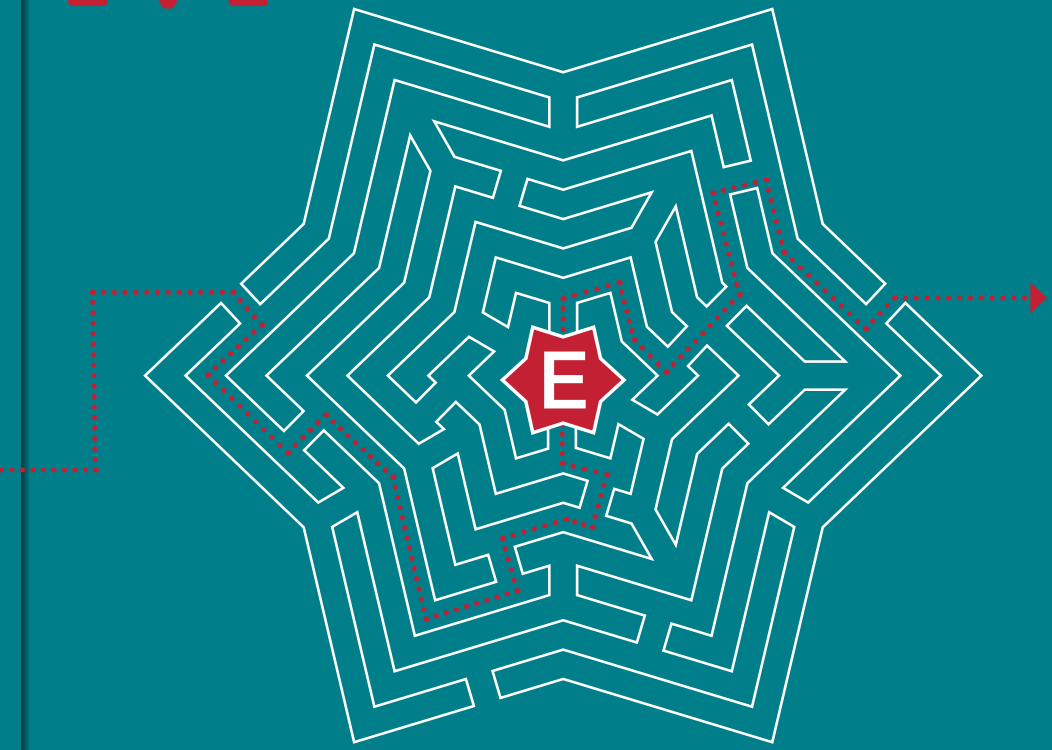
REGULATION

MANUFACTURERS
SYNTHESIS



DM

EUROPEAN MEDICAL DEVICE REGULATION (MDR)

The information herein is given as guidance only. It is not necessarily exhaustive and cannot take the place of the applicable regulation.

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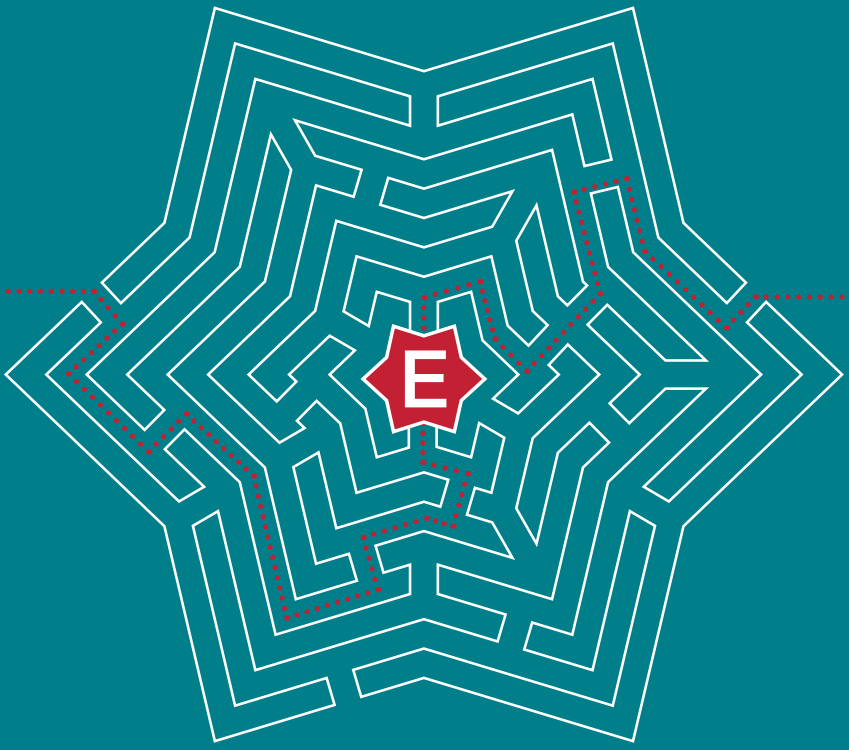


This document is likely to change over time: SNITEM will regularly update the information herein.

February 2024 version

CONTENTS

SUMMARY OF THE MANUFACTURER'S OBLIGATIONS

Manufacturer's obligations relating to its organisation		Ref. [1]
Human resources	Have at least one person responsible for regulatory compliance.	Art. 15
Mandate	**Manufacturer established outside the EU:** Appoint an authorised representative established within the EU to carry out certain tasks on its behalf and under mandate.	Art. 11
Financial coverage	Provide sufficient financial coverage in the event of liability for defective products.	Art. 10, 16)
Quality Management	Have a quality management system that ensures compliance with the provisions of the regulation.	Art. 10, 9)
Regulatory monitoring	Establish a regulatory monitoring process at European level.	Art. 8, 9 and 10 Annexe I 1
Archiving	Have an archiving system for technical documentation, declarations of conformity and certificates of conformity of its devices.	Art. 10, 8)
Confidentiality	Respect the confidentiality of information and data obtained in carrying out their tasks and in particular: • personal data, • commercially confidential information and trade secrets, including intellectual property rights; unless disclosure is in the public interest, • the implementation of the regulation, in particular for the purpose of inspections, investigations or audits.	Art. 109
Cooperation	Cooperate with the competent authorities who may request documentation, information, samples or access to a device, or carry out inspections at its premises, those of its suppliers and subcontractors. It must also cooperate with the notified body which assesses or has assessed the conformity of its system and provide it, on request, with any information, document and access (to its premises, those of its suppliers and subcontractors) it may need to perform its task.	Art. 93, 3) Annexes VII, IX et XI

1. 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 repealing Council Directives 90/385/EEC and 93/42/EEC.

