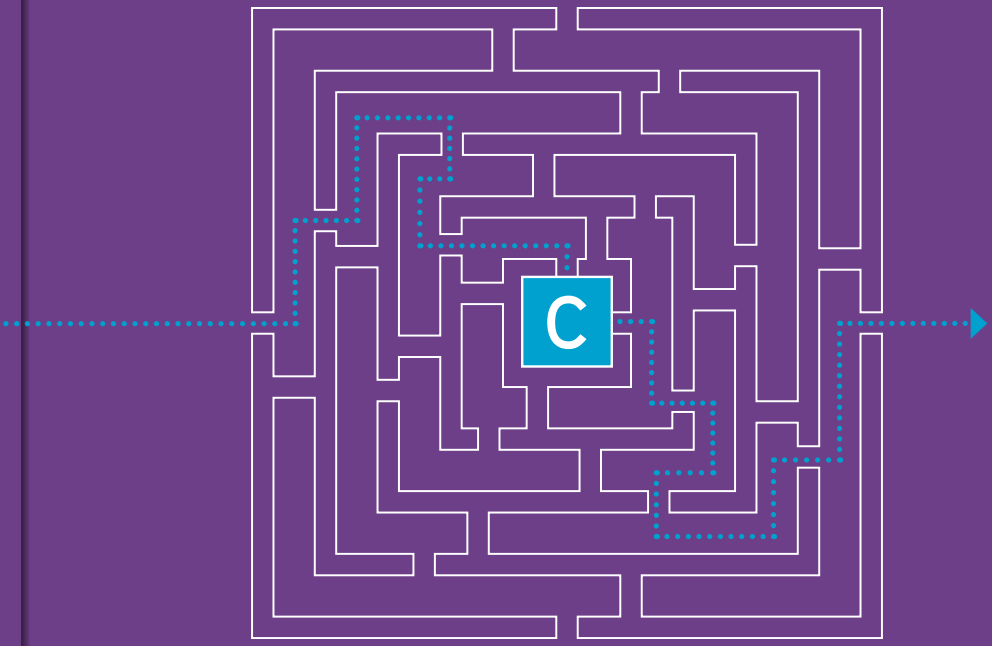
REGULATION

IMPORTERS
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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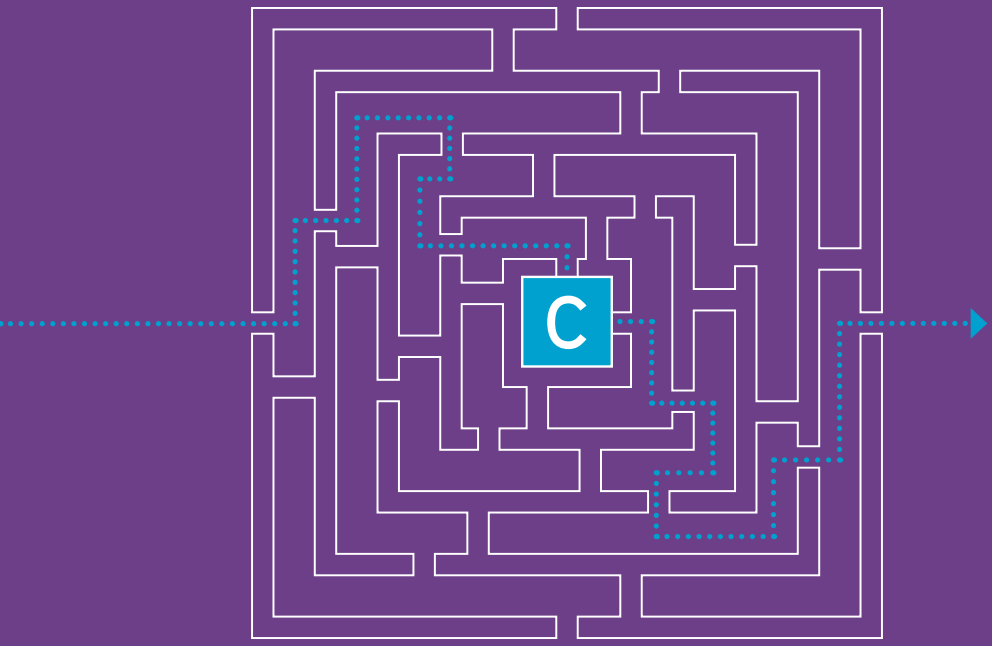

This document is likely to change over time: SNITEM will regularly update the information herein.

