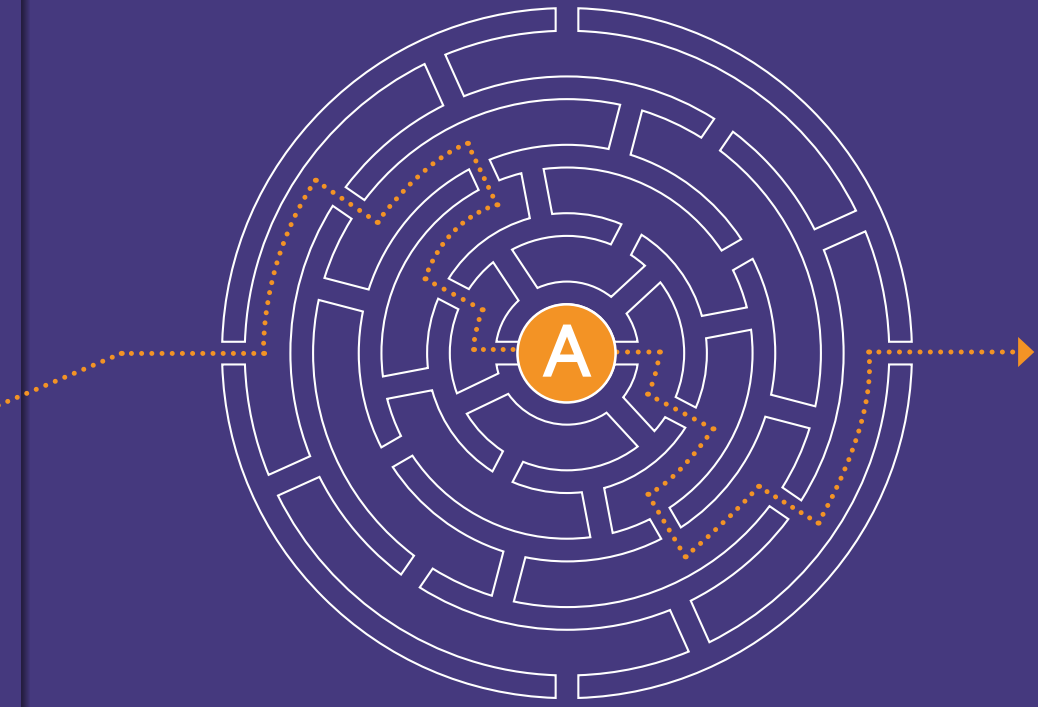
AUTHORISED REPRESENTATIVES
SYNTHESIS

REGULATION



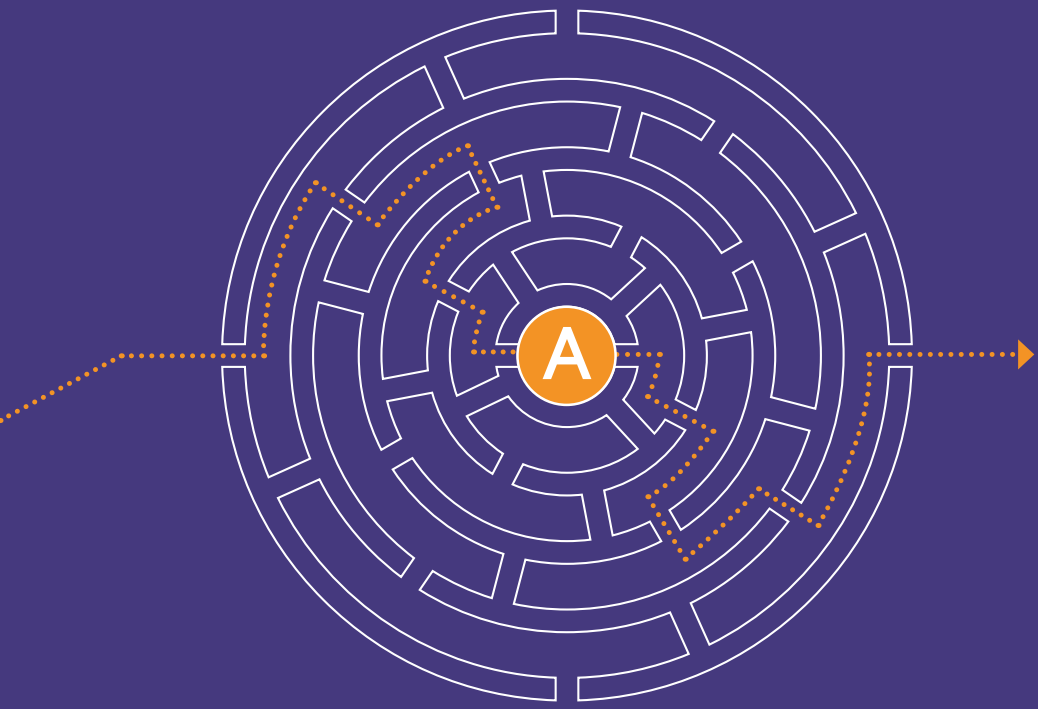
DM

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.