Manufacturer's obligations before placing its devices on the market		Ref. [2]
Status and classification of device	In particular, define the indication and intended purpose of the device, its characteristics, its mode of action and deduce its risk class.	Art. 51 Annexe VIII
Requirements	Design a device that meets general safety and performance requirements. Compliance with the applicable harmonised standards or common specifications shall presume compliance with the requirements of those standards or specifications.	Art. 8, 9 and 10, 1) Annexe I
Risk management	Ensure risk management for the entire lifecycle of the device.	Art. 10, 2) Annexe I 3
Manufacture and validation of device	Validate the manufacturing process and ensure series production in accordance with the requirements of the regulation.	Art. 10, 9)
Clinical evaluation	Produce a clinical evaluation to demonstrate conformity of the device with the general safety and performance requirements, evaluate the undesirable side effects and decide on the benefit-risk ratio.	Art. 5, 3) and 61
Information supplied by the manufacturer	Assign a UDI to each of its devices and affix it to the label and all levels of packaging (except transport packaging). The UDI must be affixed to the device itself when it is reusable. The manufacturer must record the UDI of each device in the UDI database: • before the request for conformity assessment for class III and class IIb implantable MDs, • before placing on the market for the other MDs.	Art. 27
	Accompany the device with a label and, where applicable, instructions for use, which comply with regulation 2017/745. This information shall be provided in the languages accepted in the Member States where the device is envisaged to be sold.	Annexe I 23

2. Regulation (EU) 2017/745 f 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 repealing Council Directives 90/385/EEC and 93/42/EEC.

Manufacturer's obligations before placing its devices on the market (after)		Ref. [3]
	The media and communications accessible to the user or patient (labelling, instructions, advertising) must not contain any information that may mislead the user or the patient with regard to the device's intended purpose, safety and performance.	Art. 7
	For Class III devices and implantable devices: provide a summary of the safety and clinical performance of its devices.	Art. 32
	For implantable devices: • provide information allowing the identification of the device and the manufacturer, safety information, as well as the lifetime of the device and the materials and substances to which patients can be exposed, • provide information allowing the identification of the device in the form of an implant card issued to the patient.	Art. 18
Technical documentation	Draw up and keep up-to-date technical documentation for each of its devices.	Art. 10, 4)
Conformity assessment	Prior to placing a device on the market, undertake an assessment of the conformity of that device with the applicable procedures.	Art. 52
	Then draw up the EU declaration of conformity and affix the CE marking.	Art. 19 et 20
Registration in Eudamed	Register as a manufacturer, if not already done, before the first submission of a conformity assessment application to a notified body or before the first making available of a device on the market. It then obtains a single registration number.	Art. 31
	Register each device it places on the European Union market or for which it submits an assessment application to a notified body (through the basic UDI-DI).	Art. 29

3. Regulation (EU) 2017/745 f 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 repealing Council Directives 90/385/EEC and 93/42/EEC.

Manufacturer's obligations after placing its devices on the market		Ref. [4]
Traceability	Be able to identify any economic operator to whom it has directly supplied a device, who has directly supplied it with a device and any health institution or healthcare professional to which it has directly supplied a device.	Art. 25, 2)
	Keep up-to-date a list of all the UDIs that it has assigned.	Art. 27, 7)
	Store and keep, preferably by electronic means, the UDI of the class III devices it has supplied or with which it has been supplied.	Art. 27, 8)
Post-market surveillance	Have a post-market surveillance system. This system is based on a post-marketing surveillance plan that is detailed in the technical documentation of the device.	Art. 83 and 84
	Gather data on the quality, performance and safety of its devices throughout their entire lifetime.	Art. 83
	Prepare a post-market surveillance report (for its class I devices) and a periodic safety update report (PSUR) (for its class IIa, IIb and III devices). These reports must be updated at the frequency defined in the regulation.	Art. 85 and 86
Vigilance	Have a system for recording incidents and field safety corrective actions. Report these incidents to the competent authorities via Eudamed, according to the periods taking into account the severity thereof.	Art. 10, 13) and 87
	The manufacturer must report to the competent authorities via Eudamed any statistically significant increase in the frequency or severity of certain incidents that could have a significant impact on the benefit-risk ratio of the device in a trend report.	Art. 88
	Perform the necessary investigations following a serious incident and send a report to the competent authorities via Eudamed.	Art. 89
Field safety corrective actions	The report sent by the manufacturer to the competent authorities after reporting a serious incident must indicate the field safety corrective actions to be taken.	Art. 89
	Immediately take the necessary corrective action to bring a device into conformity, to withdraw it or to recall it and inform the relevant economic operators.	Art. 10, 12)

4. 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 repealing Council Directives 90/385/EEC and 93/42/EEC.

CHECK-LIST: BECOMING A MANUFACTURER OF DEVICES PLACED ON THE EU MARKET

Does the operator meet the conditions to be qualified as a manufacturer and does it have the necessary tools?

01 The operator must meet the definition of manufacturer in the regulation

Localisation	The operator is established within the European Union or outside the European Union. If established outside the EU, it must appoint an authorised representative established within the EU who must carry out certain minimum tasks.
Activity	• The operator manufactures or fully refurbishes devices or has devices designed, manufactured or fully refurbished. • It markets devices under its name or trademark. • It changes a device or the intended purpose of a device. These devices are placed on the market within the European Union.

02 The operator must be able to fulfil all the obligations applicable to manufacturers

Financial coverage	The operator can provide sufficient financial coverage in the event of liability for defective products.
Personnel	• The operator has the necessary resources (in particular human, financial, technical) to fulfil the obligations laid down in the regulation. • The operator has provided a back-up system for certain tasks (in particular those performed by the person responsible for regulatory compliance).
Processes for...	• risk management, • quality management, • regulatory monitoring, • clinical evaluation, • manufacturing, • post-market surveillance, • vigilance, • traceability. Processes must be documented and applied: the operator must be able to prove at all times that it complies with the obligations laid down in the regulation (procedures and associated records).

Tools

- Identification of any stakeholder likely to need to be contacted (contact person and contact details):
  - authorised representative, importer, distributor,
  - competent authorities of the Member States in which the devices are made available,
  - notified body where appropriate.
- Definition of the criteria triggering a communication.
- System for recording and storing documentation (technical documentation, EU declaration of conformity, certificates, etc.), UDIs, traceability and vigilance information.

