Ministry of Health

ORDER No. 3.753 of 6 November 2023

on approval of the methodological rules regarding the introduction on the market of in vitro diagnostic medical devices and registration of economic operators into the European Database on Medical Devices (Eudamed), as well as into the national database and exemption from compliance assessment procedures

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On seeing approval report no. AR 20.279/2023 of the Pharmaceutical and Medical Devices Directorate and notification 122.664E of 11.10.2023, of the National Agency for Medicines and Medical Devices of Romania, registered at the Ministry of Health with no. Reg2/2.300 of 12.10.2023,

Taking into account the following provisions:

- Articles 3 (2), 9 (3) and 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) points 1 and 10 of Law no. 134 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented,
- Art. 29 of Government Decision no. 798/2003 on establishment of conditions for placing on the market of in vitro diagnostic medical devices and their use, as amended, as further amended and supplemented,

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

the minister of health hereby issues the following order:

Art. 1 - The methodological rules regarding the introduction on the market of in vitro diagnostic medical devices and registration of economic operators into the European Database on Medical Devices (Eudamed), as well as into the national database and exemption from compliance assessment procedures, mentioned in the Annex which is an integral part of this Order, are approved.

Art. 2 - The National Agency for Medicines and Medical Devices of

Romania, hereinafter referred to as the NAMMDR, is the competent authority in line with the provisions of Art. 16 (4) and Art. 28 paragraphs (6) and (8) 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.

Art. 3 – The NAMMDR shall carry out the provisions of this Order.

Art. 4 - This Order shall be published in the Official Gazette of Romania, Part I.

Minister of Health,
Alexandru Rafila

Annex

METHODOLOGICAL RULES
regarding the introduction on the market of in vitro diagnostic medical devices and registration of economic operators into the European Database on Medical Devices (Eudamed), as well as into the national database and exemption from compliance assessment procedures

SECTION I
General provisions

Art. 1 – The object of these Methodological rules is the introduction on the market of in vitro diagnostic medical devices and registration of economic operators into the European Database on Medical Devices (Eudamed), as well as into the national database and exemption from compliance assessment procedures, for enforcement of the provisions of Art. 3 (2), Art. 9 (3) and 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, and of the provisions of Art. 29 of Government Decision no. 798/2003 on establishment of conditions for placing on the market of in vitro diagnostic medical devices and their use, as amended, as further amended and supplemented.

Art. 2 – The terms used in these Methodological Rules have the meaning established 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 referred to the ***Regulation.***

SECTION II
Registration of manufacturers, authorised representatives and importers

Art. 3 - (1) The National Agency for Medicines and Medical Devices of Romania ***(NAMMDR)*** checks the data entered by the manufacturer, the authorised representative or the importer into the Eudamed and evaluates the application for registration within a maximum period of 15 days from the date of registration of the application into the Eudamed, in compliance with the provisions of paragraph (2). As part of the evaluation process, the NAMMDR analyses the application for registration, on which occasion it may validate, reject or request corrections.

(2) In accordance with Annex VI, Part A, Section 1 of the Regulation, the information to be provided when registering the manufacturer, authorised representative or importer in Eudamed is as follows:

a) the type of economic operator, namely: manufacturer, authorised representative of the manufacturer or importer;

b) the name, address and contact details of the economic operator;

c) in the event that the provision of information is carried out by another person, on behalf of the economic operator referred to in letter a), the name, address and contact details of that person shall be communicated;

d) the name, address and contact details of the person or persons responsible for compliance with the regulations, in line with Art. 15 of the Regulation.

(3) Following the validation provided for in paragraph (1), a unique registration number is generated into the Eudamed, which is sent by e-mail to the economic operator.

Art. 4 - When registering into the Eudamed, the recommendations of the Eudamed User Guide - Actor registration module for economic operators, developed by the European Commission, shall apply; the Guide is available online at:https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/md_user_guide_actor_modul e_en.pdf.

Art. 5 - (1) The economic operator referred to in Art. 3 paragraph (1) is obliged, no later than one year after transmission of the information into the Eudamed and, thereafter, every two years, to confirm the accuracy of the data referred to in Art. 3 paragraph (2), in accordance with the provisions of art. 28 paragraph (5) of the Regulation.

