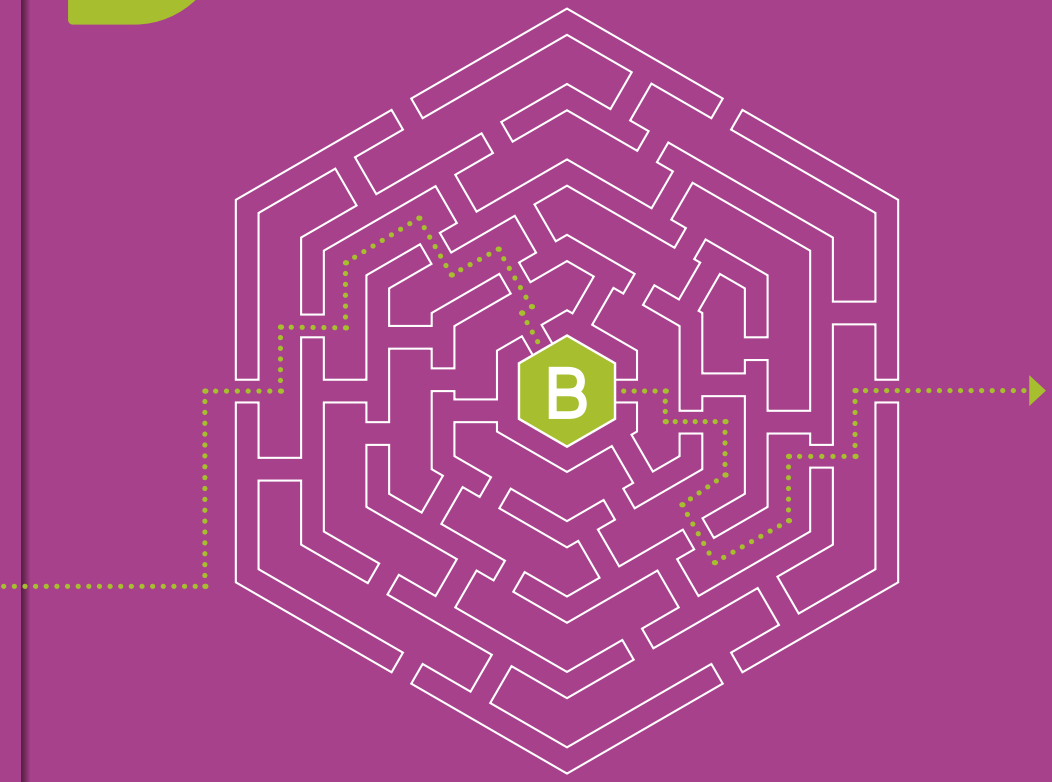
REGULATION

DISTRIBUTORS
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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LE DISPOSITIF MÉDICAL
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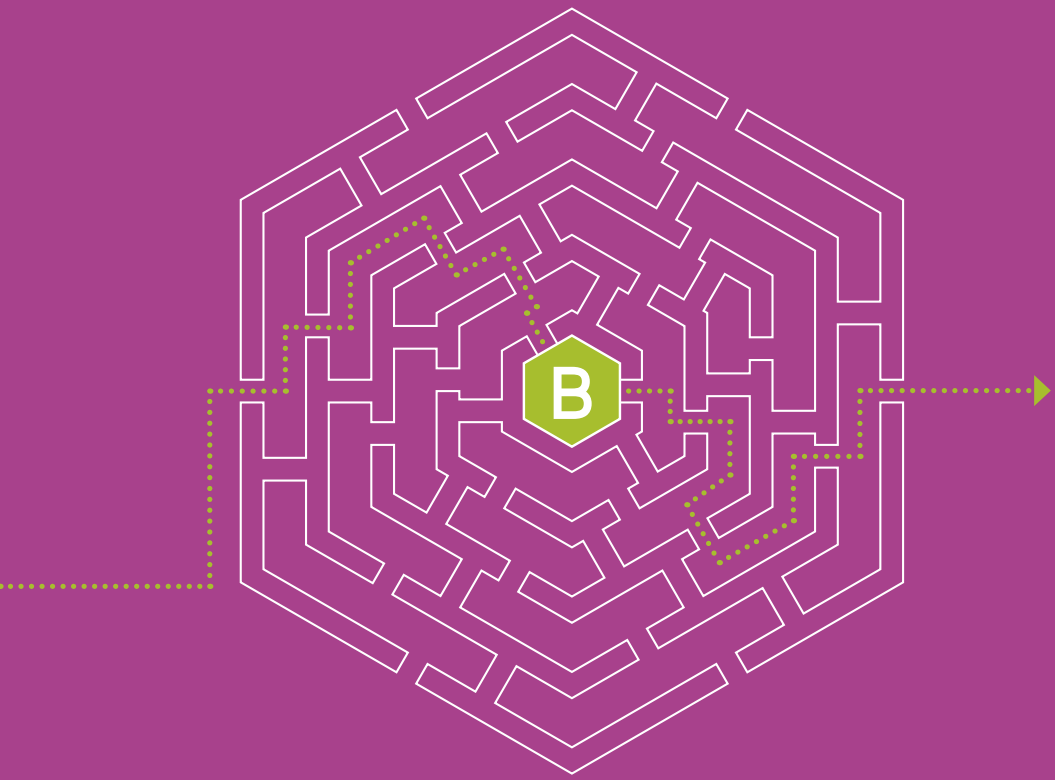

This document is likely to change over time: SNITEM will regularly update the information herein.

January 2024 version

CONTENTS

SYNTHESIS OF OBLIGATIONS OF DISTRIBUTORS

Before making a device available		Ref.[1]
Verification	Distributors 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 device is made available (sampling possible), • The device is accompanied by a label and an information leaflet (sampling possible), • A UDI has been assigned to the device by the manufacturer, where applicable, in accordance with article 27 (sampling possible), • Where applicable, the information about the importer is on the device, on its packaging or in a document accompanying the device.	Art. 14.2
	• Distributors shall ensure that storage and transport conditions comply with the conditions set by the manufacturer.	Art. 14.3
Reporting	Distributors that consider that a device is not in conformity shall inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer and shall only make the device available once it has been brought into conformity. It shall also inform the competent authority if it considers the device presents a serious risk or is a falsified device.	Art. 14.2

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 making a device available		Ref.[2]
Product traceability	Distributors 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
	Distributors 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	Distributors that consider that a device which they have made available on the market is not in conformity with the Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer, and shall cooperate to ensure that the necessary action is taken. They shall inform the competent authority if the device presents a serious risk.	Art. 14.4
