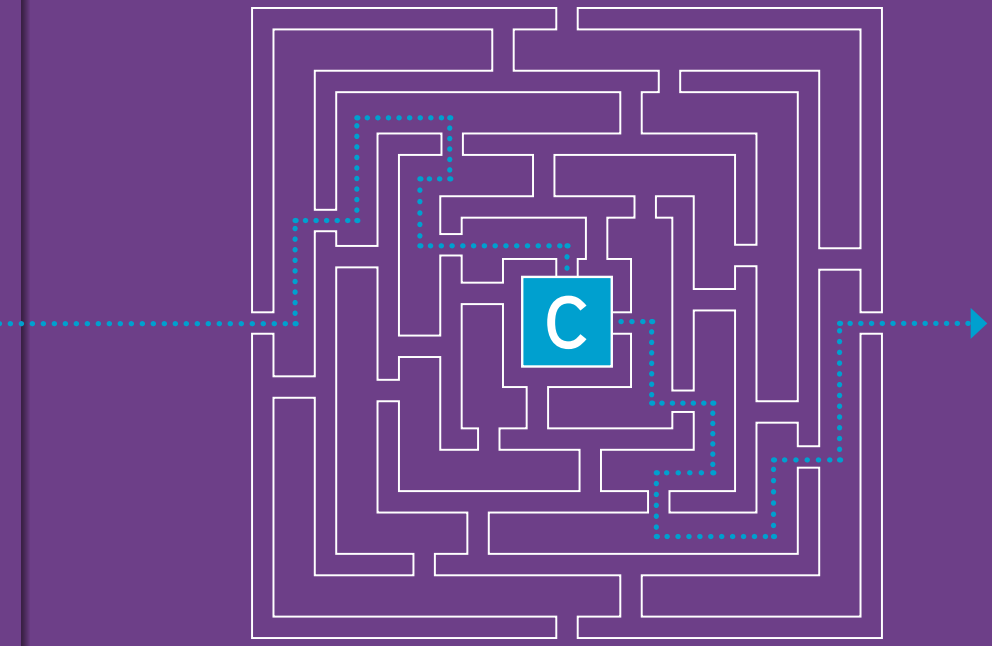
REGULATION

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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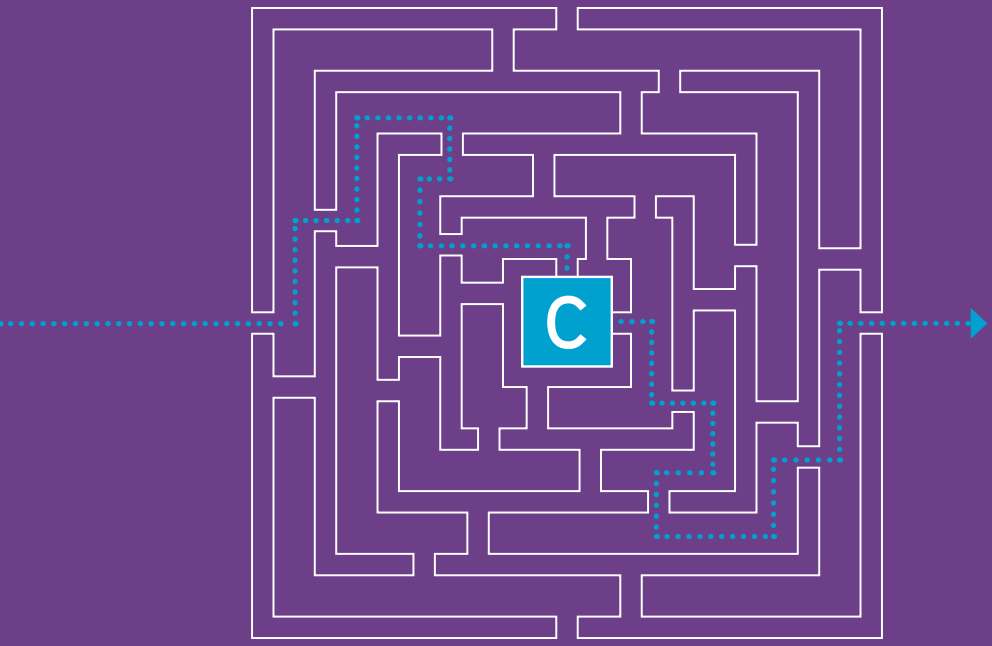

This document is likely to change over time: SNITEM will regularly update the information herein.

