



Conselho  
Nacional de  
Ética para as  
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**OPINION ON THE PROPOSAL FOR A DECREE-LAW  
TO ENSURE THE APPLICATION OF REGULATION  
(EU) 2017/746 ON *IN VITRO* DIAGNOSTIC  
MEDICAL DEVICES**

January 2024



## **OPINION ON THE PROPOSAL FOR A DECREE-LAW TO ENSURE THE APPLICATION OF REGULATION (EU) 2017/746 ON *IN VITRO* DIAGNOSTIC MEDICAL DEVICES**

### **Executive Summary**

The present opinion was prompted by a request addressed to the National Council of Ethics for Life Sciences (CNECV) by the Board of Directors of INFARMED - National Authority of Medicines and Health Products, I.P., for the Council's reflection and recommendation on the proposal for a Decree-Law aimed at ensuring the application of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

The Regulation harmonises the rules regarding the placing on the European market and putting into service of *in vitro* diagnostic medical devices and their accessories, benefiting from the principle of free movement of goods; lays down the rules to be complied with by the medical devices sector; the rules on the use and traceability of the devices, the designation and supervision of the activities of notified bodies, as well as market surveillance and supervision; and establishes in its provisions the penalties for non-compliance with its provisions.

The CNECV is of the opinion that the proposed Decree-Law complies with the ethical principles that should guide decisions and actions in health care, namely by promoting:

- a) the quality and traceability of healthcare services using *in vitro* diagnostic medical devices;
- b) the promotion of safety and surveillance of any health acts involving *in vitro* diagnostic medical devices, thus realising the principle of democracy in health, by giving a voice to both the patients and health professionals;
- c) the respect for the technical competences of the various professionals involved;
- d) in the most complex cases, the protection of the patient's vulnerability and the realisation of the principle of non-maleficence in health intervention, by avoiding to leave



the patient in a situation of great vulnerability in the face of information of a clinical nature that is difficult to understand and frame;

e) the proper application of the legal provisions, and the adoption of an adequate and proportional sanctioning framework, thus defending ethical and legal values of public health, physical integrity and the protection of the health of people who use these devices;

To which the National Council of Ethics for Life Sciences has given its favourable ethical opinion.

The President, *Maria do Céu Patrão Neves*.

Rapporteurs: *André Dias Pereira and Hélder Mota Filipe*.

This opinion was adopted unanimously on 5 January 2024.