People.Health.Care.

What is the MDR?

The MDR (Medical Device Regulation) is a **new EU Regulation** concerning medical devices (EU 2017/745), which came into force at the end of May 2017 and, following a transitional period, shall be applied from no later than May 2021; the date of application is **26 May 2021.**

What does the MDR regulate?

- The new European Medical Device Regulation regulates the placing on the market of medical devices throughout Europe and stipulates henceforth the **requirements for the conformity assessment of medical devices.**
- The Regulation applies to all medical device manufacturers seeking to place their devices on the market within the EU.

Why the new MDR?

Diverging interpretations of the applicable Directives and various medical device scandals led to the introduction of the new EU Regulation, which will bring uniform standards to all EU countries.*

The aim is to improve safety, traceability and transparency in EU countries.*

* Medical device portal of the European Commission: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

What is the legal status of the MDR?

- As a European **Regulation,** separate from European Directives, the Medical Device Regulation shall be applied as pan-European law within the stated period.
- National specifications and requirements can be additionally regulated by national law in the individual countries of the EU.

What devices does the MDR apply to?

The new MDR applies to all medical devices once the respective transitional periods have elapsed.

Medical devices:
70% are Class I or Class Is

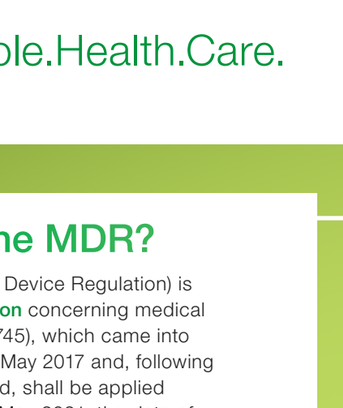
Class I
64%

Class Is sterile/ measuring function
6%

Class IIa
20%

Class IIb
8%

Class III
2%



MDR

We are ready.

What changes will this mean, e.g. for L&R standard devices in the OR?

Once the technical documentation has been revised, the devices will continue to be available for use in the OR and on wards.

Be safe with L&R.

The TÜV Süd Product Service is the notified body for L&R that is MDR certified.

L&R is one of the first European firms that passed an MDR audit in Q3 2019 with the quality management systems in place at its companies.

For more information on the MDR, go to:
www.Lohmann-Rauscher.com/MDR

Certificates are available and can be provided upon request.

MDR requirements – implementation at L&R with important milestones.

Class I devices (non-sterile devices)
After 26 May 2021, these devices must be in compliance with the provisions of the MDR when placed on the market.

Class Is devices (sterile devices)
Transitional period: Devices within this device class can be sold with the existing MDD certificate** until 26 May 2024.

Class II & Class III devices
Transitional period: Devices within this device class can be sold with the existing MDD certificate** until 26 May 2024.

** Depending on the expiry date of the MDD certificate.

Important information:

- Class I devices placed on the market before 26 May 2021 in accordance with the existing MDD regulations continue to comply after 26 May 2021.
- This means that devices in compliance with the MDD regulations will also be on the market after 26 May 2021.
- Customers have no way of knowing if a device on the market was certified on the basis of the MDD or the MDR.
- L&R will continue to place its devices on the market in compliance with the law.

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