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New obligations for distributors under the terms of the European Regulation on medical devices

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This recommendation is the result of the work carried out by the following industry bodies:

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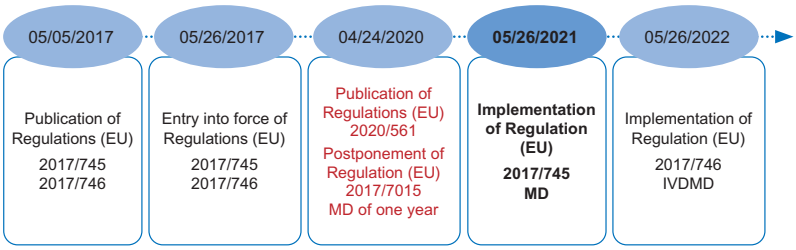
Central purchasing organization: CACIC

Introduction

Against a background of constant change and development in the medical device sector, the European Union has revised its regulations. As a result, the European Commission has published two regulations for medical devices:



It is important to stress that manufacturers were able to implement Regulation (EU) 2017/745 MD before May 26, 2021, provided that they were able to comply with all the provisions it imposes.

Purpose

The purpose of this document is to list the obligations of distributors and importers within the meaning of Regulation 2017/745 (in particular wholesaler-distributors, pre-wholesalers and dispensing pharmacists), to provide the latter with a standard that enables them to check that their practices comply fully with European requirements for the listing and distribution of medical devices. This recommendation includes those points incumbent on distributors and importers to prepare them for the implementation of Regulation 2017/745 and in particular the UDI (Unique Device Identifier). It also provides manufacturers with guidance intended to facilitate distribution chain logistics processes.

! By amending and adding certain definitions, Regulation 2017/745 has the effect of broadening the scope of the regulation. So as a wholesaler-distributor, pre-wholesaler or pharmacist, you may, depending on the nature of your business, be regarded as an importer, distributor or even manufacturer within the meaning of this regulation. This document details these assumptions to help you in your implementation of the regulation.

This document has been developed on the basis of current knowledge. New versions may be issued at a later date if and when new information becomes available.

Legislative texts and interpretative 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.
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
- 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.
- The European Commission Blue Guide on the implementation of the EU regulation. This is one of the main explanatory reference documents for implementing the legislation based on the new approach, which is now covered by the new legislative framework governing the

marketing of products within the EU. The medical devices regulation forms part of this framework.

1. Definitions from Regulations 2017/745 MD and 2017/746 IVDMD

Medical device[1]

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- Devices for the control or support of conception,
- Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point;

The Regulation defines many other concepts, including implantable devices, single-use devices, accessories for medical devices, etc.

Risk classes for medical devices

There are four risk classes for devices in increasing order of criticality, and these are defined on the basis of the potential risk to the patient, caregiver or any other person involved in the use of the device: Class I, Class IIa, Class IIb and Class III.

European Regulation 2017/745 adopts this principle of risk classification. However, it does modify some existing rules and introduces new ones, the result of which is a change of class for some MDs.

The classification rules are defined in Chapter III of Annex VIII of the Regulation. It is the manufacturer's responsibility to provide this information to distributors.

In vitro diagnostic medical device[2]

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

- Concerning a physiological or pathological process or state;
- Concerning congenital physical or mental impairments;
- Concerning the predisposition to a medical condition or a disease;
- To determine the safety and compatibility with potential recipients;
- To predict treatment response or reactions;
- To define or monitor therapeutic measures.

Risk classes for in vitro diagnostic medical devices

– List A IVDMDs: Reagents and reagent products, including calibrators and control materials for the determination of the following blood groups: ABO system, rhesus (C, c, D, E and e) and Anti-Kell. Reagents and reagent products, including calibrators and control materials for the detection, confirmation and quantification in human specimens of infection markers for HIV (HIV 1 and 2), HTLV I and II and hepatitis B, C and D.

– List B IVDMDs: Reagents and reagent products, including related calibrators and control materials for the determination of the Anti-Duffy and Anti-Kidd blood groups, irregular and anti-erythrocytic antibodies, the detection of rubella and toxoplasmosis, for the diagnosis of phenylketonuria, cytomegalovirus and chlamydia, HLA DR tissue groups A and B, the PSA tumor marker, trisomy 21 risk evaluation and blood glucose measurement.