November 2020 version

CONTENTS

SYNTHESIS OF OBLIGATIONS OF IMPORTERS

Before placing a device on the market		Ref.
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

After placing a device on the market		Ref.
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

After placing a device on the market (after)		Ref.
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.
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

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...	• For the verification of products and the documentation accompanying them • For the addition of its information on the device • For market surveillance • For 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

03 The operator shall be registered as an importer in Eudamed (this stage depends on the date on which the Eudamed database will be up and running)

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 liability that is the responsibility of the importer's activity: the importer is solely responsible for the obligations incumbent on it under the Regulation.
- Not be delegated any obligation or liability that is the responsibility of the activity of other economic operators: the latter are solely responsible for the obligations incumbent on them 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[1]

http://eur-lex.europa.eu/legal-content/FR/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC

2. ***The 'Blue Guide'*** *on the implementation of EU products rules 2016 (2016/C272/01)*

Le Guide bleu relatif à la mise en œuvre de la réglementation de l'Union européenne sur les produits 2016 (2016/C272/01), ci-après « le Guide bleu »

http://eur-lex.europa.eu/legal-content/FR/ALL/?uri=OJ%3AC%3A2016%3A272%3ATOC

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.

1. 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)

TERMS OF REFERENCE

1. DEFINITION OF IMPORTER IN THE REGULATION 2017/745 MEDICAL DEVICES REGULATION (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"[2]. "Placing on the market" means the **first** making available of a device on the Union market[3].

→ **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[4]. 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 can bring a device into the EU for the first time and then distribute it in the territory. In this case, 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"[5]. "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[6].

So, for the same device (for each batch or each product depending on the distribution channel):

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

2. Article 2(33) of the MDR.
3. Article 2(28) of the MDR.
4. Article 2(33) of the MDR.
5. Article 2(34) of the MDR.
6. 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 tasks, when accomplished by a distributor, an importer or other persons, oblige these persons to meet the obligations incumbent on the manufacturer [7].

→ 3.1 The importer provides information or changes the packaging

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 [8].

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 [9]. This repackaging must not affect the original condition of the device.

In both these cases, the importer shall [10]:

- have a quality management system 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;

- at least 28 days prior to making the device available on the market, 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 importer is compliant with requirements;

- 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;

7. Article 16 of the MDR.
8. Article 16(2)(a) of the MDR.
9. Article 16, point b) of the MDR.
10. Article 16(3) & (4) of the MDR.

- at least 28 days prior to making the relabelled or repackaged device available on the market, inform the manufacturer and the competent authority of the Member State in which it plans to make the device available of the intention to make the relabelled or repackaged device available;

- upon request, provide them with a sample or mock-up of the relabelled or repackaged device;

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.

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 registered trade mark, their registered place of business and the address at which they can be contacted[11]. 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 [12]. 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 or if it assembles or adapts for an individual patient a device already on the market without changing its intended purpose.**

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.

11. Article 13(3) of the MDR.
12. Article 16(1) of the MDR.

MISSIONS AND OBLIGATIONS OF IMPORTERS

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

The requirements imposed on importers by the Regulation have to be assumed by importers themselves. Unless the text expressly provides for it, they cannot be assumed by another operator because of delegation of any kind.

→ 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[13], except in cases where these devices benefit from the grace 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 there is a declaration of conformity in the languages of the Member States in which the importer shall place the devices on the market, 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[14].

→ 1.2 Obligation to register in Eudamed[15]

Importers shall register in Eudamed before placing a device, other than a custom-made device, on the market[16]. Importers shall keep the information concerning them up to date and shall make any changes within one week of any change occurring.