	Distributors 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.	Art. 14.5
	Distributors that have received complaints or reports from healthcare professionals, patients or users related to or possibly related to a device they have made available shall immediately forward this information to the manufacturer and, where applicable, to the manufacturer's authorised representative and the importer.	Art. 14.5

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 making a device available

Ref.[3]

Corrective action	Distributors shall take the appropriate corrective action when a competent authority identifies an unacceptable risk for health or safety.	Art. 95.1
	Where a non-conformity does not present an unacceptable risk to health or safety, distributors shall bring the non-compliance to an end within a reasonable period.	Art. 97.1
	Distributors shall cooperate with competent authorities on any action taken to eliminate or mitigate the risks posed by devices which they have made available on the market. They shall provide competent authorities with free samples of or access to the device.	Art. 14.6
	Distributors shall cooperate with the competent authorities when the latter carry out an evaluation of the device.	Art. 94

Continuously

Ref.[3]

Due care	When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.	Art. 14.1
Confidentiality	Distributors 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 distributors 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 A DISTRIBUTOR OF DEVICES IN THE EU

Organisation and internal tools

01 The enterprise meets the definition of distributor

Location	The enterprise is established in the European Union
Activity	• The enterprise buys devices compliant with the Regulation from a manufacturer or an importer. • The enterprise makes these devices available on the EU market. **Beware of certain activities that make the enterprise switch over to manufacturer status (cf. page 8).**

