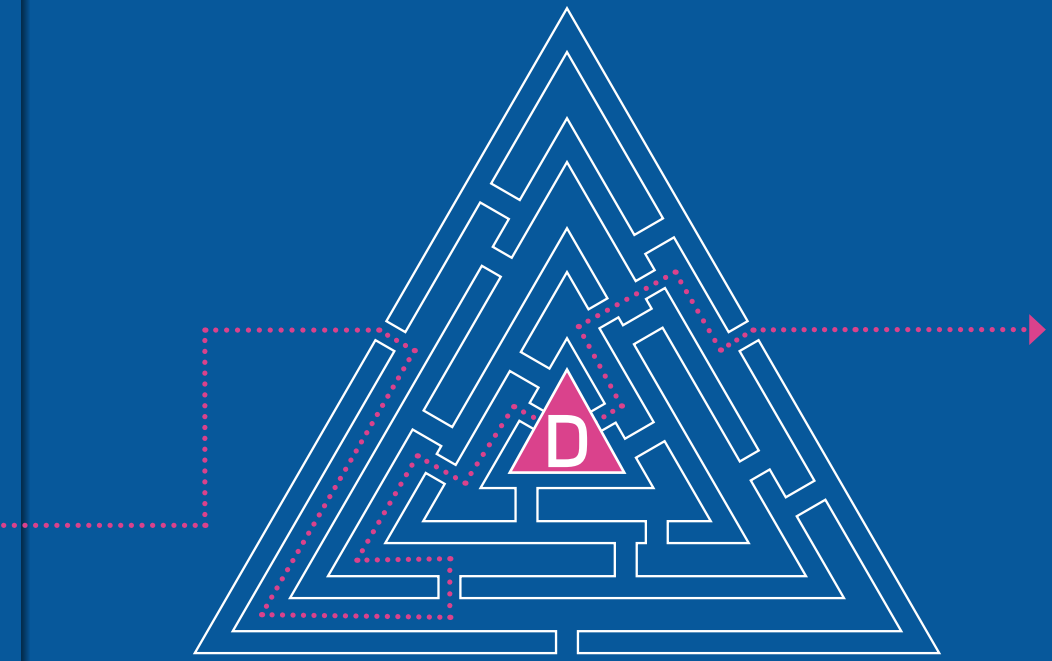
REGULATION

PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

SYNTHESIS



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EUROPEAN MEDICAL DEVICE REGULATION (MDR)

The information herein is given as guidance only. It is not necessarily exhaustive and cannot take the place of the applicable regulation.

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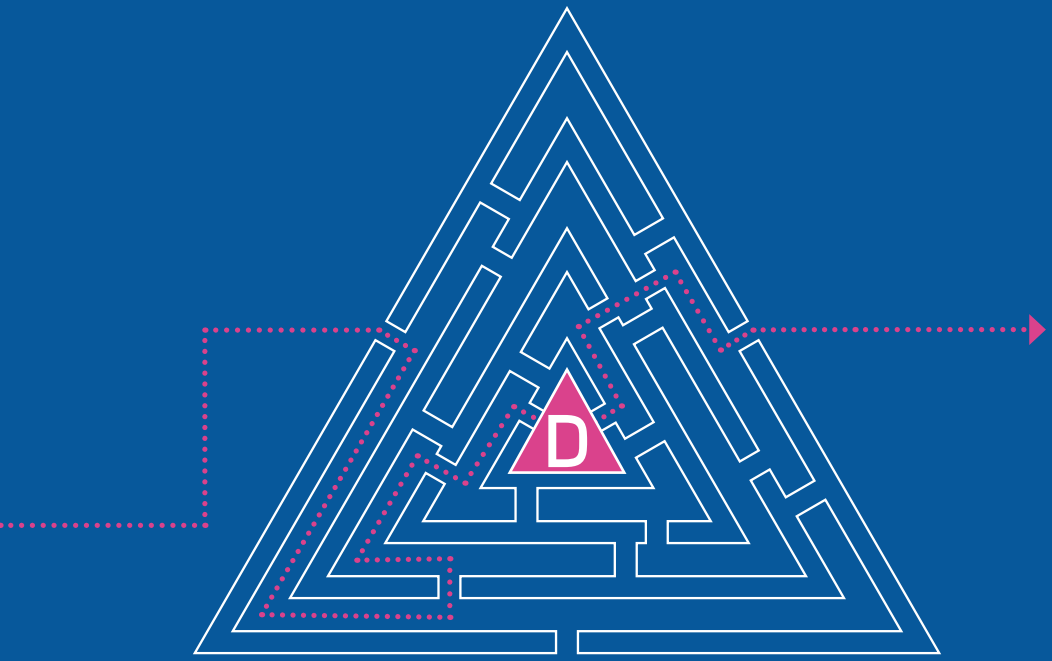

This document is likely to change over time: SNITEM will regularly update the information herein.

