MINISTRY OF HEALTH

ORDER No. 650
of 27 February 2025
on approval of the procedural rules for the application of the provisions of Art. 5 paragraph (5) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC on medical devices and in vitro diagnostic medical devices manufactured and used only within healthcare institutions

Published in: the Official Gazette of Romania, no. 220 of 13 March 2025

***) Important note:**
For the application of this Order, please see the provisions of Art. 12.

On seeing approval report no. R 650 of 27.02.2025 of the Pharmaceutical and Medical Devices Directorate, the General Directorate for Healthcare and Public Health and the National Agency for Medicines and Medical Devices of Romania and notification no. 104.766E of 2.03.2023, registered at the Ministry of Health with no. Reg2/4.398 of 6.03.2023,

taking into account the provisions of:

- Art. 12 of Emergency Government Ordinance no. 46/2021 on establishment of an institutional framework and measures for enforcement of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;
- Art. 10 of Emergency Government Ordinance no. 137/2022 on establishment of an institutional framework and measures for enforcement of provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, approved through Law 289/2023;
- Art. 932 paragraphs (1) and (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;
- Art. 4 paragraph (4) point 1 and 28 of Law no. 134 of 12 July 2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented,

pursuant to Article 7 (4) of Government Decision No. 144/2010 on organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following Order:

Art. 1 - (1) This order regulates the procedural rules regarding medical devices and in vitro diagnostic medical devices manufactured and used only within healthcare institutions, further called ***medical devices manufactured and used only within healthcare institutions,*** in line with the provisions of Art. 12 of Emergency Government Ordinance no. 46/2021 on establishment of an institutional framework and measures for enforcement of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and of Art. 10 of Emergency Government Ordinance no. 137/2022 on establishment of an institutional framework and measures for enforcement of provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, approved through Law 289/2023.

(2) The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the NAMMDR, is the competent national authority in the field of medical devices and in vitro diagnostic medical devices, responsible for the control of medical devices manufactured and used only within healthcare institutions.

Art. 2 - (1) The terms used in this order have the meaning established through Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, hereinafter ***Regulation (EU) 2017/745,*** as well as through Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, hereinafter ***Regulation (EU) 2017/746***.

(2) In line with the provisions of this Order, healthcare institutions mean public and private healthcare units provided for in Art. 2 point 36 of Regulation (EU) 2017/745, Art. 2 point 29 of Regulation (EU) 2017/746 and Art. 1 paragraph (3) of Emergency Government Ordinance no. 137/2022, approved through Law 289/2023.

Art. 3 - (1) Healthcare institutions may manufacture and use medical devices only within their own facilities to meet the specific needs of a target patient

group which cannot be met or fulfilled at the appropriate level of performance by means of an equivalent medical device or in vitro diagnostic medical device bearing the CE marking and available on the market. ***The target patient group*** is a group of patients who share the same disease, condition or characteristics and who could benefit from the use of the internal medical device.

(2) The specific needs mentioned in paragraph (1) should be understood as needs for a specific device as defined under Art. 2 point 1 of Regulation (EU) 2017/745 or Art. 2 point 2 of Regulation (EU) 2017/746, as required, or for a certain level of performance of a device with certain performance characteristics.

(3) The appropriate level of performance mentioned in paragraph (1) is established by healthcare institutions, through clinical benefits for patients, as defined under Art. 2 point 53 of Regulation (EU) 2017/745 or Art. 2 point 37 of Regulation (EU) 2017/746, as required.

(4) Custom-made devices, as well as medical devices manufactured and used exclusively within healthcare institutions solely for economic reasons or financial interests, without clinically relevant reasons, do not fall within the scope of this Order.

(5) The manufacture and use of medical devices manufactured and used exclusively within healthcare institutions is limited to healthcare institutions defined in Article 2 paragraph (2) and may not be transferred to another healthcare institution or economic operator.

(6) The use of the medical devices mentioned in paragraph (1) shall be carried out only within the healthcare institution in which they were manufactured and only by healthcare professionals within that healthcare institution, when used in the care or diagnosis of a patient, in any of the premises of the healthcare institution which manufactured them.

