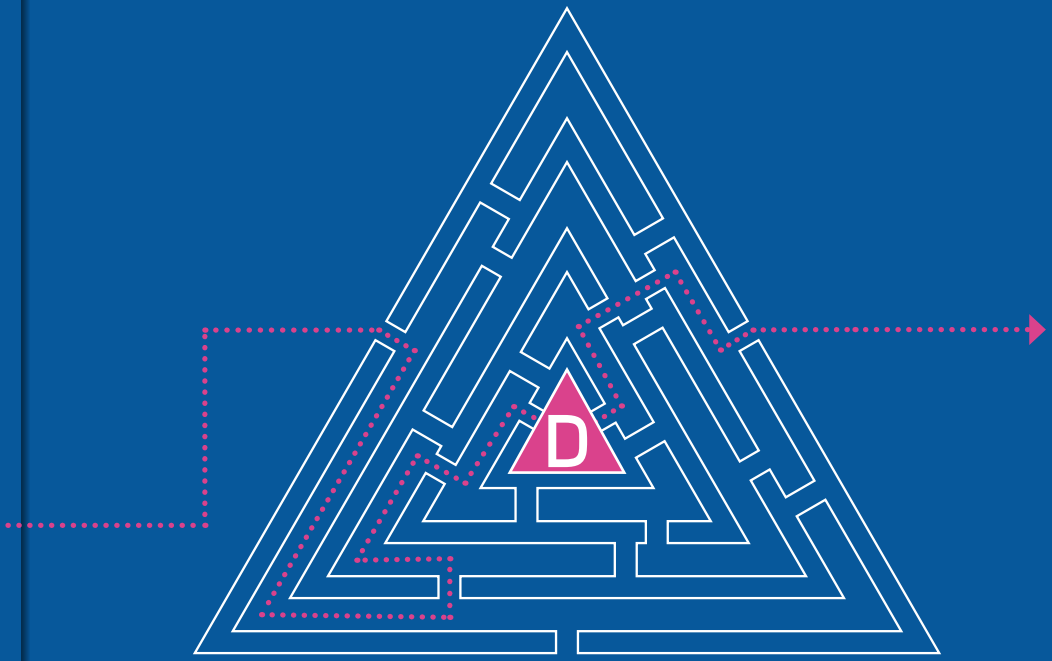
REGULATION

PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

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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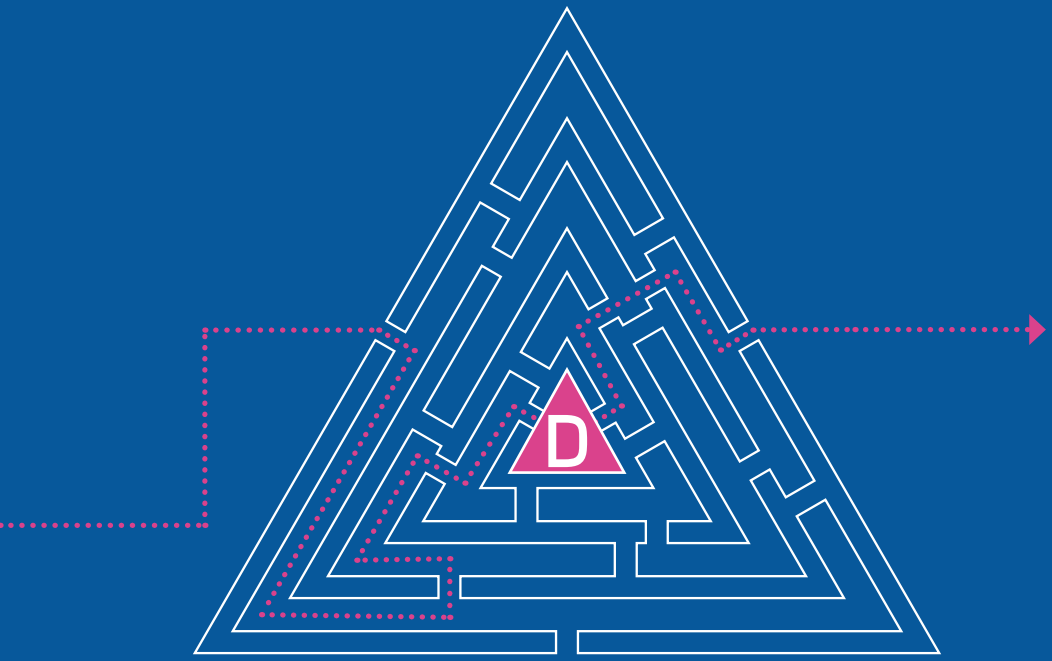