Economic operators (common to both Regulations)

The following are 'economic operators' within the meaning of Regulations 2017/745 and 2017/746: manufacturer, authorized representative, importer, distributor and person referred to in Article 22:

Manufacturer[3]: a 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.

Authorized representative[4]: 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

[1] *Article 2, point 1 of Regulation (EU) 2017/745 on medical devices.*
[2] *Article 2, point 2 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.*

behalf in relation to specified tasks with regard to the latter's obligations under this Regulation. The authorized representative is not involved in the sale of products.

Importer[5]: any natural or legal person established within the Union that places a device from a third country on the European Union market.

Distributor[6]: any natural or legal person in the supply chain, other than the manufacturer or the importer, which makes a device available on the market, up until the point of putting into service.

Person referred to in art.22[7]: this person manufactures and/or sterilizes systems or procedure packs (kits). Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:

a) Other devices bearing the CE marking;

b) In vitro diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;

c) Other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or when their presence in the system or procedure pack is otherwise justified.

Are you importers or distributors?

Activities involving the provision of devices include the acquisition, ownership and supply of devices within the European Union. For example, within the meaning of the European Regulation, importers and distributors may be: wholesaler-distributors, pre-wholesalers, dispensing pharmacists, health institutions and home health care providers, etc.

To help you, the European Regulation clarifies the following concepts to facilitate comprehension of the distinction between importer and distributor:

Placing on the market[8]	**The first making available** of a device, other than an investigational device, on the Union market.
Making available on the market[9]	Any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.
Putting into service[10]	The stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose.

! Remember: The status of an economic operator **is defined by product:**

The same company can be a manufacturer, authorized representative, importer and/or distributor!

Depending on its precise business activities, each company will have to comply with the obligations attached to the status(es) that applies(apply) to it.

[3] *Article 2, point 30 of Regulation (EU) 2017/745 on medical devices and Article 2, point 23 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.*
[4] *Article 2, point 32 of Regulation (EU) 2017/745 on medical devices and Article 2, point 25 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.*
[5] *Article 2, point 33 of Regulation (EU) 2017/745 on medical devices and Article 2, point 26 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.*
[6] *Article 2, point 34 of Regulation (EU) 2017/745 on medical devices and Article 2, point 27 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices.*
[7] *Article 22, points 1 and 3 of Regulation (EU) 2017/745 on medical devices.*
[8] *Article 2, point 27 of Regulation (EU) 2017/745 on medical devices.*
[9] *Article 2, point 28 of Regulation (EU) 2017/745 on medical devices.*
[10] *Article 2, point 29 of Regulation (EU) 2017/745 on medical devices.*