(2) In case of non-compliance with the provisions of paragraph (1), within six months of their completion, the economic operator referred to in art. 3 paragraph (1) shall be sanctioned by the NAMMDR in line with the provisions of Art. 18 paragraph (16) of Government Emergency Ordinance no. 137/2022, approved through Law 289/2023.

SECTION III
Registration into the national database

Art. 6 - (1) The manufacturer or the manufacturer's authorised representative, established in Romania, who places devices on the market under its own name, is obliged to register with the NAMMDR, in accordance with the provisions of Art. 29 of Government Decision no. 798/2003, as further amended and supplemented, when placing on the market the following types of in vitro diagnostic medical devices:

a) class A in vitro diagnostic medical devices;

b) class B in vitro diagnostic medical devices;

c) class C in vitro diagnostic medical devices;

d) class D in vitro diagnostic medical devices.

(2) For the registration of in vitro diagnostic medical devices provided for in paragraph (1), the manufacturer or the manufacturer's authorised representative, responsible for their introduction on the market, shall submit the NAMMDR the notification form, filled in with the data requested therein, accompanied by the documents specified therein, as the case may be, in line with Annex 1, which is an integral part of these methodological rules.

(3) The NAMMDR may request from the manufacturer or the manufacturer's authorised representative, in addition, technical documents provided for in the legislation applicable to the type of in vitro diagnostic medical device placed on the market, for the registration of in vitro diagnostic medical devices referred to in paragraph (1).

Art. 7 - (1) Based on the documents provided for in Art. 6 paragraph (2), the NAMMDR shall register into the national database the information concerning in vitro diagnostic medical devices placed on the market and the information concerning the manufacturer or the manufacturer's authorised representative established in Romania and shall inform the latter regarding the registration of the in vitro diagnostic medical devices through an information notice, in line with Annexes 2 and 3, which are integral parts of these methodological rules, as the case may be.

(2) The information notice regarding registration of in vitro diagnostic medical devices shall include data on the in vitro diagnostic medical device and its manufacturer and/or authorised representative established in Romania, as the case may be, and shall be issued in two original copies, one of which shall remain in the NAMMDR records.

(3) The NAMMDR issues the information notice regarding the registration of in vitro diagnostic medical devices within maximum 60 days from receipt of the notification form, provided for in Art. 6 paragraph (2), fully filled in by the manufacturer or the manufacturer's authorised representative, with all data and accompanied by the appropriate documents.

Art. 8 - (1) The manufacturer or the manufacturer's authorised representative, who has registered the in vitro diagnostic medical devices provided for in Art. 6 paragraph (1), is obliged to immediately communicate to the NAMMDR any change that occurs after receiving the information notice of registration of the in vitro diagnostic medical devices, including the interruption/termination of the placing on the market of registered in vitro diagnostic medical devices.

(2) Within 60 days from communication of the changes, as provided for in paragraph (1), the NAMMDR shall update the changes in the national database and inform the manufacturer or the manufacturer's authorised representative by means of a notification.

(3) The change of the headquarters or name of the manufacturer, the establishment/deletion of workpoints is updated by the NAMMDR into the national database, based on the certificate of verification issued by the trade register office.

SECTION IV
Waiver from compliance assessment procedures

Art. 9 - (1) Based on a justified request, the NAMMDR authorises the placement on the market or putting into service on Romanian territory of a certain in vitro diagnostic medical device for which the compliance assessment procedures have not been carried out, but whose use is in the interest of public health or of the safety or patient’s health, in accordance with the provisions of Art. 54 paragraph (1) of the Regulation.

(2) The national waiver provided for in paragraph (1) shall apply for a limited

period of time, only in exceptional, well-justified cases, such as, but not limited to: when there is no similar product on the market, when the manufacturer demonstrates that it has started the compliance assessment procedures or, as the case may be, that it has been prevented from completing/initiating these procedures by exceptional and unforeseeable circumstances, in the event of unavailability of a notified body in the field of interest, of a long waiting time until the application is accepted by the notified body, of a long time required for the clinical testing/verification/investigation of the product in question, of a suspicion of an epidemic or in the case of a confirmed epidemic with pathogens, toxins, as well as in the case of a suspicion of the spread or confirmed spread of chemical agents or nuclear radiation which could endanger the health of the population or in other cases of health crisis preventing the activity from being carried out under normal conditions.