February 2024 version

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The Medical Device Regulation («MDR»), published in the OJEU on 5 May 2017 and entered into application on 26 May 2021, 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 is 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]

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20250110

➔The MDCG (Medical Device Coordination Group) has drawn up a guide concerning the person responsible for regulatory compliance, revised in December 2023 (MDCG 2019-7 rev. 1).
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

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)
- 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)

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.

This is also the case when reprocessing and reusing reprocessed single-use devices[5], or making available a system or pack incorporating devices that are not CE-marked, or whose combination is not compatible given the original purpose of the devices, or whose sterilization has not been carried out in accordance with the manufacturer's instructions[6].

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 the regulation.

SPECIFIC CASES

Manufacturers meeting the definition of **micro or small enterprises**[7], 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 On this subject, see the "Importer" and "Distributor" booklets also available.
5. Article 17 of regulation 2017/745
6. Article 22.4 of regulation 2017/745
7. 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** [8]	**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[9],

- 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.

8. The MDCG 2019-7 rev.1 guide specifies that the notion "within the organization" is to be understood as the obligation for the person to be an employee of the organization.

9. The MDCG 2019-7 rev. 1 guide specifies that this experience must be substantial and recent, enabling the person to fulfill the obligations incumbent upon him or her.

The training and/or experience of the designated person may be checked by the notified body during a certification, renewal or annual follow-up audit, or in the event of inspection by a competent authority. 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[10]:

- 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. Note that some of the manufacturer's obligations, listed in article 11.4 of the Regulation, cannot be delegated to the authorised representative (see booklet on authorised representative).

10. 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.**

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**[11], 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.

DESIGNATION 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 with whom he contracts[12]

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.

11. The MDCG 2019-7 rev. 1 guide gives the example of a termination or penalty.

12. 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 DESIGNATION

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 designation 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[13]

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.

13.This step depends on when the Eudamed base is made mandatory, in accordance with the deadlines set out in article 123 of the regulation.

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[14].
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[15].
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).

14.Article 113 of regulation 2017/745.

15. 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

1. GÉNERAL TIMELINE

Regulation 2017/745 was published on 5 May 2017 and entered into force on 26 May 2017. It was expected to enter into force three years later, on 26 May 2020, except for certain provisions for which an earlier (e.g. for notified bodies and competent authorities) or later (e.g. for the UDI) date of application is foreseen. In the context of the covid-19 health crisis, the date of application of the regulation has been postponed to 26 May 2021[16]. Please note that the specific calendars (grace period, staggered calendar for the application of the IUD, etc.) are not postponed.

A transitional period is provided for, during which certain devices complying with Directives 90/385/EEC and 93/42/EEC may be placed on the market even though the date of application of the regulation has passed[17].

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[18] 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 for post-market surveillance, market surveillance, vigilance and registration of economic operators and devices[19].

2. PRECISION REGARDING THE PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

The provisions of Regulation 2017/745 regarding the person responsible for regulatory compliance are applicable from the regulation's entry into force on May 26, 2021. Manufacturers and authorised representatives of MDR devices must therefore have designated this person.
On the other hand, the MDCG 2021-25 guide[20] specifies that Article 15 of the regulation does not apply to “legacy devices” (MDD devices benefiting from the transition period).

16. 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.

17. Article 120 of regulation 2017/745 as amended by the 2nd corrigendum (December 2019).

18. 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.

19. Article 120 point 3 of regulation 2017/745. Some steps depend on when the Eudamed base is made mandatory, in accordance with the deadlines set out in article 123 of the regulation. In the meantime, operators are using the means and formats provided for in the Directives and transposed by the Member States.

20.MDCG 2021-25 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC. 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

