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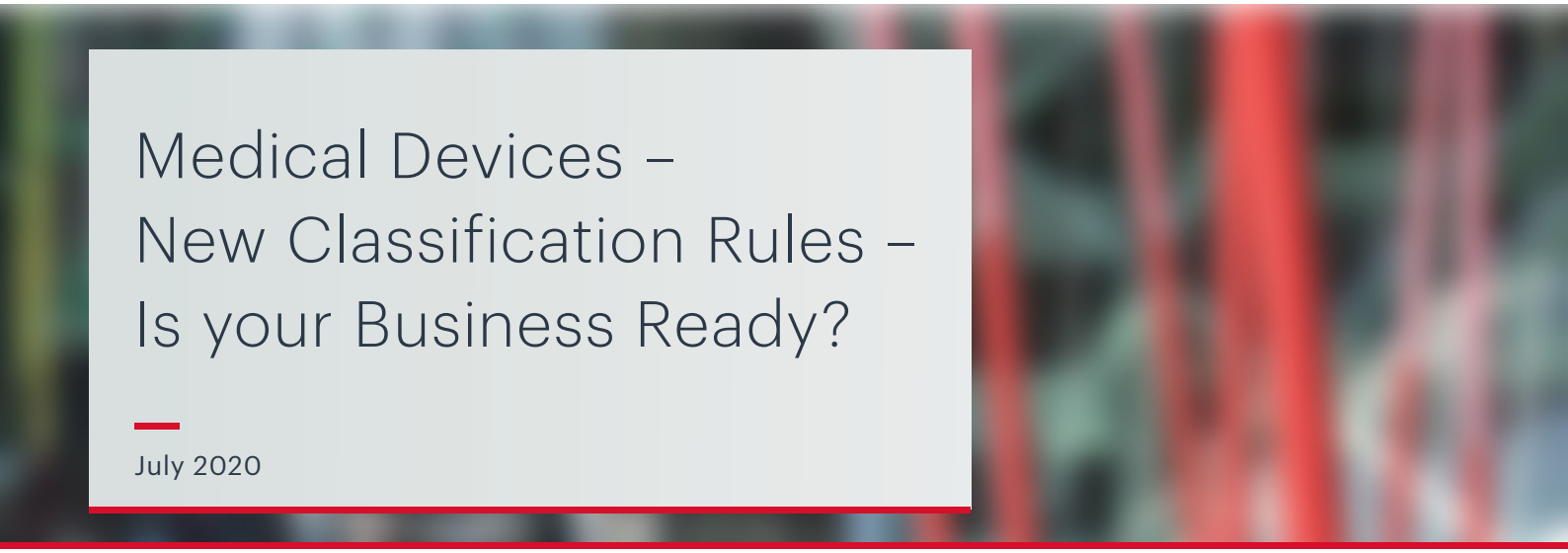


Medical Devices – New Classification Rules – Is your Business Ready?

July 2020

Welcome to the first in a series of publications on the Medical Devices Regulation (EU) 2017/745 (the **MDR**) and the In Vitro Diagnostic Devices Regulation (EU) 2017/746 (the **IVDR**) (together the **Regulations**). Both Regulations are set to become fully applicable on 26 May 2021 and 26 May 2022 respectively. These Regulations will replace the current Directives which have been in place for over 25 years.

Two principal changes are:

- the Regulations now extend the MDR regime to all economic operators in the supply chain; and
- expands the range of products subject to its requirements.

For your preparation, we have a collection of topic-based articles, commencing with the classification of devices, to guide medical device companies through the Regulations and to ensure a smooth transition into the new regulatory framework.

CLASSIFICATION UNDER THE MDR

Under the MDR, Medical Devices (MDs) are graded in accordance to the risk they pose to health and safety, starting with the lowest risk category at Class I, up to the highest at Class III.

Examples of devices that fall into the four classes:

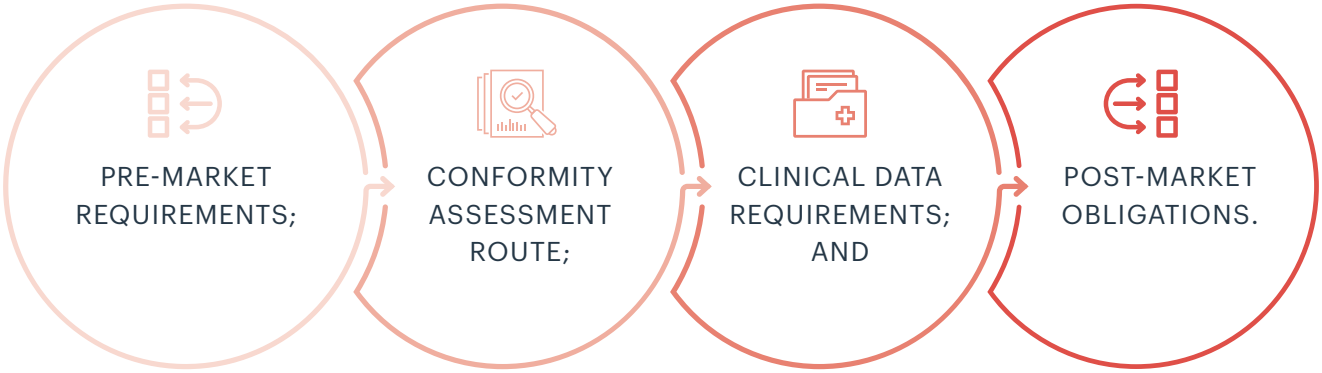
INCREASING RISK

CLASS I	CLASS IIa	CLASS IIb	CLASS III
• Wheelchairs • Band-aids • Stethoscopes • Syringes (some)	• ECG machines • Dental fillings • Contact lenses (some)	• Blood bag • Ventillators • Bone fixation plates	• Pacemakers • Balloon Catheters • Breast implants

