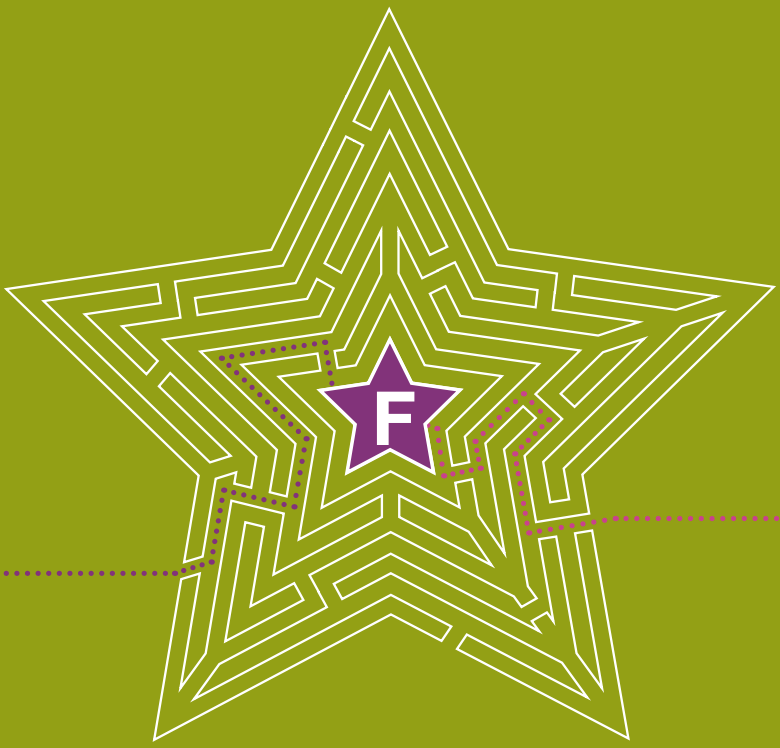
REGULATION

THE PERSON REFERRED TO IN ARTICLE 22 OF THE MDR

SYNTHESIS



DM

EUROPEAN MEDICAL DEVICE REGULATION 2017/745

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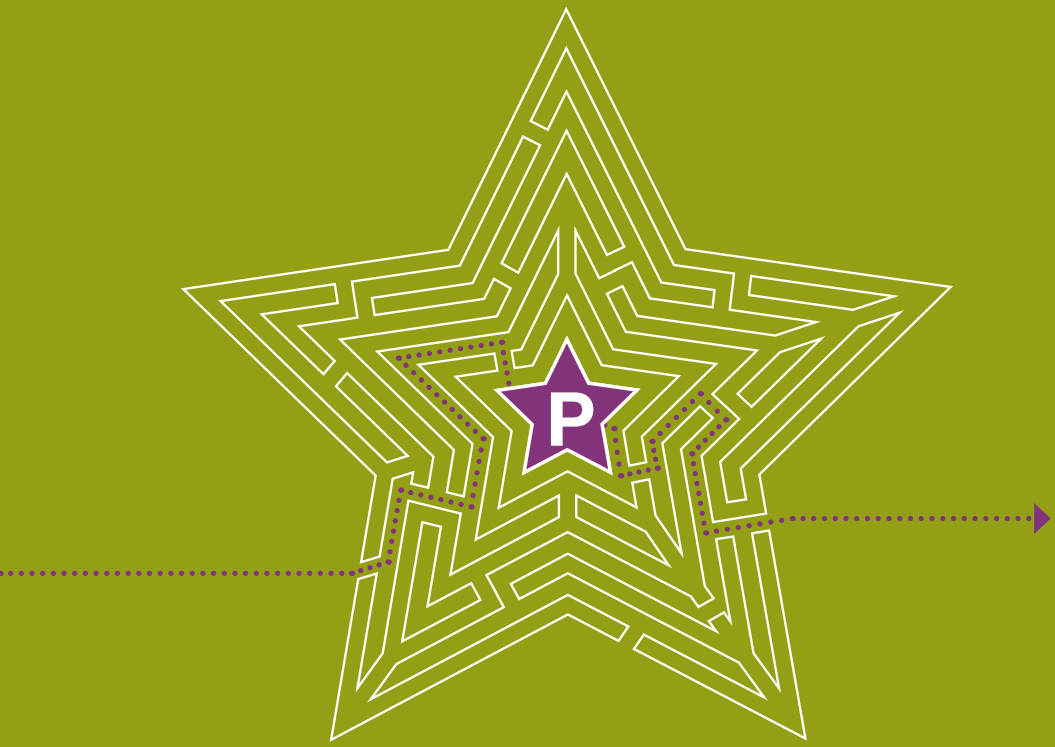

This document is subject to change over time: SNITEM will update the information of booklet as necessary.