(7) Remote use is allowed for the software of medical devices and in vitro diagnostic medical devices, provided that they are not made available to another healthcare institution.

(8) By exemption to paragraph (5), an in vitro diagnostic medical device for self-testing may also be used by patients. An in vitro diagnostic medical device manufactured in the laboratory of a healthcare institution may be used for the analysis of samples collected by healthcare professionals as well as by patients.

(9) The provisions of Art. 5 paragraph (5) of Regulation (EU) 2017/745, namely of Art. 5 paragraph (5) of Regulation (EU) 2017/746, as required, do not apply to medical devices and in vitro diagnostic medical devices manufactured in healthcare institutions, which during their life cycle are intended for use both within the healthcare institution and outside of it.

Art. 4 - (1) The manufacture of devices within healthcare institutions is carried out in order to obtain clinical benefits, as provided for in Article 3 paragraph (1) and (3), and includes one of the following activities:

a) the manufacture of devices from raw materials, parts or components or from an existing device;
b) the combination of a medical device or an in vitro diagnostic medical device with another medical device or an in vitro diagnostic medical device or with another type of product, for medical purposes, where the combination creates a new device;
c) the significant change of an existing medical device or an in vitro diagnostic medical device, with regard to its intended purpose, in order to create a new device to be used by the healthcare institution in accordance with the new intended purpose.

(2) Products manufactured solely for research purposes cannot be considered medical devices manufactured and used solely within healthcare institutions.

(3) If a healthcare institution assigns a product a purpose for research use, within it, which falls within the definition provided in Art. 2 point 1 of Regulation (EU) 2017/745 or Art. 2 point 2 of Regulation (EU) 2017/746, as required, the provisions of Art. 5 paragraph (5) of Regulation (EU) 2017/745 or Art. 5 paragraph (5) of Regulation (EU) 2017/746 shall be applied, as required.

(4) Medical devices manufactured and used only within healthcare institutions may include products intended for research use which are components, provided that the resulting internal medical device complies with the requirements set out in Article 5 paragraph (5) of Regulation (EU) 2017/745 or Article 5 paragraph (5) of Regulation (EU) 2017/746, as required.

(5) In vitro diagnostic medical devices manufactured and used by a laboratory of a healthcare institution are pathological tests developed or modified by the laboratory or a network of laboratories in order to perform tests on human samples, where the results are intended to aid to clinical diagnosis.

(6) Tests manufactured by a laboratory for therapeutic purposes, such as diagnostic tests, screening tests, tests for susceptibility or predisposition to disease, tests for monitoring a disease or exposure to toxic metals and chemicals, whether or not they are subject to clinical diagnosis, if used by the same laboratory, are in vitro diagnostic medical devices manufactured and used for their own purpose.

(7) Internal tests developed by a laboratory for research purposes only, without reporting the results to the patient/client, do not fall within the category of medical devices mentioned in paragraph (6).

Art. 5 - (1) Healthcare institutions must ensure that medical devices manufactured and used only within them comply with the relevant general safety and performance requirements of Annex I to Regulation (EU) 2017/745 or Annex I to Regulation (EU) 2017/746, as required.

(2) The manufacture and use of medical devices manufactured and used only within healthcare institutions must take place under appropriate quality management systems.

Art. 6 - In order to comply with the obligations set out in Aart. 5 paragraph (5) of Regulation (EU) 2017/745, for medical devices, or in Art. 5 paragraph (5) of Regulation (EU) 2017/746, for in vitro diagnostic medical devices, healthcare institutions that manufacture and use medical devices manufactured and used only within them are obliged to:

a) to establish and identify the manufactured device as a medical device or, as required, an in vitro diagnostic medical device;

b) to establish the applicable essential safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 or Regulation (EU) 2017/746;

c) to document, implement and maintain a quality management system in accordance with the EN ISO 9001 or ISO 13485 standard for the healthcare institution and/or the EN ISO 15189 standard for the laboratory, as required, which includes:

1. design and development control;
2. manufacturing control, process and facility control, internal and external audit, and preventive and corrective actions;
3. nomination of a person responsible for compliance with the regulations, in accordance with the provisions of Art. 15 of Regulation (EU) 2017/745 and Art. 15 of Regulation (EU) 2017/746;
4. risk analysis and management;
5. management responsibility;
6. identification, generation and analysis of data, including data relating to market prospection in order to identify an equivalent medical device bearing the CE marking;
7. monitoring, analysis and continuing improvement of the quality management system;
8. procedures for communication with the competent authorities;
9. incident reporting and management;
10. description of the market examination process regarding the presence and availability of the medical device or in vitro diagnostic medical device and the justification for the need to manufacture a medical device prior to the decision to manufacture a medical device;
11. presentation of the findings of the examination in a report. The conclusion of the report must be the justification that the specific needs of the target patient group cannot be met, or cannot be met at the appropriate performance level, by an equivalent device available on the market;
12. drawing up and maintaining technical documentation in accordance with the provisions of Art. 5 paragraph (5) point f) of Regulation (EU) 2017/745 or of Art. 5 paragraph (5) point f) of Regulation (EU) 2017/746, as required;

a) to provide the NAMMDR with all requested information and documents relating to manufactured and used medical devices;

b) to notify the NAMMDR of incidents occurring in the use and/or operation of

manufactured medical devices;

c) to apply the measures ordered by the NAMMDR in the event of identifying risks to the life or health of patients, users or third parties, including the established conditions;

d) to allow the NAMMDR access for inspection in order allow in-use monitoring of medical devices manufactured and used within the institution;

e) to permanently collect information on the market availability and performance of medical devices or in vitro diagnostic medical devices potentially bearing the CE marking, in order to keep their internal manufacturing up to date with market developments, and to review its justification for the need to manufacture the medical device manufactured and used only within healthcare institutions on a regular basis, taking into account its findings;

f) to review and update its justification for the manufacture of the medical device used only within healthcare institutions, if after its use an equivalent medical device or in vitro diagnostic medical device bearing the CE marking has become available on the market;

g) to make the transition to the use of a medical device or in vitro diagnostic medical device bearing the CE marking, available on the market, if it has been identified as a result of the market examination, and it is equivalent to the one manufactured within the healthcare institution and can meet the specific requirements of the target patient group within 6 months at the latest from the identification of the equivalent medical device.

Art. 7 - In order to ensure the level of security and performance appropriate to the purpose for which medical devices are made and to avoid incidents, healthcare institutions are obliged to:

a) to carry out a risk analysis relating to the manufactured medical devices;

b) to implement a systematic design-development procedure;

c) to carry out the clinical and technical evaluation of the safety and performance of the manufactured medical device;

d) to plan the ongoing maintenance of the manufactured medical device;

e) to plan and carry out the post-commissioning surveillance of the manufactured medical device;

f) to apply the necessary corrective actions resulting from the post-commissioning surveillance;

g) to keep records of the manufactured and used medical devices, identifying the patients and the followed procedures.

Art. 8 - To demonstrate that they are not equivalent to CE marked medical devices, healthcare institutions must provide a documented justification based on the technical, biological and clinical characteristics set out in Annex XIV, point A, point 3 to Regulation (EU) 2017/745, as well as the provisions of MDCG 2020-5 Guidelines on Clinical Evaluation - Equivalence (MDCG 2020-5 guidance on

Clinical Evaluation - Equivalence) posted on the website of the European Commission: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_5_guidance_clinical_evaluation_equivalence_en_0.pdf.

Art. 9 - (1) Healthcare institutions which manufacture and use medical devices for their own purposes are required to draft in Romanian and publish on their website the declaration on the safety and performance of medical devices provided for in Art. 5 paragraph (5) point e) of Regulation (EU) 2017/745, for medical devices, or in Art. 5 paragraph (5) point e) of Regulation (EU) 2017/746 for in vitro diagnostic medical devices, according to the pattern provided for in Annex 1, which is an integral part of this Order.

(2) The declaration referred to in paragraph (1) shall be revised whenever changes occur regarding the medical devices covered by it.

(3) Healthcare institutions shall notify the NAMMDR before using a medical device, using the notification form provided in Annex 2 which is an integral part of this Order.