2. The obligations of MD distributors/importers

A. General obligations

Obligations	Importer	Distributor *	References
Within the context of their activities, act with due care (to the best of their abilities and as quickly as possible) to ensure compliance with the applicable requirements		Continuously	Art. 14.1
Place on the Union market only devices that are in conformity with this Regulation	BEFORE		Art. 13.1
Verify that the device has been CE marked	BEFORE placing the device on the market	BEFORE making a device available**	Art. 13.2 Art. 14.2
Verify that the EU declaration of conformity has been drawn up for the device	BEFORE placing the device on the market	BEFORE making a device available**	Art. 13.2 Art. 14.2
Verify that the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10, paragraph 11	BEFORE placing the device on the market	BEFORE making a device available	Art. 13.2 Art. 14.2
Verify that the manufacturer has appointed an authorized representative in accordance with Article 11	BEFORE placing the device on the market		Art. 13.2
Verify that the device, its packaging or a document accompanying the device displays their **name, registered trade name or registered trade mark, their registered office address and the address** at which they can be contacted, so that their location can be established. Ensure that **no additional labels** conceal the information shown on the manufacturer's label.	BEFORE placing the device on the market		Art. 13.3
Verify that the importer is identified on the label (where applicable) and is compliant with the requirements contained in Article 13, paragraph 3		BEFORE making a device available	Art. 14.2
Register in EUDAMED and update information within one week of any change	BEFORE placing the device on the market		Art 31.3 Art 31.4
Verify that a UDI is assigned by the manufacturer (where applicable)	BEFORE placing the device on the market	BEFORE making a device available**	Art. 13.2 Art. 14.2
Verify that the device is registered in the electronic system in accordance with Article 29. Add contact details to this registration in accordance with Article 31	BEFORE placing the device on the market		Art. 13.4
Where the operator considers or has reason to believe that a **device is not in conformity with the requirements of the Regulation,** it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorized representative	BEFORE placing the device on the market	BEFORE making a device available	Art. 13.2 Art. 14.2
Where the distributor considers or has reason to believe that the **device presents a serious risk or is a falsified device,** it shall also inform the competent authority of the Member State	BEFORE placing the device on the market	BEFORE making a device available	Art. 13.2 Art. 14.2
Ensure that the **conditions governing storage and transportation** comply with the conditions set by the manufacturer **while the device is under its responsibility**	BEFORE placing the device on the market	BEFORE making a device available	Art. 13.5 Art. 14.3
Where the operator considers or has reason to believe that the **device made available on the market is not in conformity with the Regulation,** it shall inform the manufacturer, the authorized representative and the importer, and will cooperate with the manufacturer and the competent authorities to facilitate the implementation of corrective action to ensure that the MD is either brought into conformity, withdrawn or recalled	AFTER placing the device on the market	AFTER making a device available	Art. 13.7 Art. 14.4
Where the operator considers or has reason to believe that the **MD presents a serious risk,** it shall also immediately inform the competent authorities of the Member States in which it has made the MD available, giving details, in particular, of the non-compliance and of any corrective action taken	AFTER placing the device on the market	AFTER making a device available	Art. 13.7 Art. 14.4
Where operators receive **complaints or adverse reports,** they forward this information to the manufacturer, the manufacturer's authorized representative and the distributor/importer, maintain a **register** of complaints, non-conforming devices, recalls and withdrawals, keep the manufacturer, the manufacturer's authorized representative and importer informed of such monitoring, and provide them on request with any and all information they may need in order to investigate complaints	AFTER placing the device on the market	AFTER making a device available	Art. 13.8 Art. 13.6 Art. 14.5
Provide the competent authority with all requested information and/or documents required to **demonstrate the conformity of the MD**	BEFORE placing the device on the market	AFTER making a device available	Art. 94 Art. 14.6
Cooperate with manufacturers and their authorized representatives to achieve an appropriate level of **traceability**		AFTER making a device available	Art.25.1
Enter and save - preferably electronically - the UDIs of Class III implantable MDs	AFTER placing the device on the market	AFTER making a device available	Art.27.8
Identify upstream and downstream economic operators, and retain historical records for between 10 and 15 years	AFTER	AFTER	Art. 25.2
Retain, for the period referred to in Article 10(8), a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56.	AFTER		Art.13.9
Respond to any request from a competent authority for information, documentation, samples or access to a device	AFTER	AFTER	Art. 94 Art. 93.3 Art. 13.10 Art. 14.6
Maintain confidentiality of personal data, commercially confidential information, trade secrets and information regarding application of the Regulation, particularly with regard to inspections, investigations and audits	Continuously	Continuously	Art.109

* See Annex I - Summary of the requirements imposed on distributors by Regulation (EU) 2017/745 on medical devices
** Regulation (EU) 2017/745 provides for the possibility of performing these verifications by sampling only for distributors

B. Focus on the obligations of distributors and importers to verify the labeling and instructions for use of a MD at the time of its listing[12]

1. The device shall be accompanied by all the information that its manufacturer is required to provide. This information shall be provided in one of the **official EU languages** defined by the Member State in which the MD is made available; where appropriate, the information shall be indicated in the form of internationally recognized symbols or descriptions;
2. The device shall be accompanied by the **information needed to identify the device and its manufacturer,** and by any safety, performance and residual risk information relevant to the user, or any other person, as appropriate
3. The information shown on the **label** shall be provided in a **human-readable** format, **indelible** and clearly comprehensible to the intended user or patient
4. **Instructions for use** shall be written in **readily understandable terms** and supplemented by **drawings and diagrams,** where necessary; instructions for use are **optional for Class I and IIa MDs** where the MD concerned can be used safely without **instructions; instructions for use may be in printed or electronic form** (in this precise case it is subject to certain conditions, and is not an option for all devices);

