sempermed®
YOUR GLOBAL GLOVE EXPERT

CHANGES IN THE REGULATORY FRAMEWORK FOR MEDICAL GLOVES

THE NEW EU MEDICAL DEVICE REGULATION

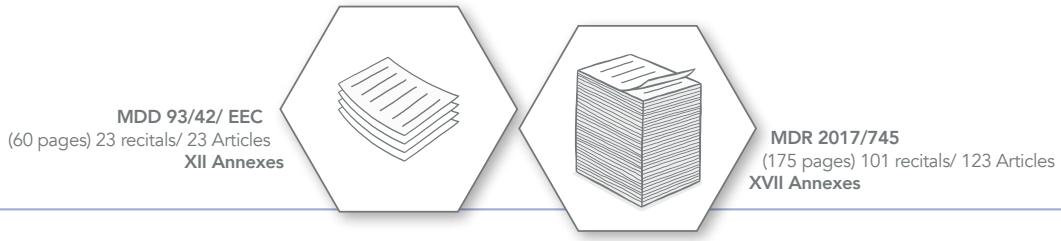
The new Medical Device Regulation 2017/745 (EU) ("MDR") brings new rules for all market participants that are expected to create an unprecedented transparency for medical devices. How will technical documentation requirements, the new EUDAMED database, the requirement of a responsible person or new post market duties affect you? Sempermed highlights for you the most relevant changes.

THE NEW MDR

The final text of the new European Medical Devices Regulation (MDR) entered into force on May 25th 2017 and replaces the medical device directive 93/42/EEC ("MDD") that has been the applicable European Community legislation for the last 25 years. It marks the start of the transition period for manufacturers selling medical devices into Europe in the framework of a fully harmonized medical device law that is directly applicable to all the member states of the European Union.

MDR provides a much more comprehensive set of rules

The new MDR provides a much more comprehensive set of rules than the MDD: it contains 123 Articles and 17 Annexes on 175 pages and requires increased interaction, traceability and follow up throughout the life cycle of a product.



MDR is applicable to all market participants

In the MDD manufacturers are the main subject of regulation. The new MDR broadens the scope and additionally includes the other market participants, together now called "economic operators": authorized representatives, importers and distributors.
Importers and distributors have the responsibility to commercialize only products they will be able to see in the new EUDAMED database. Authorized representatives – in addition to their post market duties they have under the MDD - need to ensure that manufacturers based outside the EU register themselves and their products in EUDAMED and they receive a copy of the technical documentation.

EUDAMED and the new transparency

The new EUDAMED database currently being designed will serve as a central platform for authorities and market participants and will make more information on devices public. The main goal of EUDAMED is to achieve transparency on the products and their source and which way they have been taking in the supply chain: economic operators need to be able to track from whom they have received a medical device and to whom they have sold it in a documented manner.

Manufacturers and authorized representatives will obtain a single registration number (SRN) and provide a defined set of device information including a basic device identifier ("basic UDI-DI" – e.g. a Global Trade Item Number (GTIN)) when EUDAMED goes live. Also, importers can register and obtain a SRN number. At a later stage, also Production Identifier information (UDI-PI) will need to be labelled on devices or – where not feasible – on their packaging; this will be however the case no sooner than 2023 for our surgical gloves and 2025 for our examination gloves.
The planned go-live date for the EU-DAMED is currently end of March 2020. It is not yet clear if this deadline can be met. Sempermed will keep you updated on the developments.

Quality System required for all manufacturers

The new MDR requests all manufacturers, also of Class I devices, to have a quality system in place. Sempermed introduced a certified quality system years ago and therefore is already fully compliant with this requirement.

Technical documentation for MDR

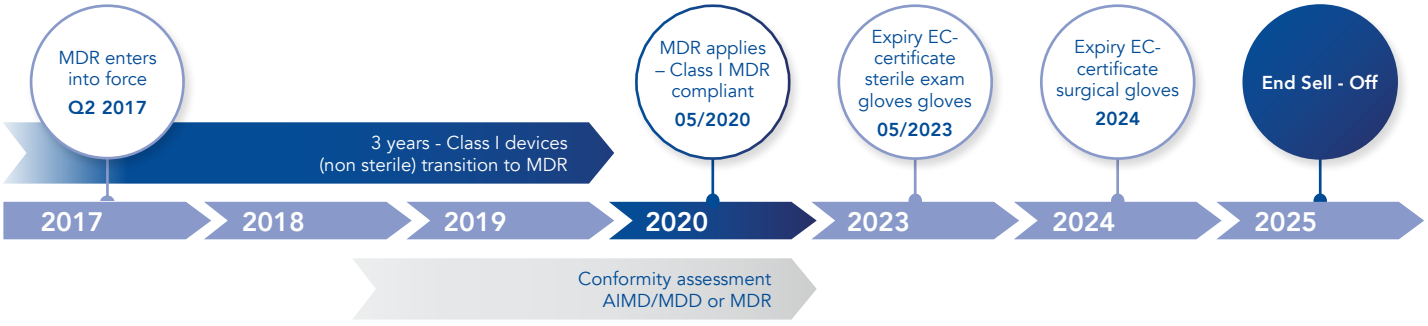
The new MDR provides new rules for the technical documentation for medical products (Annex II) and requests manufacturers to create a new documentation on post market surveillance for its products (Annex III). In contrast to the MDD this obligation is now also applicable for private label manufacturers who could previously refer to the technical documentation being physically available only at the OEM manufacturer. The legal manufacturer must have the full technical documentation available (production- and market-related documentation), must have the ability to assess a product's conformity based on that information, constantly keep up-to-date and observe record retention obligations (10 years).

Responsible person for regulatory compliance

Manufacturers and authorized representatives will need to have at least one qualified responsible person to ensure pre-market and post-market MDR requirements are met. Small and Medium Enterprises may outsource this role.

TIMELINE

All Class I devices (such as our examination gloves) entering the EU market after 26 May 2020 need to be compliant with the new MDR. Higher class devices, where a notified body is involved (such as our surgical gloves), may be marketed under the MDD rules until their EC-type certificates lapse, which is at the very latest in 2024. Until May 2025 all MDD products must finally be cleared from the market.



Sempermed will ensure a well planned transition in the new MDR-framework:

Examination gloves certified for MDR will be available by **05/2020**

Surgical gloves changeover date to be defined

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Sempermed *Always keeping you up to date.*

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