WHITE PAPER

"MEDICAL DEVICES LABELLING: INSTRUCTIONS FOR USE"

This White Paper addresses the issue of *labelling*, from a regulatory point of view. In the Medical Devices Regulation MDR (EU) 2017/745, there are several parts dealing with this issue. We advise you to read this article to have a comprehensive overview of the legislative requirements.

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INTRODUCTION

The **White Paper "Medical Devices Labelling: instructions for use"** explains from a regulatory point of view what are the **labelling requirements of Medical Devices** according to the MDR (EU) 2017/745 Regulation.

It is mandatory and fundamental to apply the requirements for the labelling of Medical Devices as the information on the **product label** helps the user to **identify and use it correctly**. It contributes to high standards of **quality and safety of devices** produced or marketed in Europe.

While the **Medical Devices labelling** is dealt with in different parts of the MDR (EU) 2017/745 Regulation, in this White Paper you can find **the most important labelling requirements for Medical Devices in a single document.**
The **main labelling requirements and other related aspects** are explained according to the MDR (EU) 2017/745 Regulation.

First of all, the **requirements of the instructions for use (IFU)** in **Annex I** of the **MDR (EU) 2017/745 Regulation** are further developed. They are fundamental because it is through this information that the Manufacturer can provide the user with details of the composition and operation of the product, also indicating the safety warnings.

Secondly, we focus on the **linguistic requirements** necessary to be able to distribute a Medical Device in the Member States of the European Union, as provided for in **art. 10 of the MDR (EU) 2017/745 and in annex II of the MDR.** For example, it is necessary the provision of the information in the official language established by the Member State in which the product is marketed.

Given the importance of language for achieving compliance with regulations and ensuring the use of devices in the European market, the **validation process of the translation of contents** is also fundamental, as provided for in **art. 16** of the MDR (EU) 2017/745.

The use of **symbols** on the labels of Medical Devices, in compliance with the MDR (EU) 2017/745 Regulation, is another aspect that has been decided to address in the White Paper. Although not yet official, the standardization proposals elaborated by **MedTech Europe** are being examined by the ISO. **MedTech Europe** is a European trade association representing medical technology industries, from diagnosis to treatment.

Moreover, in the White Paper ample space is given to the **UDI** system as it is also a requirement of Medical Devices labelling provided by the Regulation. The UDI system allows the Manufacturer to identify and label devices through a unique identifier that increases its traceability throughout the supply chain, in order to be able to act promptly in case of need.

Lastly, you will find some **useful tips** to prepare yourself for the implementation of these essential requirements

INSTRUCTIONS FOR USE (IFU) AND USER MANUALS

IFU (instructions for use or user manuals) are an **integral part of the device** and they constitute the means by which the Manufacturer addresses the user to illustrate the composition and operation of the device itself and to indicate safety warnings together with any integration feature.
Even if often little considered by the user and, consequently, by the Manufacturer, the document is however often decisive in cases of litigation, as it clarifies and allocates responsibilities between the parties.

In the MDR (EU) 2017/745, there are several sections dealing with the subject, sometimes taking up topics already fixed with the MDD or AIMDD, sometimes establishing new requirements.

Article 10 (11) of the MDR states that "Manufacturers shall ensure that the device is accompanied by the information specified in point 23 of Annex I, in one of the official languages of the Union established by the Member State in which the device is made available to the user or patient".

In describing the minimum content of the technical documentation, **Chapter 2 of Annex II** reiterates that the dossier must contain a full set of instructions for use in the languages accepted by the Member States where the device is to be sold.

The general requirements of information are accurately listed in **Annex I, chapter III,** section 23.1 and 23.4, while in **art. 18** they are specified the characteristics of the information that must be provided to patients with implantation.

As mentioned, some of the requirements already exist in MDD and/or AIMDD, but others are new and therefore an accurate analysis is needed. It is therefore advisable to read the entire text of the MDR (EU) 2017/745 to have a complete overview of the legislative requirements.

