# Analysis of the new Medical Devices Regulation (MDR) and *In vitro* diagnostic Medical Devices Regulation (IVDR) draft texts

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## Introduction: background information and next steps

On 25 May 2016, the European Parliament and the European Council jointly announced the agreement reached about the Regulations for Medical Devices (MDR) and In Vitro Diagnostic Medical Devices (IVDR). Following the agreement, the draft texts of the MDR and the IVDR were published on 15 June 2016 and the consolidated texts on 27 June 2016. Once the draft regulations have been translated into all official languages and after their legal-linguistic revision, the final texts must be approved by the Council and the European Parliament.Formal publication of the final texts is expected by early 2017.

As regards the MDR, the publication of the final text will be followed by a three-year application period. The new regulation will enter into force in early 2017 and apply from early 2020. In terms of implications for CE Marking, certificates issued prior to date of application of the MDR in early 2020 will have a maximum validity of five years. However, all CE Mark certifications issued before implementation of the new regulations will automatically expire four years after the date of application of the new regulations.


The IVDR application period will last five years as it will apply starting from early 2022. In this case, CE Mark certificates issued before final implementation of the IVDR will remain valid for a maximum of two years following final implementation of the new regulations.

## Changes introduced by the MDR and IVDR draft texts

The draft text of the MDR brings about major changes compared tothe previous medical devices legislation. It includes an expanded definition of medical devices –also defining new types of products as medical devices requiring CE marking–the introduction of more checks to increase level of patient safety and the definition of new competences for already existing EU bodies, including the

European Commission, as well as for new actors that will be established following the adoption of the Regulations.

The sectionsbelow provide an overview of these changes with a particular focus on those that will extensively influence hospital activities. Given the importance for hospital activities of the changes introduced by the new legislation to reprocessing of single-use medical devices, the topic is addressed separately in a dedicated section.

## Expanded definition

The MDR defines the term "medical device" as any "instrument, apparatus, appliance, software, implant, reagent, material or other article" intended to be used for any of the following 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 data via *in vitro* examination of samples derived from a human body.
- Products specifically intended for cleaning, disinfection, or sterilisation of medical devices and devices for control or support of conception shall be considered medical devices.

The definition is therefore expanded to include devices with purposes related to prediction and prognosis of diseases. As a consequence, the MDR covers devices previously regulated by more than a single piece of legislation. Specifically, the medical devices falling into the scope of the MDR were previously regulated by two separate European directives, the Medical Devices Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD). I*n vitro* diagnostic devices will be covered by the new In Vitro Diagnostics Regulation.

### *New MDs falling into the scope of the Regulation*

The new definition of medical devices will also apply to a group of products without an intended medical purpose (such as contact lenses, dermal fillers, etc.), as listed in Annex XV of the Regulation on Medical Devices. These products will have to meet common specifications that address risk management and, where necessary, clinical evaluations regarding safety.

They also include products of common use in health infrastructures, such as:

- products intended for cleaning, disinfection and sterilization of medical devices (e.g. scope disinfector);
- software used for any purpose covered by MDR's definition of a medical device;
- products introduced into the body via surgically invasive means in order to modify anatomy, products and substances used for facial or other subcutaneous filling, equipment used for liposuction, lipolysis or lipoplasty;
- devices for purposes of control or support of conception (e.g. condom, intrauterine device).

The inclusion of software within the scope of the Regulation will have an impact on the mHealth sector, as all software and mobile applications designed for any of the purposes included in the definition shall be considered as medical devices. However, it must be noted that the Regulation specifies that general purpose software shall not be considered as a medical device, even if it is used in a healthcare context. This may include software used for administrative purposes in healthcare facilities. Likewise, lifestyle or wellbeing software shall also not be considered a medical device.

Additionally, the Regulation considers that products with an aesthetic rather than medical purpose, may be similar to medical devices in terms of functionality and risk profile, and as such must be considered medical devices.These types of products must comply with requirements that apply to those with both a medical and non-medical purpose.