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CONTENTS

SYNTHESIS OF OBLIGATIONS OF IMPORTERS

Before placing a device on the market		Ref.[1]
Conformity	Importers shall only place devices in conformity with the Regulation on the market.	Art. 13.1
Eudamed registration	Importers shall register in Eudamed and then shall keep the information updated within one week of any change occurring.	Art. 31.1 and 31.4
	Importers shall verify that the device has been registered in the UDI database by the manufacturer and shall add their contact details to this registration.	Art. 13.4
Verification	Importers shall verify that the following requirements are met: • the device has been CE marked and the EU declaration of conformity of the device has been drawn up in the languages of the Member States in which the importer plans to place the device on the market, • a manufacturer is identified and has designated an authorised representative in accordance with article 11, • the device is labelled in accordance with the Regulation and accompanied by the required instructions for use, • where applicable, a UDI has been assigned to the device by the manufacturer in accordance with article 27.	Art. 13.2
	Importers shall ensure that storage and transport conditions do not jeopardise the safety and performance of the device and are compliant with the conditions set by the manufacturer.	Art. 13.5
Addition of information	Importers shall add to the device, its packaging or a document accompanying the device: their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted.	Art. 13.3
Reporting	Where an importer considers that a device is not in conformity, it shall inform the manufacturer and the manufacturer's authorised representative and shall only place the device on the market once it has been brought into conformity. The importer shall also inform the competent authority of the Member State in which the importer is established in the event of a serious risk or falsified device.	Art. 13.2

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.

After placing a device on the market		Ref.[2]
Verification	Within two weeks of placing a device on the market, importers shall verify that the manufacturer or authorised representative has provided to Eudamed the information enabling them to be identified. Importers shall inform the manufacturer or authorised representative if the information is not included or is incorrect.	Art. 30.3
Product traceability	Importers shall store and keep, preferably by electronic means, the UDI of class III implantable devices which they have supplied or with which they have been supplied.	Art. 27.8
	Importers shall keep a copy of the EU declaration of conformity and a copy of any relevant certificate for 10 or 15 years at least after the last device concerned has been placed on the market.	Art. 13.9
	Importers shall be able to identify any economic operator to whom they have directly supplied a device, who has directly supplied them with a device and any health institution or healthcare professional to which they have directly supplied a device.	Art. 25.2
Market surveillance	Importers who consider that a device which they have placed on the market is not in conformity with the Regulation shall immediately inform the manufacturer and its authorised representative, and shall cooperate to ensure that the necessary action is taken. They shall inform the competent authority and the notified body if the device presents a serious risk.	Art. 13.7
	Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals. They shall provide information to other economic operators at their request in order to allow them to investigate complaints.	Art. 13.6
	Importers who have received complaints or reports from healthcare professionals, patients or users related to or possibly related to a device they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.	Art. 13.8

2. 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.

After placing a device on the market (after) — Ref.[3]

Corrective action	Importers shall take the appropriate corrective action when a competent authority identifies an unacceptable risk to health or safety.	Art. 95.1
	Where a non-conformity does not present an unacceptable risk to health or safety, importers shall bring the non-compliance to an end within a reasonable period that is clearly defined.	Art. 97.1
	Importers shall cooperate with competent authorities on any action taken to eliminate or mitigate the risks posed by devices which they have placed on the market. They shall provide competent authorities with free samples of or access to the device.	Art. 13.10
	Importers shall cooperate with the competent authorities when the latter carry out an evaluation of the device.	Art. 94

Continuously — Ref.[3]

Confidentiality	Importers are under an obligation of confidentiality regarding: • personal data, • commercially confidential information and trade secrets, including intellectual property rights, unless disclosure is in the public interest, • implementation of the Regulation, in particular for the purpose of inspections, investigations or audits.	Art. 109
Cooperation	General obligation to cooperate with the competent authorities that may require importers to make available documentation, information, samples of or access to a device or to carry out inspections of their premises.	Art. 93.3

3. 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.