February 2024 Version

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REFERENCE TEXTS AND DOCUMENTS

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

MDCG (Medical Device Coordination Group) guidance available on the European Commission website: : https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

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 to the implementation of the provisions applicable to products in the European Union (directives drawn up on the basis of the provisions of the new approach and the global approach, implementation of the new legislative framework, Lisbon Treaty). The aim of this guide is to clarify these provisions and to contribute to their uniform and consistent application in the different sectors and throughout the single market.
The Blue Guide therefore provides guidance on the application of the new Medical Devices Regulation.

1. Regulation (EU) 2017/745 was amended by:
- corrigendum published inthe EU OJ of 3 May 2019 (https://eur-lex.europa.eu/eli/reg/2017/745 corrigendum/2019-05-03/oj
- corrigendum published in the EU OJ 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

The concepts of systems and procedure packs existed in Directive 92/42, but Regulation 2017/745 provides new definitions:

- A "**procedure pack**" means a combination of products packaged together and placed on the market with the purpose of being **used for a specific medical purpose**[2].

- A "**system**" means a combination of products, either packaged together or not, which are intended to be **connected or combined to achieve a specific medical purpose**[3].

The **assembler** is not defined by the Regulation but is the term used in the sector to designate the operator who produces and markets systems and procedure packs on its behalf. Thus, it is the assembler that is referred to in Article 22 of the new Regulation when it lays down the obligations applicable to any natural or legal person who combines devices bearing a CE marking with other devices or products in order to place them on the market as a system or procedure pack . The Regulation includes in this Article persons who sterilise systems or procedure packs for the purpose of placing them on the market .

To cover these two activities, this booklet will therefore refer to "the person referred to in Article 22 of Regulation 2017/745".

2. Article 2(10) of Regulation 2017/745.
3. Article 2(11) of Regulation 2017/745.
4. Article 22(1) of Regulation 2017/745.
5. Article 22(3) of Regulation 2017/745.

SYNTHESIS OF THE OBLIGATIONS OF THE PERSON REFERRED TO IN ARTICLE 22

Before a system or procedure pack is placed on the market		Ref.[6]
Possible combinaisons	The person referred to in Article 22 shall combine a device with compatible products that may be combined with it. These products may be: - other devices bearing the CE marking; - in vitro diagnostic medical devices bearing the CE marking in conformity with Regulation 2017/746; - other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified. **The combination shall be made in a manner that is compatible with the intended purpose of the products and within the limits of use specified by their manufacturers**	Art. 22, 1)
Compliance	The person referred to in Article 22 shall verify the mutual compatibility of the products they combine, in accordance with the manufacturers' instructions.	Art. 22, 2) a)
	The person referred to in Article 22 shall have subjected the activity of combining products as a system or procedure pack to appropriate methods of internal monitoring, verification and validation.	Art. 22, 2) c)
	The person who sterilises a system or procedure pack shall apply one of the sterilisation procedures set out in Annex IX or Annex XI and be assessed by a Notified Body under the Regulation for this type of activity. They carry out the sterilisation in accordance with the manufacturer(s)' instructions and issues a statement to that effect.	Art. 22, 3) a)
Packaging	The person referred to in Article 22 shall package the procedure pack and package the system in one or more components. They shall provide the relevant information to users, incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together.	Art. 22, 2) b)
	The systems and procedure packs shall be supplied with a label and instructions in accordance with Regulation 2017/745. For systems not packaged in one components, each package shall bear a label.	Art. 22, 5)
	The systems or procedure packs do not bear an additional CE marking.	Art. 22, 5)
	The person combining and/or sterilising the products shall add on the system or procedure pack: their name, registered trade name or registered trademark and the address at which that person can be contacted.	Art. 22, 5)

6. 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.

Before a system or procedure pack is placed on the market		Ref.[7]
Statement	The person performing the combining activity shall draw up a statement that they have fulfilled the obligations listed in Article 22(2)(a), (b) and (c), i.e.: - verify the mutual compatibility of the products in accordance with the manufacturers' instructions; - package the system or procedure pack and supply relevant information to users; - subject the activity of combining products to appropriate methods of internal monitoring, verification and validation. The person who sterilises systems or procedure packs shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions. These statements shall be kept at the disposal of the competent authorities for 10 years, or 15 years for implantable devices, after the last system or procedure pack has been placed on the market.	**Art. 22, 1) 2)** and **5)**
UDI	The person referred to in Article 22 shall assign an UDI-DI to the system or procedure pack and affix it to the packaging of the procedure pack or system packaged as a single component or to the device itself[8]. If not affixed to the outside of the packaging, the UDI shall be readable or scannable (transparent packaging).	**Art. 29, 2)** and **Annex VI, part C, 6.3.1** to **6.3.3**
Registration	The person referred to in Article 22 shall register on Eudamed and provide to the UDI database the information listed in Annex VI Part B of Regulation 2017/745.	**Art. 29, 2)**

7. 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.
8. At this stage, the interpretation is not clear on the affixing of the UDI of a multi-component packaged system, nor on the possibility of affixing the UDI of the system or procedure pack directly to the product (which potentially has its own UDI if it is a MD bearing the CE marking).

