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INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

New Rules for Medical Devices: Decree-Law 29/2024

Decree-Law no. 29/2024, which was published on 5 April 29/2024, implements Regulation (UE) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on medical devices ("**MDR**")., in the Portuguese legal system.

The coming into force of the MDR necessitated the recasting of the Portuguese legislation regarding medical devices. Consequently, Decree-Law no.145/2009. of 17 June, which established the rules governing the research, manufacture, marketing, putting into service, monitoring and advertising of medical devices and their accessories, by transposing Directive 2007/47/EC, of the European Parliament and the Council, of 5 September 2007 into Portuguese law, has been repealed, and the legal framework governing medical devices and their accessories has been modified in line with the provisions of the MDR.

Decree-Law 29/2024 therefore governs various aspects applicable to economic operators and healthcare institutions that produce and use medical devices on their premises. It also institutes the rules on the use and traceability of devices and the appointment and supervision of the activities of notified bodies.

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The decree-law now published also establishes the necessary conditions and requirements for the reprocessing and use of single-use devices reprocessed in Portugal, in order to ensure their safe use and performance.

In this way, the decree-law establishes a more inclusive and detailed framework which, in conjunction with MDR, aims to ensure safety at all stages of the life cycle of medical devices and their accessories, from design to end use.

Eduardo Nogueira Pinto
Ricardo Rocha
Inês Cabugueira
Healthcare, Life Sciences & Pharmaceuticals team

In addition to the manufacture, import, distribution and use of medical devices, Decree-Law 29/2024 introduces rules applicable to devices manufactured and used in healthcare institutions, and also introduces specific rules regarding the traceability of such devices, in order to ensure effective monitoring of these devices throughout their life cycle.

The concentration of supervisory powers in INFARMED, I.P., is intended to ensure the uniform application of the regulations throughout Portugal.

The decree-law also confirms the appointment of INFARMED, I.P. as the market monitoring and supervisory authority in Portugal and gives it extended powers to monitor compliance with the new rules. The concentration of supervisory powers in INFARMED, I.P., is intended to ensure the uniform application of the regulations throughout Portugal, and to ensure that only medical devices that meet high standards of safety and efficacy are placed on the Portuguese market.

The administrative offence provisions of the Decree-Law 29/2024 provide that all violations of the rules introduced by the decree-law are serious administrative offences punishable by the imposition of the administrative law fines applicable under the Legal Framework governing Economic Administrative Offences.

Decree-Law 29/2024 also establishes a transitional legal framework that temporarily extends the application of some provisions of Decree-Law 145/2009 of 17 June.

Accordingly, and until the implementation and operationalisation of the European medical devices database (EUDAMED), manufacturers, authorised representatives, distributors, and notified bodies, must ensure compliance with the notification and registration obligations applicable to them in Portugal, namely:

- Articles 9 (sterilisation procedure), 10 (special procedure for systems and procedure packs) and paras 1, 2, 3 and 5 of article 11 (duties inherent in placement on the market) of Decree-Law 145/2009; which apply to manufacturers and authorised representatives.

- Article 41(1)(b) (distributors' obligations) of Decree-Law 145/2009 applies to distributors;

- Wholesale distributors are also subject, , to Ministerial Order 256/2016, of 28 September (good practices in the distribution of medical devices), with the necessary adaptations.

The following provisions of Decree-Law 145/2009 remain in force under the transitional provisions of Decree-Law 29/2024:

- As far as monitoring obligations are concerned, and pending the adoption, by the Commission, of the implementing act regarding the time limits for the notification, by manufacturers, of safety corrective measures, and for the submission of periodic summary reports and trend reports; safety corrective measures reports and the corresponding safety notice, must be submitted by manufacturers to INFARMED, I. P., no later than two days prior the date proposed by the person responsible for placing the product on the market, except in cases of a serious threat to public health;

Bodies that carry on activities related to the provision of devices on a loan or consignment basis must adapt to and comply with the obligations established by Decree-Law no. 29/2026, within 90 days of its publication.

- Chapter XIII, Article 61(1)(mm) and (nn) and Article 62 (regarding advertising of medical devices) of Decree-Law 145/2009 will remain in force; pending the publication of the new legislation governing the advertising of medical devices

- Pending the publication of the legislation that implements Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, in Portuguese domestic law, the provisions of Articles 66 (in vitro diagnostic medical devices), 67 (in vitro diagnostic medical devices for self-testing) and 68 (in vitro diagnostic medical devices for restricted use) of Decree-Law 145/2009 will remain in force.

Bodies that carry on activities related to the provision of devices on a loan or consignment basis must adapt to and comply with the obligations established by Decree-Law 29/2026, within 90 days of its publication.

Decree-Law 29/2024 came into force on 6 April 2024 and takes effect 90 days after its publication. ■