HEALTH

Office of the Secretary of State for Health

Ordinance No …/2025

Summary: approve the list of single-use medical devices whose reprocessing is prohibited.

Decree-Law No 29/2024 of 5 April 2024 ensured the implementation in the national legal order of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, as amended, on medical devices (Regulation (EU) 2017/745).

The aforementioned law applies to:

a) medical devices, accessories to medical devices and products listed in Annex XVI to Regulation (EU) 2017/745, as well as activities provided for in that Regulation taking place on or destined for the national territory, carried out throughout the life cycle of the medical device;

b) the reprocessing and use of single-use devices reprocessed under Article 17(2) of Regulation (EU) 2017/745, provided that the reprocessed single-use devices and their manufacturers comply with all the rules and obligations applicable to them and laid down in the legislation in force;

c) the reprocessing and use of single-use devices reprocessed under Article 17(3) of Regulation (EU) 2017/745 in health institutions, as well as in entities assigned to the health care network or its subcontractors, constituted as hospitals, hospital centres or health care establishments duly registered for that purpose with the Health Regulatory Authority.

In the context of the reprocessing and use of reprocessed single-use devices, in addition to Regulation (EU) 2017/745, it is important to take into account the provisions of Commission Implementing Regulation

(EU) 2020/1207 of 19 August 2020 [Regulation (EU) 2020/1207], laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices, in particular with regard to the fact that certain single-use devices are not suitable for reprocessing.

Within this framework, it is important to ensure the exclusion of single-use devices that cannot be safely reprocessed due to their particular potential hazards or specific technical characteristics.

This Ordinance has been subject to the procedure provided by Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015, transposed by Decree-Law No. 30/2020 of 29 June, which sets forth a notification procedure in the field of technical regulations and of rules on Information Society services.

Thus, under the provisions of Article 22-A of Decree-Law No. 29/2024 of 5 April, in its current wording, in conjunction with Article 8(2), Article 10(1) and Article 23, all of Decree-Law No. 87-A/2025 of 25 July, which approves the organisation and functioning of the XXV Constitutional Government, and in the exercise of the powers delegated to me by Order No. 9578/2025, of 12 August, of the Minister of Health, published on the Official Journal of the Republic No. 154/2025, 2nd series, of 12 August 2025, I hereby determine the following:

Article 1

Reprocessing prohibited

The reprocessing on Portuguese territory of single-use devices included in the list annexed to this Ordinance and forming an integral part thereof shall be prohibited.

Article 2

Review of the list of prohibitions

The list annexed to this Ordinance relating to single-use medical devices the reprocessing of which is prohibited on Portuguese territory may be revised whenever necessary in the light of developments in technical, scientific and clinical knowledge.

Article 3

Entry into force

This Ordinance shall enter into force on the day after its publication.

The Secretary of State for Health

(Ana Margarida Pinheiro Povo)

ANNEX

List of single-use medical devices whose reprocessing is prohibited in the national territory

a) Devices that emit radiation;

b) Devices used to administer cytostatic or radiopharmaceuticals;

c) Devices incorporating medicinal substances;

d) Devices for use in invasive procedures of the central nervous system, eyes or pituitary gland;

e) Devices posing a risk of transmission of spongiform encephalopathies;

f) Implantable devices;

g) Devices with batteries that cannot be changed or that present a risk of malfunction after reprocessing;

h) Devices with internal data storage necessary for the use of the device and which cannot be replaced or which present a risk of malfunction after reprocessing;

i) Devices with cutting or scraping blades, drill bits or other wear components which are no longer suitable after first use and which cannot be replaced or refined before the next medical procedure;

j) Devices whose original device has already been reprocessed by another entity or by another process;

k) Custom-made devices;

l) Devices manufactured and used in accordance with Article 5(5) of Regulation (EU) 2017/745 and other applicable legislation.

m) Products listed in Annex XVI to Regulation (EU) 2017/745;

n) Single-use devices used in a patient with neurological pathology of unknown origin, which includes at least two of the following symptoms: progressive dementia, myoclonia or ataxia.