(3) In vitro diagnostic medical devices referred to in paragraph (1) may be placed on the market or put into service only if the following conditions are met:

a) the manufacturer has implemented a quality management system in accordance with Article 5(5)(b) and Article 10(8) of the Regulation, ensuring that the requirements of the Regulation relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and devices are duly fulfilled;

b) no safety issues have been identified for the respective in vitro diagnostic medical device;

c) a notified body has accepted the application for certification in line with the Regulation by 31 December 2023;

d) there are no significant changes to the design or intended purpose of the in vitro diagnostic medical devices.

(4) The validity period of the national waiver provided for in paragraph (1) is of 6 months, with the possibility of extension for a period considered reasonable until completion of the conformity assessment procedure for in vitro diagnostic medical devices subject to the national waiver.

(5) The NAMMDR is not obliged to inform the European Commission and the other Member States of the European Union, in accordance with the provisions of Art. 54 paragraph (2) of the Regulation, in the case of the decision to authorise the placement on the market or putting into service of an in vitro diagnostic medical device, granted for a product intended for a single patient.

Art. 10 - (1) To obtain the national waiver provided for in Art. 9 paragraph (1), the economic operator shall submit to the NAMMDR an application filled in with the data requested therein and accompanied by the documents specified therein, as the case may be, in line with Annex 4 which is an integral part of these methodological rules.

(2) The NAMMDR verifies the information filled in in the application provided for in paragraph (1), as well as the documents submitted by the applicant and validates or rejects the application, within maximum 30 days from its registration with the NAMMDR.

(3) To solve the request provided for in paragraph (1), the NAMMDR may additionally request documents provided for in the legislation applicable to the type of the in vitro diagnostic medical device.

SECTION V
Exemption from the translation into Romanian of the information provided by the manufacturer together with the medical device

Art. 11 - (1) In line with the provisions of Art. 3 paragraph (2) of Government Emergency Ordinance no. 137/2022, approved through Law 289/2023, the NAMMDR, as the competent authority in the field of in vitro diagnostic medical devices, may advise that the information provided by the manufacturer together with the in vitro diagnostic medical device be in English exclusively for professionals, based on their written agreement and on submission by the economic operator of the application filled in with the data requested therein and accompanied by the documents specified therein, as appropriate, according to annex 5, which is an integral part of these methodological rules.

(2) The NAMMDR verifies the information filled in the application provided for in paragraph (1), as well as the documents submitted by the applicant and validates or rejects the request for exemption from translation into Romanian of the information provided by the manufacturer together with the in vitro diagnostic medical device, within maximum 30 days from the date of its registration with the NAMMDR.

(3) In order to resolve the request provided for in paragraph (1), the NAMMDR may additionally request documents provided for in the legislation applicable to the type of the in vitro diagnostic medical device.

(4) The exemption from translation into Romanian of the information provided by the manufacturer together with the medical device shall be granted by the NAMMDR only in well-justified cases, when there is no similar product on the market and the need for the medical devices subject to the exemption can be justified.

SECTION VI
Cases where the obligations of manufacturers apply to importers, distributors or other persons

Art. 12 - (1) If distributors or importers carry out any of the activities referred to in Art. 16 paragraph (2) points a) and b) of the Regulation, they must inform the NAMMDR about making available the relabelled or repackaged in vitro diagnostic medical device on the market, according to the provisions of art. 16 paragraph (4) of the Regulation.

(2) In the situation provided for in paragraph (1), distributors or importers shall submit to the NAMMDR the filled-in form with the data requested therein and a copy or a mock-up of the relabelled or repackaged in vitro diagnostic medical device, including any label and instructions for use of the device translated into Romanian, in line with Annex 6, which is an integral part of these methodological rules.

(3) Based on the form provided for in paragraph (2) and the documents related to it, if the relabelled or repackaged in vitro diagnostic medical device complies with the requirements of the Regulation, the NAMMDR shall register the economic operator into the national database with the activity performed by it, of translation and/or repackaging, and shall issue an address confirming this registration, according to the model in Annex 7, which is an integral part of these methodological rules.