The following information shall be clearly shown on the packaging:

5. The **name or trade name** of the device
6. **The identification, content and intended purpose** are easily understandable by the user;
7. The name, registered trade name or registered trade mark of the **manufacturer** and the address of its registered office;
8. The name and registered office address of the **authorized representative** where the manufacturer has its registered office outside the EU;
9. **The time limit for using or implanting the device or, where these are not available, the date of manufacture;**
10. **Warnings and precautions for use;**
11. Information stating that the device is a **medical device**
12. The affixing of the **UDI (Unique Device Identifier);**
13. **Storage, transportation and handling conditions;**

Depending on the type of product, the following conditional statements must be included:

14. An indication that the MD contains or incorporates a **medicinal product or tissues or cells** of human or animal origin, or their derivatives; indicates the presence of **substances that may pose a risk** and identifies those patient groups at risk;
15. The serial number for active implantable devices, and the **serial number or batch number for all** other implantable devices;
16. **The indication 'sterile' and the sterilization method,** where applicable;
17. **The indication 'single use',** where applicable;
18. **Reprocessing, the number of reprocessing cycles and any limitation on the number of reprocessing cycles,** where applicable;
19. **The indication 'custom-made device',** where applicable;
20. **The indication 'for clinical investigations only',** where applicable;
21. **Qualitative and quantitative composition** for MDs composed of substances intended to be introduced into the body or applied to the skin.

> **i** It is strongly recommended that the following information be included - as a minimum - to facilitate logistics processing in the distribution chain: product code (UDI-DI), batch number, expiry date and serial number in the form of a Datamatrix barcode.

[11] *Annex I Chapter III 23.1 and 23.2 of the Regulation (EU) 2017/745 on medical devices.*
[12] *Other logistics issues, particularly acceptance, preparation and return, will be described in a later version of this document.*

3. Cases in which the obligations of manufacturers may apply to importers and/or distributors[13]:

Three cases in which the obligations of manufacturers apply to importers, distributors or other persons in accordance with Article 16 of Regulation (EU) 2017/745:

- Making available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation
- Changing the intended purpose of a MD already placed on the market or put into service
- Changing a device already placed on the market or put into service where such change affects its conformity, EXCEPT in the event of any relabeling/repackaging necessary for marketing in a Member State, and where the distributor ensures that the safety of the device is not affected by such change. It must then indicate its contact details and business description on the device, implement a specific quality management system certified by an approved certification body and submit this certificate to the competent authority of the relevant State at least 28 days before marketing the modified device, and notify, within the same period of time, the legal manufacturer and the relevant competent authority of its intention to market this modified device

! N.B.: The deconditioning of devices falls into this category of changes to medical devices when the resulting sales unit is not covered by the CE marking.

4. Acting ahead of Regulation implementation

Companies must conduct an internal audit and apply updates in preparation for the new regulation, which requires the integration of both internal and external obligations:

– Internal obligations:
  - Determining the status of the company relative to each product
  - Considering the scope and status(es) of each company within a group of companies
  - Identifying the obligations applicable to each status and each product
  - Identifying the processes to be updated or introduced
  - Determining the resources required in terms of time, costs, people (hiring, training, contracting, etc.) and means (databases, etc.)
  - Documentation

– In conjunction with other links in the distribution chain:
  - Identifying regular / occasional partners
  - Determining the updates required to existing and new contracts
  - Determining the means and resources required to carry out verifications, labeling, registration and storage of information, notifications, etc.
  - Documentation

5. EUDAMED database[14] and ACL database

The purpose of the European database on medical devices - Eudamed - is to centralize information relating to all medical devices marketed in the EU, as well as manufacturers, authorized representatives and importers marketing devices in the European Union. The competent authorities and manufacturers will also be able communicate via the Eudamed database. It will be managed and developed by the European Commission.

A link is planned between medical devices and certain economic operators (manufacturers, authorized representatives and importers) concerned by them in order to increase overall transparency and streamline and facilitate the exchange of device vigilance information.

The ACL product database will contain the link between the basic UDI, the packaging UDI(s) including the UDI of the ordered unit, and the codes of all higher levels of packaging (logistics hierarchy). ACL also provides the management service for these codes and ensures correspondences. The ACL product database can provide distributors with the product data available in the Eudamed database, as well as existing logistics and descriptive data.