GENERAL REQUIREMENTS FOR THE PERFORMANCE AND SAFETY OF INFORMATION CONTAINED IN THE INSTRUCTIONS FOR USE

In accordance with **Annex I point 23**, each device must be accompanied by the information necessary to identify both the device itself and the Manufacturer. In addition, all relevant safety and performance information must be present for users or other persons, as appropriate.

This information shall be implemented by the Manufacturer for the demonstration of conformity, it may appear on the device itself, on the packaging and in the instructions for use and it may be made available on the website by the Manufacturer, taking into account the following:

- ✓ **support, format, content, la legibility and location of the label and of the instructions for use** must be suitable for the device and its intended use. In particular, instructions for use shall be drafted in terms easily understandable to the user;

- ✓ the information on the label must be affixed **to the device** itself. In case it is not possible, this information may appear, in part or in full, on the unit **packaging** and/or on the packaging of several devices;

- ✓ labels must be provided in a **human readable format** and they can be integrated with **optical reading information**;

- ✓ instructions for use are provided **along with the devices**. By way of exception, they are not required for Class I and lla devices where the products can be used safely without such instructions (23.1d). if no instructions are provided with the device, it is necessary to explain the reasons within the **technical documentation**;

- ✓ where appropriate, the information supplied by the Manufacturer may take the form of internationally recognised **symbols.**

Among the requirements of Annex I point 23, there are also some **innovations**, such as:

- **if multiple devices are provided** to a single user and/or in a single location, it may be agreed with the buyer that **only one copy of the instructions for use is provided**. In addition, it is possible to demand that other copies are provided free of charge (23.1e);

- **instructions for use** may be provided to the user in a non-paper format (for example in **electronic format**) respecting the conditions established by the **Regulation (EU) n° 207/2012** or by subsequent implementing rules adopted pursuant to the Regulation (23.1f);

- among the information provided by the Manufacturer there must also be **residual risks** relating to restrictions, contra-indications, precautionary measures or warnings.

INFORMATION CONTAINED IN THE INSTRUCTIONS FOR USE

Instructions for use are part of the technical documentation of the device.

From the usability point of view, IFUs are fundamental. For this reason, the European Union requires a precise language in all markets, in order to ensure proper and safe use by patients and operators.

Following, the **news** about the information that must be present in the IFU:

1. the **intended purpose** of the device (23.4b) indicating the intended use of a device according to the data provided by the Manufacturer on the label, in the instructions for use or in the promotional/sales materials and as specified by the Manufacturer in the Clinical Assessment;

2. list of **expected clinical benefits** as demonstrated in the Clinical Assessment (23.4c);

3. information on **safety** and **clinical performance** (23.4d);

4. if necessary: **details** allowing the health care provider to verify whether the device is suitable;

5. if the device supplied is **sterile:** insertion of instructions in case the device packaging is damaged or unintentionally opened before use;

6. if the device has been reconditioned under the responsibility of the Manufacturer: warning of the **possible reuse of a device**;

7. in the case of **implantable devices**: inclusion of qualitative and quantitative information on substances and materials coming into contact with the patient (23.4u);

8. **list** of cases where the end-user must consult a health professional (23.4w);

9. information on **risks related to the use** of the device;

10. introduction of **instructions for reporting to the Competent Authorities** of any serious accident associated with the medical device, together with the relevant warning (23.4z).

INSTRUCTIONS FOR USE AND LANGUAGE REQUIREMENTS

Article 10 (11) and **Annex II** state that manufacturers shall ensure that the device is accompanied by the information **in one of the official languages of the Union established by the Member State** in which the device is made available to the user or patient.
It is therefore necessary to include in the **technical documentation** the precise indication of the countries of the European Union in which the device is marketed, together with the language accepted by the Country itself, as well as the description of the corresponding IFU translation.

