BILLERUDKORSNÄS

A new MDR. Part 2 – how to prepare for the new regulation

As you've heard, big changes are coming up for MDMs. The old Medical device directive (MDD 93/42/EEC) is being replaced by the new Medical device regulation (MDR 2017/745). In our last post, we gave you a brief overview of key points in the MDR. In this post, we'll take you through a step-by-step guide to MDR compliance.

What should MDMs do to get ready for MDR?

- **Make a plan to bring your products into compliance**
  Even if your products are currently in compliance with MDD, new rules and requirements will be in place for MDR, so you will have to go through the compliance process from the beginning.

- **Appoint a Compliance Officer**
  MDR stipulates that every MDM has a Compliance Officer responsible for all aspects of compliance related to MDR. This person must have appropriate training and medical devices expertise.

- **Prepare to meet more stringent requirements**
  Clinical safety and vigilance requirements are stricter in MDR, and each manufacturer will be required to proactively collect and evaluate clinical data. This clinical evaluation and post-market clinical follow-up will be required for all risk classes.

- **Update technical documentation**
  According to MDR, technical documentation needs to be updated throughout the product's entire life cycle. This includes vigilance reports, post-market surveillance reports and periodic safety update reports. If you manufacture Class III devices and implants, you are required to provide a Summary of Safety and Clinical Performance, which will be made publicly available.

- **Review product labelling**

  MDR has stricter requirements for product labelling. Product information must be kept up to date. Instructions for Use (IFU) can be provided in a non-paper format and include new symbols. The label must also contain information on the manufacturer´s EC symbol, name and address. Additional symbols must be added relating to device reprocessing and safety.

- **Ensure all systems are in place**

  MDR requires all MDMs to have the following systems in place:

  - ✓ a quality management system (QMS);
  - ✓ a post-market surveillance system (PMS);
  - ✓ a risk management system;
  - ✓ a system for reporting incidents and safety corrective actions (vigilance) to the competent Authorities.

It can feel daunting to take on all the changes required by the new regulation, but the key thing is to start now. Since a large number of medical devices will require a new review and approval process, it is recommended that you consult with your NB and prepare a plan to quickly bring your products into compliance.

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.