6. Use of UDIs by distributors[15]

The Unique Device Identifier (UDI) is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It enables unambiguous identification of specific devices on the market. It consists of the UDI-DI, a static element identifying the unit of use specified by the manufacturer, and the UDI-PI, a dynamic element identifying the production unit or the packaged product unit. The word 'Unique' does not imply serialization of individual production units.

Basic UDI code: the main identifier of a device model. It will act as a key for interconnecting the multiple databases that together make up Eudamed, thereby facilitating the transversal exchange of information. The Basic UDI code will enable access to information held in each of

[13] *Article 16 of Regulation (EU) 2017/745 on medical devices.*
[14] *Article 33 of Regulation (EU) 2017/745 on medical devices.*
[15] *Annex VI, Part C, point 1 of Regulation (EU) 2017/745 on medical devices.*

the other databases. The Basic UDI does not appear on any packaging, because it is a grouping number, but will be shown in regulatory documents, such as the relevant certificates and EU declarations of conformity.

The UDI-DI is a unique numeric or alphanumeric code specific to a level of device packaging and that is also used as the 'access key' to information stored in the Eudamed database. It is unique at each level of device packaging.

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. UDI-PIs may contain: the batch number, the manufacturing or expiration date, serial number (if MD concerned) and software identifier (if MD concerned).

The UDI carrier is the way in which the UDI is communicated using AIDC (Automatic Identification and Data Capture) and HRI, where applicable. UDI carriers include, inter alia, ID/linear bar coding and 2D/Matrix bar codes.

! **The only marking that can be read in the pharmaceutical distribution channel is the Datamatrix barcode with GS1 structure.**

It must be legible during normal use and throughout the expected life of the device.

Example of marking:

IUD-DI (01)09876543212345
AI Product Code

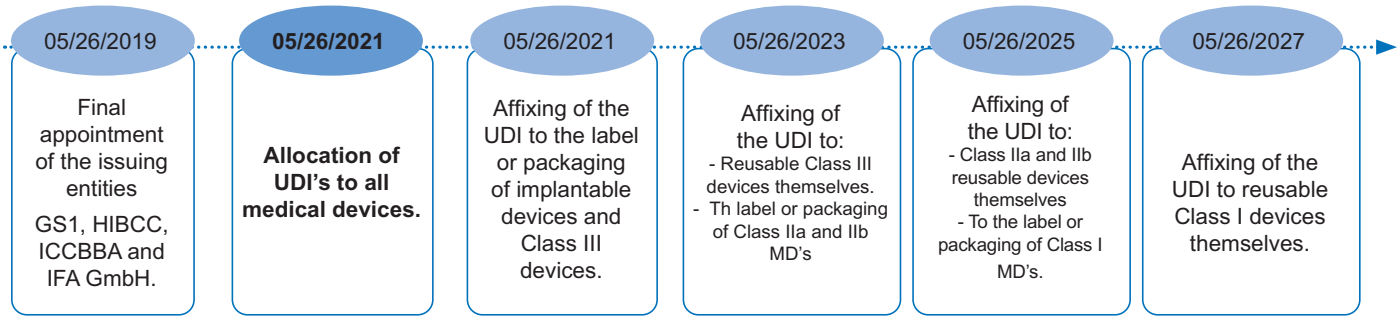
IUD-IP (17)220630(10)ABC(21)567FG891HI23
AI Expiration Date AI Batch Number AI Serial Number

AI Application Identifier (Identifiant de donnée)

7. UDI implementation

UDI application timeline

The entry into force of Regulation (EU) 2017/745 on May 26, 2017 marks the start of the UDI timeline. Several stages are planned on the basis of device type and risk class:



Affixing of the UDI to the product[16]

The UDI is an integral part of the labeling requirements. It must be affixed to the device label wherever possible, or to its packaging, and each packaging level must have its own UDI except for transportation packaging. For some reusable devices, particularly surgical instruments, the UDI shall be affixed directly to the device.

Upstream, ACL manages the Basic UDIs and UDIs on behalf of suppliers wishing to take advantage of this service; these UDIs apply the product packaging and all higher levels of packaging (logistics hierarchies).

