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L&R & the MDR –
Frequently Asked Questions

Are all L&R products MDR-certified?

L&R Class I products have been MDR-compliant since 2021. L&R submitted the technical documentation for all higher-class devices (Is, II and III) and procedure packs (treatment units), e.g. Kitpack and CNP sets, to TÜV Süd in good time. On 24 May 2024, L&R was awarded certificates for its Class Is, IIa and IIb devices and its procedure packs (e.g. Kitpack and CNP sets). Existing L&R products for which the MDD has been extended or for which transition periods apply until 2027–2028 (Regulation 2023/607) will continue to be placed on the market legally by L&R. L&R therefore ensures that only products that are MDR- or MDD-compliant (under the transition periods) shall be placed on the market.

Which notified body is responsible for issuing MDR certificates for L&R products?

TÜV Süd is the notified body for L&R. On 24 May 2024, TÜV Süd awarded L&R MDR certificates for all its Class Is, IIa and IIb products and its procedure packs (e.g. Kitpack and CNP sets), thus confirming their conformity with the MDR.

From a regulatory perspective, is L&R permitted to supply all of its products to customers?

Yes. L&R ensures that only products that are MDR-compliant or for which MDD extensions apply are placed on the market. We can therefore continue to reliably supply our products to healthcare systems and to our customers.

Does the Kitpack, L&R's OR custom procedure tray, and other procedure packs that contain multiple individual items also comply with the MDR?

Yes. TÜV Süd also issued the MDR certificate for L&R procedure packs on 24 May 2024, including the Kitpack and CNP sets, thereby confirming compliance with the MDR.

What are the implications of the MDD extension and the transition periods?

In 2023, EU Regulation 2023/607 defined new transitional regulations by amending Article 120 of the MDR. The Regulation states that certificates that were issued under the MDD after 25 May 2017 and were still valid as of 26 May 2021 will continue to be valid regardless of their expiry date. Depending on the risk class of the medical device, new transition periods now apply.

L&R has applied for an extension of the MDD for certain existing products. This has been approved by the notified body, TÜV Süd, so L&R can continue to legally market these products until the end of the new transition periods.

The transition period for Class III devices (or implantable Class IIb devices, with some exceptions) goes until 31 December 2027 (Art. 120 (3a(a)) MDR). For other Class IIb devices, Class IIa devices and Class Is devices (sterile Class I medical devices), or Class I devices with measuring functions, the transition period ends 31 December 2028 (Art. 120 (3a(b)) MDR).

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The new transitional regulations are linked to conditions which are explained in Art. B. 120 (3c) MDR (which stipulates that the device must continue to comply with the MDD, its intended purpose must be unchanged, and it must not pose an unacceptable risk to the health or safety of patients, etc.). L&R meets all of these requirements.

As a customer, should I expect longer delivery times or product unavailability due to the work involved in MDR compliance?

No. Our product stocks and delivery service continue to be independent of the work involved in MDR compliance. Our customers can depend on us to supply them with the products they want and need. Besides, we have long finished preparing the technical documentation relating to MDR compliance.

Lohmann & Rauscher GmbH & Co. KG · Westerwaldstrasse 4 · D-56579 Rengsdorf , Germany
Lohmann & Rauscher GmbH · Johann-Schorsch-Gasse 4 · A-1141 Vienna, Austria
Lohmann & Rauscher AG · Oberstrasse 222 · CH-9014 St. Gallen, Switzerland

2004959 0524 en