MDR Classification Rules

The MDR provides 22 rules which are used to classify a MD. These classification rules, which are based on the vulnerability of the human body, consider the potential risks associated with the technical design and manufacture of the devices.

Like the 'old' system, under the Medical Devices Directives 93/42/EEC and 90/385/EEC (the **MDDs**), these rules are based on risk criteria and their application will depend on the intended purpose of the MD. The classification of a device will affect many aspects of a MD's life cycle, such as:



OUT WITH THE OLD AND IN WITH THE NEW

Below are some of the key changes from the 'old' MDDs system of classification:

KEY CHANGES

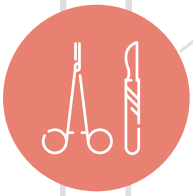
1

The MDR adds new rules relating primarily to software, nanomaterials, ingested products and non-viable human tissues, cells and derivatives.

2

'Invasive Devices' rules under the 'old' MDDs regime did not sufficiently take account of the level of invasiveness and potential toxicity of certain devices. In contrast, the MDR introduces specific classification rules for such devices. These rules now consider the following factors in relation to the MD:

- where it performs its action in or on the human body;
- where it is introduced or applied;
- whether a systemic absorption of the substances of which the device is composed occurs; and/or
- whether a systemic absorption of the products of metabolism in the human body of those substances occurs.



3

The MDR does not regulate cosmetic products, which are covered by Regulation (EC) No 1223/2009. However, it now classifies for the first time the following aesthetic products as a MD:

- Liposuction equipment
- Coloured contact lenses
- Dermal fillers
- Collagen implants
- Laser hair removal equipment
- Skin resurfacing equipment
- Tattoo removal equipment (tattooing and piercing products are not considered MDs) and
- equipment intended for brain stimulation that penetrates the cranium to modify neuronal activity in the brain.

KEY POINTS:

Transition phase:

Until 26 May 2021 MDs CE marked in accordance with the MDDs can continue to be placed on the market. There are however some key nuances, including:

- MD certificates issued **prior to 25 May 2017** remain valid until the end of the period indicated on the certificate (except for certificates issued under Annex 4 of the MDDs which become void on 27 May 2022). MDs subject to these certificates, which are placed on the market prior to 26 May 2021, may continue to be made available once in the supply chain until 26 May 2025.
- MD certificates issued **after 25 May 2017** will remain valid until the end of the period indicated on the certificate, which cannot exceed 5 years from its issue date (and will in any event become void on 27 May 2024). Similarly, MDs subject to these certificates, which are placed on the market prior to 26 May 2021, may continue to be made available once in the supply chain until 26 May 2025.
- Following a recent amendment to the MDR, a class I MD which was CE marked prior to 26 May 2021 may be placed on the market or put into service until 26 May 2024 (and may continue to be made available once in the supply chain until 26 May 2025) provided that from 26 May 2021:

  a) the MD continues to comply with the MDDs and there are no significant changes in the MD's design or intended purpose; and

  b) the requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are applicable in lieu of the corresponding provisions in the MDDs.

- Alternatively, manufacturers can, and we recommend should, on a voluntary basis, certify their devices under the MDR before 26 May 2021.
- Manufacturers should contact their Notified Body to ensure they understand the process for re-certification and are fully prepared for the MDR.

Certification Dispute:

- If a dispute arises between a manufacturer and the Notified Body as to the classification of a MD, it is for the Health Products Regulatory Authority (HPRA) to determine.
- It is crucial that companies fully document the justification for their decision on classification, should it be disputed.

Up-classification of certain MDs:

- MD companies should be alert to the introduction of a new class of high-risk software under Rule 11 of the MDR. Such software may include for example a smartphone application to assist in patient daily drug dosage calculations.
- The MDR has also provided for the up-classification of many other MDs and also for the classification of many aesthetic products as a MD. Consequently, MD and cosmetic companies should commence a full review of their portfolio of devices.
- If a device is intended to be used with a combination of other devices, each device must be classified independently of the other.

Guidance

- The HPRA is currently drafting a detailed implementation plan for the MDR. It is closely monitoring the Commission's Implementation Rolling Plan (which is revised quarterly) to ensure it has identified all essential implementing acts and other relevant initiatives adopted.
- An essential part of the HPRA's implementation plan is engagement with stakeholders. Therefore, we encourage companies likely to be affected by the MDR to engage with the HPRA via their designated mailbox devices@hpra.ie.

CONTACT US

If you require any further information on the classification of medical devices or any other aspect of the MDR or IVDR, please contact Charleen O'Keeffe or Laura Scott.

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