

Impact of changes under the new EU Medical Devices Regulation (EU) 2017/745 to international registrations

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Introduction

Regulation (EU) 2017/745 on medical devices (MDR) introduces a major update of the regulatory framework in the European Union (EU). This modernisation of the European regulatory system brings about several changes to the information provided with the devices and their regulatory documentation. It is important to note that not all changes will apply to all medical devices. Therefore, changes to regulatory documentation because of the MDR are likely to vary from product to product.

Most of these changes will simply mean that additional information is available for existing devices. This in no way changes the use, effectiveness, performance or safety profile of the devices and as such should have no particular impact on registrations since all jurisdictions allow additional information to be provided with a medical device.

The regulatory documentation around a device will be updated – this can include changes to notified body certificates, free sales certificates, and declarations of conformity. The update of the regulatory documentation does not necessarily impact the device characteristics, i.e. changes to the regulatory documentation do not imply changes to the composition of the ingredients or the manufacturing processes unless otherwise indicated.

The European Commission continues to publish useful information communicating changes to the regulatory framework in the European Union (EU). The '[Factsheet for Authorities in non-EU/EEA States on Medical Devices and in vitro Diagnostic Medical Devices](#)' is a useful resource about the changes brought by the EU legislation, that is aimed specifically at regulatory/competent authorities outside of EU/EEA (EEA – European Economic Area). All other factsheets published by the Commission can be found here: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_de

This document analyses the changes to the regulatory documentation due to the MDR that might be relevant for product registrations outside of EU/EEA. It is addressed to economic operators, and to regulators who are based outside of EU/EEA.

This document does not tackle specific issues that may arise at customs due to the transition to the new legislation, however, it is important that customs officers are alerted to the changes to the legislation in the EU to avoid misunderstandings and any unnecessary delays at the point of customs clearance.

Transitional Provisions

Before diving into the relevant MDR requirements, it is worth taking note of the complex transition period that has been introduced under the regulation (MDR, Article 120). The MDR provides a gradual transition into the new regulatory framework to avoid market disruption and allow a smooth transition from the directives to the regulation. Some medical devices with certificates issued by notified bodies under the directives may continue to be placed on the market until 27 May 2024.

The COVID-19 pandemic severely disrupted the preparation for the entry into application of the MDR. As a consequence, the EU MDR was amended by Regulation EU 2020/561 to delay the date of application of the MDR by one year to 26 May 2021. In addition, the possibility of EU wide derogations was brought forward so that in crucial cases these derogations can be issued from 25 April 2020 onwards. Current directives remain in application up to the 26 May 2021.

The Commission '[Factsheet for Authorities in non-EU/EEA States on Medical Devices and in vitro Diagnostic Medical Devices](#)', highlights explicitly that: *"during the transition period, products certified under the directives and products certified under the Regulations will coexist on the market. Both will have equal status under the law, provided that they are accompanied by appropriate certificates, and no discrimination in eligibility criteria in public tenders may take place"*.

The amended date of application for the MDR will need to be taken into account by the reader when reviewing some of the reference documents, as not all documents have been updated.

Additional information on the transitional provisions is [available](#).

Labels

The requirements of the new regulation will trigger changes to the labels of medical devices. These changes will include:

- **Reprocessing of Single Use Devices:** the MDR lays down specific rules for the reprocessing of single use devices, which may only take place where permitted by national law and only in accordance with Article 17 of MDR. The legal or natural person who reprocess single use devices assumes the responsibilities of the manufacturer, therefore, their name and address need to be indicated on the label, as well as other relevant information that may be required, e.g. the fact that the device has been reprocessed (MDR Article 17; Annex I, Chapter III, section 23).
- **UDI:** the MDR establishes the Unique Device Identification (UDI) system to facilitate identification of devices within the supply chain and achieve an appropriate level of traceability. The UDI carrier

needs to be placed on the label of the device or on its packaging (MDR Article 27; Annex I, Chapter III, section 23).

- **Carcinogenic, mutagenic or toxic to reproduction and endocrine disrupting substances:** where applicable, indication of presence of certain substances that are carcinogenic, mutagenic or toxic to reproduction (CMR) of category 1A or 1B, and/or substances having endocrine-disrupting properties (ED) where there is scientific evidence of probable serious effects to human health. This information will be available for products that contain such substances in a concentration above 0,1% weight by weight.

This labelling requirement does not mean that the device is unsafe. The fact that the device has been CE marked means that both the manufacturer and the notified body have established a positive benefit-risk ratio analysis, justifying the use of the substance in the device (MDR Annex I, Chapter II, section 10.4.1).

- **Symbols:** the MDR lays down several new requirements asking various kinds of information to be indicated on the label of medical devices. To comply with these requirements, the information required to be supplied on the device's label, may take form of symbols (MDR Annex I, Chapter III, section 23). The international standard ISO 15223-1 is undergoing a revision, in a meantime, MedTech Europe has published a guidance document on ['Use of Symbols to Indicate Compliance with the MDR'](#).