In particular, the national legislation may provide for different languages depending on whether it is a **household** or **professional** device.

Below, a brief overview of the possible languages required by European Countries for the instructions for use.
Attention! Official information on this subject is that contained in the binding national legislative measures.

STATE	LANGUAGE
Austria	German
Belgium	French, German and Dutch
Bulgaria	Bulgarian

STATE	LANGUAGE
Croatia	Croatian, but English is accepted for professional devices
Cyprus	English, Greek and Turkish
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish and Swedish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxembourg	French or German
Malta	English
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovak
Slovenia	Slovenian, but English is accepted for professional devices
Spain	Spanish
Sweden	Swedish

TRANSLATIONS CARRIED OUT BY THIRD PARTIES (E.G. DISTRIBUTORS)

Language is essential to achieve compliance with regulations and to ensure safe use of medical devices in the European Union. For this reason, the **validation process of the translation of the contents** is essential.

The case in which a Third Party, for example the Distributor, deals with the translation of the instructions for use, it is disciplined by **art.16**.
In particular, the Third Party does not assume the same responsibilities as the Manufacturer, but it is nevertheless the holder of specific obligations in particular when performing the supply, including the translation of the information provided by the Manufacturer.

The obligations provided for by art.16 are the following:

- if an instruction translation activity has been carried out, this must be highlighted on the **packaging or document of the device**;

- Distributors and importers must have a certified **Quality Management System** specific for translation activities;

- the Quality Management System shall include procedures for the collection and recording of any **corrective action** taken by the Manufacturer in relation to the device;

- **within 28 days** of the placing on the market of the relabelled or repackaged device, Distributors and Importers must inform the Regulatory Authority of the Member State and the Manufacturer. Within the same period, they must submit the certificate of the Quality System to the Regulatory Authority of the Member State;

- upon request, Distributors, Importers or Third Parties may provide the Manufacturers and the Competent Authority with a **sample** of the relabelled or repackaged device, translated labels and instructions for use.

The Manufacturer will have to give evidence of the *outsourcing* of the translation processes within the technical documentation, meeting the requirements of Annex II, chapter 2 and share with the Third Party special Quality Technical Agreement for the management of the process and the definition of responsibilities.

USE OF SYMBOLS TO INDICATE COMPLIANCE WITH MDR (EU) 2017/745

The **MDR (EU) 2017/745 Regulation, in Annex 1, Chapter III, 23** details what should be included in the label of Medical Devices. In particular, in paragraph 23.1 h, it expresses the possibility of **using symbols as an alternative to the written language**. Thus, obviating the commitment of translations for each country of destination of the device thanks to the use of a universal language.

Quoting the MDR, in the dedicated paragraph: “Where appropriate, the information provided by the manufacturer shall take the form of internationally recognised symbols.
The identification symbols and colours used shall comply with the harmonised standards or with the SCs. In sectors where no harmonised standards or SCs exist, symbols end colours are described in the documentation that comes with the device”.

The MedTech Europe guide for the use of symbols in the label of Medical Devices

Before the international symbol standard is available, **MedTech Europe has published a guide on symbols (pictograms) for the Medical Devices labelling** in order to meet labelling requirements through the **use of symbols**, **in the short term and in a harmonised way**. **MedTech Europe** is a European trade association representing medical technology industries, from diagnosis to treatment.

The MedTech document is currently being revised by the ISO 15223-1 "Medical devices - Symbols to be used with information to be supplied by the manufacturer" and it is to be considered only for information purposes as it does not yet have legal value. For this reason, it will be necessary to wait for the final outcome of the ISO review process.

Pictograms can be used internationally and they shall be described in the instructions for use in accordance with the requirements of the Regulation, until they are published in a harmonised standard.

Please note! Jurisdictions outside the European Union may have different requirements regarding the "Information provided by the Manufacturer"**.**

For more details, please refer to the MedTech Europe guide on the use of symbols.