CHECKLIST: BECOMING AN IMPORTER OF DEVICES IN THE EU

Does the operator meet the requirements and does it have the necessary tools?

01 The operator shall meet the definition of importer in the Regulation

Location

The operator is established in the European Union

Activity

- The operator buys devices that are compliant with the Regulation from a manufacturer established outside the European Union
- The operator places these devices on the EU market

Beware of certain activities that make the operator switch over to manufacturer status (cf. page 9).

02 The operator shall be in a position to fulfil all the obligations applicable to importers

Personnel

- L'opérateur dispose des ressources nécessaires pour effectuer les tâches prévues par le règlement
- L'opérateur a prévu un système de back-up

Processes for...

- the verification of products and the documentation accompanying them
- product traceability
- the addition of its information on the device
- market surveillance
- the reporting of non-conformities, complaints, reports, etc.

Processes shall be documented and applied: the operator shall be able to prove at any time that it meets the obligations laid down by the Regulation.

Tools

- Identification of any player that may have to be contacted (person to contact and contact details):
  - Manufacturer, authorised representative, distributors
  - Competent authorities of Member States in which the devices are imported
  - Notified body where applicable
- Databases to store and keep documentation, traceability information and the UDI where applicable
- Identification of Member States' specific traceability and registration requirements for UDIs
- Identification of the languages in which documents, leaflets, labelling and implant cards must be provided

03 The operator shall be registered as an importer in Eudamed

(this stage depends on the date on which the Eudamed database will be made mandatory, in accordance with the deadlines set out in article 123 of the regulation)

Registration	As an importer (type of economic operator, name, address, contact details)
Updating	This information within one week after any change

Has the operator formalised its links with its commercial partners?

! The operator shall have formalised a contract with the manufacturer and the potential distributor(s)

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

TEXTS AND REFERENCE 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.

3. The MDCG (*Medical Device Coordination Group) has drawn up a guide for importers and distributors, revised in December 2023 (MDCG 2021-27 rev.1).*

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

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)

TERMS OF REFERENCE

1. DEFINITION OF IMPORTER IN THE REGULATION 2017/745 (MDR)

The Regulation defines an importer as "any natural or legal person established within the Union that places a device from a third country on the Union market"[5]. "Placing on the market" means the **first** making available of a device on the Union market[6].

→ **If you bring a device into the European Union for the first time, you are therefore an importer.**

An importer is an "economic operator" within the meaning of the MDR, which means a manufacturer, an authorised representative, an importer, a distributor, a person who combines devices and the person who sterilises systems or procedure packs[7]. All the provisions of the Regulation referring to economic operators are therefore applicable to importers.

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2. WHAT STATUS FOR AN ENTERPRISE THAT IS BOTH AN IMPORTER AND A DISTRIBUTOR FOR THE SAME DEVICE?

An importer brings a device into the EU for the first time and distributes it in the territory. Its activity is therefore similar to that of a distributor. However, its importer status takes precedence and it shall be considered as such for this device and not as a distributor. The Regulation defines a distributor as "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"[8]. "Making available on the market" means **any supply** of a device for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge[9].

So, for the same device (for each batch or each product depending on the distribution channel), an operator cannot be an importer and distributor:

- either this involves a first making available on the market and the operator therefore has the status of **importer,**

5. Article 2(33) of the MDR.
6. Article 2(28) of the MDR.
7. Article 2(33) of the MDR.
8. Article 2(34) of the MDR.
9. Article 2(27) of the MDR.

- or the first making available has already been carried out by an importer and the operator then has the status of **distributor.**

3. CASES IN WHICH OBLIGATIONS OF MANUFACTURERS APPLY TO IMPORTERS

The Regulation holds that certain activities, when accomplished by a distributor, an importer or other persons, oblige these persons to meet the obligations incumbent on the manufacturer[10].