UDI storage[17]

Traceability will be supplemented by the entry of UDIs for certain devices (the most at risk) into the internal systems of economic operators, health institutions and health care professionals concerned by virtue of the products they receive or supply. These are Class III active implantable devices (traceable to the patient) and products that may be listed by a future Commission implementing act.

Use of the ACL product database:

All this information will be present in the ACLsanté database and could be exported to the Eudamed database via an approved service provider, and vice versa; the ACLsanté database could receive this information from the Eudamed database in order to make it available to all actors in the French distribution chain.

[16] *Article 27 of Regulation (EU) 2017/745 on medical devices.*
[17] *Annex VI, Part C, point 1 of Regulation (EU) 2017/745 on medical devices*

8. Glossary

Field safety notice: a communication sent by a manufacturer to users or customers in relation to a field safety corrective action.

Device deficiency: any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer.

Intended purpose: the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

Falsified device: any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.

Health institution: an organization the primary purpose of which is the care or treatment of patients or the promotion of public health.

Label: the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

Incident: any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Serious incident: any incident that directly or indirectly led, might have led or might lead to any of the following:

- The death of a patient, user or other person
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- A serious public health threat

CE marking of conformity or CE marking: a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this regulation and other applicable Union harmonization legislation providing for its affixing.

Serious public health threat: an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

Corrective action: any action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation.

Field safety corrective action: any corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

Procedure pack: a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

Instructions for use: the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.

Recall: any measure aimed at achieving the return of a device that has already been made available to the end user (cessation of sales and return of devices already supplied to patients).

Withdrawal: any measure aimed at preventing a device in the supply chain from being further made available on the market (cessation of sales).

Risk: the combination of the probability of occurrence of harm and the severity of that harm.

Post-market surveillance: all those activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

Market surveillance: all those activities carried out and measures taken by competent authorities to verify and ensure that devices comply with the requirements set out in the relevant Union harmonization legislation and do not endanger health, safety or any other aspect of public interest protection.

System: a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose.

User: any health care professional or lay person who uses a device.

Annex I - Summary of the requirements imposed on distributors by Regulation (EU) 2017/745 on medical devices