Do not fall into the scope of the regulation the following products:

- Products that utilize viable biological components for their intended purpose (e.g. lactobacillus);
- VDs, medicinal products, cosmetics and food products, which are specifically regulated elsewhere.

### *Accessories*

According to the Article1 par. 1(b) of the draft text, accessories are included in the scope of the Regulation, similar to the requirements in the Directives.

Accessories are products that are intended to enable a device to be used in accordance with its intended purpose or to assist the medical functionality of the medical device. As some products are now added to the definition of a medical device, their accessories will also be covered by the scope of the Regulation, e.g. nets for sterilization, devices used to position or remove invasive or implantable contraceptives, software used for creating images of the expected effects of breast implants.

## Increased attention on patient safety

One of the objectives of the new Regulation on MDs is to increase patient safety. To do so, it tightens rules when already existing and establishes new mechanisms to ensure that the health of patients and users is protected.

A special focus is put on:

- pre-market conformity with requirements;
- post-market oversight;
- traceability of medical devices and in vitro diagnostic medical devices throughout the supply chain.

## *Pre-market conformity with requirements*

### Notified Bodies

While the MDR reinforce the existing regulation for marketing of medical devices, the core features of the system do not change and keep being based on the use of Notified Bodiesto assess medical devices before their launch on the market. The role of these private companies designated by the Member States' competent authorityhas not changed substantially from what provided by the previous Medical Devices Directive. However, they will have the right and duty to carry out unannounced factory inspections, thus moving from a position of "industry partners" to "policing bodies".

Moreover, the notified bodies will be subject to stricter designation requirements, which exposecurrent notified bodies lacking specific capabilities and competences to the risk of not being able to meet the new requirements.

### More checks for high risk devices

The MDR text introduces new procedures aimed at increase the number of checks when it comes to high-risk devices (e.g. as implants)carried out by experts of the competent authoritiesbefore they are placed on the market.

Specifically, Notified Bodies may seek advice from an expert panel designated by the European Commission on applications for conformity assessment for high-risk devices. The Notified Body shall give due consideration to the views expressed by the expert panel.Where the expert panel raises concerns about certain matters such as the sufficiency in the level of clinical evidence or serious concerns about the benefit/risk determination of the device, the Notified Body is required to advise manufacturers to take certain action to address those concerns. In the event that the Notified Body has not followed the advice of the expert panel, it shall provide a full justification. [8]

Another amendment that could have a major impact on manufacturers is the inclusion of a scrutiny procedure (Article 44), which, for certain types of class III and class IIb devices, will enable the competent authorities to review the checks carried out by the Notified Body to verify technical documents. The procedure is criticised by industries as it could involve a duplication of work. Moreover, competent authorities may also request further information, which could delay the procedure for a number of months and reduce the margin of advantage of the manufacturer on its competitors.

Manufacturers of in vitro diagnostic medical devices will experience a greater change as—under the current directive—one in five in vitro devices requires the involvement of the Notified Body whereas, according to industry data, the amendments implemented by the Regulations could mean that up to 80% of devices will require the involvement of the Notified Body.

In addition to the above procedures, the MDR assigns new competencies to the European Commission and establishes the Medical Device Coordination Group ("MDCG"), whose roles are further explained below in Section "New competences".

## *Post-market oversight*

### Clinical investigations

With a backdrop of increasing transparency in the area of clinical trials for medicinal products, the new Regulations aim to improve the availability of clinical investigation data on devices.

Sponsors of clinical investigations will be required to publish the results of clinical investigations and a summary of the results in layman's language on Eudamed which will be available to the public. Eudamed is a database for information on medical devices collected by competent authorities and the European Commission. Presently, only such competent authorities and the European Commission have access to Eudamed. The Regulations will now grant access to Eudamed to a broader spectrum of stakeholders, including members of the public.

These documents must be published on Eudamed regardless of the outcome of the investigation and must be done within one year from the end of the investigation or within three months from its early termination or halt, whichever is the earliest.

