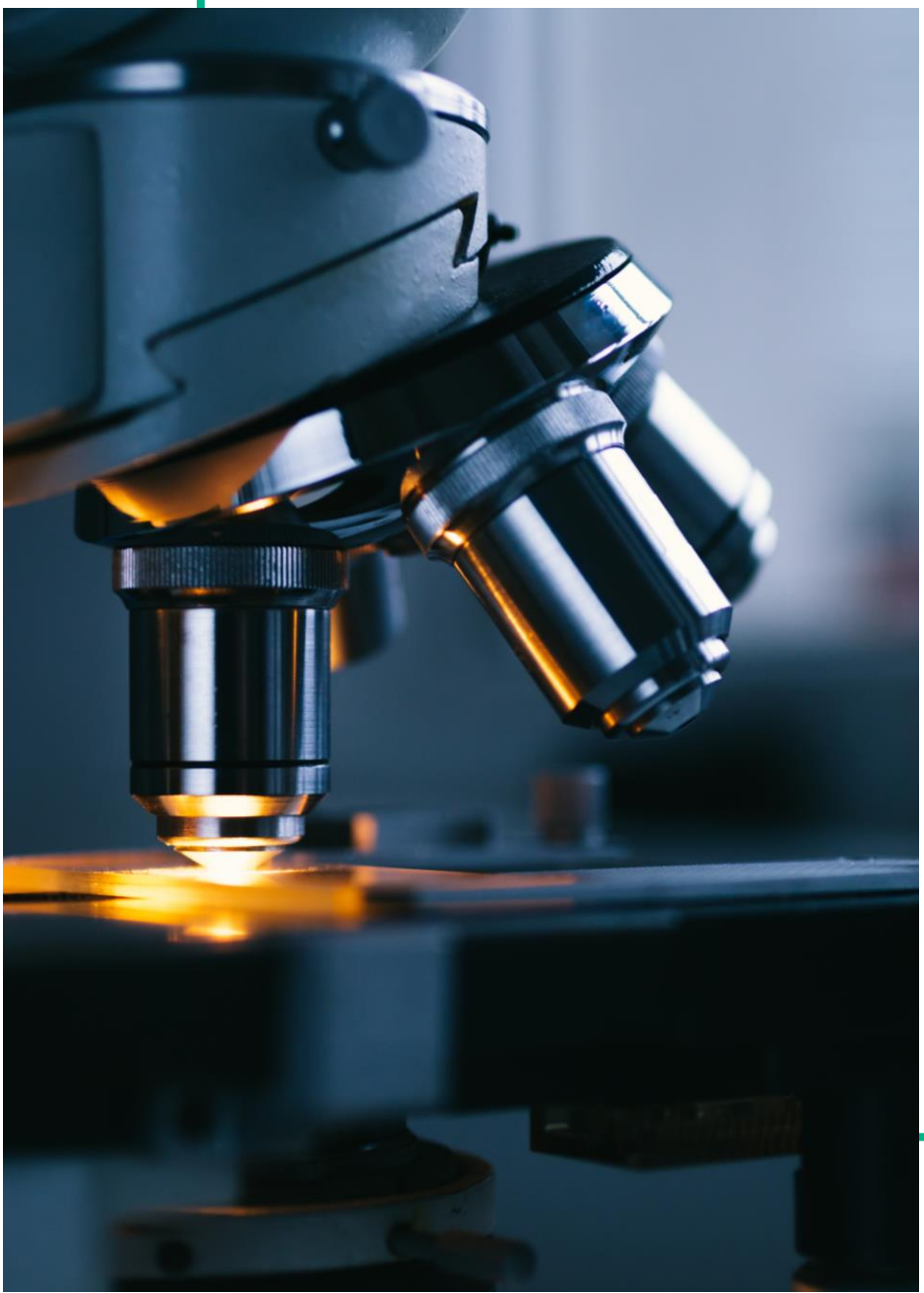
VIEIRA DE ALMEIDA

LIFE SCIENCES

MEDICAL DEVICES

VdA EXPERTISE



April 2021

Decree-Law no. 29/2024 of 5 April ensures the implementation of Regulation (EU) 2017/745 on medical devices.

