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inform®

Semperguard® Gloves:

Compliance with the New Medical Device Regulation

& Related Packaging Changes

Starting on May 26th 2020, all Class I medical devices must comply with the new Regulation (EU) 2017/745 (*European Medical Device Regulation or '**MDR**'*), which replaces the old Directive 93/42/EEC (Medical Device Directive or ***'MDD'***)

All our Semperguard® gloves, which are classified as medical devices, already comply with this new regulation; the corresponding updated Declarations of Conformity can be found at https://www.sempermed.com/en/userinformation/

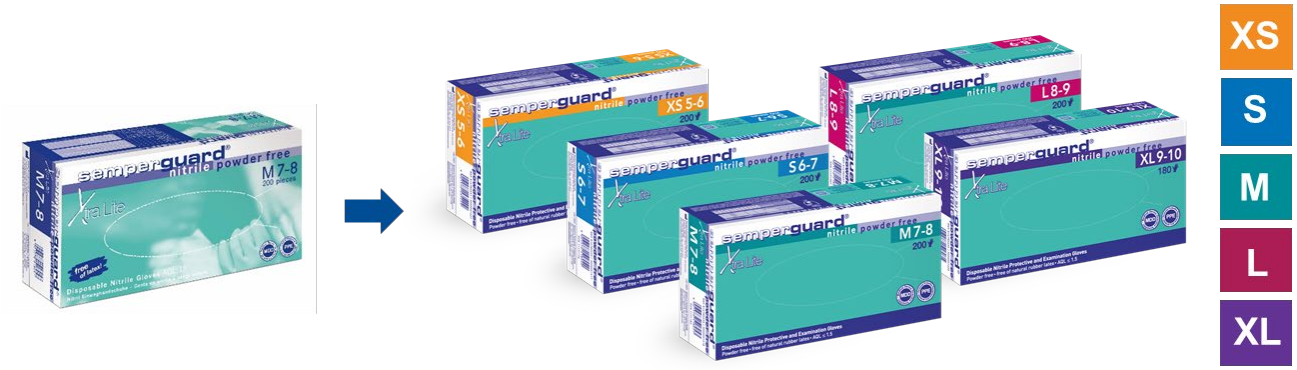
Compliance with the new MDR also results in minor changes to our packaging, which are summarized below:

- ✓ **All references to the MDD will be replaced with the new Medical Device Regulation (EU) 2017/745.**

OLD	NEW
CE • Medical Device Directive 93/42/EEC MDD	Medical Device Regulation (EU) 2017/745 MDR Class I
[EN] (…) Compliant with MD Directive 93/42/EEC, (…)	**[EN]** (…) Compliant with MD Regulation (EU) 2017/745, (…)

- ✓ **As per MDR Annex I section 23.2. Information on the label / item q)** a label must give an indication that the device is a medical device. On our packaging, this is indicated with this pictogram (ISO 15523-1): MD

You may remember that we introduced a packaging design update for all **Semperguard® products** in 2019. Part of this design refresh were size labels in different colors, which allow for the quick and easy identification of the different glove sizes.



Please note that compliance with the new MDR does not result in any changes to packaging dimensions, product codes or article numbers. Kindly contact us if you need more detailed information regarding the changes in the regulatory framework regarding medical gloves!

Your Sempermed Team

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