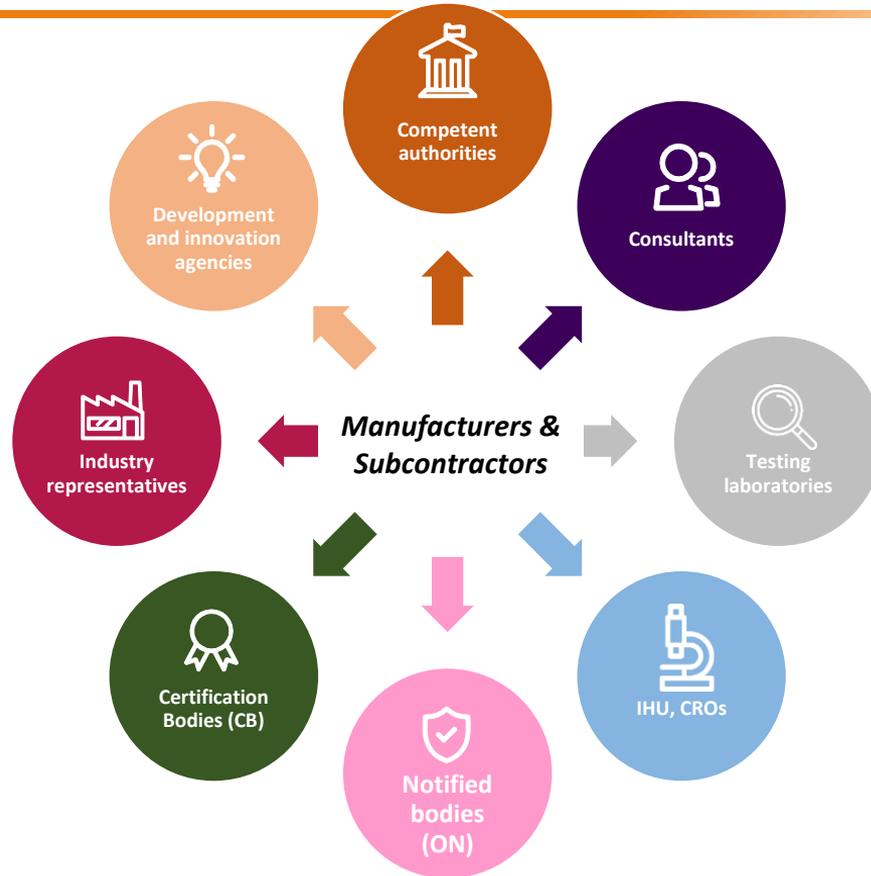
MDR QMS+PRODUCT certificates: longer time

- For 40% of NBs: **13-18 months** to issue a new product certificate
- For 71% of NBs: ≥ 13 months

Notes:

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under MDR.
- One NB stated that the learning curve leads to a slight reduction of time frames, another NB mentioned that the time is increasing.
- One NB mentioned that major impact comes from assessment postprocessing, CAPA closure, etc.
- 6 NBs mentioned that this question is not applicable for them and/or they have not issued a certificate yet; one out of these 6 NBs stated that estimates were indicated.
- One NB stated that for QMS-only certificates the usual timeframe is shifted towards the 12-month mark.

Complementary skills for patient safety and all Medical Devices companies





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