03 The operator must have registered as a manufacturer in Eudamed (this step depends on the date on which the Eudamed database is operational)

Registration As a manufacturer (type of economic operator, name, address, contact details) before the first submission of a conformity assessment application to a NB or before the first placing on the market of a device.

Updating This information within one week of any change.

04 The operator must have registered its devices in Eudamed (this step depends on the date on which the Eudamed database is operational)

Registration The basic UDI-DI of each device.

Has the operator formalised its relations with its partners?

! The operator must have a contract with the authorised representative (if applicable) and the importer(s) or distributor(s), as well as with its subcontractors

- Not delegate any obligation or responsibility falling within the scope of the manufacturer's activity: the manufacturer remains solely responsible for the obligations incumbent thereto under the regulation and which cannot be delegated.
- Not delegate any obligation or responsibility relating to the activity of other economic operators: they remain solely responsible for the obligations incumbent thereto under the regulation.

REFERENCE LEGISLATION AND DOCUMENTS

1. ***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 repealing Council Directives 90/385/EEC and 93/42/EEC*

Règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux, modifiant la directive 2001/83/CE, le règlement (CE) no 178/2002 et le règlement (CE) no 1223/2009 et abrogeant les directives du Conseil 90/385/CEE et 93/42/CEE [4]

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20250110

2. ***The 'Blue Guide'*** *on the implementation of EU products rules* ***2022 (2022/C 247/01)***

Le Guide bleu relatif à la mise en œuvre de la réglementation de l'Union européenne sur les produits **2022 (2022/C 247/01)** ci-après « le Guide bleu »

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2022_247_R_0001

This is a Guide on the enforcement of provisions applicable to products in the European Union (directives drafted on the basis of the provisions of the New Approach and the Global Approach, implemented by the New Legislative Framework, Lisbon Treaty). The aim of this Guide is to explain these provisions and to contribute to their more uniform and coherent application across different sectors and throughout the single market. The Blue Guide therefore provides information to interpret the medical device regulation.

4. Regulation (EU) 2017/745 has been amended by :
- corrigendum published in the OJEU of 3 May 2019 (https://eur-lex.europa.eu/eli/reg/2017/745/corrigendum/2019-05-03/oj)
- corrigendum published in the OJEU of 27 December 2019 (https://eur-lex.europa.eu/eli/reg/2017/745/corrigendum/2019-12-27/oj)
- Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (https://eur-lex.europa.eu/eli/reg/2020/561/oj)
- corrigendum of March 2, 2021 (correction of translation errors)
- regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (https://eur-lex.europa.eu/eli/reg/2023/607/oj)

REFERENCE TERMS

1. DEFINITION OF MANUFACTURER IN REGULATION 2017/745

The manufacturer is the 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 [5].

The manufacturer is an «economic operator» within the meaning of regulation 2017/745, which refers to the manufacturer, authorised representative, importer, distributor, person who combines devices and person who sterilises systems or procedure pack [6]. All the provisions of the regulation concerning economic operators are therefore applicable to the manufacturer.

2. CASES IN WHICH ANOTHER ECONOMIC OPERATOR MUST COMPLY WITH THE MANUFACTURER'S OBLIGATIONS

Regulation 2017/745 provides that certain activities, when performed by a distributor, importer or any other person, require the operator to comply with the manufacturer's obligations [7].

This is the case if this operator:

- makes available on the market a device under its name or registered trademark (except in cases where the manufacturer enters into an agreement whereby he is identified as such on the label and is responsible for meeting the requirements placed on manufacturers by the regulation);
- changes the intended purpose of a device already placed on the market or modifies the actual device in such a way that compliance with the applicable requirements may be affected;
- modifies the packaging or the information accompanying a device (including when it performs and provides translations of such information) without complying with the requirements listed in article 16(2) of regulation 2017/745.

➔The MDCG (Medical Device Coordination Group) has produced two guides concerning article 16 of the regulation :

- **MDCG 2021-23 Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746**
- **- MDCG 2021-26 Q&A on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746**

The MDCG guides are available on the following page: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

5. Article 2 point 30 of regulation 2017/745.
6. Article 2 point 33 of regulation 2017/745.
7. Article 16 of regulation 2017/745.

MANUFACTURER'S OBLIGATIONS RELATING TO ITS ORGANISATION

1. PERSONNE CHARGÉE DE VEILLER AU RESPECT DE LA RÉGLEMENTATION

Regulation 2017/745 specifies that the manufacturer must have at least one person responsible for regulatory compliance[8]. Depending on the size and turnover of the organisation, either this person must be part of the organisation or these duties can be outsourced.

> Regulation 2017/745 applies to any device manufacturer. Manufacturers established outside the European Union are therefore also concerned by the obligation to have a person responsible for regulatory compliance. They will not be able to delegate all their obligations to their authorised representative.

The person responsible for regulatory compliance must have the minimum skills and experience provided for in the regulation and must carry out specified tasks. The manufacturer must appoint a person who meets these conditions and register them in Eudamed.

→The MDCG (Medical Device Coordination Group) has produced a guide concerning the person responsible for regulatory compliance (MDCG 2019-7).

The MDCG guides are available on the following page: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

2. DESIGNATION OF AN AUTHORISED REPRESENTATIVE

If the manufacturer is not established within the European Union, it may place a device on the market of the Union provided that it has designated an authorised representative, established in the European Union, to perform certain tasks on its behalf. Regulation 2017/745 strictly regulates this mandate and stipulates in particular that:

- it must be accepted in writing by the authorised representative,
- it must cover at least all devices of the same generic device group of the manufacturer,
- it must provide for a sole authorised representative per product,
- it must provide for at least the list of tasks laid down in article 11(3) of regulation 2017/745,
- it must not entrust the authorised representative with any of the manufacturer's obligations listed exhaustively in article 11(4) of regulation 2017/745.