02 The enterprise is in a position to fulfil all the obligations applicable to distributors

Personnel	• The operator has the necessary resources to carry out the tasks provided for in the Regulation. • The operator has set up a back-up system.
Processes for	• the verification of products and documentation accompanying them, • market surveillance, • product traceability, • the reporting of non-conformities, complaints, reports, etc.
Tools	• Identification of any player that may have to be contacted (person to contact and contact details): - Manufacturer, authorised representative, importer, - Competent authorities of Member States in which the devices are imported. • Databases to store and keep traceability information and the UDI where applicable. • Identification of specific requirements of Member States for traceability and registration of UDI. • Identification of the languages in which the documents, instructions, labeling, implant card must be provided.

03 The enterprise is registered as a distributor in the national database where applicable

- Identification of the specific requirements of the Member States in which the products are distributed with regard to the registration of operators.
- Registration of information and updating when required.

Links with commercial partners

! Make a contract with the manufacturer and, where applicable, the importer

- Not delegate any obligation or responsibility falling within the scope of the distributor's activity: the distributor 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

Il s'agit d'un guide relatif à la mise en application des dispositions applicables aux produits dans l'Union européenne (directives élaborées sur la base des dispositions de la nouvelle approche et de l'approche globale, mise en œuvre du nouveau cadre législatif, Traité de Lisbonne). L'objectif de ce guide est d'expliciter ces dispositions et de contribuer à leur application uniforme et cohérente dans les différents secteurs et dans l'ensemble du marché unique. Le Guide bleu fournit donc des éléments d'interprétation du règlement dispositifs médicaux.

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 DISTRIBUTOR IN THE MDR

The distributor is defined by the MDR 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]. The notion of "making available on the market" means any supply of a device, other than an investigational 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]. The Regulation stipulates that a distributor's activities are deemed to include acquisition, holding and supplying of devices [4].

Within the meaning of the MDR, a distributor is an "economic operator", which here refers to the manufacturer, authorised representative, importer and distributor[7]. Failing any specific details, all the provisions of the Regulation referring to economic operators are therefore applicable to distributors.

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

If an operator brings a device into the European Union for the first time, he is placing the device on the market, i.e. making it available for the first time in the EU. In this case, the operator has the status of importer within the meaning of the Regulation and has to comply with the provisions applicable to importers [9].

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,**

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

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

3. CASES IN WHICH OBLIGATIONS OF MANUFACTURERS APPLY TO DISTRIBUTORS

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 distributor provides information or changes the packaging of the device

The distributor may provide a label and/or information 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 distributor may 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 distributor 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 distributor 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(2)(b) of the MDR.
13. Article 16(3 and 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 distributor 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.

→ 3.2 The distributor 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 a distributor has to assume the obligations applicable to the manufacturer[14].

Firstly, where the distributor makes available on the market a device under its name, registered trade name or registered trade mark, **except in cases where a distributor 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 a distributor changes the intended purpose of a device already placed on the market or put into service.

And lastly where a distributor 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 16(1) of the MDR.

MISSIONS AND OBLIGATIONS OF DISTRIBUTORS

1. OBLIGATIONS OF DISTRIBUTORS BEFORE MAKING A DEVICE AVAILABLE

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 regulation.

→ 1.1 Obligation to register

Unlike other economic operators, distributors have no obligation to register in the Eudamed base. On the other hand, the Regulation holds that Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory [15]. This is the case in France.

→ 1.2 Aspects to be verified by the distributor

• Regarding the device

Before making a device available, distributors shall verify that [16]:

- the device is CE marked,

- the EU declaration of conformity has been drawn up in the official language/languages of the Member State/States in which the device is made available,

- the device is accompanied by a label and an information leaflet in the official language/languages of the Member State/States in which the device is made available,

- where applicable, the information about the importer is on the device, on its packaging or in a document accompanying the device.