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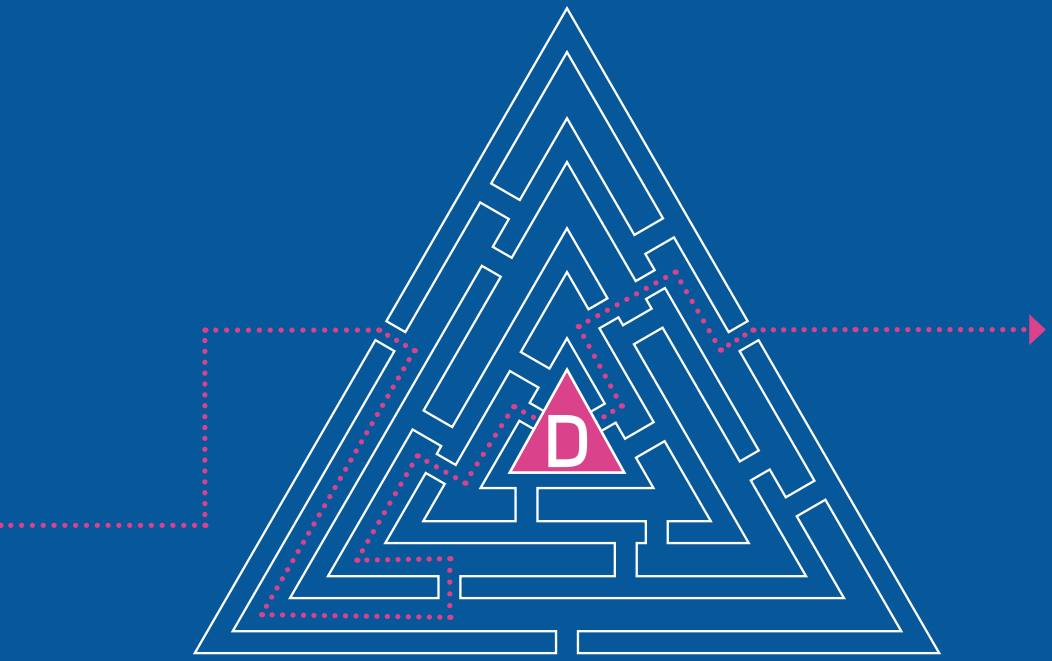
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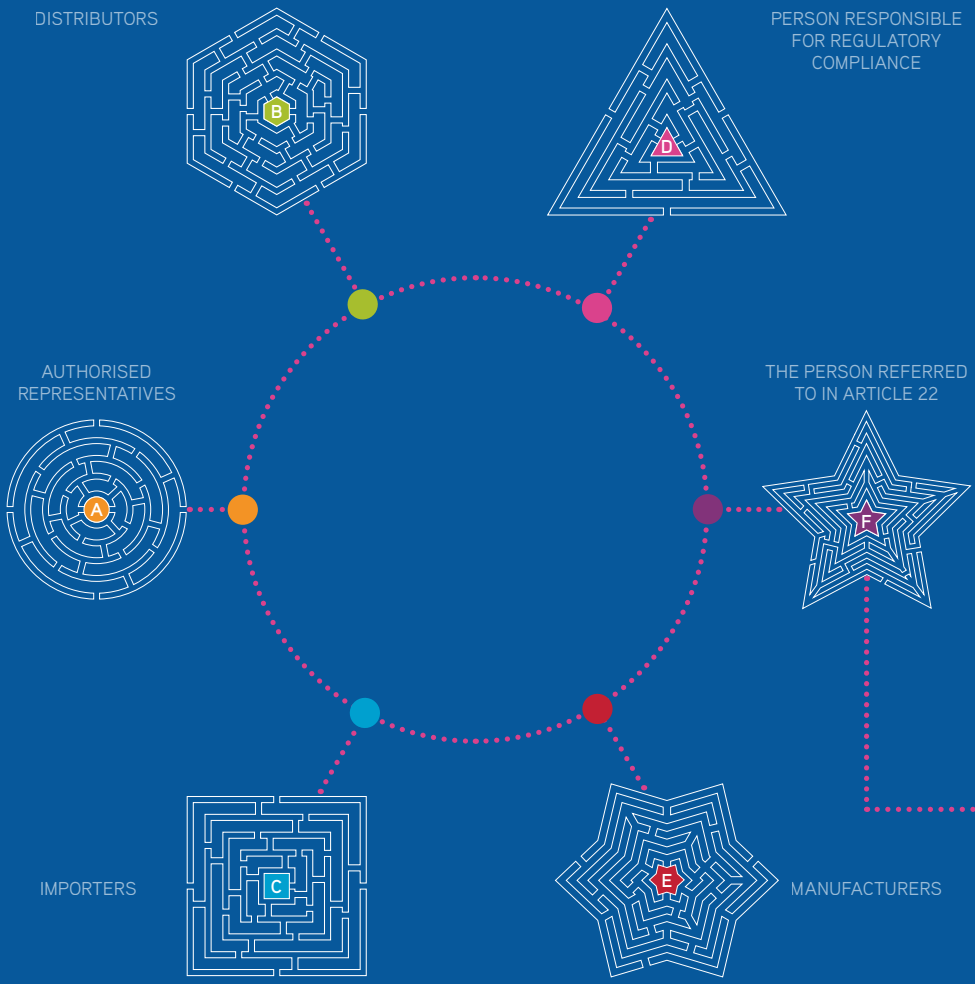

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