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A new MDR. Part 1 – what MDMs need to know about new regulation

By now, most of us have understood that the old Medical device directive (MDD 93/42/EEC) is soon to be replaced by the new Medical device regulation (MDR 2017/745). **But what does this actually mean for MDMs and what do you need to do to prepare?**

We've put together a brief overview of key points in the MDR that you should get familiar with now:

The new Medical device regulation

The new MDR was supposed to be fully adopted in May 2020 but due to the situation with Covid 19 it was moved to May 2021. It is applicable to all medical devices produced, sold, and distributed in the EU. The regulation outlines the requirements that manufacturers and importers must follow in order to achieve the CE mark and be able to market and sell their devices within the EU.

Since the MDR is a regulation instead of a directive, member states must adopt it directly and stringently, assuring a uniform regulatory framework across the EU and greatly increasing predictability.

Responsibility for the full product life cycle

While the old MDD focused mostly on the procedure for getting products approved and onto the market, the new MDR takes a more comprehensive view of a product's life cycle. The regulation imposes increased responsibility on all actors along the chain, through the entire active life of a medical device, including the time that comes after the product has been sold.

It also places stricter demands on medical device manufacturers (MDMs) and on the Notified Bodies (NBs) – a completely new approach.

Traceability and identification

The new regulation imposes new traceability and identification requirements aimed at improving control, transparency, and the ability to quickly react to various situations on the market.

To be able to identify individual products, a new identification requirement - unique device identification (UDI) – has been implemented. Each device must now be marked with a device identifier (DI), and each batch must be marked with a production identifier (PI).

EUDAMED – A new database for medical devices

There is increasing pressure to provide greater transparency around technical information regarding medical devices. To satisfy this pressure, a new database for medical devices – EUDAMED – has been created. The database is available to MDMs, consumers, Notified Bodies and the general public. In the database, medical devices are registered by their UDI numbers along with information about clinical investigations, testing, technical documentation, product registrations, and post-market surveillance.

New classification rules

The new MDR requires manufacturers to review new classification rules and update their technical documentation accordingly. In some cases, this may lead to re-classification of devices.

Notified Bodies

The new regulation includes new requirements regarding responsibility and expertise of Notified Bodies (NBs). Each NB must now be accredited in order to be able to certify that medical devices are in compliance with MDR. Thus, NBs now have to apply for a new designation before being approved for certification. It also appears that the expertise standards for NBs are higher than before, which could lead to fewer Notified Bodies on the market.

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Increased audits and testing

To reduce the risks from unsafe devices, MDR includes more unannounced audits, product sample checks and product testing.

Timeline

The regulation will be fully adopted by May 2021. The MDR transition deadline for your device will depend on the risk class of your device and the date your current MDD certificate expires etc,

As always, BillerudKorsnäs is happy to help in any way we can. We always stay up to date with new requirements and are focusing on the areas of MDR which relate directly to medical packaging and consequently to medical paper, such as the effects of temperature fluctuations and humidity on devices and packaging. For more detailed information on how paper produced by BillerudKorsnäs withstands high relative humidity and keeps microbial barrier, visit our website.

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