8. Article 15 of regulation 2017/745.

Tasks that the authorised representative must at least perform

- Verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
- Keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, at the disposal of 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 (15 years for implantable MDs).
- Register in the Eudamed database, keep this information up-to-date, confirm the accuracy of the information one year after registration and every second year thereafter and verify that the manufacturer has complied with its obligations to register products and systems in the UDI database and that the information is correct, complete and up-to-date
- In response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned
- Forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device
- Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or mitigate the risks posed by devices
- Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated
- Terminate the mandate if the manufacturer acts contrary to its obligations under the regulation

Tasks that the manufacturer must not entrust to the authorised representative

- Ensure that the devices it places on the market have been designed and manufactured in accordance with the requirements of this regulation
- Establish, implement, maintain and document a risk management system
- Perform a clinical evaluation, including post-market clinical follow-up
- Draw up and keep up-to-date the technical documentation to enable the evaluation of the conformity of the device with the requirements of this document
- Draw up an EU declaration of conformity and affix the CE marking of conformity
- Comply with the UDI system obligations and manufacturer and device registration obligations
- Ensure that procedures are in place to keep series production in conformity with the requirements of this regulation.
- Establish, document, implement, maintain, keep up-to-date and continually improve a quality management system that shall ensure compliance with the regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device
- Implement and maintain a post-market surveillance system
- Accompany the device with a label and instructions for use which comply with the regulation
- Immediately take the necessary corrective action, when it considers or has reason to believe that a device which it has placed on the market or put into service is not in conformity with the regulation, to bring it into conformity, to withdraw or recall it

In addition, the manufacturer must ensure that its authorised representative has the necessary documentation permanently available to fulfil its obligations [9].

→ The MDCG (Medical Device Coordination Group) has produced a guide concerning the authorised representative (MDCG 2022-16).

The MDCG guides are available on the following page: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

3. SUFFICIENT FINANCIAL COVERAGE

Regulation 2017/745 requires the manufacturer to have sufficient financial coverage in respect of its potential liability for defective products under Directive 85/374/EEC, without prejudice to more protective measures under national law [10]. This coverage is proportionate to the risk class, type of device and size of the enterprise.

4. QUALITY MANAGEMENT SYSTEM

Manufacturers of devices (other than investigational devices) must establish, document, implement, maintain, keep up-to-date and continually improve a quality management system that shall ensure compliance with the provisions of regulation 2017/745, in a manner that is proportionate to the risk class and the type of device [11].

The quality management system must address at least:

- a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system,
- identification of the general safety and performance requirements and exploration of options to address those requirements,
- responsibility of the management,
- resource management, including selection and control of suppliers and sub-contractors,
- risk management,
- clinical evaluation, including post-market clinical follow-up (PMCF),

9. Article 10 point 8 of regulation 2017/745.
10. Article 10 point 16 of regulation 2017/745.
11. Article 10 point 9 of regulation 2017/745.

- product realisation, including planning, design, development, production and service provision,
- verification of the unique device identification (UDI) to all relevant devices and ensuring consistency and validity of information provided,
- setting-up, implementation and maintenance of a post-market surveillance system,
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders,
- processes for reporting of serious incidents and field safety corrective actions in the context of vigilance,
- management of corrective and preventive actions and verification of their effectiveness,
- processes for monitoring and measurement of output, data analysis and product improvement.

Manufacturers must determine the cases in which their quality management system must be certified by a notified body.

5. REGULATORY MONITORING SYSTEM

The manufacturer must set up a monitoring process at European level in order to ensure that its device is designed and manufactured taking into account the state of the art, and that it is based on the correct legislation, whether existing harmonised standards published in the Official Journal of the European Union (OFEU) or common specifications and any implementing acts adopted by the European Commission.

6. ARCHIVING SYSTEM

The manufacturer must set up a system for archiving its technical documentation, the EU declaration of conformity and, where appropriate, any certificate of conformity issued by a notified body, including any amendments and supplements for a period of at least 10 years or 15 years if an implantable device is concerned, after the last device covered by the EU declaration of conformity has been placed on the market[12].

12. Article 10 point 9 of regulation 2017/745.

7. CONFIDENTIALITY

Finally, like all persons involved in the application of the regulation, the manufacturer is bound by an obligation of confidentiality concerning information and data obtained in carrying out its tasks in order to protect[13]:

- personal data,
- commercially confidential information and trade secrets, including intellectual property rights, unless disclosure is in the public interest,
- the implementation of the regulation, in particular for the purpose of inspections, investigations or audits.

8. COOPERATION WITH COMPETENT AUTHORITIES AND NOTIFIED BODIES

In general, economic operators, and therefore the manufacturer, must cooperate with the competent authorities, which may require, inter alia, that operators make available to them the necessary documentation and information to carry out their activities. The competent authorities may also require the provision of samples or access to devices free of charge. Finally, the competent authorities may carry out inspections, announced or unannounced, of the premises of economic operators, their suppliers and subcontractors, who must therefore welcome them and cooperate with them[14].

In addition, the manufacturer must cooperate with the competent authorities when they carry out an evaluation of the device with regard to the risk it presents or any other non-compliance, based on data obtained by vigilance, market surveillance activities or on other information[15].

Similarly the manufacturer must also cooperate with the notified body which evaluates or evaluated the compliance of its device and provide it, on request, with any information, document and access (to its premises, those of its suppliers and subcontractors) it may need to carry out its task.

13. Article 109 of regulation 2017/745.
14. Article 93 point 3 of regulation 2017/745.
15. Article 94 of regulation 2017/745.

MANUFACTURER'S OBLIGATIONS RELATING TO ITS DEVICES

1. MANUFACTURER'S OBLIGATIONS BEFORE PLACING DEVICES ON THE MARKET

→ 1.1 Status and classification of device

During the design process, the manufacturer must, for each device, define and document[16]:

- its indication,
- its intended purpose,
- its characteristics,
- it mode of action
- its operating principle

and deduce its risk class in accordance with annex VIII of regulation 2017/745.

→ 1.2 Applicable standards for design

The manufacturer must justify and document the design stages of its device. It must check its compliance with the requirements set out in Annex I of Regulation 2017/745 on general safety and performance requirements.

The manufacturer may benefit from a presumption of conformity if it complies with:

- the harmonised standards[17] relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up (PMCF),
- the harmonised standards and monographs of the European Pharmacopoeia relating to the device,
- the common specifications[18] adopted by the European Commission, which may be applicable to the device.

→ The list of harmonized standards under Regulation 2017/745 is available on the following page: https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

16. Article 51, and annex VIII of regulation 2017/745.
17. Article 8 of regulation 2017/745.
18. Article 9 of regulation 2017/745.

→ 1.3 Risk management

The manufacturer must ensure a system for risk management and update it periodically and systematically throughout the entire lifecycle of each device[19].

In order to carry out risk management, the manufacturer must:

- establish and document a risk management plan,
- identify and analyse the known and foreseeable hazards,
- estimate and evaluate the risks associated with the intended use and during reasonably foreseeable misuse,
- eliminate or control the risks whenever possible.