The symbols presented by the MedTech guide are useful for the following information:

- Medical Device.
- Human blood or plasma derivatives.
- Medicinal product.
- Hazardous substances.

- Biological material of human origin.
- Biological material of animal origin.
- Sterilized using vaporized hydrogen peroxide.
- Translation.
- Repackaging.
- Single patient multiple use.

Use of symbols for sterile Medical Devices

In Annex 1, Chapter III, point 23.3 of the MDR "information on packaging that maintains the sterility of a device («sterile packaging»)", they shall be provided the specific labelling indications with regard to the sterile devices and packaging, the method of sterilisation used and other information; however, without any reference to symbols and pictograms.

For this reason, the Sterile Barrier Association (SBA) – European trade association for companies producing sterile barrier systems – has developed **proposals for appropriate symbols for sterile Medical Devices,** in accordance with the MDR (UE) 2017/745 Regulation.

The association has sent a **ISO 15223-1 guidance document to standardisation bodies**, so that their proposals for universal symbols can be taken into account. These proposals also include recommendations for the placement of the new "STERILE" symbol.

UDI SYSTEM

The **UDI**, Unique Device Identification, is the coding system that allows to recognize in a sure and clear way all the Medical Devices and in vitro Diagnostic Medical Devices along the supply chain in Europe, the United States and other Countries. In Europe, the UDI is provided for in the MDR (EU) 2017/745 and IVDR (EU) 2017/746 Regulations.

It consists of a complex **alphanumeric code** that uniquely identifies a device placed on the market and it is an important **labelling requirement**.

It is formed by the **UDI-DI, a** numeric or alphanumeric code that identifies Manufacturer and device, and by the **UDI-PI,** a numeric or alphanumeric code that identifies the unit of production of the device**.**

The UDI allocation system is managed by organisations accredited by the European Commission.

Why is the UDI system important?

Through the UDI code, the Manufacturer shall identify and label its devices to increase traceability throughout the supply chain, so that immediate action can be taken if necessary.

Traceability cannot be ensured without proper identification of devices. It is therefore important that, when placing the MD on the market, they are clearly identified. This is because in case of malfunction or alteration of characteristics and/or performances of the products, systemic withdrawal must be possible.

Therefore, the UDI facilitates **the traceability of Medical Devices**, it significantly **improves** the effectiveness of **post-market safety** activities of devices and it allows better **monitoring** by the **Competent Authorities**. It also helps to **contain the risk of medical error** and to detect **falsified devices**.

Lastly, the UDI system optimizes purchasing policies, disposal and management of stocks by health institutions and Economic Operators.

When should the UDI be applied?

The UDI system is applied to all MDs, except for custom devices and devices used for studies/surveys on performances.

In addition, according to Annex VI Part C of the two Regulations, UDI is attributed to the system level of the software. Only commercially available softwareas and those that constitute **Meical Devices in their own right (SaMD)** are subject to this requirement.
Software identification is considered to be the manufacturing control mechanism and it is featured in the UDI-PI.
The document published by the European Commission is very useful. It contains the main FAQ on the implementation of the UDI system and provides a wide range of responses to the application of this code.

Economic Operators and UDI responsabilities

The Manufacturer is responsible for meeting all UDI requirements.
According to Art. 25 of the MDR Regulation, Distributors and Importers cooperate with Manufacturers or Authorised Representatives in order to achieve an appropriate level of traceability of devices.
Moreover, any Distributor, Importer or other natural or legal person who assumes the same obligations as the Manufacturer, is responsible for all responsibilities relating to the UDI (Art. 16 MDR).

The **MDCG 2018-6** "Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation (EU) 2017/745 and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746" guideline provides further information on this aspect.

How to implement the UDI system

According to Art. 27 MDR, the unique identification system of the device provides for:

- production of a UDI (including a UDI-DI and a UDI-PI);
- affixing the UDI on the device label or on its packaging;
- registration of the UDI by Economic Operators, health institutions and health professionals;
- establishment of an electronic system for the unique identification of the device (EUDAMED database).