Instructions for use

The MDR identifies the information that needs to be included in the instructions for use (IFU) in order to inform the user of a device's intended purpose and proper use, as well as of any precautions. For devices CE-marked under the MDR, additional information will be provided in the IFU in comparison to devices that have been CE-marked under the medical device directives. To highlight selected examples, the additional information may include:

- **Intended user:** the IFU will include information regarding the device's intended purpose and also the intended user (MDR Annex I, Chapter III, section 23.4).
- **Reprocessing of single use devices:** the MDR provides that the name and address of the manufacturer of the original single use device shall no longer appear on the label, but shall be mentioned in the IFU of the reprocessed device. The IFU of a reprocessed device should also include other relevant information in accordance to Annex I, section 23.2 (MDR Article 17; Annex I, Chapter III, section 23.4).
- **Carcinogenic, mutagenic or toxic for reproduction and endocrine disrupting substances:** considering space limitation in case of labels of certain devices, if the presence of carcinogenic, mutagenic or toxic for reproduction and endocrine disrupting substances is indicated on a label by

means of a symbol, further information about the substances can be found in the IFU. (MDR, Annex I, Chapter III, section 23.4).

- **Implant card:** information to be supplied to the patient with an implanted device in accordance with Article 18 (MDR Article 18; Annex I, Chapter III, section 23.4.).
- **Symbols:** explanation to of the new symbols that appear on the label. (MDR, Annex I Chapter III, section 23.1).

Consult Annex I, Chapter III, section 23.4 of the MDR for the full list of information to be provided in the IFU.

It should be noted that none of these changes is considered to impact the functionality or risk profile of the medical device and simply serve to explicitly state additional information (if needed), allow for the traceability of the device (UDI) and reflect the new regulatory oversight (NB number).

Certificates issued by a Notified Body

New notified body certificates will be issued under the MDR. These notified body certificates contain new information, such as Basic UDI for the devices which they cover. The certificates will also clearly be issued under the regulation. Annex XII, Chapter II of the MDR specifies the minimum contents of the NB certificates.

Declaration of Conformity

New declarations of conformity (DoC) will be issued under the MDR. These reflect not only the fact that conformity will be claimed to the regulation but will also include additional information, such as Basic UDI, or where applicable, references to any common specifications (CS).

Given the overall strengthening of requirements under the regulation, a DoC under the regulation should be considered at least equivalent to that under the directives. Annex IV, of the MDR specifies the information to be included in the DoC.

Scope and classification

In general, the MDR has an enlarged scope in comparison to the scope of the medical device directives. Provided that a product qualifies as a medical device in accordance to the definition laid down in the MDR, the scope of the MDR expands to products that were not subject to the requirements of the medical device directives, including:

- Products without an intended medical purpose that are similar to medical devices on the basis of their functioning and risk profile. Annex XVI of the MDR lists such products.

- Certain products that are manufactured utilising derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable
- Products intended for cleaning, disinfection and sterilisation of medical devices
- Many software products that fall under the definition of a medical device under the MDR even if they may not have been qualified as a medical device under the directives.

In addition, the classification of some medical devices may change under the MDR. Certain medical devices e.g. surgical meshes have been up classified from Class IIb to Class III. Changes to the classification rules in Annex VIII of the MDR may result in a higher risk class for some devices, leading to more stringent conformity assessment requirements. Further guidance regarding the interpretation of the classification rules that may impact classification of certain devices, e.g. software, is expected from the Medical Device Coordination Group.

Certificates of Free Sale

New certificates of free sale (CFS) will apply - these certificates will refer to the new regulation. However, they will be covering essentially the same devices as before. The question of how devices are identified is important in this case - as UDI and even catalogue numbers may change for the medical devices under the regulation.

The transition period is also important to note when it comes to CFS. As noted in the Commission '[Factsheet for Authorities in non-EU/EEA States on Medical Devices and in vitro Diagnostic Medical Devices](#)', during the remaining validity of a NB certificate, a device can be covered by both a directive certificate and a regulation certificate. CFS may therefore be issued with the corresponding certificates under both the MDD/AIMDD and the MDR and both types of CFS will be equally valid. To avoid any unintended adverse impact on the supply of products, it will be important that regulatory authorities in non-EU/EEA countries recognise that the validity of CFS issued for devices placed on the market under the directives after 26 May 2021 (the date of application of the MDR), until the corresponding certificates issued by notified bodies expire.

Conclusion: Assessment of the changes due to transition to MDR

It is important to note that not all changes will apply to all medical devices. The table below provides an assessment of the changes due to transition to MDR. When reading this table, it is important to note that changes to regulatory documentation because of the MDR are likely to vary from product to product.

Type of information	Type of change	Change in risk / benefit profile of the device	Change in use of the device	Assessment of the impact of the change
Change to ingredients and manufacturing process	None	None	None	No impact on use or patient safety
Labels	Additional information, including UDI, new symbols e.g. indication that a product is a medical device or that it contains CMR/ED substances, etc.	None	None	No impact on use or patient safety
IFU	Additional information and clarification (e.g. intended user, where applicable, information about CMR/ED substances, information to be supplied to the patient with an implanted device, explanation of new symbols that appear on the label), etc.	None	None	No impact on use or patient safety

Type of information	Type of change	Change in risk / benefit profile of the device	Change in use of the device	Assessment of the impact of the change
Notified Body Certificates	Additional information e.g. UDI, the registration number of the manufacturer (if already issued), etc.	None	None	No impact on use or patient safety
Declaration of conformity	Additional information, including UDI, registration number of manufacturer and of European authorised representative (if already issued), etc.	None	None	No impact on use or patient safety
Classification	Changes to the classification rules in Annex VIII of the MDR may result in a higher risk class for some devices, leading to more stringent conformity assessment requirements.	None	None	No impact on use or patient safety
Certificate of Free Sale (CFS)	New data, including Basic UDI, notified body certificate number. Possible new layout for the CFS as MDR foresees the possibility to adopt a model format.	None	None	No impact on use or patient safety

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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