### New post-market follow up mechanism

Safety has also been increased via the use of a new post-market follow-up mechanism, the purpose of which is to ensure that manufacturers document and operate a monitoring system after products have gone to market by means of a plan based on product type and risk. This will ensure that manufacturers regularly report the results and conclusions of their analysis over the useful life of the device.

This plan must be used to collect information about events and their effects, relevant technical literature, complaints submitted by consumers, distributers and importers and information available in the public domain about similar medical devices.

## *Traceability throughout the supply chain*

### Unique Device Identification for devices (UDI)

Manufacturers will be required to place a Unique Device Identification ("UDI") on their medical devices to ensure traceability,post-sales monitoring of devices, application of corrective measures and healthcare authority monitoring activities.

The UDI will need to be included on the label of the device. Entities involved will be able to identify from whom and to whom a device has been supplied in a "one step back"-"one step forward" approach.

The UDI will include information concerning the identity of the device, any warnings, precautions or measures to be taken by the patient or a healthcare professional and a description of potential adverse events.

### Implant card

Manufacturers of implantable devices will have to provide patients with an implant card that must contain the name of the device, serial number, batch code, UDI, device model and relevant warnings, precautions and information about the useful life of the implant.

This information must be made available to patients in such a way so as to ensure it can be accessed quickly and understood. Information must be updated on the manufacturer's website on an ongoing basis.Certain specific types of implants do not require this level of information. These include sutures, staples, dental implants and dental appliances.

## New competences for different actors

The agreed text of the MDR also assigns new competences to different actors, including the **European Commission**, which is now entitled to categorise and classify devices. Article 3 of the Regulation on Medical Devices provides that at the request of Member States or at its own initiative, the European Commission may determine, after consulting with the Medical Device Coordination Group (MDCG), whether or not a specific device should be classified as a medical device or as an accessory to a medical device. Moreover, the Commission must share its expertise in the field with Member States.

To date and in accordance with Directive 93/42/EEC of 14 June, Member States are responsible for clarifying which categories certain products belong to. The change introduced by the new Regulation will require manufacturers of medical devices to invest more time into deciphering what category a product falls into. Furthermore, it is not yet known how this new reality will be implemented, which could give rise to the Commission making decisions that contradict the criteria applied by Member States.

The above-mentioned **Medical Device Coordination Group**(MDCG) is an additional innovation brought about by the MDR. Its creation is regulated by Article 78 of the text, while Article 80 defines its tasks. The MDCG is composed by an expert (and one alternate) appointed by each Member State to provide expertise in the field of this Regulation, as well as an expert (and one alternate) providing expertise on the IVDR. Each Member State can also appoint only one expert for both the Regulations.

The experts of the MDCG will contribute to the assessment of applicant conformity assessment bodies and Notified Bodies, advice the European Commission in matters concerning the coordination group of Notified Bodies, contribute to developing devices standards, of Common Specifications and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable and class III devices. The MDCG will also assist the competent authorities of the Member States in their coordination activities in particular in the fields of classificationand regulatory status of devices (Art. 80).

At industry level, the Regulation requires the appointment of the **regulatory compliance manager**, namely the individual responsible for ensuring regulatory compliance within the manufacturing organisation. The compliance manager is required to have proven experience in the field of medical

devices. SMEs are not required to employ this professional figure within their business; however they must have access to the expert when necessary.

Last but not least, all the medical device manufacturers selling in Europe will need to establish risk management systems (Art. 8.1a) and quality management systems (Art. 8.5), with the main exception of Class I self-certified devices. They will indeed be exempted from being required to have their quality management systems assessed by a Notified Body (Art. 42.5).

## Reprocessing of single-use medical devices

Reprocessing refers to enabling a device to be safely reused through cleaning, disinfection, sterilisation and related procedures, including testing and restoration of the technical and functional safety of the previously used device.

It represented one of the most contentious points during the negotiations, with some stakeholders strongly in favour of allowing reprocessing by default while others were strongly against such activities without the consent of the individual Member States.

