The impact of changing regulations on material selection for rigid medical packaging

EU MDR—European Union Medical Device Regulation 2017/745

Commencing 26 May 2017 and taking effect on 26 May 2020, European Union (EU) Medical Device Regulation 2017/745 (MDR) will repeal existing Medical Device Directive 93/42/EEC (MDD). The new legislation seeks to improve harmonization, collaboration, transparency, and traceability for medical devices marketed in the EU. These goals will be accomplished through increased emphasis on a life-cycle approach to safety that is reinforced by clinical data, more stringent requirements for Notified Body (NB) and Competent Authority reviews, new requirements for unique device identification, and requirements for information on medical devices and clinical studies to be made public.

With the date of implementation fast approaching, it is imperative that all members of the medical device supply chain who market products in the EU be prepared to meet the requirements of the new regulation as outlined here. Understanding regulatory requirements for the medical industry is critical to provide high quality products that meet the expectations set by the regulatory bodies. Eastman has dedicated global regulatory support staff to ensure the compliance of our medical grade materials. They will answer questions about our products, share relevant documentation necessary for filing a Declaration of Conformity, and provide general support to our customers, whether they are submitting a new device or transitioning to MDR compliance for an existing device.

CHANGE IN SCOPE

MDR expands the scope of regulated medical devices to include devices for which the manufacturer does not claim an intended medical purpose but have a risk profile similar to medical devices. Consequently, products not previously regulated under MDD may now be regulated under MDR. Manufacturers of medical equipment and medical devices should carefully review MDR to determine if their product is classified as a device under the new legislation.

Notably, the new regulation does not allow any grandfathering of devices currently on the market. All devices that were CE marked prior to 26 May 2020 must be CE marked again under the new regulation to be legally marketed in the EU. Devices with a valid CE mark issued under MDD may continue to be placed on the market until May 2024 or until the certificate expires. All manufacturers of medical devices should have a transition plan in place to ensure their devices are in compliance with the regulation at the time of certificate expiration.

CLASSIFICATION OF DEVICES

There are six classes of devices with 18 rules of classification in MDR. Based on the risk profile, existing devices may be up-classified. Products in the orthopedic space, devices to administer medication via inhalation, and active therapeutic devices are among those most likely to be up-classified. The complexity of the conformity assessment increases with each class according to the risk profile. Device manufacturers should carefully assess their device classification under MDR and prepare accordingly for any additional technical documentation to be included in the Declaration of Conformity for the device and/or packaging.

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Risk and safety are key focuses of MDR. The regulation states that devices shall be designed and packaged in such a way as to minimize the risk posed by contaminants and residues to patients. Accordingly, the number of General Safety and Performance Requirements has increased from 13 under MDD to 23 under MDR.

The need for well-characterized and compliant materials is increasingly important under MDR. Eastman is prepared to provide documentation regarding the compliance of our medical grade polymers with MDR.

PRODUCT VERIFICATION AND VALIDATION

Manufacturers must demonstrate their device's conformity with safety and performance requirements through technical documentation. This documentation should include a description of the key functional elements, a description of raw materials incorporated into key functional elements, and identification of all sites, suppliers, and subcontractors where design and manufacturing activities are performed.

Increased supply-chain control is imposed under MDR. Unannounced audits by NBs are included as part of the regulation and may extend all the way down the supply chain to critical suppliers. Robust quality management systems will be necessary under MDR for all members of the supply chain.

Eastman is committed to quality management and holds current ISO 9001:2015 certification for the manufacturing of medical grade polymers. By employing strict manufacturing and quality guidelines of the products through good manufacturing practices, Eastman ensures the reliability and consistency of the materials that fulfill this requirement. To further support our customers in regulatory compliance, Eastman will be prepared to host unannounced audits by NBs at our manufacturing facilities as required under MDR beginning in May 2020.

PACKAGING REQUIREMENTS

The reach of regulation extends to medical packaging and specifies the following requirements for packaging:

- Non-sterile packaging:
  - Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilized prior to use, minimize the risk of microbial contamination.
  - The packaging system shall be suitable, taking account of the method of sterilization indicated by the manufacturer.
- Sterile barrier packaging:
  - It is considered a modification of device if a product is on the market in sterile condition and the packaging necessary for maintaining the sterile condition is opened, damaged, or negatively affected by repackaging.
  - The integrity of sterile packaging must be clear to the final user.

NOTIFIED BODIES

NBs will experience the impact of greater rigor and scrutiny under MDR to institute more stringent criteria for clinical competence. Similar to the lack of grandfathering for devices, there is no grandfathering of NB designation under MDR. All NBs designated for medical device review under MDD must be redesignated for medical device review under MDR. This process is arduous and involves both national and European authorities.

It is anticipated that multiple NBs will receive MDR designation in July 2019. Device manufacturers should be cognizant of the status of their NB to avoid delays or interruptions in market access. Eastman will work closely with our customers to provide regulatory support in a timely manner to assist with meeting important MDR timelines.

TIMELINES

- **26 May 2020:** MDR will be enforceable for new devices and devices with expiring certificates issued under MDD.
- **26 May 2024:** All devices placed on the market must be in conformity with MDR.
- **27 May 2025:** Devices certified under MDD can no longer be sold or distributed.

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