This document is likely to change over time: SNITEM will regularly update the information herein.

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CONTENTS

REFERENCE TEXTS 3

RELEVANT ECONOMIC OPERATORS 3

PROFILE OF PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE 5

TASKS OF PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE 6

APPOINTMENT OF THE PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE 7

1. Identification of a qualified person 7
2. Formalisation of the appointment 8
3. Registration in Eudamed 8

PENALTIES INCURRED 9

TIMELINE 9

The Medical Device Regulation («MDR»), published in the OJEU on 5 May 2017 and entered into force on 26 May 2017, requires manufacturers and authorised representatives to have a person responsible for regulatory compliance[1]. This person must have the expertise and experience laid down in the Regulation, and will be assigned specific tasks.

1. Article 15 of regulation 2017/745.

REFERENCE TEXTS

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[2]

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

RELEVANT ECONOMIC OPERATORS

Regulation 2017/745 specifies that the manufacturer and the authorised representative must have at least one person responsible for regulatory compliance.
The Regulation first of all concerns the **manufacturer** and therefore any natural or legal person who:

• manufactures or fully refurbishes a device,
or
• has a device designed, manufactured or fully refurbished,

and markets that device under its name or trademark on the territory of the European Union.

2. Le règlement (UE) 2017/745 a été modifié par :
- le corrigendum publié au JOUE du 3 mai 2019 (https://eur-lex.europa.eu/eli/reg/2017/745/corrigendum/2019-05-03/oj)
- le corrigendum publié au JOUE du 27 décembre 2019 (https://eur-lex.europa.eu/eli/reg/2017/745/corrigendum/2019-12-27/oj)
- le règlement (UE) 2020/561 du Parlement européen et du Conseil du 23 avril 2020 modifiant le règlement (UE) 2017/745 relatif aux dispositifs médicaux en ce qui concerne les dates d'application de certaines de ses dispositions (https://eur-lex.europa.eu/eli/reg/2020/561/oj)

RELEVANT ECONOMIC OPERATORS

No distinction is made according to product: manufacturers of class I, IIa, IIb and III devices, implantable and non-implantable, active and non-active, mass-produced and custom-made, with and without an intended medical purpose[3], are concerned.

ATTENTION

Regulation 2017/745 provides for several cases in which the manufacturer's obligations, and therefore in particular the obligation to have a person responsible for regulatory compliance, apply to **distributors, importers** or **any other** natural or legal **person**[4]**.** This is the case if this person:

- makes available on the market a device under its name, registered trade name or registered trade mark (except in cases where the manufacturer enters into an agreement whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers by the regulation),
- changes the intended purpose of a device already placed on the market or put into service,
- 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.

Regulation 2017/745 also refers to the **authorised representative,** i.e. any natural or legal person established within the European 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.

SPECIFIC CASES

Manufacturers meeting the definition of **micro or small enterprises**[5]**,** as well as **authorised representatives** regardless of their size, are not required to have a person responsible for regulatory compliance within their organisation. In this case, they must have such a person **permanently and continuously at their disposal.** They may therefore entrust this task to a third party by means of a contract, which must in particular provide for an on-call or back-up system so that a person fulfilling the required conditions is effectively available on a continuous basis.