According to the text of the new Regulations, reprocessing of devices will only be permitted in accordance with individual Member State legislation and in accordance with what provided by the MDR in Article 15.

The draft MDR text published in mid-June presents some differences in comparison to the previous Council-EP compromise and the Commission proposal of 29 April (WK 310/2016). In particular, the final text has reintroduced paragraph 1b (deleted from the Commission proposal WK 310/2016) which reads:

“Member States may choose to apply provisions referred to in paragraph 1a also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution provided that the reprocessed device in its entirety is returned to that health institution and the reprocessor complies with the requirements referred to in paragraph 1a(a) and 1a(b).”

Moreover, the draft text has completely removed the possibility that the Commission, by means of implementing acts, shall establish and regularly update the list of categories or groups of single-use devices for critical use which may be reprocessed (par. 4 and 4a).

As in the previous version of the text, the Commission is tasked with drawing up a report within four years after the date of application of the Regulations on the operation of these provisions and submit it to the European Parliament and to the Council for consideration.

### Major changes introduced by the IVDR draft text

The major changes brought about by the In Vitro Diagnostic Medical Devices Regulation are listed in the table below.

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| Performance evaluations | All IVDs will be subject to performance evaluations, and studies targeting incapacitated subjects, minors, pregnant and breastfeeding women and emergency situations will have to meet additional requirements. |
| Notified Bodies | Many more IVD manufacturers will have to engage Notified Bodies as part of their conformity assessment procedures. |
| Distribution issues | Requirements for importers, distributors and Authorized Representatives will align with requirements listed in Decision 768/2008/EC; importers, distributors and Authorized Representatives will need to meet additional IVDR requirements. |
| Classification changes | There will be four risk-based classes for IVDs—Class A, B, C and D, with most "self-testing" falling under Class C and many IVDs which have currently been classified as self-certified would be classified as higher risk. |
| Responsible Person requirements | IVD manufacturers will have to appoint Persons Responsible for Regulatory Compliance (art. 13) to handle batch releases, technical documentation and post-market surveillance and vigilance efforts. |
| Class D scrutiny | Notified Bodies will have to inform relevant Competent Authorities about all new CE Mark certificates issued to Class D IVDs; Competent Authorities may at their discretion appoint experts to evaluate clinical data for such devices. |
| Near- versus self-tests | The IVDR considers near-patient tests as different products from self-testing. |
| Stricter allowances for "homebrew" IVDs | So-called "homebrew" devices are only allowed under the IVDR in instances where no adequate alternative products are available on the market. |
| Authorized Representatives to IVD manufacturers | Authorized Representatives to IVD manufacturers will be held "jointly and severally liable" for defective devices. |

## Conclusion

The new MDR and IVDR have been largely welcomed as they increase the level of patient safety in comparison to the previous legislation. More mechanisms and checks will be introduced as a consequence of the adoption of these new pieces of legislation in order to ensure that the devices on the market are safe and that comply with the quality standards required to ensure full protection of patients and users.

Increased security will be guaranteed both in the pre- and post-market stages thanks to the introduction of systems such as the UDI, which increases the level of traceability of medical

devicesvia the supply chain.The UDI will indeed enable the competent authorities to quickly and efficiently withdraw from the market those medical devices that may present risks. Therefore, it will also help in the fight against counterfeit devices.

However, the core system of pre-market scrutiny of medical devices keeps being based on decision made by Notified Bodies, thus private companies, rather than public authorities such as in the case of pharmaceuticals.

As for the case of reprocessing of single-use medical devices, the MDR does not add much to the current situation, leaving the Member States free to decide on the subject. By contrast, confusion between criteria set by the Commission and Member States when it comes to the definition of MD categories may become a reality during the implementation phase.

Finally, while users such as healthcare professionals will be allowed to work in better conditions and with higher safety standards, manufacturers will be highly affected by the new Regulations. These is true especially in terms of increased costs and time required for producing the devices and placing them on the market, in particular as a consequence of increased checks on low-risks medical devices and the introduction of the UDI system for traceability of medical devices.