- where applicable, the manufacturer has assigned a UDI to the device.

15. Article 30(2) of the MDR.
16. Article 14(2) of the MDR.

The Regulation holds that to fulfil its obligations, distributors may use sampling, except for checking the presence of information regarding the importer[17].

Distributors must be able to prove that they have fulfilled this obligation and therefore that they have carried out these checks, for example by setting up a verification procedure which all the products that they intend to make available.

Distributors may ask the operator that provides them with the device for a provision to be made in the contract binding them stating that the operator agrees to provide any information and any document enabling the distributor to fulfil its verification obligations.

• Regarding transport and storage of the device

Distributors shall ensure that the storage or transport conditions of the device, while under their responsibility, meet the requirements set by the manufacturer[18].

Distributors must therefore clearly identify whether the manufacturer has laid down specific conditions for the storage and/or transport of the devices and may plan to refer to them in the contract with the manufacturer or the distributor, or in any other contractual document. In addition, in their contracts with operators who supplies them with devices, and possibly in their contracts with operators to whom they supply it, distributors must state exactly from which moment and up until when the product is legally their responsibility and therefore for which period they are answerable for those conditions. Distributors would be well advised to ensure that their responsibility ceases when they are no longer in control of the device and consequently of its transport and/or storage conditions.

→ 1.3 Obligations in terms of reporting

If a distributor considers or has reason to believe that a device is not in conformity, it shall only make this product available once it has been brought into conformity. It shall inform the manufacturer thereof and, where applicable, the authorised agent and the importer, as well as the competent authority of the State in which it is established in the case of a serious risk or if it has reason to believe that it is a falsified device [19].

17. Article 14(2)(c) of the MDR.
18. Article 14(3) of the MDR.
19. Article 14(2) of the MDR.

2. OBLIGATIONS OF DISTRIBUTORS AFTER MAKING A DEVICE AVAILABLE

→ 2.1 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 distributors shall cooperate with manufacturers or their authorised representative in order to achieve an appropriate level of traceability of devices [20].

• Identification of links in the distribution channel upstream and downstream

Distributors must 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 made available on the market [21]:

- 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.

• Storage and keeping of UDI

Where class III implantable devices are concerned, the Regulation holds that economic operators shall store and keep, preferable by electronic means, the UDI of the devices which they have supplied or with which they have been supplied [22].

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, distributors will have to set up a database enabling them to save and to keep the information required.

20.Article 25(1) of the MDR.
21. Article 25(2) of the MDR.
22.Article 27(8) of the MDR.

→ 2.2 Obligations in terms of market surveillance

• Reporting to the manufacturer, the authorised representative and the importer

Distributors that have received complaints or reports from healthcare professionals, patients or users related to or possibly related to a device they have made available shall immediately forward this information to the manufacturer and, where applicable, to the manufacturer's authorised representative and the importer [23].

Distributors that consider or have reason to believe that a device which they have made available is not in conformity with the Regulation shall immediately inform the manufacturer thereof and, where applicable the manufacturer's authorised representative and the importer, and shall cooperate with them and with the competent authority to ensure that corrective action be taken [24].

When a device presents a serious risk, the distributor shall immediately inform the competent authorities of the Member States in which it has made the device available.

> As this reporting must be carried out **immediately** by the distributor, it is important that all the operators (manufacturer, authorised representative, importer and distributor) provide the name and contact details of the persons that the distributor has to inform. It is also important to ensure that a back-up system is in place with each of the operators.

• Keeping a register

Distributors shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals. They shall keep the manufacturer, its authorised representative and the importer informed of these activities and, at their request, shall provide them with any information to allow them to proceed with investigating these complaints [25].

→ 2.3 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

23. Article 14(5) of MDR.
24. Article 14(4) of the MDR.
25. Article 14(5) of the MDR.

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 [26]. The distributor must also make immediately sure that any corrective action is taken for all the devices that it has made available on the EU market [27].