→ 3.1 The importer provides information or changes the packaging **of the device**

The importer can provide a label and/or instruction leaflet, including their translation, relating to a device already placed on the market, as well as further information which is necessary in order to market the device in the relevant Member State [11].

The importer can also change the outer packaging of a device already placed on the market if the repackaging is necessary in order to market the device in the relevant Member State [12]. This repackaging must not affect the original condition of the device.

In both these cases, the importer shall[13]:

- have a quality management system certified by a notified body ensuring that:
  - the activities performed on the device are done so by a means and under conditions that preserve the original condition of the device,
  - the translation of information is accurate and up to date,
  - the packaging of the repackaged device is not defective, of poor quality nor untidy,
  - the importer is informed of any corrective action taken by the manufacturer in relation to the device in question;
- indicate on the device or, where that is impracticable, on its packaging or on a document accompanying the device, the activity carried out on the device together with its name and address at which it can be contacted;
- inform the manufacturer and the competent authority of the Member State in which they plan to make the device available, at least 28 days prior to making it available, of their intention to make the relabelled or repackaged device available and provide them with a sample or mock-up of the relabelled or repackaged device upon request ;

10.Article 16 of the MDR.
11. Article 16(2)(a) of the MDR.
12.Article 16, point b) of the MDR.
13. Article 16(3) & (4) of the MDR.

- within the same period of time, submit to the competent authority a certificate, issued by a notified body designated for the type of devices in question, attesting that the quality management system of the distributor is compliant with requirements.

If relabelling or repackaging are carried out in accordance with these requirements, these activities will not make the importer change status to that of manufacturer. On the other hand, if one of the requirements is not met, the operator must fulfil all the obligations applicable to manufacturer status.

PLEASE NOTE

Before placing a device on the market, importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registed trade mark, their registered place of business and the address at which they can be contacted [14]. The information on the label provided by the manufacturer must not be obscured by the information added by the importer. This addition of information does not switch the importer over to manufacturer status. It adds this information to comply with an obligation on importers.

→ 3.2 The importer makes a device available on the market under its name or modifies a device or changes its intended purpose

The Regulation provides for three cases in which an importer has to assume the obligations applicable to the manufacturer[15]. Firstly, where the importer makes available on the market a device under its name, registered trade name or registered trade mark, **except in cases where an importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers.**

Next, the case where an importer changes the intended purpose of a device already placed on the market or put into service.

And lastly where an importer modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

14. Article 13(3) of the MDR.
15. Article 16(1) of the MDR.

MISSIONS AND OBLIGATIONS OF IMPORTERS

1. OBLIGATIONS OF IMPORTERS BEFORE PLACING A DEVICE ON THE MARKET

Distributors are personally responsible for complying with their obligations. Even if they choose to delegate certain tasks, they remain responsible for ensuring that they are carried out properly, and therefore that they comply with the regulations.

→ 1.1 General obligation of placing devices compliant with the Regulation on the market

As from application of the Regulation, importers shall place on the market only devices that are in conformity with the Regulation [16], except in cases where these devices benefit from the transition period (cf. article 120 paragraph 3).

This general obligation of importers may be mentioned in a contract with a manufacturer or a distributor as an undertaking on the part of the importer. However, this undertaking shall not prevent the joint contracting party from having to carry out all the verifications that the Regulation requires it to do.
For example, despite the importer's undertaking to place devices in conformity with the Regulation on the market, the distributor will have to verify that the device is CE marked and that the declaration of conformity has been drawn up, that it is labelled and accompanied by an instruction leaflet in the languages of the Member States in which the importer shall place the devices on the market, that there is a UDI where applicable and that the importer features on the labelling[17].

→ 1.2 Obligation to register in Eudamed [18]

Importers shall register in Eudamed before placing a device, other than a custom-made device, on the market [19]. Importers shall keep the information concerning them up to date and shall make any changes within one week of any change occurring.