(4) Within a maximum period of 90 days from the registration of the form mentioned in paragraph (3), the NAMMDR may request the following documents from the healthcare institution:

a) the health operating authorisation;

b) the declaration on the safety and performance of medical devices;

c) technical memorandum on the justification of the need to manufacture the medical device or the in vitro diagnostic medical device, as required, and the description of the target patient group, indicating the role of the internal medical device in the application of the procedures;

d) quality management system manual;

e) a brief description of the manufacturing process and of the necessary resources;

f) description of the operating mode;

g) other documents considered relevant.

(2) In the event that the healthcare institution does not make available to the NAMMDR all the documents mentioned in paragraph (4), in maximum 60 days from the request, the NAMMDR shall take the necessary measures according to its abilities, through inspections at its headquarters, to ensure that internal medical devices are manufactured and used by the healthcare institution in accordance with the provisions of Art. 5 paragraph (5) of Regulation (EU) 2017/745 or of Art. 5 paragraph (5) of Regulation (EU) 2017/746, as required.

(3) If the NAMMDR finds that the healthcare institution does not meet the general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 or to Regulation (EU) 2017/746, as required, with regard to the medical device manufactured and used only within the healthcare institution and/or the need to manufacture a medical device to be used only within the healthcare institution is not justified due to the availability of equivalent CE marked medical devices or in vitro diagnostic medical devices that meet the needs of the target

patient group and meet the appropriate performance level, prior to the manufacture of the medical device in question, availability resulting from market examination, the provisions of Art. 28 point b) and Art. 29 paragraph (2) of Emergency Government Ordinance no. 46/2021 or of Art. 17 point c) and Art. 18 paragraph (3) of Emergency Government Ordinance no. 137/2022, approved through Law 289/2023 shall be applied, as required.

(4) Healthcare institutions are obliged to notify the NAMMDR whenever changes occur regarding the medical device manufactured and used only within healthcare institutions, using the notification form provided in Annex No. 2.

(5) If the healthcare institution makes the transition specified in Art. 6 point j) to use an equivalent device bearing the CE marking instead of the device manufactured and used within it, it shall inform the NAMMDR specifying the start and end date of the transition. Starting with the date of completion of the transition, the device manufactured within the healthcare institution may no longer be used.

Art. 10 - (1) The NAMMDR collects information regarding the risks to which patients, users or third parties are exposed following the use of medical devices manufactured and used only within healthcare institutions, including the name, address, telephone number and e-mail address of patients, the medical services they received and the medical devices used for them.

(2) The collection by the NAMMDR of the data mentioned in paragraph (1) is carried out within the framework of inspections carried out in order to monitor the use of medical devices or by requesting their provision by the healthcare institution, with the patients' express consent to use the electronic health record under the conditions of Title IX of Law 95/2006 on healthcare reform, republished, as further amended and supplemented.

(3) If there are suspicions that a certain type of medical device poses a threat to the life and health of patients, the NAMMDR may contact patients treated with the respective medical device, who have expressed their consent mentioned in paragraph (2), for the purpose of collecting information.

(4) The processing of personal data obtained for the purposes mentioned in paragraph (1) is carried out in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), of Law 190/2018 on implementing measures for Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), as amended, as well as other specific regulations in the field of data protection.

Art. 11 - (1) In order to protect the life and health of users and public health, the

NAMMDR may condition the manufacture of a certain type of medical device in healthcare institutions.

(2) The conditions mentioned in paragraph (1) shall take into account one or more of the following measures:

a) requiring the healthcare institution to meet certain mandatory minimum requirements when using the medical device in question;

b) limiting the number of medical devices manufactured in relation to the estimated number of patients in the target group who can be treated in the institution;

c) providing mandatory personal protective equipment for operating personnel and their appropriate qualification for handling the medical device in question.

(3) The conditioning mentioned in paragraph (1) shall be applied depending on the identified risks associated with the type of medical device for patients, users or third parties.