After a system or procedure pack is placed on the market

Ref.[9]

Product traceability	The person referred to in Article 22 shall store and keep, preferably by electronic means, the UDI of the Class III implantable devices they have supplied or with which they have been supplied.	Art. 27, 8)
	The person referred to in Article 22 shall be able to identify any economic operator to whom they have directly supplied a device, any economic operator who has directly supplied them with a device and any health institution or healthcare professional to whom they have directly supplied a device.	Art. 25, 2)
Post-market surveillance	The person referred to in Article 22 must apply the provisions for importers and distributors concerning the handling of reports and complaints[10] (reporting).	
	In the event of a vigilance report, the person referred to in Article 22 must assess whether the incident may be attributable to their own activity and take any necessary corrective action.	
Correctives measures	Where a competent authority identifies an unacceptable risk to health or safety in relation to any of their products, the person referred to in Article 22 shall take appropriate corrective action.	Art. 95, 1)
	In the event of a non-compliance that does not present an unacceptable risk to health or safety in relation to any of their products, the person referred to in Article 22 shall bring the non-compliance to an end within a reasonable period.	Art. 97, 1)
	The person referred to in Article 22 shall cooperate with the competent authorities when they carry out an evaluation of the device.	Art. 94

Continuous

Ref.[9]

Confidentiality	The person referred to in Article 22 shall be bound by an obligation of confidentiality of information and data obtained in carrying out their tasks to protect: - personal data, - commercially confidential information and trade secrets, including intellectual property rights, unless disclosure is in the public interest, - the 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 who may request documentation, information, samples or access to a device from the person referred to in Article 22 or carry out inspections of their premises.	Art. 93, 3)

9. 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.
10. Guide MDCG 2021-27 rev.1 indicates that the person referred to in Article 22 must apply the obligations of Article 13 (importer) or 14 (distributor) as appropriate.

CHECK-LIST : BECOMING A COMPLIANT OPERATOR UNDER ARTICLE 22 OF REGULATION 2017/745

Internal organisation and tools

01 The operator shall meet the definition of a person referred to in Article 22

Location

The provisions of the Regulation do not require the person referred to in Article 22 to be established in the EU.

Activity

- The operator:
  - combines devices and products that may be combined according to Article 22 of the Regulation as a system or procedure pack, and/or
  - sterilises systems or procedure packs,
- the operator makes these systems or procedure packs available on the EU market.

Beware of certain cases which make the operator switch to the status of manufacturer:

- when the system or procedure pack includes products that do not comply with the regulations applicable to them (e.g. medical devices not bearing the CE marking),
- where the system or procedure pack includes products not covered by Article 22 of the Regulation,
- when the combination of products is not compatible given their original intended purpose,
- where sterilisation has not been carried out in accordance with the manufacturer's instructions.

02 The company shall be able to fulfil all the obligations applicable to the person referred to in Article 22

Ressources and staff

- the operator has the necessary resources (notably human, financial, technical) to fulfil the obligations laid down in the Regulation.
- the operator has a back-up system for certain tasks (e.g. to ensure that any corrective action can be taken as soon as necessary)

Processus for

- verification of products and accompanying documentation (validation of industrial processes, sterilisation, packaging, etc.),
  - packaging,
  - traceability,
  - corrective measures.

  The processes shall be documented and applied: the operator shall be able to prove at any time that they are in conformity with the obligations laid down in the regulation (procedures and associated records).

Tools

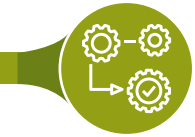
- identification of any stakeholders who may need to be contacted (contact person and details):
  - manufacturer, agent, importer, distributor
  - competent authorities of the Member States in which the systems and procedure packs are imported and distributed and, where applicable, the notified body
- systems to store and keep maintain documentation and traceability information for all systems and procedure packs and the UDI of Class III implantable devices.

Interaction with trade partners

! Contract with manufacturers and, where appropriate, the importer, distributor

Do not delegate any obligation or responsibility that falls within the scope of the Article 22 activity

Not to be delegated any obligation or responsibility that falls within the activity of other economic operators



PRODUCTS THAT MAY BE COMBINED AS A SYSTEM OR PROCEDURE PACK

One of the new features of Regulation 2017/745 is to provide for the possibility of combining one or more products with another status with at least one device to form systems or procedure packs.

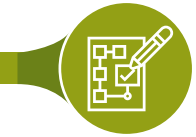
The products that may be combined with at least one device bearing the CE marking, subject to their compatibility, as a system or procedure pack are listed in Regulation 2017/745[11]. These are:

- other devices bearing the CE marking;
- *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation 2017/746;
- other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified (this could be the case, for example, of a device that is in conformity with the directive, an antiseptic drug in a treatment pack, etc.).

In addition, the products shall be combined as a system or procedure pack with the purpose of being used for a specific medical purpose[12].

The Regulation specifies that the combination shall be made in a manner that is compatible with the intended purpose of the devices and other products and within the limits of use specified by their manufacturers[13].
→Attention: if the operator does not respect the intended purpose and/or the conditions of use of the devices and products, they become a manufacturer and shall respect all the provisions of Regulation 2017/745 applicable to the manufacturer.