snitem.fr

LE DISPOSITIF MÉDICAL
snitem
Pour faire avancer la santé



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

February 2024 version

CONTENTS

TEXTS AND REFERENCE DOCUMENTS 2

TERMS OF REFERENCE 3
1. Legal definition of mandate and authorised agent 3
2. Definition of authorised representative in the regulation 2017/745 (MDR) 3

CONDITIONS OF VALIDITY FOR THE MANDATE LAID DOWN IN THE REGULATION 2017/745 (MDR) 5

MISSIONS OF AUTHORISED REPRESENTATIVES LAID DOWN BY THE MDR 6
1. Tasks that manufacturers cannot entrust to authorised representatives 6
2. Tasks that authorised representatives shall at least perform 7
3. Other obligations on authorised representatives: 9
   - Corrective action 9
   - Cooperation with the competent authorities 10
   - Confidentiality 13

RESPONSIBILITY OF AUTHORISED REPRESENTATIVES 14
1. Cases in which the authorised representative may be held liable 14
2. Person responsible for regulatory compliance 14
   - Obligation for authorised representatives to have one person responsible for regulatory compliance within their organisation or at their disposal 14
   - Expertise of the person responsible for regulatory compliance 14
   - Protection of the person responsible for regulatory compliance 15
   - Missions of the person responsible for regulatory compliance 15

END OF THE MANDATE 17
1. Decision to terminate the mandate 17
   - Change of authorised representative 17
   - End of the mandate without new authorised representative 18
2. Cessation of business activities 18
   - Cessation of manufacturer's business activities 18
   - Cessation of authorised representative's business activities 18

ADAPTATION OF NATIONAL LEGISLATION 19

PENALTIES INCURRED 19

CALENDAR FOR IMPLEMENTATION 19

ANNEX: Synthesis of missions of authorised representatives 20

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]

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.

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)
-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)

3. French Civil Code (articles 1984 to 2010)

https://www.legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000006445236&idSectionTA=LEGISCTA000006136404&cidTexte=LEGITEXT000006070721&dateTexte=20170224

TERMS OF REFERENCE

1. LEGAL DEFINITION OF MANDATE AND AUTHORISED AGENT

→ Mandate

A mandate (or power of attorney) is a notion defined in the French Civil Code under article 1984.

A mandate is a document by which one person, the principal, gives another person, the agent, the authority to do something for him and in his name.

The mandate may be verbal, although it is mainly written. It may be general or special (a mandate to carry out a given task – e.g. one to complete a sale).

The mandate is an intuitu personae contract (by reason of its strictly personal nature). It normally ends on expiry of the period provided for by the contracting parties or through termination by the principal, but also on the death of the principal or the agent. It also terminates through insolvency of the principal.

Furthermore, the agent is liable to his principal for his faults, and the principal is bound by the acts that the agent has performed in his name within the limits of his powers; in turn, the agent is answerable for the person he has substituted for himself in performing the mandate that has been conferred upon him.

→ Agent or authorised agent

The person who, in the mandate, receives authority from the principal and the mission to act on his behalf [2].

2. Vocabulaire juridique, Gérard Cornu, 7th edition [Definitions taken from a book of legal vocabulary by Gérard Cornu).

2. DEFINITION OF AUTHORISED REPRESENTATIVE IN THE REGULATION 2017/745 (MDR)

"Authorised representative" means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation [3].

The MDR holds that a manufacturer established outside the EU is obliged to designate an authorised representative located within the Union to place the device on the Union marketon [4] and shall supervise the authorised representative's activity and the content of the mandate.

On principle, special law derogates from general law. The provisions of the Civil Code regarding the mandate are of general law insofar as they set a framework and broad definitions of the mandate and the authorised agent. The provisions of the MDR, which hold specific and more precise definitions and obligations, are of special law (specific to the sector in question). Operators in the sector shall apply as a priority the special law where it exists, in other words the provisions of the MDR concerning the mandate.
Consequently, manufacturers outside the EU and current authorised representatives are advised to check that their contractual relations do in fact correspond to the notion of mandate within the meaning of the MDR and to the obligations pertaining thereto (cf. below) and, if this is not the case, to bring their mandates into conformity.