It may be based on the applicable harmonised standards published in the Official Journal of the European Union (OFEU) on risk management, compliance with which gives rise to a presumption of conformity. The principles to be applied for risk management are detailed in Annex I, sections 3 to 5 of regulation 2017/745.

→ 1.4 Manufacture and validation of device

During the production of each device, the manufacturer must carry out and follow procedures to ensure the conformity of the series production of its devices[20]. It must validate the manufacturing processes and define the complete specifications.

→ 1.5 Clinical evaluation

The manufacturer must produce a clinical evaluation to demonstrate, under the normal conditions of the intended use, conformity of the device with the general safety and performance requirements, evaluate the undesirable side-effects and decide on the benefit-risk ratio 20[21].

This clinical evaluation must be planned, documented and formalised in the form of a report included in the technical documentation. It must be based on sufficient clinical data and comply with the requirements laid down in annex XIV of regulation 2017/745.

19. Article 10, point 2 of regulation 2017/745.
20. Article 10 point 9 of regulation 2017/745.
21. Article 61 of regulation 2017/745.

The clinical assessment is based on (cumulative elements):

- a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device (provided it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate),
- a critical evaluation of the results of all available clinical investigations and
- a consideration of currently available alternative treatment options for that purpose, if any.

ATTENTION

The use of clinical data from a device considered equivalent is covered by the regulation. The device must be technically, biologically and clinically equivalent. Manufacturers wishing to base their clinical evaluation on the clinical data of an equivalent device must also be able to demonstrate that they have sufficient access to these data, and therefore to the device's technical documentation.

→ The MDCG (Medical Device Coordination Group) has drawn up a guide concerning equivalence in clinical evaluation (MDCG 2020-5).

The MDCG guides are available on the following page: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

In the case of implantable devices and class III devices, the manufacturer is obliged to perform clinical investigations except if (cumulative conditions):

Case n° 1

- the device has been designed by modifications of a device already marketed by the same manufacturer,
- the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device and this demonstration has been endorsed by the notified body, and
- the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements,
- the PMCF plan is appropriate and includes post-marketing studies to demonstrate the safety and performance of the device.

Case n° 2

- the manufacturer has demonstrated that the device is equivalent to a device already marketed and manufactured by a third party, in accordance with Section 3 of Annex XIV, and this demonstration has been approved by the notified body,
- the original clinical evaluation of the marketed device is sufficient to demonstrate conformity of the second device with the relevant safety and performance requirements
- the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis,
- the original clinical evaluation has been performed in compliance with the requirements of regulation 2017/745 and
- the PMCF plan is appropriate and includes post-marketing studies to demonstrate the safety and performance of the device.

Case n° 3

- the device was legally placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC
- the clinical evaluation is based on sufficient clinical data
- clinical evaluation complies with applicable common specifications where these exist

Case n° 4

- devices include sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors
- the clinical evaluation is based on sufficient clinical data
- clinical evaluation complies with applicable common specifications where these exist

→ The MDCG has drawn up a guide specifying the conditions for these exemptions and illustrating the notion of "sufficient access to data" as part of the demonstration of equivalence (MDCG 2023-7).

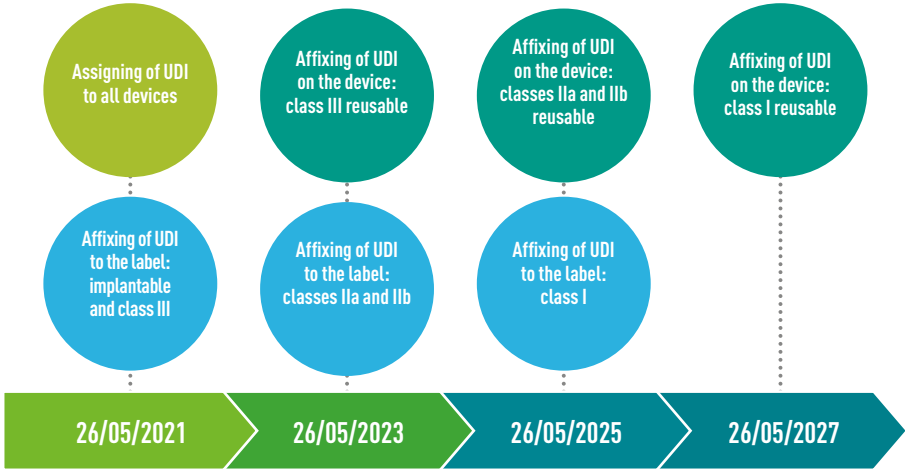
The MDCG guides are available on the following page: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

→ 1.6 Information supplied by the manufacturer

- Unique device identification (UDI)

The manufacturer must assign a UDI to each of its devices (except for custom-made devices) [22]. The UDI must be placed on the label of devices and on all higher levels of packaging (except shipping packaging) and, for reusable devices, on the device itself.
The UDI must also appear on the EU declaration of conformity, in the technical documentation and in the summary of safety and clinical performance where applicable.

If the assignment of a UDI to each device must be made by 20 May 2021, the affixing follows a specific timeline according to the risk class of the devices [23]:



22. Article 27 of regulation 2017/745.
23. Article 123 point 3 f) of regulation 2017/745.

• Label and instructions for use

The manufacturer must ensure that its devices are accompanied by labelling and, where applicable, instructions for use, which comply with the requirements of regulation 2017/745. These requirements are detailed in annex I of the regulation [24].

Instructions are not required for class I and IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in regulation 2017/745 [25].

• Summary of safety and clinical performance

Manufacturers of class III devices and implantable devices [26], except custom-made devices, must provide a summary of safety and clinical performance [27].

This summary must include at least the following aspects:
- the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number,
- the intended purpose of the device and any indications, contraindications and target populations,
- 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,
- possible diagnostic or therapeutic alternatives,
- reference to any harmonised standards and common specifications applied,
- the summary of clinical evaluation as referred to in annex XIV, and relevant information on post-market clinical follow-up,
- suggested profile and training for users,
- information on any residual risks and any undesirable effects, warnings and precautions.

This summary must be submitted to the notified body to be validated to obtain the CE marking. It must be incorporated into the technical documentation.

The summary is made available to the public via Eudamed [28].

24. Annex I point 23 d) of regulation 2017/745.
25. Annex I, point 23 d) of regulation 2017/745.
26. Except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.
27. Article 32 of regulation 2017/745.
28. This step depends on when the Eudamed base is made mandatory, in accordance with the deadlines set out in article 123 of the regulation

• Information accompanying implantable devices

The manufacturer of an implantable device[29] must provide together with the device the following[30]:

- identification of the device (name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer),
- warnings and precautions,
- the lifetime of the device and any necessary follow-up,
- the materials and substances to which patients can be exposed.