Where, having performed an evaluation in this 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 [28].

The distributor forwards to the competent authority who makes the request all the information and all the documents in its possession which are needed to demonstrate the conformity of a device [29].

> The Regulation states that a distributor is said to have fulfilled this obligation when the manufacturer or its authorised representative has furnished the information required.

Furthermore, distributors 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 made available on the market [30].

3. OTHER OBLIGATIONS ON DISTRIBUTORS CONTINUOUSLY

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

→ 3.1 General obligation of due care

The Regulation holds that, when making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable [31].

26. Article 95(1) of the MDR.
27. Article 95(3) of the MDR.
28. Article 97(1) of the MDR.
29. Article 14(6) of the MDR.
30. Article 14(6) of the MDR. This obligation to cooperate is taken for all economic operators from article 93 of the MDR to enable the competent authorities to fulfil their market surveillance obligations.
31. Article 14(1) of the MDR.

→ 3.2 General obligation of cooperation with the competent authorities

Generally speaking, economic operators, and therefore distributors, 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 [32].

Furthermore, distributors, 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 [33].

Mention could be made in the contract between the manufacturer and the distributor or between the importer and distributor that the distributor undertakes 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.

→ 3.3 Confidentiality

Lastly, like all persons involved in the application of the Regulation, distributors are bound by an obligation of confidentiality concerning [34]:

- 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.

32. Article 93(3) of the MDR.
33. Article 94 of the MDR.
34. 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[35]. 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[36].
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).

35. Article 113 of the MDR..
36. 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 [37]. Please note that the specific calendars (grace period, staggered calendar for the application of the IUD, etc.) are not postponed. An enterprise may however decide to apply the Regulation before this date if it complies with all of its provisions.
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 [38]. 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[39] 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 [40].

→ 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

37. 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.
38. Article 120 of the MDR as amended by the 2nd corrigendum (December 2019).
39. 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.
40. 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.