Decree-Law no. 29/2024 of 5 April ("DL 29/2024"), which ensures the implementation of Regulation (EU) 2017/745 on medical devices ("**Regulation**"), was recently approved.

Finally, the complementary rules to the Regulation applicable to medical devices, accessories, and products without a medical purpose were approved – covering both activities carried out in Portugal and those intended for this territory.

Under the degree of freedom provided to the Member States on this matter, DL 29/2024 also establishes the regime for reprocessing and use of single-use medical devices – activity which will be subject to notification to the Portuguese Agency, Infarmed, and to compliance with several requirements.

The cases where reprocessing is forbidden (*e.g.*, implantable devices or those that produce radiation), are also listed.

We highlight a few aspects of this new regime:

Manufacturing

Only the manufacturing of custom-made devices and in healthcare institutions requires notification to Infarmed – other manufacturing activities being subject to notification in EUDAMED.

Wholesale Distribution

As for wholesale distribution, the rules of the previous regime are essentially maintained. Wholesale distribution of medical devices continues to be subject to notification, the appointment of a Technical Responsible is needed, as well as compliance with the Good Distribution Practices ("**GDP**"), as approved by Ordinance No. 256/2016, of September 28, or in any other regime that may replace it in the future.

Advertising

The advertising of medical devices is not addressed, the previous regime continuing in force until the approval of a new decree on this matter.

Loans and Consignments

The terminology included in the GDP is now upheld in the law. DL 29/2024 resorts to the notions of loans and consignments without, however, defining them. Part of the regime of the GDP is also now provided for in this Decree, which, amongst others, provides that the making available of medical devices on a loan or consignment basis requires the execution of a written contract "*between the entity that makes them available and the respective user.*" It is added that these devices can only be made available "without the transfer of ownership".

Healthcare Institutions

Contrary to the previous regime, DL 29/2024 now imposes specific obligations on healthcare institutions, including related with the amongst which those applicable to the acquisition, storage, and use of medical devices.

Similarly to what is already provided for distributors, health institutions are now to obliged to ensure the conformity of the devices they acquire, store, and use.

The rules applicable to the manufacturing of medical devices and their use within the institution itself and to the reprocessing of single-use devices by the institutions are also listed.

DL 29/2024 establishes, among other changes, a new framework for loans and consignments.

Activities which do not affect conformity

Activities related to devices that do not to affect their conformity, including, sterilization, calibration, or technical assistance of devices, are now subject to a specific regime.

Medical devices without conformity assessment

In line with the Regulation, and upon duly justified request to the Portuguese Agency, Infarmed, the placement on the market of devices that have not yet been subject to conformity assessment procedures may exceptionally be authorized, if their use contributes to public health or the safety or health of patients.

The procedures applicable in these cases are yet to be approved by Infarmed.

Guarantee of conformity

All entities in the supply chain are now bound to ensure that their intervention does not undermine the conformity of medical devices, and must, amongst others, refrain from holding, storing, or using devices in poor condition or time-expired.

Entry into force and transitional provisions

DL 29/2024 has already entered into force, taking effect 90 days after its publication.

Transitional provisions are set-forth, such as, the registration and notification obligations provided for under the previous regime continue to apply to manufacturers, representatives, and distributors until the implementation and operationalization of EUDAMED.

In turn, activities such as lending, consignment, maintenance, calibration, technical assistance of devices, amongst others, benefit from a transitional period of 90 days after the publication of DL 29/2024 to adopt the necessary measures to comply with the rules applicable to these activities.

Lastly, it is up to the Board of Directors of Infarmed, as the competent authority, to adopt the necessary provisions for the regulation or application of DL 29/2024.

It being a long-awaited regime for the medical devices industry, it raises several queries that will certainly be discussed in the near future.

Contacts

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