This information must be made available to the particular patient who has been implanted with the device. It must allow rapid access, written in the language or languages of the Member State concerned and readily understood by a lay person. Updates of the information must be made available to the patient via the manufacturer's website.

In addition, information regarding the identification of the device must be issued to the patient in the form of an implant card.

• Information accompanying custom-made devices

Any custom-made device must be accompanied by a statement drawn up by the manufacturer or its authorised representative [31]. The content of the statement is described in annex XIII of regulation 2017/745.

→ 1.7 Technical documentation

The manufacturer must draw up and keep up-to-date technical documentation for each of its devices [32]. The technical documentation must be such as to allow the conformity of the device with the requirements of regulation 2017/745.

This technical documentation must comply with the content laid down in annexes II and III of the regulation and contain, inter alia, the following parts:

• description and specifications of the device, including variants and accessories,

• information that must be supplied by the manufacturer,

29. Except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.
30. Article 18 of regulation 2017/745.
31. Article 21 point 2 of regulation 2017/745.
32. Article 10 point 4 of regulation 2017/745.

• information on the design and manufacture,

• general safety and performance requirements,

• benefit-risk determination and risk management,

• verification and validation of the product.

With regard to custom-made devices, the technical documentation is described in annex XIII of regulation 2017/745.

The technical documentation and the summary thereof must be presented in a clear, organised and unambiguous manner, in a readily searchable form.

The manufacturer must keep the technical documentation of each of its devices up-to-date.

→ 1.8 Conformity assessment

Prior to placing a device on the market or putting into service, manufacturers must undertake an assessment of the conformity of that device in accordance with the applicable conformity assessment procedures [33]. These procedures depend in particular on the risk class of the device.

Some of these procedures require the manufacturer to involve a notified body for the certification of its quality management system, the conformity of the technical documentation, or based on type examination.

After demonstrating the conformity of the device, the manufacturer must draw up an EU [34] declaration of conformity and affix the CE marking of conformity [35].

The EU declaration of conformity must be translated into a language or languages required by the Member State(s) in which the device is made available. It must comply with the minimum information content listed in annex IV of regulation 2017/745, and must be kept up-to-date.

33. Article 52 of regulation 2017/745.
34. Article 19 of regulation 2017/745.
35. Article 20 of regulation 2017/745.

The manufacturer must affix the **CE marking** to the device before it is placed on the market [36]. The CE marking must be affixed visibly, legibly and indelibly. Where applicable, it must be followed by the identification number of the notified body responsible for the conformity assessment procedures and this number must also be indicated in any promotional material which mentions that the device complies with the requirements for CE marking.

The CE marking must be affixed to the device itself if possible, to the packaging (including the sterile packaging of the device) and on the instructions for use.

The design to be used for the CE marking is defined in annex V of regulation 2017/745. It must not be less than 5 mm except for small-scale devices.

If the device is subject to other EU legislation which also provides for the affixing of the CE marking, the CE marking indicates that the device also fulfils the requirements of that other legislation.

Custom-made devices and devices under clinical investigation are not required to bear the CE marking.

→ 1.9 Registrations in the Eudamed base [37]

• Registration of manufacturer

In order to be able to place devices on the EU market, the manufacturer must register as a manufacturer in the Eudamed databased [38]. To do so, it must submit certain information listed in annex VI of regulation 2017/745.

The competent authority must then issue the manufacturer with a single registration number to be used when applying to a notified body for conformity assessment of a device.

• Registration of each device

By means of the single registration number, the manufacturer must register each device it places on the European Union market [39]. To do this, it must assign to each device a basic UDI-DI and forward it to the Eudamed database with the other information listed in annex VI of regulation 2017/745 (quantity per package, risk class, model or reference, dimensions, etc.).

36. Article 20 of regulation 2017/745.
37. These steps depend on when the Eudamed base is made mandatory, in accordance with the deadlines set out in article 123 of the regulation. Some modules of the Eudamed base have been made accessible, such as those for registering actors and devices. Use of these modules is initially voluntary.
Link to Eudamed : https://ec.europa.eu/tools/eudamed/#/screen/home
38. Article 30 of regulation 2017/745.
39. Article 29 of regulation 2017/745.

For class IIb and III devices [40], the basic UDI-DI must be assigned before submitting an application to a notified body to assess the conformity of the device insofar as the notified body must refer to the basic UDI-DI on the certificate it issues.

Manufacturers of custom-made devices do not have to register their devices in Eudamed, nor do they have to register themselves in this database if they are the only devices they place on the European market.

→ 1.10 Media and communications related to the device

The media and communications accessible to the user or patient (labelling, instructions, advertising) must not contain any element that may mislead the user or the patient with regard to the device's intended purpose, safety and performance [41].

With regard to this media, the manufacturer shall be prohibited from:

- ascribing functions and properties to the device which it does not have,
- creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have,
- failing to inform the patient or user of a likely risk associated with the use of the device in line with its intended purpose,
- suggesting uses for the device other than those stated for which the conformity assessment was carried out.

40. Except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.
41. Article 7 of regulation 2017/745.

2. MANUFACTURER'S OBLIGATIONS AFTER PLACING DEVICES ON THE MARKET

→ 2.1 Traceability obligations

Regulation 2017/745 requires manufacturers to cooperate with importers and distributors to achieve an appropriate level of traceability of devices [42].

• Identification of operators within the supply chain

Manufacturers must be able to identify, for a period of 10 years for all non-implantable devices and for 15 years for implantable devices after the last device has been placed on the market [43]:

- any economic operator to whom they have directly supplied a device,
- any economic operator who has directly supplied them with a device,
- any health institution or healthcare professional to which they have directly supplied a device.

• Product traceability

The manufacturer must maintain an up-to-date list of all UDIs it has assigned and indicate all UDIs in the technical documentation of the device [44].

In addition, the manufacturer must store and keep, preferably by electronic means, the UDI of any class III implantable device it has supplied or with which it has been supplied [45].

→ 2.2 Post-market surveillance

• Post-market surveillance system

The manufacturer must have a post-market surveillance system based on a post-market surveillance plan[46]. The content of the technical documentation for post-market surveillance is defined in annex III of regulation 2017/745.

