

# Entry into force of the amendments to the medical devices regulation

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Decree-Law No. 118/2025 of 13 November (“DL 118/2025”) entered into force on 12 January, amending Decree-Law No. 29/2024 of 5 April (“DL 29/2024”), which establishes the legal framework applicable to medical devices and their accessories, and ensures the implementation, within the national legal order, of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (“MDR”).

In addition to introducing certain corrections and clarifications to DL 29/2024, DL 118/2025 also implements a number of significant changes to the legal framework applicable to medical devices, namely:

**Prohibition on reprocessing medical devices:** DL 118/2025 introduced changes to the prohibition on the reprocessing of single-use medical devices. The list of devices whose reprocessing is prohibited will no longer be set out, as was previously the case, in DL 29/2024, but instead will be established by an order (*Portaria*) to be issued by the Minister of Health. This order has not yet been published and is still awaited.

**Written procedures for the reprocessing of medical devices:** DL 29/2024 clarifies that the obligation to have written procedures for the reprocessing of medical devices applies only to operators who supply medical devices on a loan basis. In this context, the amendments introduced by DL 118/2025 definitively clarify that this obligation does not apply to other entities in the supply chain that reprocess medical devices, such as healthcare institutions.

**Notified bodies:** DL 29/2024 now provides that the designation of notified bodies is to be reassessed every five years, thereby aligning it with the provisions of the MDR.

### **Immediate practical consequences for operators**

The amendments now in force eliminate some of the grey areas that remained under DL 29/2024, making the legal framework clearer and more predictable.

Nevertheless, the publication of the order establishing the medical devices whose reprocessing is prohibited is still awaited.

While this new mechanism facilitates the updating of the list of medical devices whose reprocessing is prohibited and ensures better alignment with technological developments, it also requires operators to closely monitor legislative activity in order to track changes to the devices included in and/or removed from the order and to adapt their operational and compliance procedures accordingly.



**Thinking about tomorrow? Let's talk today.**

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