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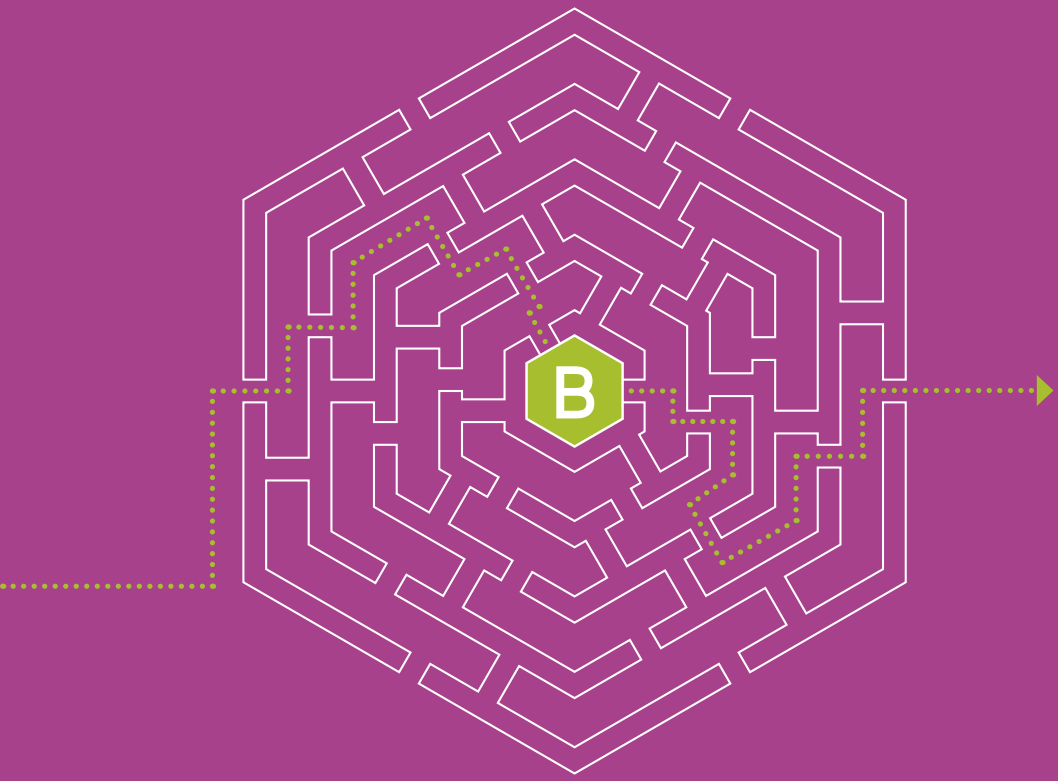
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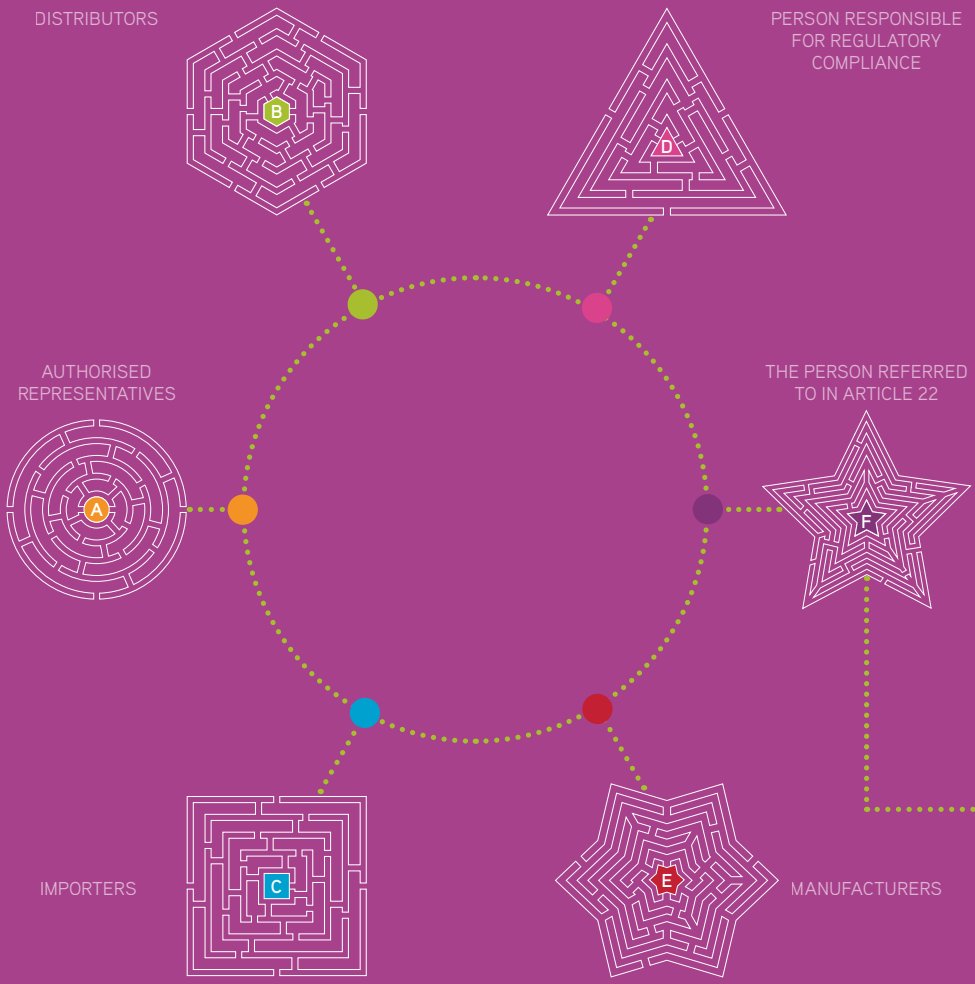

LE DISPOSITIF MÉDICAL

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Syndicat national
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des technologies médicales

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