13. Article 13(1) of the MDR.
14. See the sheet for distributors to find all the obligations that are applicable to them.
15. This step depends on the date on which the Eudamed database is operational.
16. 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[17].

→ 1.3 Aspects to be verified by importers

• Regarding the device

Before placing a device on the market importers shall verify that[18]:

- 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 setting up a verification procedure which all the products that they import pass through. 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[19].

17. Article 13(4) of the MDR.
18. Article 13(2) of the MDR.
19. Article 13(5) of the MDR.

In its contract with the manufacturer or in any contractual document, the importer shall clearly identify if the manufacturer has laid down any specific storage and/or transport conditions of devices.
Furthermore, in its contract with the manufacturer or 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 [20].

→ 1.5 Information to be added to the device

Importers shall add to the device, its packaging or a document accompanying the device [21]:

- 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 [22].

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.

20. Article 13(2) of the MDR.
21. Article 13(3) of the MDR.
22. Article 13(3) of the MDR, second sentence.

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 [23]. 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 [24].

• 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 [25]:

- 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 [26]:

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

23. Article 30(3) of the MDR. This step depends on the date on which the Eudamed database is operational.
24. Article 25(1) of the MDR.
25. Article 25(2) of the MDR.
26. 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 [27]. 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 [28].

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 [29]. 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.

27. Article 27(8) of the MDR.
28. Article 13(8) of the MDR.
29. 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 [30].

→ 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 [31], 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 [32]. 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 [33].

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 [34].

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 [35]. Importers shall also provide free of charge samples or access to a device that they have placed on the market to any competent authority that so requires.

30. Article 13(6) of the MDR.
31. Article 94 of the MDR.
32. Article 95(1) of the MDR.
33. Article 95(3) of the MDR.
34. Article 97(1) of the MDR.
35. 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' 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[36].

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[37].

> 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[38]:

- 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.

36. Article 93(3) of the MDR.
37. Article 94 of the MDR.
38. Article 109 of the MDR.

PENALTIES

The Regulation leaves it up to the Member States to lay down the rules on penalties applicable for infringement of its provisions [39]. The Member States shall notify the Commission of those penalties three months at the latest before the application date of the Regulation, in other words by 25 February 2021 at the latest.

CALENDAR FOR IMPLEMENTATION

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 [40]. 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 [41]. However, even for products benefiting from this transitional period, the following provisions of the MDR will be immediately applicable as of May 26 2021: the requirements relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and of devices [42].

→ The importer must comply with the provisions of the Regulation as soon as that it imports products marked CE under the regulation and obligatorily after May 26 2021.