3. Article 2(32) of the MDR.
4. Article 11(1) of the MDR.

CONDITIONS OF VALIDITY FOR THE MANDATE LAID DOWN IN THE MDR[5]

The Regulation 2017/745 defines several aspects concerning the manufacturer, the authorised representative and the form and content of the mandate. These aspects are cumulative.

The manufacturer

- shall be **established outside the EU.**

The authorised representative

- shall be **established in the EU territory;**
- shall have permanently and continuously at their disposal at least **one person responsible for regulatory compliance** who possesses the requisite expertise (cf. below).

The mandate

- shall be **accepted in writing** by the authorised representative;
- shall cover at least **all devices of the same generic device group**[6] provided by the manufacturer;
- shall provide for **a sole authorised agent per product;**
- shall at least specify the **list of tasks provided for by the Regulation**[7]**;**
- shall not delegate to the authorised representative **any of the manufacturer's obligations listed exhaustively in the Regulation**[8]**.**

Before signing the mandate, **all of these points are to be verified by each of the parties,** as the validity and therefore the existence of the mandate may be challenged if one of the conditions is not fulfilled. In case of invalidity of the mandate, the manufacturer outside the EU would be placing its devices illegally on the Union market.

5. Article 2(32), article 11(1),(2),(3) & (4) and article 15(6) of the MDR.
6. The MDR defines a «generic device group» as "a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics" - Article 2(7) of the MDR.
7. These tasks are provided for in article 11(3) of the MDR. Cf. below.
8. These obligations are listed in article 11(4) of the MDR. Cf. below.

MISSIONS OF AUTHORISED REPRESENTATIVES LAID DOWN BY THE MDR

The Regulation provides for:

- tasks that manufacturers cannot entrust to authorised representatives,
- tasks that authorised representatives shall at least perform as part of their mandate,
- various obligations applicable to all economic operators (manufacturers, authorised representatives, importers, distributors).

PLEASE NOTE

The Blue Guide points out that the tasks that may be delegated to the authorised representative are of an **administrative** nature. The manufacturer may neither delegate the measures necessary to ensure that the manufacturing process assures compliance of the products nor the drawing up of technical documentation, unless otherwise provided for. An authorised representative cannot modify the product on its own initiative in order to bring it into line with the applicable Union harmonisation legislation[9].

1. TASKS THAT MANUFACTURERS CANNOT ENTRUST TO AUTHORISED REPRESENTATIVES

The manufacturer shall not entrust the authorised representative with the following missions[10]:

- ensure that the devices it places on the market have been designed and manufactured in accordance with the requirements of the Regulation;
- establish, implement, maintain and document a system of risk management ;
- conduct a clinical evaluation, including post-market clinical follow-up;
- draw up and keep up to date technical documentation for those devices such as to allow the conformity of the device to be assessed;

9. Point 3.2 of the Blue Guide.
10. Article 11(4) of the MDR.

- draw up an EU declaration of conformity and affix the CE marking of conformity;
- fulfill obligations concerning the UDI system and those linked to registration of the manufacturer and devices in the EUDAMED database;
- ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation, establish, document, apply, maintain, keep up to date and continually improve the quality management system that shall ensure conformity with the requirements of this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device;
- implement and keep up to date the post-market surveillance system;
- ensure that the device is accompanied by a label and an instruction leaflet complying with the requirements of the regulation;
- if it considers or has reason to believe that a device which it has placed on the market or put into service is not in conformity with the Regulation immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it.

Before signing the mandate, the future authorised representative is advised to check that the mandate does not contain any of the tasks listed above as the authorised agent is not allowed to perform them.
The manufacturer shall ensure that, through the mandate, it does not entrust any of the tasks listed above to the authorised representative as these tasks must be performed by the manufacturer personally.

NOTE

The MDCG specifies that while the manufacturer is prohibited from delegating responsibility for the tasks listed above to his authorised representative, the latter may nevertheless assist the manufacturer in carrying them out [11].

2. TASKS THAT THE AUTHORISED REPRESENTATIVE SHALL AT LEAST PERFORM

The MDR holds that the authorised representative shall perform "at least the following tasks in relation to the devices that its mandate covers" [12]:

- verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

11. MDCG 2022-16 Guidance on authorised representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746)
12. Article 11(3) of the MDR.

- keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, at the disposal of competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market (15 years for implantable devices);

- be registered in the electronic system for economic operators [13], update this information within a period of one month following a change to this information, confirm the validity of the information one year after submitting it and every second year thereafter and verify that the manufacturer has complied with the registration obligations for products and systems other than custom-made ones in the UDI database [14] and that the information is accurate, complete and up to date;

- in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

- forward to the manufacturer any request made by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

- cooperate with the competent authorities on any preventive or corrective action to eliminate or, if that is not possible, mitigate the risks posed by devices;

- immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

- terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation. Please note: an authorised representative shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device, of the termination of the mandate and the reasons therefor [15].

