Understanding the European Medical Device Regulation (EU MDR 2017/745)

May 26, 2020 Deadline

In 2017, the European Council along with European Parliament published a new European Union Medical Device Regulation. This new regulation is commonly known as the EU MDR 2017/745. It is replacing what was formerly known as the MDD, Medical Device Directive.

Who?

The EU MDR 2017/745 regulation is far more detailed (four times longer, with five additional annexes) than the MDD and impacts items that were not previously covered by the MDD. Because of this, some companies that were not previously impacted by the MDD, will have products regulated under the EU MDR such as:

- Some cosmetic device companies
- Some CPG companies that sell cleaning products for disinfection of devices
- Companies that sell liposuction equipment
- Contact lens suppliers
- Reusable Class I Products

When?

The regulation was published on May 5, 2017 and came into force on May 25, 2017. After May 26, 2020 all new medical device submissions must comply with the MDR.

What?

With a redefinition of the what constitutes a medical device, an overhaul of the MDD was issued.

Per the EU MDR 2017/745 "medical device" means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific 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 information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

A particular item to note for these changes is that the MDR is a regulation, not a directive, therefore the MDR has legal force throughout all EU member states.

Also, of importance is the fact that **all medical devices need to be re-assessed** to ensure they comply with the new MDR requirements. The MDD had 18 rules for medical device classification whereas the new MDR has 22 classification rules, the result is that some devices will need to be reclassified.

Why?

The MDD (Medical Device Directive) was published in the early 1990's. Since those directives came into law new technologies have developed (for example, software as a medical device). The MDD focused more on the approval process, whereas the MDR will better incorporate post market performance.

The new EU MDR 2017/745 regulation is more standardized and encourages wider compliance. It is available for download (all 175 pages!) - https://eur-lex.europa.eu/eli/reg/2017/745/oj

Below are a few additional items covered by the MDR which were not part of the previous MDD:

- Unique Device Identification (UDI) will be required on all labels.
- Medical purpose devices and Active Implantable Medical Devices (AIMD) are included under MDR.
- The definition of medical device will be broadened to include non-medical and cosmetic devices not previously regulated.
- Manufacturers will need to report all incidents, injuries and deaths into an EU portal that will centralize relevant data so that patients have access to more safety-related information.
- Many medical devices will be reclassified to a higher risk class.

How?

Ensuring your products are compliant with EU-MDR is essential to avoid regulatory consequences. With the level of detail involved, working with regulatory compliance experts to evaluate your products and packaging is the most efficient way to avoid non-compliance.

If you are overwhelmed on where to begin evaluating for the new EU-MDR regulations, or want to double check your work, contact us at Adept Packaging.

80% of top Life Sciences companies in the world rely on our experts to supplement their packaging teams.

Contact our regulatory experts to ensure your packaging is compliant:
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