16. Article 13(1) of the MDR.
17. See the sheet for distributors to find all the obligations that are applicable to them.
18. This step depends on the date on which the Eudamed database will be made mandatory, in accordance with the deadlines set out in Article 123 of the Regulation. Certain modules of the Eudamed database have been made accessible, in particular those relating to the registration of actors and devices. Use of these modules is initially voluntary. Link to Eudamed: https://ec.europa.eu/tools/eudamed/#/screen/home
19. Article 31 of the MDR. The information to be submitted is listed in Annex VI, part A, point 1 of the MDR.

Furthermore, not later than one year after submission of the information, and every second year thereafter, the importer shall confirm the accuracy of the data.

After verifying that the device has been registered by the manufacturer in the UDI database, importers shall also add their details to the registration [20].

→ 1.3 Aspects to be verified by importers

• Regarding the device

Before placing a device on the market importers shall verify that [21]:

- the device is CE marked,

- the EU declaration of conformity has been drawn up in the languages of the Member States in which the importer plans to make the device available,

- the manufacturer is identified and has designated an authorised representative,

- the device is labelled in accordance with the provisions of the Regulation and accompanied by the required instructions for use,

- where applicable, the manufacturer has assigned a UDI to the device in accordance with the provisions of the Regulation.

Importers must be able to prove that they have fulfilled these obligations and therefore that they have carried out these checks, for example by having set up a verification procedure for all the products they intend to place on the market. Unlike distributors, importers cannot fulfil these verification requirements by sampling. Importers may ask the manufacturer for a provision to be made in the contract binding them stating that the manufacturer agrees to provide any information and any document enabling the importer to fulfil its verification obligations.

• Regarding transport and storage of the device

Importers shall ensure that the storage or transport conditions of the device, while under their responsibility, do not jeopardise its conformity in terms of safety and performance and meet the requirements that may be set by the manufacturer [22].

20.Article 13(4) of the MDR.
21. Article 13(2) of the MDR.
22.Article 13(5) of the MDR.

The importer must therefore clearly identify whether the manufacturer has laid down any specific storage and/or transport conditions of devices, and may include a reference to these in the contract with the manufacturer or in any other contractual document.
Furthermore, in its contract with the manufacturer and, where applicable, in his contract with a distributor, the importer shall state exactly from which moment and up until when the products are legally its responsibility and therefore for which period it is answerable for those conditions. Importers would be well advised to ensure that their responsibility ceases when they are no longer in control of the devices and consequently of their transport and/or storage conditions.

→ 1.4 Obligations in terms of reporting

If an importer considers or has reason to believe that a device is not in conformity, it shall only place this device on the market once it has been brought into conformity. It shall inform the manufacturer and its authorised representative thereof and it shall also inform the competent authority of the Member State in which the importer is established in the case of a serious risk and if it has reason to believe that the device is a falsified device [23].

→ 1.5 Information to be added to the device[24]

Importers shall add to the device, its packaging or a document accompanying the device[25]:

- their name,
- their registered trade name or registered trade mark,
- their registered place of business,
- the address at which they can be contacted.

The information on the label provided by the manufacturer must not be obscured by the information added by the importer[26].

Warning: any other action to change the packaging is liable to make the importer switch over to manufacturer status and consequently to have to meet all the obligations applicable to manufacturers[27].

23. Article 13(2) of the MDR.
24. Article 13(3) of the MDR.
25. The MDCG 2021-27 guide specifies that a 'document accompanying the device' is a document that the importer is certain will reach the end user. The ANSM also states in the FAQ available on its website that a delivery note or invoice are not suitable media for including the importer's name.
26. Article 13(3) of the MDR, second sentence.
27. See pages 9 and 10 of this booklet.

2. OBLIGATIONS OF IMPORTERS AFTER PLACING A DEVICE ON THE MARKET

→ 2.1 Aspects to be verified by importers

Within two weeks of placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or its authorised representative has provided to Eudamed the information that is necessary to identify the manufacturer of the device or its authorised representative [28]. If it sees that the information has not been registered or is incorrect, the importer shall inform the manufacturer or its authorised representative thereof. Importers shall add their details to the relevant entry/entries.

