pbbr.a SOCIEDADE DE ADVOGADOS, SP, RL

Saúde 04-2023

Regulation (EU) 2023/607 changes MDR & RDIV

Regulation (EU) 2023/607 of March 15, 2023 *amending Regulations (EU) 2017/745 (hereinafter "MDR") and (EU) 2017/746 (hereinafter "RDIV") regarding the transitional provisions of such legal statutes, applicable to certain medical devices and in vitro diagnostic medical devices has been published in the Official Journal of the European Union.*

An extension of deadlines became necessary to ensure a high level of protection of public health, including patient safety, and to avoid the disruption of the supply of medical devices necessary for the proper functioning of health services, without hindering current quality or safety requirements.

The main changes introduced by ***Regulation (EU) 2023/607*** *are the following:*

1. For medical devices covered by certificate or declaration of conformity issued before 26 May 2021, the transition period for the new rules is extended from 26 May 2024 to:

- ***December 31, 2027*** *for higher risk medical devices: applicable to all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.*
- ***December 31, 2028*** *for medium and low-risk medical devices: applicable to class IIb devices other than those covered by point (a) of this paragraph, for class IIa*

devices, and for class I devices placed on the market in sterile condition or having a measuring function.
The extension of the transition period will be subject to certain conditions, being applicable only to devices that are safe and for which manufacturers have already made arrangements for te adaptation to the rules laid down in the RDM.

2. A transition period until 26 May 2026 is also introduced with respect to custom-made implantable devices belonging to class III, giving their manufacturers more time to obtain certification by a notified body. Again, the transition period is subject to the condition that the manufacturer submits an application for conformity assessment of such devices before 26 May 2024.

3. The application of a deadline for making available on the market or putting into service ("sell-off"), previously established in Article 110/4 of the RDIV and Article 120/4 of the RDM, is eliminated. The removal of this deadline will ensure that safe and essential medical devices that are already in the market remain available to health systems and patients who need them.

This diploma entered into force on the date of its publication, 20 March 2023.

Contact:
Rita Roque de Pinho – rita.pinho@pbbr.pt
Raquel Soares Lourenço – raquel.lourenco@pbbr.pt