3. List of devices without an intended medical purpose in Annex XVI of Regulation (EU) 2017/745.
4. Article 16 of regulation 2017/745.
5. The MDR refers to Commission Recommendation 2003/361/EC of 6 May 2003 which sets the following staffing and financial thresholds:
   - Microenterprise: an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million
   - Small enterprise: an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million.

→ Summary

	MANUFACTURER [(including operator modifying a device - label, instructions, packaging, etc. (see box above)]		AUTHORISED REPRESENTATIVE
Size of organisation	**More than 50 persons** OR Annual turnover or annual balance sheet total **exceeds EUR 10 million**	**Less than 50 persons** AND Annual turnover or annual balance sheet total **exceeds EUR 10 million**	Regardless of size and annual turnover
Requirement	Obligation to have a person responsible for regulatory compliance **in-house**	**Possibility of outsourcing** the duties provided that the person is **permanently and continuously at the disposal of the enterprise**	

PROFILE OF PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

Regulation 2017/745 provides for minimum conditions of qualification and/or professional experience that the person responsible for regulatory compliance must meet in order to be able to perform this task. This person must have:

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

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

- or, **for custom-made devices,** at least two years of professional experience within a relevant field of manufacturing.

Regulation 2017/745 does not specify that the person's qualification and/or experience conditions are to be audited a priori. Alternatively, in the event of an audit, the manufacturer or authorised representative must be able to prove that it has a clearly identified person who meets the defined conditions.

TASKS OF PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

With regard to manufacturers, the person responsible for regulatory compliance must be responsible for ensuring [6]:

- the **conformity of the devices** is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released,
- the **technical documentation** and the **EU declaration of conformity** are drawn up and kept up-to-date,
- the manufacturer applies and keeps up-to-date a **post-market surveillance system** in accordance with regulation 2017/745,
- the **vigilance** obligations are fulfilled,
- in the case of a device under **investigation,** a statement that the device in question complies with the general safety and performance requirements regardless of the aspects of the clinical investigation and that, with respect to those aspects, all precautions have been taken to protect the health and safety of the participant, is issued.

With regard to **authorised representatives,** their tasks are established by the mandate entered into with the manufacturer. The minimum tasks of the authorised representative are listed in article 11.3 of the Regulation and some of the manufacturer's obligations, listed in article 11.4 of the Regulation, are not transferable to the authorised representative (see booklet on authorised representative).

6. Article 15, 3. du règlement 2017/745.

→ **Compliance with the obligations referred to in article 11.4 may therefore not be the responsibility of the person responsible for regulatory compliance of the authorised representative.** On the other hand, the other tasks, in particular those described in Article 11.3, may be assigned to the person responsible for regulatory compliance of the authorised representative.

Regulation 2017/745 specifies that in the fulfilment of its tasks, the person responsible for regulatory compliance must not suffer **any disadvantage** within the manufacturer's organisation **in relation to the proper fulfilment of its duties,** regardless of whether or not they are employees of the organisation.

Several people can be responsible for ensuring compliance within an organisation. Their respective areas of responsibility must be stipulated in writing.

APPOINTMENT OF THE PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

1. IDENTIFICATION OF A QUALIFIED PERSON

The person responsible for regulatory compliance may, depending on the organisation and internal resources of the manufacturer or authorised representative, be:

- an employee who is proposed and agrees to assume this responsibility,
- a person decided to be recruited,
- under certain conditions, an external service provider decided to be contracted[7].

Before appointing this person, the manufacturer or authorised representative must ensure that they meet the required qualification and/or experience requirements.

In order to verify that the person fulfils the required qualification and/or experience conditions, the operator may refer to its qualification diplomas and certificates, its employment contract, its job description, its seniority, and, if the person is recruited, to a certificate of employment (dated and detailing the position held), its CV or even references.

7. The latter possibility is only available to micro and small enterprises with the status of manufacturer and to enterprises with the status of authorised representative (see section on "relevant economic operators").