13. See the list of information to be recorded in Annex VI, Part A, 1. of the MDR. This step depends on when the Eudamed base is made mandatory, in accordance with the deadlines set out in article 123 of the regulation.
14. See the list of information to be recorded in Annex VI, Part A, 2. of the MDR. This step depends on when the Eudamed base is made mandatory, in accordance with the deadlines set out in article 123 of the regulation.
15. Article 9(6) of the MDR.

PLEASE NOTE

The Regulation holds that a manufacturer shall make sure that its authorised representative has the documentation needed to fulfil the tasks entrusted to it permanently available[16].

Furthermore, the MDR holds that the authorised representative shall **provide a copy of the mandate** to the competent authority, upon request[17].

Warning: the Civil Code holds that the authorised agent can do nothing beyond what is written in its mandate [18]. So in practice, it is advisable to mention in the mandate all of these tasks entrusted to the authorised representative so that the mandate is compliant with the French law (if the authorised representative is established in France and the parties wish to submit the mandate to the French law).

Before signing the mandate, the future authorised representative shall therefore ensure that the mandate expressly holds that the manufacturer is entrusting it with all of these tasks. It can also request that mention be made in the mandate of the manufacturer's obligation to keep permanently at its disposal the documentation needed to fulfil the tasks entrusted to it.

3. OTHER OBLIGATIONS ON AUTHORISED REPRESENTATIVES

The authorised representative is also under other obligations which are not specific to it but apply either to the manufacturer or to its authorised representative or to all the economic operators (manufacturer, authorised representative, importer, distributor, etc.).

→ Corrective action

The competent authority shall inform the authorised representative when a previously unknown risk is identified or when the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination and the authorised representative shall then **take the necessary corrective actions [19].**

Where, having performed an evaluation pursuant to article 94 of the MDR, 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

16. Article 10(8) of the MDR.
17. Article 11(3) of the MDR.
18. Article 1989 of the Civil Code.
19. Article 90 of the MDR.

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 [20].

Pursuant to article 94 of the MDR, the competent authorities may carry out an evaluation of a device. In this context, they may find that the device is not in conformity, but does not present an unacceptable risk to the health and safety of patients, users or other persons, or to other aspects of the protection of public health. In this case, the competent authorities shall require the relevant economic operator to **bring the non-compliance concerned to an end within a defined period [21].**

→ Cooperation with the competent authorities

The competent authorities shall carry out an evaluation relating to an unacceptable risk or a non-conformity of a device based on data obtained by vigilance or market surveillance activities or on other information. In this case, the authorised representative, as economic operator within the meaning of the MDR, shall cooperate with the competent authorities [22].

Authorised representatives shall also **keep at the disposal of competent authorities** for a period of **at least ten years** or, for implantable devices, **fifteen years** after the last device has been placed on the market, certain documents the list of which depends on the basis of conformity assessment of the relevant product. This obligation ends if there is a change of authorised representative insofar as the outgoing authorised representative shall transfer the documents to the incoming authorised representative (cf. below).

20. Article 95(1) of the MDR.
21. Article 97(1) of the MDR.
22. Article 94 of the MDR.

List of documents that the authorised representative shall keep at the disposal of competent authorities :

Conformity assessment based on a quality management system and on assessment of technical documentation [23]

- The EU declaration of conformity.
- The documentation on the manufacturer's quality management system.
- any substantial changes to the quality management system or the device-range covered of which the manufacturer shall inform the notified body which approved this system.
- The decisions and reports from the notified body as part of the conformity assessment and assessment of technical documentation.

Conformity assessment based on type-examination [24]

- The technical documentation on the device and the technical documentation on post-market surveillance.
- Information relating to changes to the type.
- Copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

Conformity assessment based on product conformity verification [25]

→ **Regarding production quality assurance**

- **For classes IIb and III devices**
  - the EU declaration of conformity,
  - the documentation on the manufacturer's quality management system,
  - the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance,
  - any substantial changes to the quality management system or the device-range covered of which the manufacturer shall inform the notified body which approved this system,
  - the decisions and reports from the notified body as part of audits and assessments.

23. Annex IX (7) of the MDR.
24. Annex X (7) of the MDR.
25. Annex XI (9), (10.5), (17) and (18.4) of the MDR.

- **For class IIa devices**
  - the EU declaration of conformity,
  - the technical documentation on the device and the technical documentation on post-market surveillance,
  - the certificate issued by the notified body confirming that the device conforms to the technical documentation and meets the requirements of the Regulation.