39. Article 113 of the MDR.
40. 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.
41. Article 120 of the MDR as amended by the 2nd corrigendum (December 2019).
42. 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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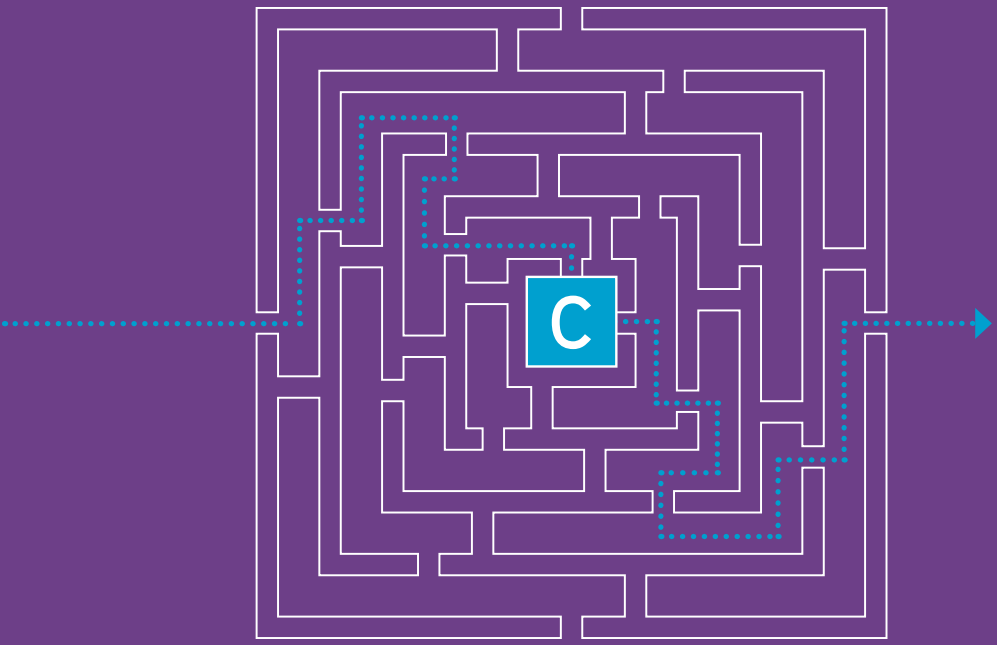
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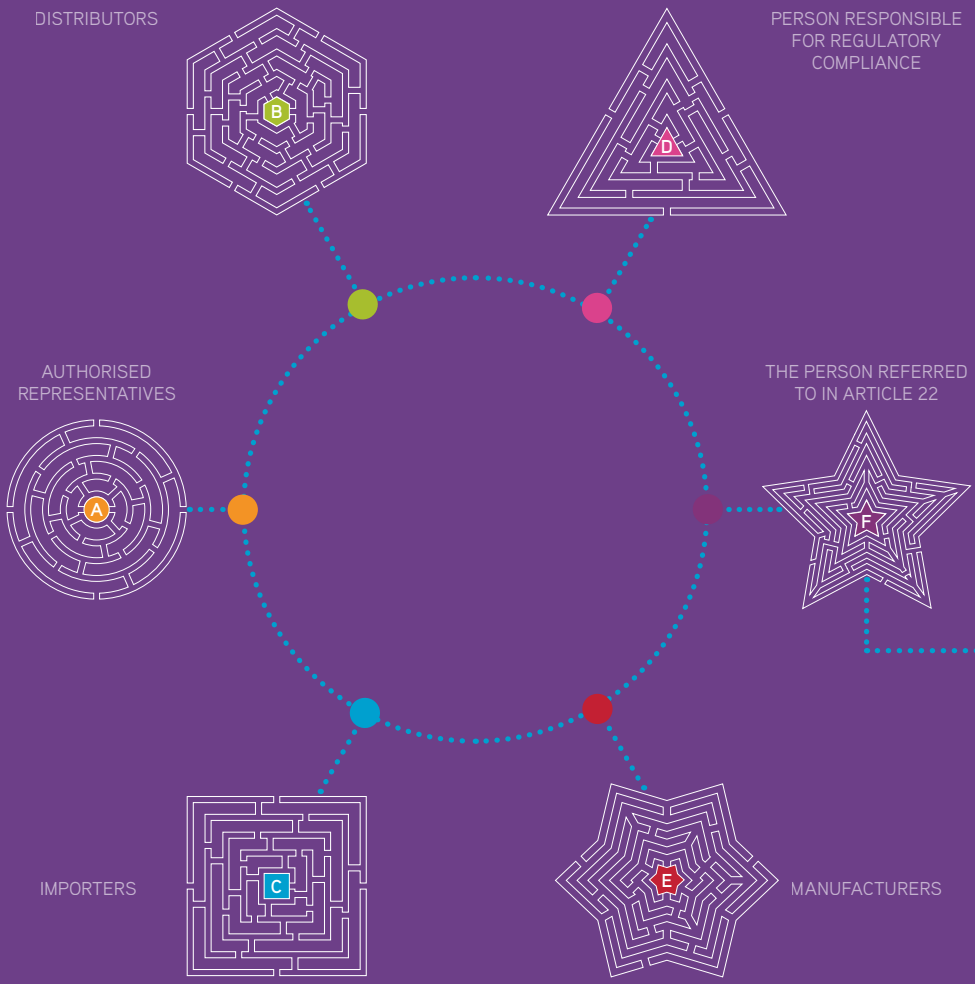

LE DISPOSITIF MÉDICAL

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