The UDI code shall also be:

- included in the technical documentation;
- used to report serious accidents and recall actions;
- indicated in the information provided to patients who have received implants;
- stored electronically by Economic Operators and health institutions;
- registered in the EUDAMED database.

A new UDI-DI is necessary every time that changes which may cause incorrect identification of the device and/or ambiguity in traceability are made.

UDI implementation Timeframe

The **obligation to assign the UDI** is expected from 26 May 2021, date of application of the MDR (EU) 2017/745 Medical Devices Regulation.

Instead, the **obligation to submit UDI data in the EUDAMED database** shall take effect from 26 November 2022, provided that EUDAMED is fully functional before the date of application of the regulation.

The **MDCG 2019-4** "Timelines for registration of device data elements in EUDAMED" guidance document provides further information on this aspect.

In detail, it is mandatory to **place the UDI** according to the deadlines in the following table.

Device as per Regulation (EU) 2017/745 (MDR)	Implantable devices and Class III devices	Class IIa and Class IIb devices	Class I devices
Placing UDI-carriers on the labels of devices MDR Article 123(3)(f), Article 27(4)	26 May 2021	26 May 2023	26 May 2025
Direct marking of the reusable devices MDR Article 123(3)(g), Article 27(4)	26 May 2023	26 May 2025	26 May 2027

UDI positioning on the device and packaging

The Manufacturer is responsible for placing the **UDI carrier on the label** or **device itself** and **on all packaging levels of the device**.

The UDI shall consist of **legible characters** that are easily understandable by people (Human Readable Interpretation - HRI) and in AIDC format. AIDC is the technology used for automated data collection (for example: barcode and smart card).
The Manufacturer shall report the UDI carrier in such a way that AIDC is accessible during normal operating or storage conditions.

If the **UDI** carrier is easily **readable** or **can be scanned** (AIDC format) through the device packaging, the Manufacturer shall not carry the UDI carrier on the packaging.

In the case of a **single finished device consisting of several parts** that must be assembled before they are put into use, it is sufficient to carry the UDI carrier on only one part of each device.

Identification information which includes the name of the Manufacturer, type or product code and lot number must be visible to the user and affixed on the **packaging** containing several packages, on the **individual package** and on the **device** for **maximum identification and traceability.**

In the case of a **component** that is considered a device and is available separately on the market, a separate UDI shall be assigned unless the component is part of a configurable device bearing its own UDI. If, however, it is a kit, a UDI of its own shall be assigned.

Reusable devices carry a UDI carrier on the device itself that must be legible under normal conditions of use and throughout the expected life of the device.

Instead, for individually packaged and labelled Class I and lla **disposable Medical Devices**, it is sufficient for the UDI carrier to appear on an external layer of packaging.

However, for example, in the case of home healthcare, the UDI is on the packaging because the health care professional does not have access to the external packaging level of the device.

Lastly, for **products intended exclusively for retail outlets,** UDI-PI in AIDC does not need to appear on the store packaging.

HOW TO MEET MDR (EU) 2017/745 REQUIREMENTS ON THE INFORMATION PROVIDED IN THE INSTRUCTIONS FOR USE

Here are some useful tips to prepare for the implementation of these essential requirements:

- proceed to a careful reading of the MDR (EU) 2017/745 and, in particular, Annex I e II;
- pay attention to other applicable requirements, such as guidelines and regulations recalled;
- trust on Thema experts for a strategic-regulatory consultancy.

SOURCE:

- *Medical Devices Regulation MDR (EU) 2017/745*

For more information

Thema supports companies operating in the field of Medical Devices and in Vitro Diagnostic Medical Devices in the process of adapting to regulatory requirements, facilitating access to the global market
For further information visit **www.thema-med.com**