→ Concerning product verification

- **For classes IIb and III devices**
  - the EU declaration of conformity,
  - the documentation drawn up by the manufacturer to define the manufacturing processes and all the pre-established procedures to ensure homogeneous production, and conformity of the devices with the type described in the EU type-examination certificate and with the requirements of the Regulation,
  - the EU product verification certificate relating to the tests and assessments carried out by the notified body,
  - the EU type-examination certificate.

- **For class IIa devices**
  - the EU declaration of conformity,
  - the technical documentation on the device and the technical documentation on post-market surveillance,
  - the certificate issued by the notified body confirming that the device conforms to the technical documentation and meets the requirements of the Regulation.

Members States shall take the necessary steps to ensure that these documents are kept at the disposal of the competent authorities for the periods stipulated (10 years after the last device was placed on the market, and 15 years for implantable) in case a manufacturer or its authorised representative goes bankrupt or ceases its business activity prior to the end of these periods[25].

25. Annex IX, Chapter III, Section 8, repeated in Annexes X and XI of the MDR.

The obligation to keep documentation available can continue after the end of the mandate if the manufacturer does not formalise a contract with any new authorised representative (for example, if the product ceases to be placed on the market in the EU).

→ Confidentiality

Lastly, like all persons involved in the application of the Regulation, authorised representatives are bound by an obligation of confidentiality concerning [26]:

- 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.

26. Article 109 of the MDR.

RESPONSIBILITY OF AUTHORISED REPRESENTATIVES

1. CASES IN WHICH THE AUTHORISED REPRESENTATIVE MAY BE HELD LIABLE

The authorised representative may be held liable if it does not comply with:

- the contractual obligations resulting from its mandate;

- the obligations stipulated by the Regulation incumbent upon it.

The MDR also holds that if the manufacturer has not complied with the general obligations incumbent upon it [27], the authorised representative and the manufacturer are jointly and severally liable for defective devices[28]. Consequently, a person considering him or herself to be the victim of damage caused by the device can take legal proceedings against the manufacturer or the authorised representative alike.

The authorised representative cannot therefore be delegated certain tasks laid down in article 10 of the MDR regarding the general obligations of manufacturers but shall ensure in practice that the manufacturer has indeed met its obligations under this article.

→ The MDCG has clarified the relationship between this joint and several liability and the obligations that the manufacturer cannot delegate to his authorised representative (MDCG 2022-16 Guidance on authorised representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746).

2. PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

→ Obligation of authorised representatives to have one person responsible for regulatory compliance within their organisation or at their disposal [29]

According to the Regulation, authorised representatives shall have "permanently and continuously" at their disposal one person responsible for regulatory compliance. This person does not need to be an employee within the structure of the authorised representative, who has the option of outsourcing the function.

27. Article 10 of the MDR "General obligations of manufacturers".
28. Article 11(5) of the MDR.
29. Article 15(6) of the MDR.

In practice, it seems necessary to plan for a back-up system so that the authorised representative always has at its disposal one person fulfilling the required conditions, whether this person be within the authorised representative's organisation or bound by a service agreement.
Regarding the notion of "permanently and continuously", the question arises of whether a person responsible for regulatory compliance should be available 24/7 and therefore whether the authorised representative needs to provide an on-call system.

→ Expertise of the person responsible for regulatory compliance[30]

The person responsible shall have the requisite expertise regarding the regulatory requirements for medical devices in the Union.

This expertise shall be demonstrated by one of the following qualifications:

- a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and a document confirming at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

- four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

In practice, it seems important for the manufacturer to ask the authorised representative for proof that it does indeed have at its disposal, in-house or via a service agreement, a person responsible for regulatory compliance with the requisite expertise (CV, diplomas, reference from an employer, etc.).

→ Status of the person responsible for regulatory compliance[31]

The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation. This person shall therefore suffer neither discrimination nor any reprisals (redundancy, termination of mandate, etc.) in relation with the performance of his or her missions.

30. Article 15(1) of the MDR.
31. Article 15(5) of the MDR.

The MDR does not contain any precise details about who the person responsible for regulatory compliance shall report to.

→ Missions of the person responsible for regulatory compliance [31]

The tasks of the authorised representative are stated in the mandate signed with the manufacturer.

The tasks that the authorised representative shall at least perform are listed in article 11.3 of the Regulation and the tasks that the manufacturer cannot entrust to authorised representative are listed in article 11.4 (see paragraph missions of the authorised representative laid down by the MDR).

The compliance with the obligations referred to in article 11.4 **shall therefore not be assigned to the person responsible for regulatory compliance of the authorised representative.** However, the other tasks can be assigned to the person responsible for regulatory compliance of the authorised representative, in particular those listed in article 11.3.