11. Article 22(1) of Regulation 2017/745
12.See definition of systems and procedure packs.
13.Article 22(1) of Regulation 2017/745.



OBLIGATIONS OF THE PERSON COMBINING PRODUCTS AS A SYSTEM OR PROCEDURE PACK

Article 22 of Regulation 2017/745 lists the obligations associated with the activity of combining for the purpose of placing a system or procedure pack on the market.

1. COMPATIBILITY OF COMBINED DEVICES AND PRODUCTS[14]

The person referred to in Article 22 shall verify the mutual compatibility of the devices and, if applicable, other products which they combine, in accordance with the manufacturers' instructions and have carried out their combination in accordance with those instructions.

2. PACKAGING AND INFORMATION SUPPLIED WITH THE SYSTEM OR PROCEDURE PACK

Regulation 2017/745 provides that a system or procedure pack shall be packaged by the person referred to in Article 22 incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together [15].

Once the system or procedure pack is packaged, if the information supplied by the manufacturers remains accessible (transport conditions, storage conditions, etc.), the person referred to in Article 22 does not need to add it to the packaging of the system or procedure pack. On the other hand, if certain information disappears (for example if the person referred to in Article 22 removes a level of packaging in order to package the products of the system or procedure pack together), they must add the mandatory information to the packaging of the system or procedure pack.

The system or procedure pack shall also be supplied with a label and instructions for use in accordance with Annex I, Section 23 of the Regulation[16]. The label must therefore indicate, inter alia, the content of the system or procedure pack. .

14. Article 22(1) of Regulation 2017/745.
15. Article 22(2)(b) of Regulation 2017/745.
16. Article 22(5) of Regulation 2017/745.

Finally, the person who produces the system or the procedure pack for the purpose of placing it on the market shall add thereto[17] :

- their name,
- their registered trade name or registered trademark,
- the address at which that person can be contacted.

For systems packaged in several components, it would appear appropriate to add the label and information on the identity of the person referred to in Article 22 to each component packaged separately so that they are all accompanied by the information required by the regulation.

ATTENTION

The media and communications accessible to the user or patient (labelling, instructions for use, advertising) must not contain any element that may mislead them with regard to the device's intended purpose, safety and performance[18].

This media shall not:

- ascribe functions or properties to the system or procedure pack which it does not have,
- create a false impression regarding treatment or diagnosis, functions or properties which the system or procedure pack does not have,
- fail to inform the patient or user of a likely risk associated with the use of the system or procedure pack in line with its intended purpose,
- suggest uses for the system or procedure pack other than those stated by the manufacturers of the products that make it up.

17.Article 22(5) of Regulation 2017/745.
18.Article 7 of Regulation 2017/745.

3. MONOTORING[19]

The person referred to in Article 22 shall have subjected the activity of combining devices and, if applicable, other products, to appropriate methods of internal monitoring, verification and validation.

Regulation 2017/745 requires the person referred to in Article 22 to draw up a statement[20] that they have fulfilled the obligations described in points 6.1, 6.2 and 6.3 (verification of conformity, packaging, information and methods of internal monitoring, verification and validation). This statement shall be kept at the disposal of the competent authorities for a period of at least 10 years after the last system or procedure pack has been placed on the market or 15 years if the system or procedure pack contains an implantable device [21].

4. CE MARKING

Systems or procedure packs made in accordance with the provisions of Regulation 2017/745 do not need to bear additional CE marking [22].

5. UNIQUE DEVICE IDENTIFICATION AND PROCEDURE PACK

→ 5.1 Assigning a UDI to the system or procedure pack

Before placing a system or procedure pack on the market, the person referred to in Article 22 shall assign it a basic UDI-DI[23]. The Regulation specifies that systems and procedure packs shall be assigned and bear their own UDI[24]. This UDI is therefore different from the UDI of the device(s) forming part of the system or procedure pack.

→ 5.2 Affixing the UDI to the content and to the system or procedure pack itself

Regulation 2017/745 provides that the UDI carrier on systems or procedure packs shall as a general rule be affixed to the outside of the packaging [25].

19. Article 22(2)(c) of Regulation 2017/745.
20. Article 22(1) of Regulation 2017/745.
21. Article 22(5) of Regulation 2017/745.
22. Article 22(5) of Regulation 2017/745.
23. Article 29(2) of Regulation 2017/745.
24. Annex VI, Part C, point 3.7 of Regulation 2017/745.
25. Annex VI, Part C, point 6.3.3(a) of Regulation 2017/745.

The carrier shall be readable or scannable, whether placed on the outside of the packaging of the system or procedure pack or inside transparent package [26].

The UDI carrier can also be affixed to the device itself [27].

