

# Prohibition on the Reprocessing of Single-Use Medical Devices

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On May 5, 2026, Ordinance No. 206/2026/1 was published, which, pursuant to Decree-Law No. 29/2024, ensuring the implementation in the national legal order of Regulation (EU) of the European Parliament and of the Council of April 5, 2017, on medical devices ("**Regulation 2017/745**"), approves the list of single-use medical devices whose reprocessing is prohibited within the national territory, entering into force on the day following its publication.

### **Devices Covered by the Ban**

The list attached to the Ordinance includes, in particular:

- Devices that emit radiation or are used in the administration of cytostatic agents or radiopharmaceuticals;
- Devices that incorporate medicinal substances;
- Implantable devices or devices for invasive use in the central nervous system, eyes, or pituitary gland;
- Devices posing a risk of transmitting spongiform encephalopathies;
- Devices with non-replaceable batteries or posing a risk of malfunction after reprocessing;
- Custom-made devices or those already reprocessed by another entity or process;
- Devices used in patients with neurological conditions of unknown origin, presenting at least two of the following symptoms: progressive dementia, myoclonus, or ataxia.

The list may be revised based on advances in technical, scientific, and clinical knowledge.

### **Practical Impact**

The Ordinance takes effect immediately for hospitals, hospital centers, healthcare facilities, and subcontractors duly registered with the Health Regulatory Authority, which must revise their internal medical device management processes accordingly.



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

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