42. Article 25, point 1 of regulation 2017/745.
43. Article 25 point 2 of regulation 2017/745.
44. Article 27 point 7 of regulation 2017/745.
45. Article 27 point 8 of regulation 2017/745.
46. Articles 83 and 84 of regulation 2017/745.

The post-market surveillance system must enable the manufacturer to collect, record and analyse, in an active and systematic way, relevant data on the quality, performance and safety of a device throughout its lifetime. If, on the basis of these data, the manufacturer decides to apply preventive and/or corrective measures, it must inform the relevant competent authorities and, where appropriate, the notified body and must monitor these measures.

The manufacturer must implement communication tools with distributors and, where applicable, importers and its authorised representative(s), for the reporting of complaints, devices not in conformity and recalls and withdrawals and the implementation of corrective actions.

• Use of data from post-market surveillance

The manufacturer must use the data collected under the post-market surveillance system in particular:

- to update the benefit-risk determination and to improve the risk management,
- to update the design and manufacturing information, the instructions for use and the labelling,
- to update the clinical evaluation,
- for the identification of needs for preventive, corrective or field safety corrective action,
- for the identification of options to improve the usability, performance and safety of the device,
- when relevant, to contribute to the post-market surveillance of other devices,
- to detect and report trends.

The manufacturer must update the technical documentation of the device using data gathered as a result of the post-market surveillance system.

For implantable and class III devices, the manufacturer must also use this data to update the summary of safety and clinical performance.

• Report

For class I devices, the manufacturer must prepare a post-market surveillance report based on the data from the post-market surveillance system [47]. This is a summary of the results and conclusions of the analyses of the post-market surveillance data collected as a result of the post-market surveillance plan. This summary must also include the description and rationale of any preventive and corrective actions taken.

47. Article 85 of regulation 2017/745.

The report must be updated when necessary and made available to the competent authority upon request.

For class IIa, IIb and III devices, the manufacturer must prepare a periodic safety update report (PSUR)[48]. This is a summary of the results and conclusions of the analyses of the post-market surveillance data collected as a result of the post-market surveillance plan. This summary must also include the description and rationale of any preventive and corrective actions taken. The PSUR is part of the technical documentation of the device. Throughout the lifetime of the device concerned, it must set out:

- the conclusions of the benefit-risk determination,
- the main findings of the post-market clinical follow-up (PMCF),
- the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

The PSUR must be updated at least annually for class IIb and III devices. It must be updated when necessary and at least every two years for class IIa devices.

→ 2.3 Vigilance

• Recording and reporting incidents

The manufacturer must have a system for recording and reporting of incidents and field safety corrective actions[49]. Via Eudamed [50] it must report, to the relevant competent authorities, within a time limit taking into account the severity of the incidents [51]:

- any serious incident involving devices made available on the European Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to article 88 of the regulation,
- any field safety corrective action in respect of devices made available on the European Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

48. Article 86 of regulation 2017/745.
49. Article 10 point 13 of regulation 2017/745.
50. This step depends on when the Eudamed base will be operational. In the meantime, operators are using the means and formats provided for by the Directives and transposed by the Member States.
51. Article 87 of regulation 2017/745.

The manufacturers must also report, by means of Eudamed [52], any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that 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 or users. This will be covered by trend reporting [53].

- **Analysis of incidents and corrective actions**

It must perform the necessary investigations following reporting of a serious incident and send the competent authority, via Eudamed [54], a final report setting out the findings from the investigation and, where relevant indicate corrective actions to be taken [55].

The manufacturer must be capable of immediately taking the necessary corrective actions to bring a non-conforming device into conformity, to withdraw it or to recall it and to inform the relevant economic operators [56].

52. This step depends on when the Eudamed base will be operational. In the meantime, operators are using the means and formats provided for by the Directives and transposed by the Member States.
53. Article 88 of regulation 2017/745.
54. This step depends on when the Eudamed base will be operational. In the meantime, operators are using the means and formats provided for by the Directives and transposed by the Member States.
55. Article 89 of regulation 2017/745.
56. Article 10 point 12 of regulation 2017/745.

ADAPTATION OF NATIONAL LEGISLATION

Although a European regulation is directly applicable in all member states, national provisions are nevertheless necessary, firstly to bring national law into conformity with the new regulation, and secondly to take the measures called for or left to the states by the regulation.

In France, these provisions were enacted by Ordinance no. 2022-582 of April 20, 2022 adapting French law to the MDR (slightly modified by Ordinance no. 2022-1086 of July 29, 2022 adapting French law to the IVDR), and by Law no. 2023-171 of March 9, 2023 containing various provisions for adaptation to European Union law in the fields of economics, health, labor, transport and agriculture (law ratifying the aforementioned ordinances). These legislative provisions will be supplemented by regulatory texts.

In addition, other national provisions may exist in fields not covered by European regulations. This is the case in France, with provisions concerning risks of breakage, advertising, etc.

PENALTIES INCURRED

Regulation 2017/745 leaves it to the Member States to determine the penalties applicable to infringements of its provisions [57].
In France, the two ordinances adapting national law to the MDR and IVDR, and the law ratifying them, have updated the applicable sanctions regime.
The ratifying law also added sanctions that can be imposed by the DGCCRF within its sphere of competence [58].
Breaches and penalties are set out in articles L.5461-1 to L.5461-8 (criminal penalties) and L.5461-9 (financial penalties) of the French Public Health Code (Code de la santé publique).