Regulation 2017/745 does not require the UDI to be affixed in the following cases (but a UDI shall be assigned to the system or procedure pack) [28] :

- individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the system or procedure pack
  ➜ **these devices shall not be required to bear their own UDI carrier;**
- devices that are exempted from bearing a UDI carrier on the relevant level of packaging (e.g. device too small)
  ➜ **these devices shall not be required to bear a UDI carrier when included within a system or procedure pack.**

➔ **Guide MDCG 2022-7 provides further details concerning the IUD system and specifies in particular that where the elements of a system are not packaged together, the person referred to in Article 22 shall assign an IUD to the system and ensure that the IUD support is affixed in such a way that the user has access to it, including once the system is installed and in use.**

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

➔ 5.3 Registration in Eudamed

The person referred to in Article 22 shall register in the Eudamed database as an economic operator and obtain an "Actor ID" registration number[29].

They shall then provide the basic UDI-DI of its systems and procedure packs to the UDI database, together with the information listed in Annex VI Part B of the Regulation relating to the system or procedure pack in question[30] (see box below).

The same basic UDI-DI is assigned to systems and procedure packs consisting of the same groups of products for the same intended purpose, even when the products are not from the same manufacturer[31].

26. Annex VI, Part C, point 6.3.3(b) of Regulation 2017/745.
27. Annex VI, Part C, point 6.3.2 of Regulation 2017/745.
28. Annex VI, Part C, point 6.3.2 of Regulation 2017/745.
29. This registration requirement is not expressly stated in Regulation 2017/745 for the person referred to in Article 22 but is included in MDCG 2021-13 guide, which specifies that the person referred to in Article 22 is allocated an 'Actor ID' and not an 'SRN' (single registration number - identifier allocated to manufacturers, agents and importers).
30. Article 29, point 2 du règlement 2017/745.
31. MDCG Guidance 2018-3.

ANNEX VI PART B: CORE DATA ELEMENTS TO BE PROVIDED TO THE IUD DATABASE TOGETHER WITH THE IUD-ID IN ACCORDANCE WITH ARTICLES 28 AND 29 OF THE REGULATION AND MDCG GUIDE 2018-4[32]

1	Quantity per package configuration
2	The basic UDI-DI as referred to in Article 29 and any additional UDI-DIs
2.a	Indication of the specific medical purpose of the system or procedure pack
3	The manner in which the system or procedure pack is controlled (expiry date or date of manufacturing date, lot number, serial number)
4	If applicable, the unit of use UDI-DI (where a UDI is not labelled on the device label at the level of its unit of use, a 'Unit of Use' DI shall be assigned so as to associate the use of a device with a patient)
5	Name and address of the person referred to in Article 22 (as indicated on the label)
6	The single registration number (SRN) of the person referred to in Article 22
7	If applicable, name and address of the authorised representative (as indicated on the label)
8	The medical device nomenclature code as provided for in Article 26
9	Risk class of the device (the highest risk class of the device components of the system or procedure pack)
10	If applicable, the name or trade name
11.a	If applicable, the system or procedure pack model associated with the basic UDI-DI
11.b	Reference or catalogue number

32. Elements crossed out are in Annex VI Part B of the MDR but have been deleted from the MDCG guide; elements underlined are additions or clarifications to the MDCG guidance.

ANNEX VI PART B: CORE DATA ELEMENTS TO BE PROVIDED TO THE IUD DATABASE TOGETHER WITH THE IUD-ID IN ACCORDANCE WITH ARTICLES 28 AND 29 OF THE REGULATION AND MDCG GUIDE 2018-4[33]

12	If applicable, clinical size (including volume, length, gauge, diameter)
13	Additional product description (optional)
14	If applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use)
15	If applicable, additional trade names of the system or procedure pack
16	Labelled as a single-use device (y/n)
17	If applicable, the maximum number of reuses
18	Labelled sterile (y/n) (~~if yes, the system or procedure pack in its entirety is labelled as sterile~~)
19	Need for sterilisation before use (y/n)
20	Containing latex (yes/no)
21	Where appropriate, information labelled in accordance with Section 10.4.5 of Annex I
22	URL for additional information, such as electronic instructions for use (optional)
23	If applicable, critical warnings or contra-indications
24	Status of the system or procedure pack (on the market, no longer placed on the market, recalled, field safety corrective action initiated)

33. Elements crossed out are in Annex VI Part B of the MDR but have been deleted from the MDCG guide; elements underlined are additions or clarifications to the MDCG guidance.

OBLIGATIONS OF THE PERSON WHO STERILISES SYSTEMS OR PROCEDURE PACKS

1. CONFORMITY ASSESSMENT PROCEDURE

Regulation 2017/745 requires the operator who sterilises systems or procedure packs for the purpose of placing them on the market to apply, at their choice, any one of the following procedures to the sterilisation information[34] :

- Annex IX: Conformity assessment based on quality management system and on assessment of technical documentation
- Annex XI: Conformity assessment based on product conformity verification, Part A: Production quality assurance

The person referred to in Article 22 shall carry out the sterilisation in accordance with the instructions of the manufacturer(s) of the devices and other products and shall draw up a statement to that effect.