→ 2.2 Obligations in terms of traceability

The Regulation increases traceability requirements and includes therein all the links in the distribution channel. The MDR consequently holds that importers shall cooperate with manufacturers or their authorised representative in order to achieve an appropriate level of traceability of devices [29].

• Identification of links in the distribution channel upstream and downstream

Importers shall be able to identify to the competent authority, for a period of 10 years for all non-implantable devices and 15 years for implantable devices after the last device in question has been placed on the market [30]:

- 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.

• Keeping documents

Importers shall keep for a period of 10 years for all non-implantable devices and 15 years for implantable devices after the last device referred to by the EU declaration of conformity has been placed on the market [31]:

- a copy of the EU declaration of conformity,
- where applicable, any relevant certificate, including any amendments and supplements.

28. Article 30(3) of the MDR. This step depends on the date on which the Eudamed database will be made mandatory, in accordance with the deadlines set out in Article 123 of the Regulation.
29. Article 25(1) of the MDR.
30. Article 25(2) of the MDR.
31. Article 13(9) of the MDR.

This is a general obligation of the importer, which is not related to the contractual bond that the importer may have with the manufacturer of products that it imports. This obligation may therefore live on beyond the contract and regardless of whether thecontractual relationship with the manufacturer continues or not.
National provisions or company policies may involve keeping certain documents beyond this period of time (for example in case of liability because of faulty products).

• Storage and keeping of UDI

When class III implantable devices are concerned, the Regulation holds that economic operators shall store and keep, preferably by electronic means, the UDI of devices which they have supplied or with which they have been supplied [32]. The European Commission may, by means of an implementing act, extend this obligation to other categories or groups of devices.

To fulfil their obligations in terms of traceability, importers will have to set up a database enabling them to save and to keep the information required.

→ 2.3 Obligations in terms of market surveillance

• Reporting to the manufacturer and the authorised representative

Importers who have received complaints or reports from healthcare professionals, patients or users related to or possibly related to a device they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative [33].
Importers that consider or have reason to believe that a device which they have placed on the market is not in conformity with the Regulation shall immediately inform the manufacturer and its authorised representative thereof and shall cooperate with them and with the competent authority to ensure that corrective action be taken [34]. When a device presents a serious risk, the importer shall also immediately inform the competent authorities of the Member States in which it has placed the device on the market and, where applicable, the notified body.

32. Article 27(8) of the MDR.
33. Article 13(8) of the MDR.
34. Article 13(7) of the MDR.

As this reporting has to be carried out **immediately** by the importer, it is important that the manufacturer, its authorised representative and the importer provide the name and contact details of the persons that the importer has to inform and that this information is updated and that they ensure a back-up system is set up on all sides.

• **Keeping a register**

Furthermore importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals. They shall provide the manufacturer, its authorised representative and distributors with any information, at their request, to allow them to proceed with investigating these complaints [35].

→ 2.4 Obligations in terms of corrective action

Where, having performed an evaluation of a device suspected of presenting an unacceptable risk or a non-compliance, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the device concerned, its authorised representative and all other relevant economic operators **to take all appropriate and duly justified corrective action,** in a manner that is proportionate to the nature of the risk, to bring the device into compliance with the requirements of the MDR relating to the risk, to restrict the making available of the device on the market, to subject the making available to specific requirements, to withdraw the device from the market or to recall it within the period defined [36]. The importer shall also immediately make sure that any corrective action is taken for all the devices that it has made available on the EU market [37].

Where, having performed an evaluation in this same context, the competent authorities find that a device does not comply with the MDR but does not present an unacceptable risk, they shall require the relevant economic operator **to bring the non-compliance** to an end within a clearly defined period [38].

Furthermore, importers shall cooperate with the competent authorities, at their request, on any action taken to eliminate or mitigate the risks posed by devices which they have placed on the market [39].

35. Article 13(6) of the MDR.
36. Article 95(1) of the MDR.
37. Article 95(3) of the MDR.
38. Article 97(1) of the MDR.
39. Article 13(10) of the MDR. This obligation to cooperate is taken for all economic operators from article 93 of the MDR so that the competent authorities can fulfil their market surveillance obligations.