Art. 12 - (1) For in vitro diagnostic medical devices manufactured and used only within healthcare institutions, in accordance with the provisions of Art. 113 paragraph (3) point i) and j) of Regulation (EU) 2017/746, the provisions of Art. 6 point c) point 10 and 11 and points i) and j), Art. 8, Art. 9 paragraph (4) point c) and paragraph (8) shall apply from 31 December 2030.

(2) The NAMMDR analyses the justification of the need to manufacture the medical device for in vitro diagnosis according to the provisions of Art. 9 paragraph (6), starting with 31 December 2030.

Art. 13 - The NAMMDR and the healthcare institutions shall carry out this Order.

Art. 14 – This Order shall be published in the Official Gazette of Romania, Part I.

Minister of health,
Alexandru Rafila

ANNEX 1

DECLARATION
on the safety and performance of medical devices/in vitro diagnostic medical devices

Name of healthcare institution (acronym): .....
Address: .....

The healthcare institution declares that the medical devices listed in the table below are manufactured and used exclusively within the healthcare institution and meet the applicable requirements of Regulation (EU) 2017/745, as follows:

No.	Name, description of the medical device's purpose	Type	Applicable requirements met (Yes/No)	Information and justifications for unmet requirements

Justification for failure to meet the requirements
.....
Date and place of issuance of the declaration
.....
Name, position, signature of the responsible person
.....

ANNEX 2

NOTIFICATION FORM
for medical devices/in vitro diagnostic medical devices manufactured and used within healthcare institutions

To

THE MINISTRY OF HEALTH
THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

<table>
<tr><td colspan="3">1. Notification identification data</td></tr>
<tr><td colspan="3">Date:</td></tr>
<tr><td colspan="3">Please state whether this is the first notification or a change:
|_| first notification |_| change</td></tr>
<tr><td colspan="3">If this is a change, please state the previously assigned number:</td></tr>
<tr><td colspan="3">Number of pages of the notification:</td></tr>
<tr><td colspan="3">2. Identification data of the healthcare institution which manufactured the medical device</td></tr>
<tr><td colspan="3">Full name:</td></tr>
<tr><td colspan="3">Abbreviated name:</td></tr>
<tr><td colspan="3">Address:</td></tr>
<tr><td colspan="2">Country:</td><td>Single registration number:</td></tr>
<tr><td>Postal code:</td><td>Sector/County:</td></tr>
<tr><td>City/Locality:</td><td>Street ..... no.:</td></tr>
<tr><td>Telephone number:</td><td>Fax number:</td></tr>
<tr><td>E-mail address:</td><td>Responsible person:</td></tr>
<tr><td colspan="3">The person responsible for compliance with regulations specific to the medical device field:</td></tr>
<tr><td colspan="3">3. Medical device identification data</td></tr>
<tr><td colspan="3">Full name of the medical device:</td></tr>
<tr><td colspan="3">Medical device class/type:
|_| Class I medical device |_| Class Is medical device |_| Class Im medical device

|_| Class IIa medical device
|_| Class IIb medical device
|_| Class III medical device
|_| Systems and procedure packages</td></tr>
<tr><td colspan="3">Class/Type of the in vitro diagnostic medical device:
|_| Class A in vitro diagnostic medical device
|_| Class B in vitro diagnostic medical device</td></tr>
</table>

☐ Class C in vitro diagnostic medical device ☐ Class D in vitro diagnostic medical device
Generic category of the medical device or brief description of the medical device and its intended purpose:
4. Attached documents
☐ certified copy of the registration certificate or other official/regulatory document attesting to the establishment of the applicant unit and the certificate of establishment issued by the trade register office indicating the company's object of activity, for applicant units which are required to register with the trade register office
☐ declaration on safety and performance of medical devices
☐ quality management system manual
☐ brief description of the manufacturing process, necessary resources
☐ description of the mode of operation
☐ other documents considered relevant

We hereby inform you that the declaration on the safety and performance of medical devices provided for in Art. 5 paragraph (5) point e) of Regulation (EU) 2017/745 or Art. 5 paragraph (5) point e) of Regulation (EU) 2017/746 was posted on the healthcare institution's website, as required, website .....
The information provided in this notification is correct.

Name, surname and position of the head of the healthcare institution
.....
Signature
.....