2. FORMALISATION OF THE APPOINTMENT

The person responsible for regulatory compliance must be clearly identified, whether within the manufacturer's or authorised representative's organisation or in an outsourced capacity. The appointment must therefore be formalised (employment contract, job description, service contract, etc.), in order to be able to justify, in the event of an audit, that a person meeting the required profile is indeed responsible for the tasks provided for in Regulation 2017/745.

> If the tasks provided for in Regulation 2017/745 are divided between several persons responsible for regulatory compliance, their precise areas of responsibility must be specified and formalised.

The person responsible for regulatory compliance must also be easily identifiable by any employee of the company who may have to call upon them (organisation chart, internal procedures, list of persons to contact, quality manual, etc.).

3. REGISTRATION IN EUDAMED [8]

Manufacturers and authorised representatives must record in Eudamed the name, address and contact details of the person or persons responsible for regulatory compliance. They shall ensure that this information is complete, accurate and up-to-date.

8. This step depends on when the Eudamed base will be operational.

PENALTIES INCURRED

Regulation 2017/745 leaves it to the Member States to determine the penalties applicable to infringements of its provisions [9]. The Member States shall notify these penalties to the Commission no later than three months before the date of application of the Regulation, i.e. no later than 25 February 2021.

TIMELINE

The provisions of Regulation 2017/745 regarding the person responsible for regulatory compliance will be mandatory on the date of application of the Regulation, i.e. **on 26 May 2021. In the context of the covid-19 health crisis, the date of application of the regulation originally planned for 26 May 2020 has been postponed by one year [10]. The person must therefore be identified and able to carry out the duties laid down in the MDR by this date.**

The enterprises concerned must therefore as soon as possible:

- ensure that they have a person who meets the required qualification requirements (internal resources, recruitment, contracting with a third party, etc.) by that date;
- formalise the appointment of the person (employment contract, job description, service contract, etc.) and identify them within the company (organisation chart, quality manual, etc.);
- ensure that the person has the means to accomplish their duties;
- ensure that the person's skills and the conditions enabling them to carry out their duties are maintained.

Regulation 2017/745 specifies that devices complying with the regulation may be placed on the market before 26 May 2021 [11]. To be placed on the market in accordance with the regulation, they must comply with the whole regulation. The manufacturer and its authorised representative, where applicable, must therefore have a person responsible for regulatory compliance.

9. Article 113 of regulation 2017/745.
10. 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.
11. Article 120, 5) of the MDR.