2. INFORMATION TO BE ADDED

The person who sterilises the system or procedure pack for the purpose of placing it on the market must add thereto[35] :

- their name,
- their registered trade name or registered trademark,
- the address at which that person can be contacted.

34. Article 22(3) of Regulation 2017/745.
35. Article 22(5) of Regulation 2017/745.

OTHER OBLIGATIONS APPLICABLE TO THE PERSON REFERRED TO IN ARTICLE 22 AS AN ECONOMIC OPERATOR

1. APPLICATION OF ARTICLES 13 (IMPORTER) AND 14 (DISTRIBUTOR) OF THE MDR

When MDCG 2021-27 was revised in December 2023, the expert group clarified that the person referred to in Article 22 combines or sterilises at least one device in order to make it available in the form of a system or pack and must therefore also be considered, for this device, as an importer (if he has directly been supplied by a manufacturer established outside the EU) or distributor (if he has been supplied by a manufacturer established on EU territory, an importer or another distributor).
The person referred to in Article 22 must therefore apply, in addition to the obligations of Article 22, those of Article 13 or Article 14, as appropriate, or both if several devices associated in the system or pack have different supply chains.
These obligations are detailed in the Snitem booklets dedicated to importers and distributors, available on the Snitem internet and extranet sites.

2. OTHER OBLIGATIONS

According to Regulation 2017/745, "economic operator" mean[36] :

- persons who combine devices and products in accordance with the Regulation for the purpose of placing them on the market as a system or procedure pack;
- persons who sterilise systems and procedure packs for the purpose of placing them on the market.

All the provisions of the Regulation concerning economic operators are therefore applicable to the person referred to in Article 22.

2.1 Traceability

As an economic operator, the person referred to in Article 22 shall be able to identify any economic operator to whom they have directly supplied a device, any economic operator who has directly supplied them with a device and any health institution or healthcare professional to which they have directly supplied a device [37].

In addition, they shall store and keep, preferably by electronic means, the UDI of the Class III implantable devices they have supplied or with which they have been supplied[38].

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36. Article 2, 35) of Regulation 2017/745 defines an economic operator as "a manufacturer, an authorised representative, an importer, a distributor **or the person referred to in Article 22(1) and (3)".**
37. Article 25(2) of Regulation 2017/745.
38. Article 27(8) of Regulation 2017/745.

2.2 Post-market surveillance

The responsibilities of the assembler are referred to in point 2 and, where appropriate, point 3 (in the case of sterilisation) of Article 22. It therefore seems logical, even if this is not explicitly stated in the Regulation, that the person referred to in Article 22 should, in the event of a vigilance report, assess whether the incident can be attributed to their own activity: compatibility of the devices and products combined, packaging and relevant information, validity of the combination, sterilisation....

If the analysis confirms accountability, the person referred to in Article 22 shall then implement the corrective action necessary to eliminate the risks or ensure compliance with the system or procedure pack, in particular by:

- restricting the system's or procedure pack's availability on the market,
- adding specific requirements,
- withdrawing it from the market,
- recalling it.

The person referred to in Article 22 may also be required to take such corrective measures where a risk or non-compliance is identified or suspected by a competent authority[39].
The time limit for such actions shall be notified to the person referred to in Article 22 by the competent authority.

Where a system or device presents an unacceptable risk to public health, the competent authorities may also confiscate, destroy or otherwise render it inoperable.

2.3 Coopération with the competent authorities

The person referred to in Article 22 shall cooperate with the competent authorities when they carry out an evaluation of an unacceptable risk or non-compliance of a device[40].

They also have a general obligation to cooperate with the competent authorities, who may request documentation, information, samples or access to a device, or carry out inspections of their premises, as well as suppliers, subcontractors or at the facilities of professional users of its systems and procedure packs[41].

39. Articles 94, 95 and 97 of Regulation 2017/745.
40. Article 94 of Regulation 2017/745.
41. Article 93(3) of Regulation 2017/745.

2.4 Confidentiality

Finally, like all economic operators involved in the application of the Regulation, the person referred to in Article 22 is bound by an obligation of confidentiality of information and data obtained in carrying out their tasks in order to protect[42] :

- personal data,
- commercially confidential information and trade secrets, including intellectual property rights, unless disclosure is in the public interest,
- the implementation of the Regulation, in particular for the purpose of inspections, investigations or audits.

42. Article 109 of Regulation 2017/745.

CASES IN WHICH THE PERSON REFERRED TO IN ARTICLE 22 MAY BE CONSIDERED A MANUFACTURER

The Regulation provides for several cases in which the system or procedure pack is considered to be a device in its own right and shall therefore be subject to the relevant conformity assessment procedure[43] :

- where the system or procedure pack includes products that do not comply with the regulations applicable to them (e.g. medical devices not bearing the CE marking),
- where the system or procedure pack includes products not covered by Article 22 of the Regulation,
- where the combination of products is not compatible given their intended purpose,
- where sterilisation has not been carried out in accordance with the manufacturer's instructions.