3. OTHER OBLIGATIONS ON IMPORTERS CONTINUOUSLY

Importers are also under other obligations that apply to all the economic operators (manufacturers, authorised representatives, importers, distributors, etc.) throughout their activity.

→ 3.1 General obligation of cooperation with the competent authorities

Generally speaking, economic operators, and therefore importers, shall cooperate with the competent authorities which may require economic operators to, inter alia, make available the documentation and information necessary for the purpose of carrying out the authorities'market surveillance activities. The competent authorities may also require the free provision of samples or access to a device. Lastly, the competent authorities may carry out both announced and unannounced inspections of the premises of economic operators who must consequently receive them and cooperate with them [40].

Furthermore, importers, as economic operators within the meaning of the MDR, shall cooperate with the competent authorities when these authorities carry out an evaluation of the device concerning the risk it presents or any other non-conformity, based on data obtained by vigilance, market surveillance or on other information [41].

> Mention could be made in the contract between the manufacturer and the importer or between the importer and distributor that the latter undertake to cooperate with the competent authorities, and in particular to provide any document or information but also any sample or any access to the device that the authorities may require of it and also to receive any visit or inspection.

→ 3.2 Confidentiality

Lastly, like all persons involved in the application of the Regulation, importers are bound by an obligation of confidentiality concerning [42]:

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

40. Article 93(3) of the MDR.
41. Article 94 of the MDR.
42. Article 109 of the MDR.

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

The Regulation leaves it up to the Member States to lay down the rules on penalties applicable for infringement of its provisions [43].
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[44].
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).

43. Article 113 of the MDR.

44. 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

The Regulation was published on 5 May 2017 and came into force on 26 May 2017. Its date of application was scheduled three years afterwards, i.e. 26 May 2020, except for certain provisions for which an earlier date of application (for example for the notified bodies and competent authorities) or a later one (for example for the UDI) is scheduled. In the context of the covid-19 health crisis, the date of application of the regulation has been postponed to 26 May 2021[45]. Please note that the specific calendars (grace period, staggered calendar for the application of the IUD, etc.) are not postponed.

A transitional period is planned during which certain devices complying with Directives 90/385/EEC and 93/42/EEC can be placed on the market even though the date of application of the Regulation has gone by [46]. 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 [47] 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 relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and of devices [48].

→ The MDCG 2021-25 guidance document sets out the requirements of the regulation applicable to legacy devices and devices placed on the market before 26 May 2021.

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

45. 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.
46. Article 120 of the MDR as amended by the 2nd corrigendum (December 2019).
47. 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.
48. Article 120(3) of the MDR. Some steps depend on when the Eudamed base will be operational. In the meantime, operators are using the means and formats provided for in the Directives and transposed by the Member States.