The parties may mention the missions of the person responsible for regulatory compliance of the authorised representative in the mandate; in this way the authorised representative can easily refer to this list and make sure that it does indeed have a designated and qualified person ensuring these missions at its disposal.

NOTE

For more information concerning the person responsible for regulatory compliance, please consult the Snitem booklet dedicated to this subject, as well as the MDCG 2019-7 rev.1 guide.
The MDCG guides are available on the following page: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

31. Article 15(3) of the MDR.

END OF THE MANDATE

A mandate can be terminated in two cases: if the manufacturer and/or the authorised representative decide(s) to terminate it or if the manufacturer or authorised representative ceases business activity.

1. DECISION TO TERMINATE THE MANDATE

The MDR holds that the authorised representative shall terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation [34]. The manufacturer and/or the authorised representative are also free to decide to terminate the mandate for any other reason.

→ Change of authorised representative

If the manufacturer decides to terminate the mandate but wishes to continue placing its devices on the EU market, it shall have to formalise a contract with another authorised representative. As the manufacturer is established outside the EU, it is obliged to have an authorised representative established in the EU territory to be able to place its devices on the Union market. The new mandate shall comply with all the obligations stated above. The MDR holds that the arrangements for a change of authorised representative shall be clearly defined in an agreement between:

- the manufacturer,
- the incoming authorised representative,
- where practicable the outgoing authorised representative.

The Regulation states the information that this agreement shall **at least** specify [35]:

- the date of termination of the mandate of the outgoing authorised representative,
- the date of beginning of the mandate of the incoming authorised representative,
- the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material,
- the transfer of documents, including confidentiality aspects and property rights,
- the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints

34. Article 11(3.h) of the MDR.
35. Article 12 of the MDR.

or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative. No period is scheduled for this obligation.

In this case, the obligation on the authorised representative to keep certain documents at the disposal of competent authorities for a period of 10 or 15 years after the last device has been placed on the market lapses for the outgoing authorised representative insofar as it shall transfer the documents to the incoming authorised representative. It is the incoming authorised representative who shall therefore take on this obligation.

→ End of the mandate without new authorised representative

If the manufacturer decides to terminate the mandate and does not need to designate a new authorised representative (for example if it ceases to place the devices covered by this mandate on the market), the MDR does not provide for any specific formalities.
In this case, the former authorised representative is under the obligation to keep certain documents at the disposal of competent authorities for a period of 10 or 15 years because these documents remain in its possession.

2. CESSATION OF BUSINESS ACTIVITIES

→ Cessation of manufacturer's business activities

The mandate is terminated if the manufacturer ceases operations. This is because, on the one hand the manufacturer does not exist as a legal entity and, on the other, it no longer places devices on the EU market. However, the authorised representative's obligation to keep certain documents at the disposal of competent authorities for a period of 10 or 15 years after the last device has been placed on the market continues.

→ Cessation of authorised representative's business activities

Insofar as a manufacturer established outside the EU must have an authorised representative established in the EU to place its products on the Union market, a change of authorised representative shall take place as quickly as possible if the authorised representative ceases trading.

> The manufacturer may lay down in the mandate that, in the event of problems likely to affect the continuation of its activity, the authorised representative shall inform the manufacturer as early as possible of its situation and assist with the change of authorised representative.

ADAPTATION OF NATIONAL LEGISLATION

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

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

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

PENALTIES INCURRED

Regulation 2017/745 leaves it to the Member States to determine the penalties applicable to infringements of its provisions [36]. 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[37].
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).

36. Article 113 of regulation 2017/745.

37. 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).

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 [38]. 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.

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].

38. 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.

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.

ANNEX

SYNTHESIS OF MISSIONS OF AUTHORISED REPRESENTATIVES

Tasks that principals shall at least entrust to authorised representatives

- Verify that the **EU declaration of conformity** and **technical documentation** have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been **carried out** by the manufacturer [38];

- Keep available a copy of the **technical documentation,** the **EU declaration of conformity** and, if applicable, a copy of the relevant certificate, including any **amendments and supplements,** at the disposal of competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market (15 years for implantable devices) [39];

- In response to a request from a competent authority, **provide that competent authority with all the information and documentation necessary to demonstrate the conformity** of a device, in an official Union language determined by the Member State concerned [40];

- **Cooperate** with the competent authorities **on any preventive or corrective action** to eliminate or, if that is not possible, mitigate the risks posed by devices [41];

- Immediately **inform** the manufacturer about **complaints and reports** from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated [42];

- **Be registered in the electronic system for economic operators, update** this information within a period of one month following a change to this information, **confirm the validity of the information** one year after submitting it and every second year thereafter and **verify that the manufacturer has complied with the registration obligations for products and systems other than custom-made ones in the UDI database** and that the information is **accurate, complete and up to date** [43]**;**

38. Article 11(3)(a) of the MDR.
39. Article 11(3)(b) of the MDR.
40. Article 11(3)(d) of the MDR.
41. Article 11(3)(f) of the MDR.
42. Article 11(3)(g) of the MDR.
43. Article 11(3)(c) of the MDR. Some steps depend on when the Eudamed base is made mandatory, in accordance with the deadlines set out in article 123 of the regulation.