In these different cases, the person referred to in Article 22 shall assume the obligations on manufacturers.

In addition, Regulation 2017/745 provides for that certain tasks, when performed by an operator outside the framework provided for in Article 16, the operator shall assume the obligations incumbent on the manufacturer[44].

This may firstly be the case where the operator provides with a device already placed on the market a label and/or instructions for use, including a translation, as well as additional information which is necessary in order to market the device in the relevant Member State[45].

This is also the case when the operator changes the outer packaging of a device already placed on the market[46], which may be the case for the person referred to in Article 22 if they unpackage a device in order to integrate into their system or procedure pack a quantity for which the manufacturer has not provided a sales unit. Such repackaging shall not affect the original condition of the device.

43. Article 22(4) of Regulation 2017/745.
44. Article 16 of Regulation 2017/745.
45. Article 16(2)(a) of Regulation 2017/745.
46. Article 16(b) of Regulation 2017/745.

In both these cases, in order not to fall into the status of manufacturer, the operator shall[47] :

- have a **quality management system** ensuring that:
  - the activities carried out on the device are performed by a means and under conditions that preserve the original condition of the device,
  - the packaging of the repackaged device is not defective, of poor quality or untidy,
  - the operator is informed of any corrective action taken by the manufacturer in relation to the device;

- submit to the competent authority a **certificate**, issued by a notified body designated for the type of device concerned, attesting that the quality management system of the operator is in compliance;

- **indicate on the device**, or where that is impracticable, on its packaging or in accompanying documents, the activity they have carried out on the device together with their contact details;
- **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;

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

Re-labelling or re-packaging, **if carried out in accordance with these conditions or if it is limited to the labelling and packaging operations required by article 22,** do not change the operator's status to that of manufacturer.

Finally, Regulation 2017/745 provides for three cases in which the operator shall assume the obligations incumbent on manufacturers[48].

Firstly, this is the case when the operator makes a product available on the market under their name, registered trade name or registered trademark, except where an agreement has been entered into with the manufacturer whereby the manufacturer is identified as such on the label and remains responsible for meeting the requirements placed on manufacturers.

This is also the case when the operator changes the intended purpose of a device already placed on the market or put into service.

Finally, this is the case when the operator 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. "except in the case of the supply of instructions/labels and in the case of repackaging, as described above".

47.Article 16 (3) and (4) of Regulation 2017/745.
48.Article 16(1) of Regulation 2017/745.

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

The Regulation leaves it to the Member States to determine the penalties applicable for infringement of its provisions[49].
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[50].
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).

49. Article 113 of Regulation 2017/745..
50. 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

Regulation 2017/745 was published on 5 May 2017 and entered into force on 26 May 2017. It was originally planned 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 UDI) date of application is foreseen. In the context of the covid-19 health crisis, the date of application of the Regulation was postponed to 26 May 2021[51]. Please note that the various specific timescales (grace period, staggered timescales for affixing the UDI, etc.) are not postponed.

A transitional period is foreseen, during which certain devices complying with Directives 90/385/EEC and 93/42/EEC may be placed on the market, although the date of application of the new Regulation has passed[52]. 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[53] 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 Regulation are immediately applicable from 26 May, 2021: the requirements for post-market surveillance, market surveillance, vigilance and registration of economic operators and devices[54]. In addition, by this date, any system or procedure pack shall have to be made available on the market in accordance with the requirements of Article 22 of Regulation 2017/745 (verification of product compatibility, packaging, labelling, statement, UDI, Eudamed registrations, etc.)[55].

51. Regulation 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation 2017/745 on medical devices as regards the dates of application of certain of its provisions.

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

53. 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.

54. Article 120(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.

55. The MDCG 2021-25 guidance specifies that a system or kit consisting solely of legacy devices and whose declaration was made before 26 May 2021 can benefit from the transition period and therefore does not have to apply the obligations of Article 22 of the MDR.