Annex 1
to the methodological rules

F.2 - Notification form for the placing on the market of in vitro diagnostic medical devices

To

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

1. Notification identification data	
Date:	
Please state whether this is the first notification or an amendment |_| first notification |_| amendment |_| suspension of marketing |_| termination of marketing If it is a modification or suspension/termination, indicate the previously assigned number:	
Number of pages of the notification:	
Status of the organisation making this notification:	
|_| manufacturer of medical devices for class A in vitro diagnostic medical devices |_| manufacturer of medical devices for class B in vitro diagnostic medical devices |_| manufacturer of medical devices for class C in vitro diagnostic medical devices |_| manufacturer of medical devices for class D in vitro diagnostic medical devices	Authorised representative of a: |_| manufacturer of medical devices for class A in vitro diagnostic medical devices |_| manufacturer of medical devices for class B in vitro diagnostic medical devices |_| manufacturer of medical devices for class C in vitro diagnostic medical devices |_| manufacturer of medical devices for class D in vitro diagnostic medical devices
2. Manufacturer identification data	

Manufacturer’s full name:	
Manufacturer’s abbreviated name:	
Address of the manufacturer's registered office:	
Country:	SRN:
Postal code:	Sector/county

City/town:	Street no.:
Telephone number:	Fax number:
E-mail address:	Contact person:
The person responsible for compliance with regulations specific to the medical device field:	
3. Identification data of the authorised representative	
Full name of the authorised representative:	
Abbreviated name of the authorised representative:	
Address of the registered office of the authorised representative:	
Country:	SRN:
Postal code:	Sector/county
City/town:	Street no.:
Telephone number:	Fax number:
E-mail address:	Contact person:
The person responsible for compliance with regulations specific to the medical device field:	
4. Medical device identification data	
Full name of the medical device:	
Medical device class/type: |_| class A in vitro diagnostic medical devices |_| class B in vitro diagnostic medical devices |_| class C in vitro diagnostic medical devices |_| class D in vitro diagnostic medical devices Generic category of the medical device and/or brief description of the device and its intended purpose:	
5. Attached documents	
|_| certified copy of the registration certificate or other official document/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 required to register with the trade register office	
|_| declaration of compliance issued by the manufacturer in accordance with the applicable legislation |_| instructions for use of the medical device |_| medical device label |_| copy of the certificate of compliance issued by a notified body (where applicable, depending on the type of medical device)	
|_| technical documentation according to Annex III of Regulation (EU) 2017/746 |_| document by which the manufacturer nominates you as an authorised representative pursuant to Article 11 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	

The information provided in this notification is correct and the medical devices identified in Section 4 comply with the applicable requirements set out in Regulation (EU) 2017/746 of the European Parliament and of the Council.

Full name and position

.....

Signature and stamp

Annex 2
to the methodological rules

INFORMATION
regarding the registration of in vitro diagnostic medical device
no. ...../.....

In line with the provisions of Art. 932 (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, of Art. 122 the last sentence 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, of Art. 29 paragraph 1) of Government Decision no. 798/2013 on establishment of conditions for placing on the market of in vitro diagnostic medical devices and their use, as amended, as further amended and supplemented, and based on the information in the notification form for the introduction of medical devices on the market registered with the National Agency for Medicines and Medical Devices of Romania (NAMMDR) with no. ...../..... and its related documentation, The NAMMDR has registered the following medical device in the national database for medical devices, medical device class ....:

Name of the medical device	Type	Code	Registration code	Class

introduced on the market by manufacturer
.....
headquartered in
.....
having the workpoint in
.....

This registration was made based on the manufacturer's declarations and does not represent an approval or authorisation by the competent authority.

The manufacturer is obliged to register into the European Database on Medical Devices (Eudamed), when it becomes fully operational, and to communicate to the NAMMDR any changes in the registered data, including the suspension/termination of the placing on the market of the device.

Annex 3
to the methodological rules

INFORMATION
regarding the registration of in vitro diagnostic medical device
no. ...../.....

In line with the provisions of Art. 932 paragraph 2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, of Art. 122 last sentence 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, of Art. 29 paragraph 1) of Government Decision no. 798/2003 on establishment of conditions for placing on the market of in vitro diagnostic medical devices and their use, as amended, as further amended and supplemented, and based on the information in the notification form for the introduction of medical devices on the market registered with the National Agency for Medicines and Medical Devices of Romania (NAMMDR) with no...../..... and its related documentation, the NAMMDR has registered the following medical device in the national database for medical devices, medical device class .....:

Name of the medical device	Tip	Cod	Registration code	Class

Manufacturer: ....., headquartered in..... , placed on the market by authorised representative .....,
headquartered in…….. ..... ,
having the workpoint in ..... .