- **Forward to the manufacturer any request** made by a competent authority of the Member State in which the authorised representative has its registered place of business **for samples, or access to a device** and verify that the competent authority receives the samples or is given access to the device [44];

- Terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation [45].

Tasks that principals shall not entrust to authorised representatives [46]

- For devices other than custom-made devices, **draw up** and **keep up to date technical documentation** for those devices such as to allow the conformity of the device with the requirements of the Regulation to be assessed;

- Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, **draw up an EU declaration of conformity** and affix the CE marking of conformity;

- Ensure that the devices it places on the market have been **designed and manufactured in accordance with the requirements of this Regulation;**

- Ensure that **procedures are in place to keep series production in conformity with the requirements of the Regulation,** establish, document, apply, maintain, keep up to date and continually improve a quality management system that shall ensure conformity with the requirements of this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device;

- If it considers or has reason to believe that a device which it has placed on the market or put into service is not in conformity with the Regulation **immediately take the necessary corrective action** to bring that device into conformity, to withdraw it or to recall it.

- **Comply with** the obligations relating to the UDI system and with the **registration obligations for manufacturers and devices;**

- **Implement and keep up to date the post-market surveillance system;**

- Conduct a clinical evaluation, including **post-market clinical follow-up;**

44. Article 11(3)(e) of the MDR.
45. Article 11(3)(h) of the MDR.
46. Article 11(4) of the MDR.

- **Establish, implement, maintain and document a system of risk management;**

- Ensure that the device is accompanied by a **label** and an instruction leaflet in an official Union language determined by the Member State in which the device is made available to the user or patient.

Other obligations on the authorised representative

- The competent authority shall inform the manufacturer and, where applicable, the authorised representative when a previously unknown risk is identified or when the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination and the manufacturer or authorised representative **shall then take the necessary corrective actions**[47].

- **Cooperate with the competent authorities** when the latter carry out an evaluation of the device concerned relating to the risk presented by the device, or to any other non-compliance, based on data obtained by vigilance or market surveillance activities or on other information, where they have reason to believe that a device may present an unacceptable risk to the health and safety of patients, users or other persons, or to other aspects of the protection of public health or otherwise does not comply with the requirements of the MDR[48];

- Where, having performed an evaluation pursuant to article 94 of the MDR, 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 a reasonable period that is clearly defined and communicated to the relevant economic operator[49].

47. Article 90 of the MDR.
48. Article 94 of the MDR.
49. Article 95(3) of the MDR.

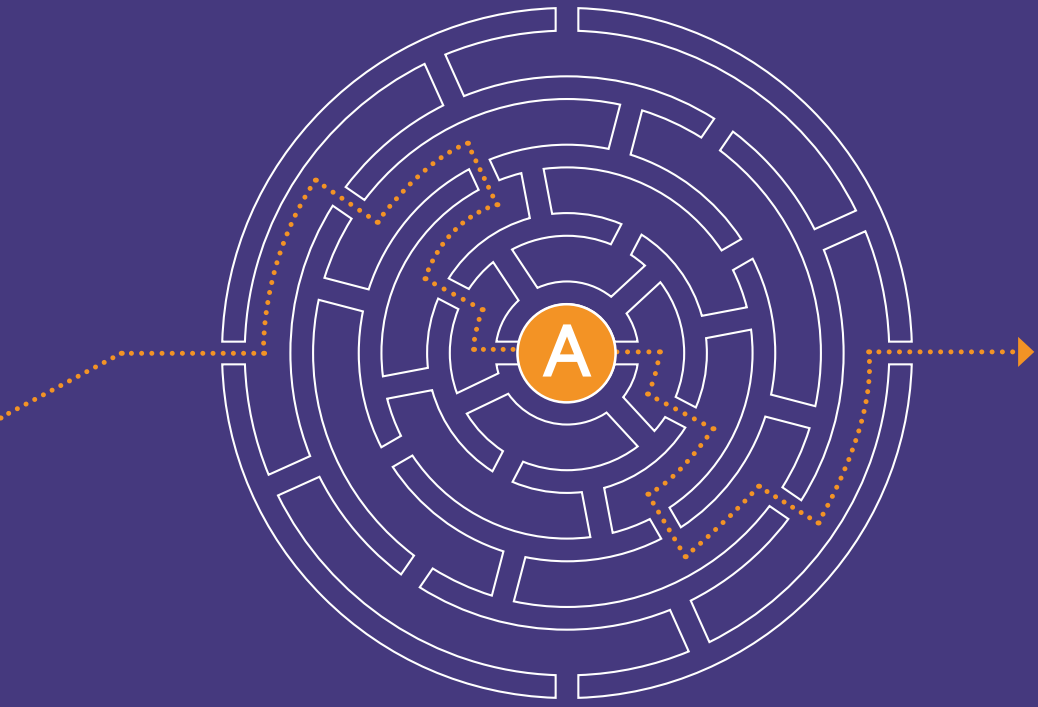
- Where, having performed an evaluation pursuant to article 94 of the MDR, the competent authorities find that a device does not comply with the MDR but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to **bring the non-compliance concerned to an end** within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance [50].