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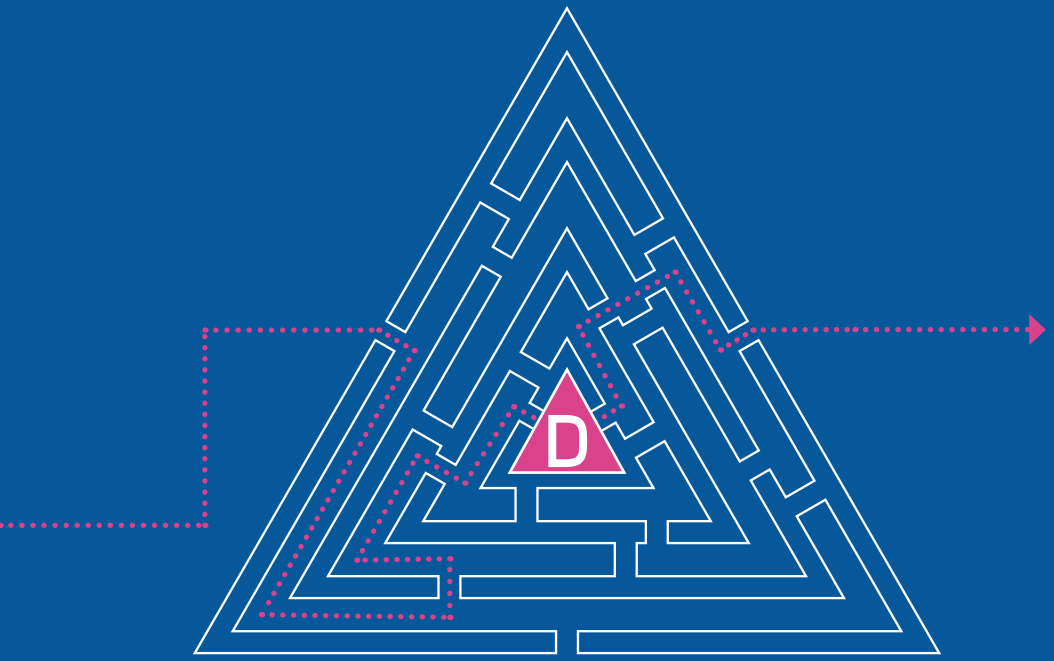
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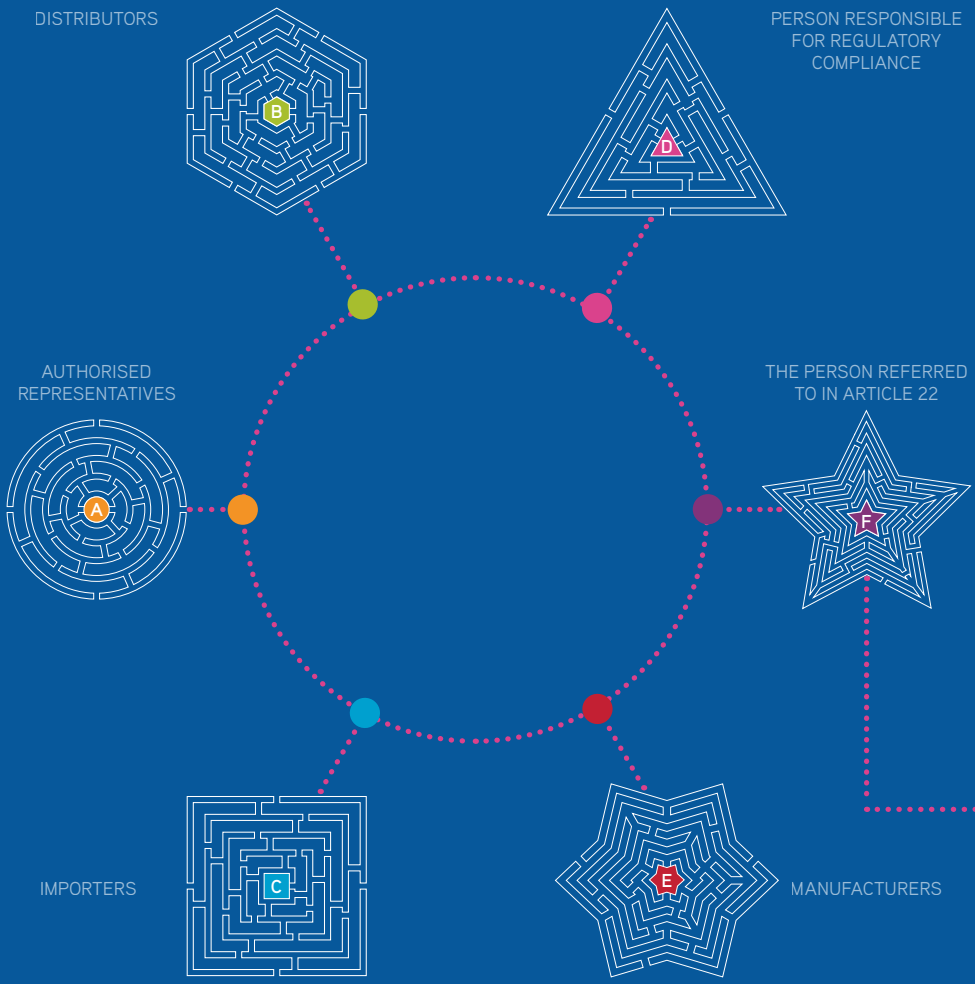

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