NOTES

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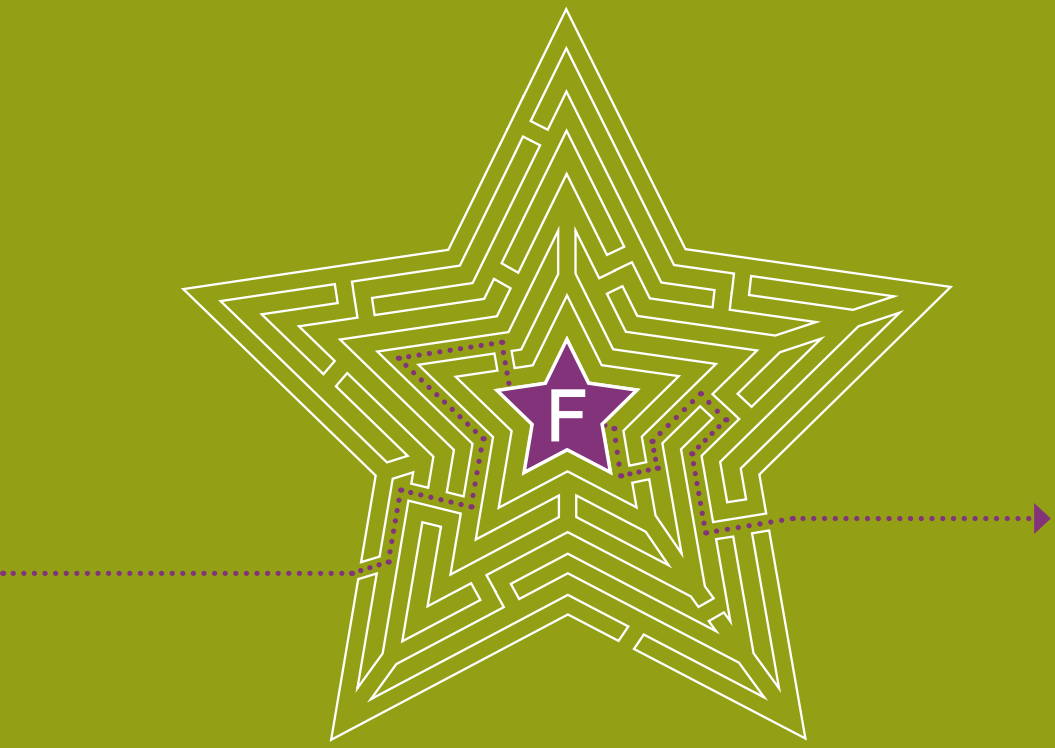
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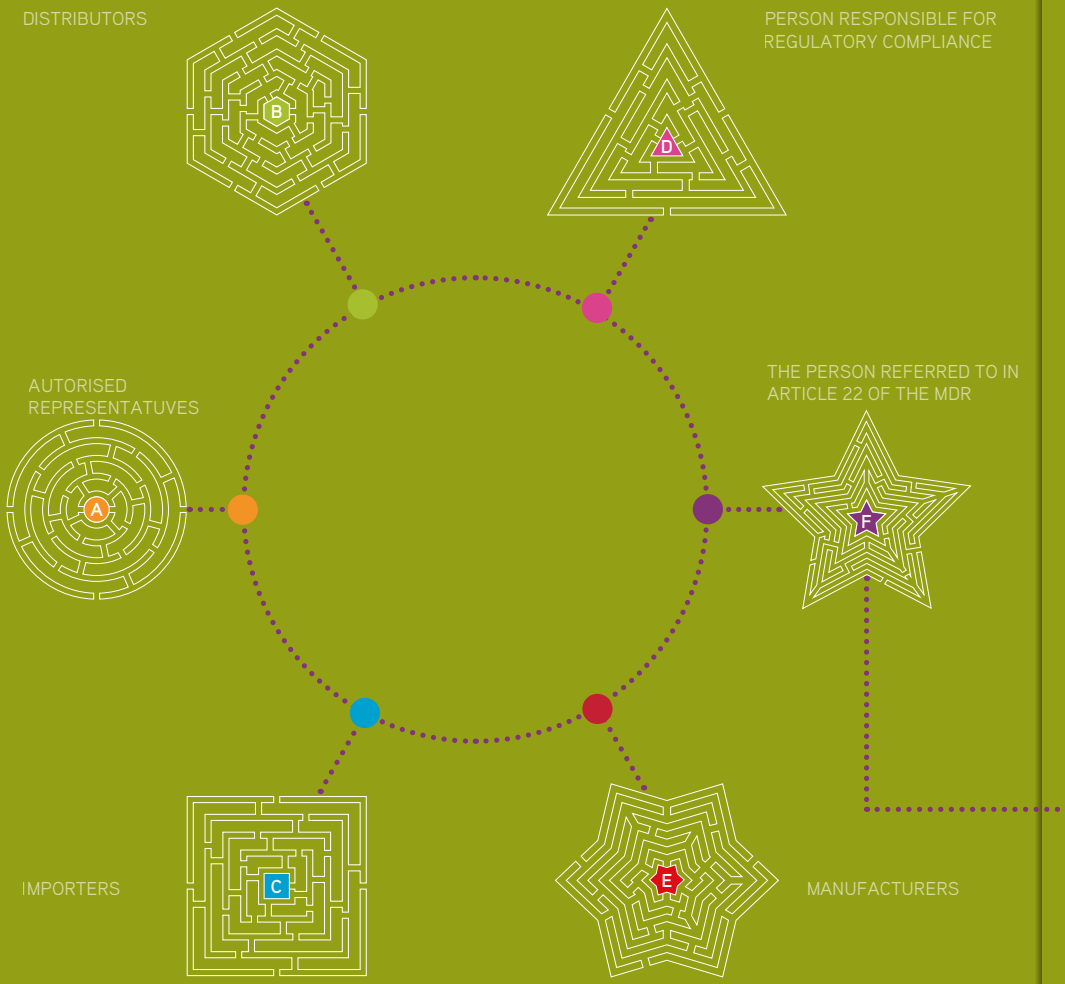

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