	The requirements imposed on distributors by Regulation (EU) 2017/745		Verifications
BEFORE A DEVICE IS MADE AVAILABLE	VERIFICATION	Check that the device is CE marked	Verify that the product packaging or flat case is CE marked
		Check that the declaration of conformity has been drawn up	Verify that the French-language declaration of non-conformity is present
		Check that the device is accompanied by a label and instructions for use	Verify that the packaging is labeled and contains instructions for use, both of which are in French
		Check that the manufacturer has assigned a UDI	Verify, where appropriate, that the manufacturer has assigned a UDI to the device
		Check that the packaging carries information about the importer	Verify, where appropriate, that information about the importer is present on the device, on its packaging or in an accompanying document
		Ensure that the conditions governing storage and transportation comply with the conditions set by the manufacturer	Under the terms of its contract with the operator supplying the device, the distributor must be able to identify precisely when its legal responsibility for the product begins and ends, and therefore over what period it is responsible for ensuring full compliance with these conditions
	NOTIFICATION	Inform the manufacturer and, where appropriate, the manufacturer's authorized representative and the importer if the distributor considers that a device is non-conforming and makes it available only after it has been returned to full conformity Inform the competent authority in the event of a serious risk or falsified device	Where a distributor considers or has reason to believe that a device is not in conformity, it makes this product available only after it has been returned to full conformity
AFTER MAKING A DEVICE AVAILABLE	TRACEABILITY	Enter and save - preferably electronically - the UDIs of Class III implantable devices provided by or to the operator	The UDIs of Class III implantable devices must be entered and saved - preferably electronically - by the operators providing them or receiving them. The European Commission may, at some future time, use an implementing act to extend this obligation to include other categories or groups of devices
		Identify any economic operator to which the distributor has supplied a device directly, which has provided it with a device directly, and any health institution or health care professional to which it has supplied a device directly	The distributor must, in response to a request by the competent authority, be able to identify all non-implantable devices for a period of 10 years, and implantable devices for a period of 15 years, after the last relevant device has been made available: the upstream and downstream operators, health institutions or health care professionals to whom it has supplied a device directly
	MARKET SURVEILLANCE	The distributor must inform the manufacturer and, where appropriate, the authorized representative and importer immediately when it believes that a device made available is not in conformity with the Regulation, and cooperate with them to ensure that corrective actions are implemented	All such notifications must be sent immediately to the relevant economic operators (manufacturer, authorized representative, importer and distributor). It is essential to ensure that contacts are up to date at all times to ensure correct provision of information. Reminder: distributors are recommended to use a generic email address for each service in order to have a backup system for each operator
		The distributor must submit to the manufacturer and where appropriate, the authorized representative and importer immediately any complaint or report from a health care professional, patient or user where such complaints or reports are potentially related to a device it has supplied	
		The distributor must maintain a register of complaints, non-conforming devices, recalls and withdrawals. It must also provide information to the other economic operators on request	The distributor must maintain a register of complaints, non-compliant devices and recalls and withdrawals. It keeps the manufacturer, the authorized representative and the importer informed of these activities and provides them on request with all the information required to facilitate investigation of such complaints
	CORRECTIVE ACTIONS	The distributor must implement appropriate corrective actions when a competent authority identifies an unacceptable risk to health or safety	Where the competent authorities conclude that a device poses an unacceptable risk to the health or safety of patients, users or other persons, or on the basis of other public health protection issues, they shall promptly require all the relevant economic operators to implement all measures that are appropriate, duly justified and proportionate to the nature of the risk in order to ensure that the device conforms fully with the risk provisions set out in the Regulation, restrict the availability of the device on the market, subject it to specific requirements, withdraw the device or recall it within a defined period
		Resolve the nonconformity within an appropriate period of time where such nonconformity does not pose an unacceptable risk to health or safety	The distributor must also ensure without delay that any and all corrective actions are applied to all devices it has made available on the market in the EU
		The distributor must cooperate with the competent authorities regarding any measures implemented to eliminate or mitigate the risks posed by a device it has made available	The competent authorities may require, inter alia, that operators provide them with all the documentation and information required to carry out their work
CONTINUOUSLY	DUE CARE	Act with due care to ensure compliance with all applicable requirements	The Regulation provides that, when making a device available on the market, the distributor must demonstrate due care in the conduct of its business, which in other words means that it must ensure compliance with all applicable requirements to the best of its ability and as promptly as possible
	CONFIDENTIALITY	Maintain confidentiality of all data relating to devices and economic operators	The distributor is bound by an obligation of confidentiality in respect of personal data, commercially sensitive information and trade secrets, and application of regulation relating to inspections, investigations and audits
	COOPERATION	Cooperate with the competent authorities, which may request the former to provide documentation, information, samples or access to a device, or permission to conduct inspections on its premises	This requirement may be included in the contract between the manufacturer and the distributor or between the importer and the distributor, where the latter undertakes to cooperate with the competent authorities as an economic operator within the meaning of the European Regulation

Summary

The European Commission has published two European regulations; one on medical devices and the other on in vitro diagnostic medical devices. In this context, the distribution chain must implement the resources and means required to comply with the new regulations.
The purpose of this document is to list the obligations of distributors and/or importers within the meaning of Regulation 2017/745 in order to provide the latter with a standard that enables them to check that their practices comply fully with European and French requirements for the listing and distribution of medical devices.
This document has been developed on the basis of current knowledge. New versions may be issued at a later date if and when new information becomes available.

KEY WORDS

Eudamed database – ACLsanté product database – Timeline – Distribution chain – Code – Product code – Coding – Code 13 referent – GTIN code – Pre-wholesaler – Medical device – Distributor – MD - eCatalog – Label – European requirements – Manufacturer – Blue Guide – Wholesale distributor – Unique Device Identifier – Importer – UDI – Authorized representative – Implementation – Instructions for use – Obligations – Economic operator – Pharmacist – Health product – Listing – European regulation - UDI.

Useful links

SNITEM, Livrets de Synthèse des opérateurs économiques, October 2018 :
https://www.snitem.fr/le-snitem-en-action/les-publications/nouveau-reglement-dm-operateurs-economiques-quelles-evolutions
European Commission, Eudamed Functional Specifications: https://ec.europa.eu/docsroom/documents/34304?locale=en

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