57. Article 113 of regulation 2017/745.

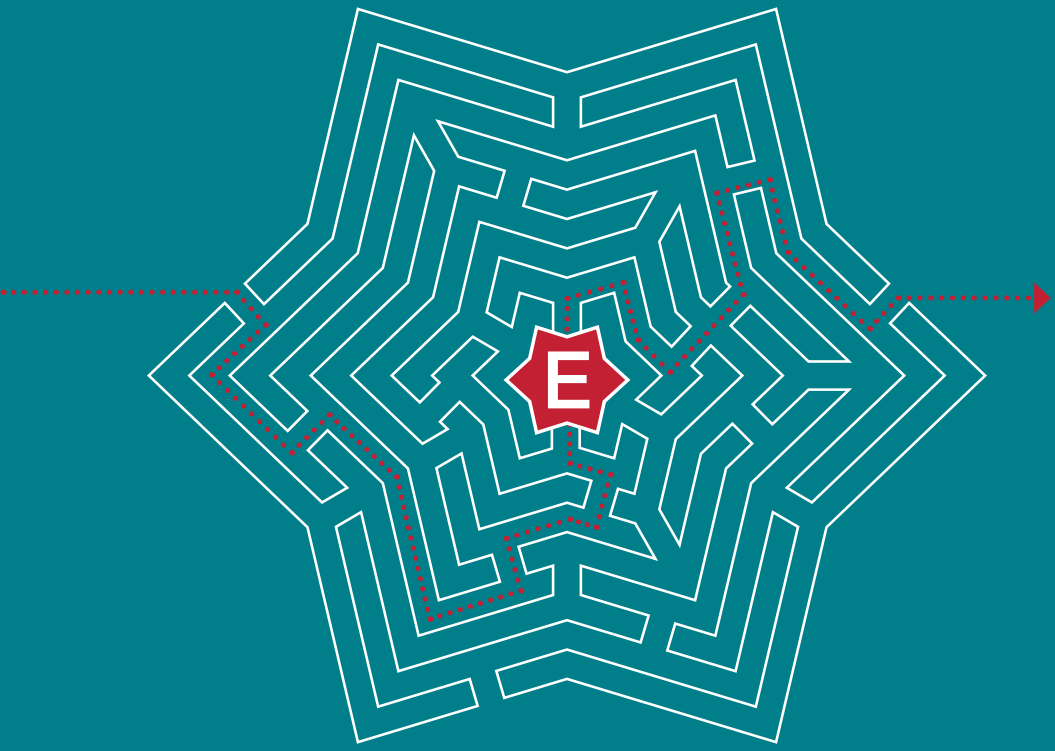
58. The DGCCRF is responsible for post-market surveillance and market surveillance of devices intended for direct use by consumers or by professional users, other than healthcare professionals, as part of a service intended for consumers (Article L.5211-2, II of the CSP).

TIMELINE

Regulation 2017/745 was published on 5 May 2017 and entered into force on 26 May 2017. It was expected to enter into force three years later, on 26 May 2020, except for certain provisions for which an earlier (e.g. for notified bodies and competent authorities) or later (e.g. for the UDI) date of application is foreseen. In the context of the covid-19 health crisis, the date of application of the regulation has been postponed to 26 May 2021[59]. Please note that the specific calendars (grace period, staggered calendar for the application of the IUD, etc.) are not postponed.

A transitional period is provided for, during which certain devices complying with Directives 90/385/EEC and 93/42/EEC may be placed on the market even though the date of application of the regulation has passed [60]. This transitional period was revised a first time in December 2019 by a corrigendum to the regulation allowing Class I devices requiring, under MDR, the intervention of a notified body in the conformity assessment procedure to benefit from the transitional provisions. It was amended a second time by regulation no. 2023/607 of March 15, 2023[62] to extend the period for certifying legacy devices under the MDR to the end of 2027 and 2028, depending on their risk class. However, even for products benefiting from this transitional period, the following provisions of the MDR are immediately applicable from May 26, 2021: the requirements for post-market surveillance, market surveillance, vigilance and registration of economic operators and devices [61].

59. Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regard the dates of application of certain of its provisions.
60. Article 120 of regulation 2017/745 as amended by the 2nd corrigendum (December 2019).
61. Article 120 point 3 of regulation 2017/745. Some steps depend on when the Eudamed base is made mandatory, in cordance with the deadlines set out in article 123 of the regulation. In the meantime, operators are using the means and formats provided for in the Directives and transposed by the Member States.
62. Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.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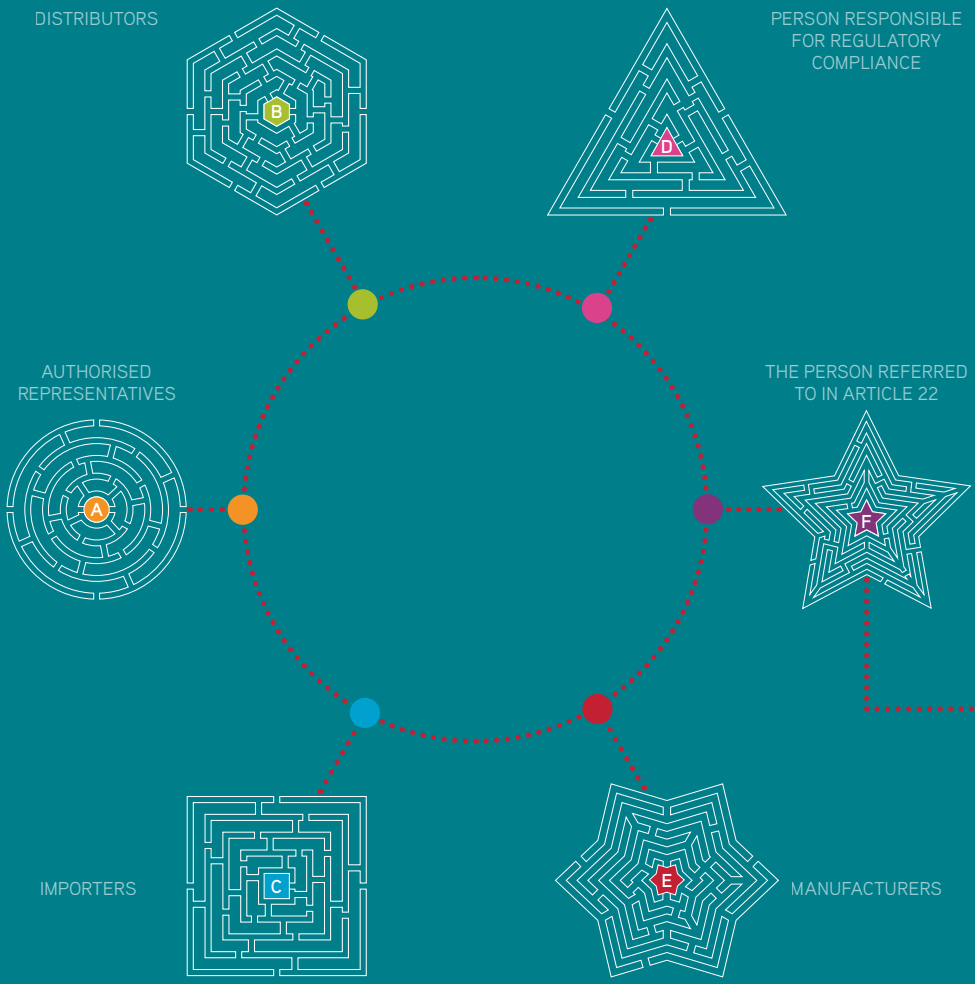

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