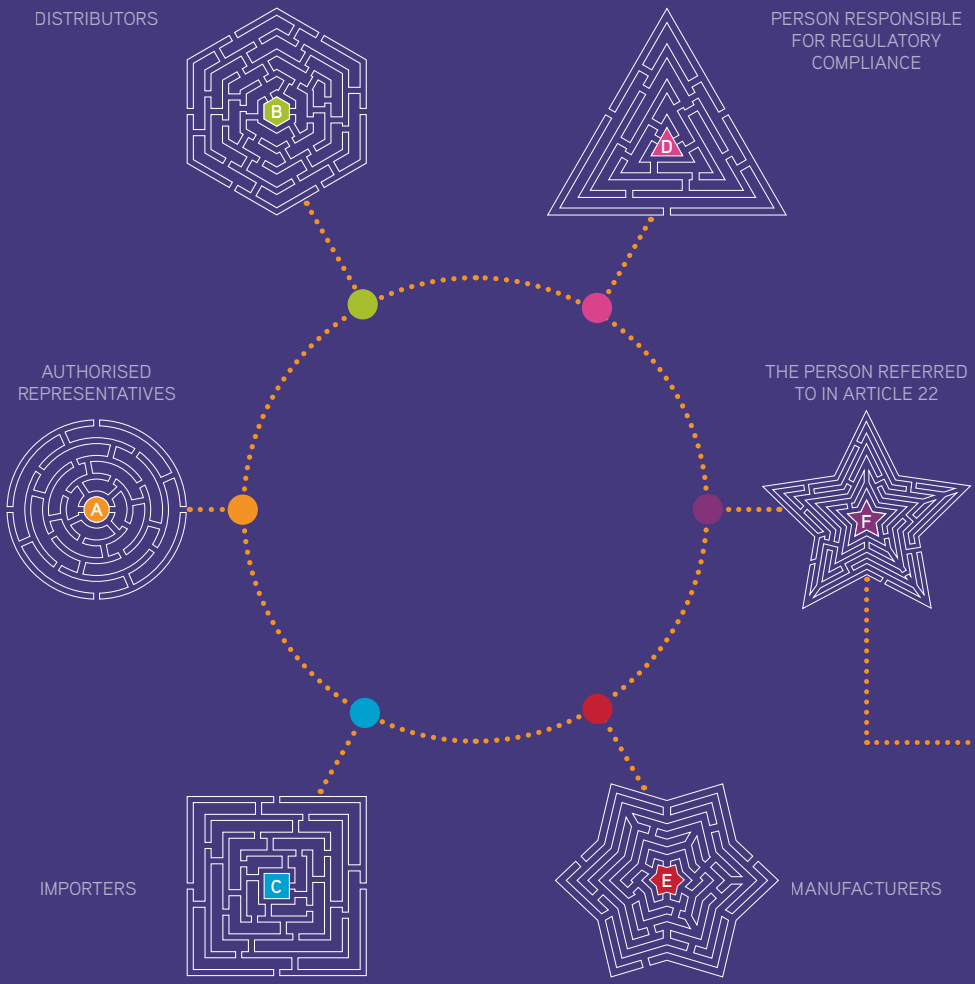
- Provide a **copy of the mandate** to the competent authority, upon request [51].

- **Keep at the disposal of the competent authorities** for a period of at least 10/15 years after the last device has been placed on the market the documents listed in Annexes IX, X and XI of the MDR.

50. Article 97(1) of the MDR.
51. Article 11(3) of the MDR.

NOTES


A



LE DISPOSITIF MÉDICAL

snitem

Syndicat national
de l'industrie
des technologies médicales

afaq ISO 9001 Qualité AFNOR CERTIFICATION

39, rue Louis Blanc - 92400 Courbevoie
Tél. : 01 47 17 63 88
Email : communication@snitem.fr

snitem.fr @SnitemDM