This registration was made on the basis of the declarations of the authorised representative and does not represent an approval or authorisation of the competent authority.

The authorised representative is obliged to register into the European Database on Medical Devices (Eudamed) when it becomes operational and to communicate to the NAMMDR any change in the registered data, including the suspension/termination of the placement on the market of the device, according to the Annex to the information on the registration of in vitro diagnostic medical devices.

Annex ...../.....
to the Information regarding registration of in vitro diagnostic medical devices no. ...../.....

In line with the provisions of Art. 932 paragraph2) of Law 95/2006 on

healthcare reform, republished, as further amended and supplemented, of Art. 122 the last sentence 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, of Art. 29 paragraph1) of Government Decision no. 54/2009 on conditions for placing on the market of medical devices, as amended, as further amended, and based on the information in the notification form for the introduction of medical devices on the market registered with the National Agency for Medicines and Medical Devices of Romania (NAMMDR) with no.. ...../..... and its related documentation, the NAMMDR modified the records into the national database for class ..... medical device, as follows:

.....

This registration was made on the basis of the manufacturer's/manufacturer's authorised representative's declarations and does not represent an approval or authorisation by the competent authority. The manufacturer/manufacturer's authorised representative is obliged to communicate to the NAMMDR any change in the registered data, including the suspension/termination of the device's placement on the market.

Annex 4
to the methodological rules

F.3 - Form for request of a waiver from compliance assessment procedures

To

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

Applicant identification data
Company name:
Registered office address: locality
Street no.:
Telephone number:
Fax number:
E-mail address:
Contact person:
Medical device identification data
Full name of the medical device
Class:
☐ A ☐ B ☐ C ☐ D ☐ EU declaration of compliance ☐ Compliance certificate issued by a notified body (as the case may be) ☐ Technical specification ☐ Instructions for use ☐ Label ☐ Document justifying the need for the waiver ☐ Other certificates/approvals/authorizations obtained

Full name of the applicant:
.....
Date:
.....
Applicant's signature:

Annex 5
to the methodological rules

F.4 - Form for requesting an opinion for the exemption of the translation into Romanian of the information provided by the manufacturer together with the in vitro diagnostic medical device

To

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

Applicant identification data
Company name:
Registered office address: locality
Street no.:
Telephone number:
Fax number:
E-mail address:
Contact person:
Medical device identification data
Full name of the medical device
Class:
☐ A ☐ B ☐ C ☐ D ☐ EU declaration of compliance ☐ Compliance certificate issued by a notified body (as the case may be) ☐ Instructions for use ☐ Label ☐ Justification for the lack of translation ☐ Written agreement of the professional

Full name of the applicant:
.....
Date:
.....
Applicant's signature:

Annex 6
to the methodological rules

F.5 – Information form based on Art. 16 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

To

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

Applicant identification data
Company name:
Registered office address: locality
Street no.:
Telephone number:
Fax number:
E-mail address:
Contact person:
Type of performed action
☐ translation of information provided by the manufacturer together with a medical device ☐ medical device packaging modification **Medical device identification data**

Full name of the medical device
Class:
☐ A ☐ B ☐ C ☐ D ☐ EU declaration of compliance ☐ Compliance certificate issued by a notified body for the medical device (as the case may be) ☐ Certificate issued by a notified body for the quality management system, issued to the applicant
☐ Instructions for use in original and translated version ☐ Original label and its translated version ☐ Medical device mock-up/sample, as the case may be ☐ Other documents translated or accompanying the medical device

Full name of the applicant:
.....
Date:
.....
Applicant's signature:

Annex 7
to the methodological rules

To:

Applicant's name .....
Headquarters address .....
Telephone number: ....., Fax number: .....
E-mail address: .....

The registration with the National Agency for Medicines and Medical Devices of Romania of Information No. DM *(medical device)* ..... is hereby confirmed, performed by the economic operator ....., in line with the provisions of Art. 16 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.

As a result of this information, in accordance with the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council, the following information:

Activity type	Certificate number for the quality management system issued by	Name and type of device	Class of device	Manufacturer

were registered by the National Agency for Medicines and Medical Devices of Romania into the national database containing medical devices-related activities.

This registration was made according to the applicant's statements and does not represent an approval or authorisation of the competent authority.