NOTES

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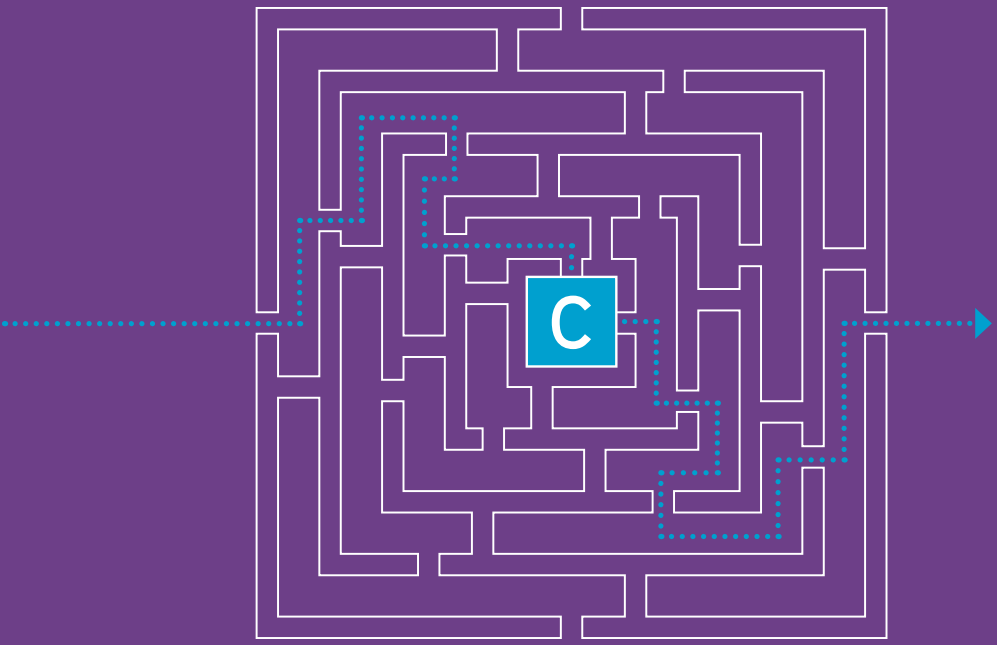
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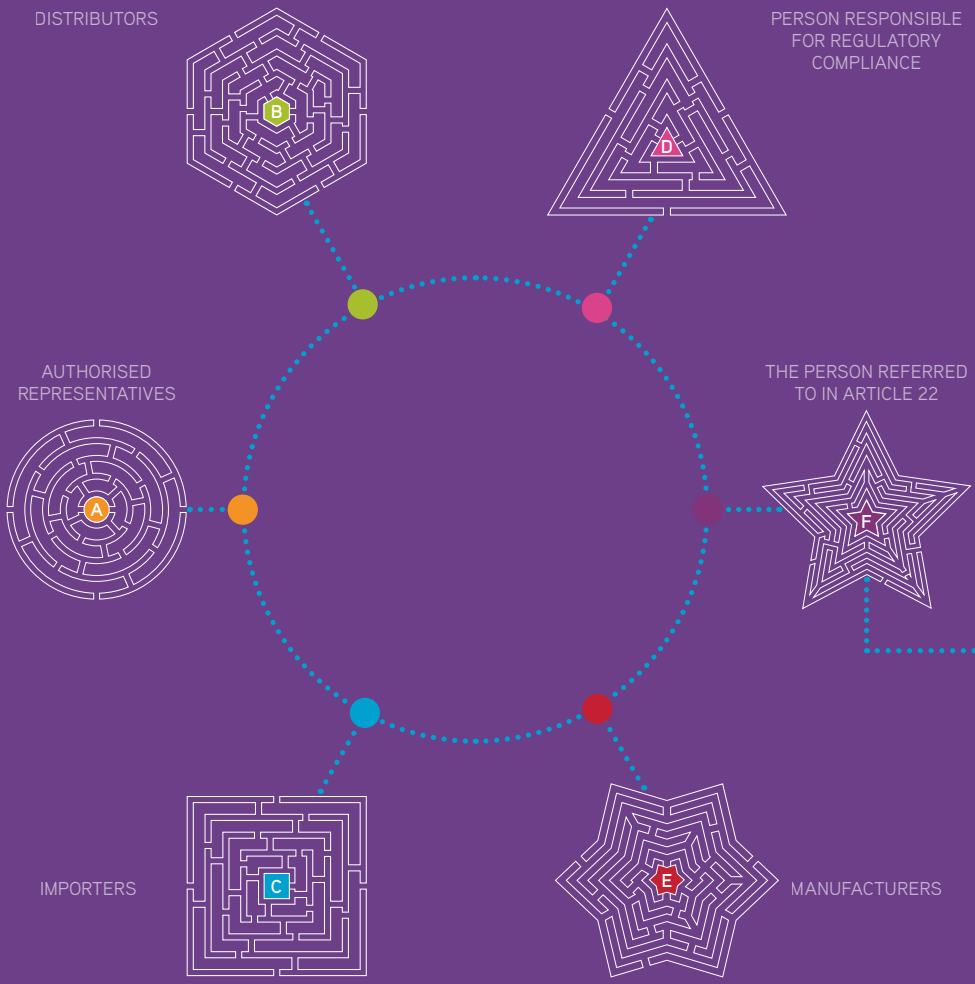

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