MINISTRY OF HEALTH

ORDER No. 3.539
of 24 November 2022
on approval of the Methodological rules for placement on the market of medical devices and registration of economic operators into the European database on medical devices (EUDAMED), as well as into the national database, and on exemption from compliance assessment procedures

Published in: the Official Gazette of Romania no. 1.180 of 9 December 2022

On seeing approval report no. AR/21.055/2022 of the Directorate for Medicinal Product Policy, Medical Devices and Technologies and the notification of the National Agency for Medicines and Medical Devices of Romania no. 63.724E of 16.06.2022, registered at the Ministry of Health with no. P 0716 from 17.06.2022,

taking into account the provisions of:

- Art. 3 (2), Art. 10 and 11 (3) 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. 31 of Government Decision no. 54 of 29 January 2009 on conditions for placing on the market of medical devices, as amended;
- Art. 29 - 33 din Government Decision no. 55 of 29 January 2009 on active implantable medical devices, as amended;
- Article 932 paragraphs (1) and (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;
- Article 4 (4) points 1 and 10 of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices of Romania and amendment of further ruling provisions, 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 for placement on the market of medical devices and registration of economic operators into the European database on medical devices (EUDAMED), as well as into the national database, and on exemption from compliance assessment procedures are approved, mentioned in the Annex which is an integral part of this Order.

Art. 2 - The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as ***the ANMDMR***, is the competent authority in line with the provisions of Art. 16 (4) and Art. 31 (6) and (8) 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. 3 - The ANMDMR 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
for placement on the market of medical devices and registration of economic operators into the European database on medical devices (EUDAMED), as well as into the national database, and on exemption from compliance assessment procedures

Section I
General provisions

Art. 1 - These methodological rules aim to regulate the placement on the market of medical devices and the registration of economic operators into the European database on medical devices (***Eudamed***), as well as into the national database and on exemption from compliance assessment procedures for enforcement of the provisions of Art. 3 (2), Art. 10 and Art. 11 (3) 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, of Art. 31 of Government Decision no. 54/2009 on conditions for placing on the market of medical devices, as amended, as well as of Art. 29 - 33 of Government Decision no. 55/2009 on active implantable medical devices, as amended.

Art. 2 - The terms used in this Order have the meaning established by 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 referred to as the ***Regulation***.

Section II
Registration of manufacturers, authorised representatives and importers

Art. 3 - (1) The National Agency for Medicines and Medical Devices of Romania (***ANMDMR***) verifies the data entered by economic operators into the Eudamed and evaluates the registration application within a maximum period of 15 days from the date of registration of the application into the Eudamed, in line with the provisions of paragraph (2). As part of the evaluation process, the ANMDMR analyses the registration application, 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 economic operators is:

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

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

c) if the submission of information is made by another person on behalf of any of the economic operators, the name, address and contact details of that person;

d) the name, address and contact details of the person(s) responsible for compliance with the regulations referred to in Article 15 of the Regulation.

(3) Following the validation provided for in paragraph (1), a unique registration number

(SRN) is generated, which is sent by e-mail to the local administrator of the manufacturer or the authorised representative or importer.

Art. 4 - When registering into the Eudamed, the recommendations of the "Guide to Using Eudamed - Actor registration module for economic operators", developed by the European Commission, shall apply; the Guide is posted on the website: https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/md_user_guide_actor_module_en.pdf.

Art. 5 - (1) The economic operator is obliged to confirm the accuracy of the data from Art. 3 paragraph (2) at the latest one year after transmission of the information to the Eudamed and, subsequently, every two years, in accordance with the provisions of Art. 31 paragraph (5) of the Regulation.

(2) In case of non-compliance within six months of the end of the deadlines provided for in paragraph (1), the economic operator shall be sanctioned by the ANMDMR in accordance with the provisions of Art. 29 paragraph (21) of Emergency Government Ordinance no. 46/2021.

Section III
Registration into the national database

Art. 6 - (1) The manufacturer or the manufacturer's authorised representative located in Romania is required to register with the ANMDMR in accordance with the provisions of Art. 31 of Government Decision no. 54/2009, as amended, and of Art. 29-33 of Government Decision no. 55/2009, as amended, when placing on the market the following types of medical devices:

a) classes I, IIa, IIb and III medical devices, including sterile/measuring medical devices;

b) systems and procedure packages provided for in Art. 22 of the Regulation;

c) active implantable medical devices.

(2) For the registration of medical devices referred to in paragraph (1), the person responsible for their introduction on the market shall submit to the ANMDMR the notification form filled in with the data requested therein and accompanied by the documents specified therein, as appropriate, according to Annex 1 to these Rules.

(3) The ANMDMR may additionally request technical documents provided for in the legislation applicable to the type of device introduced on the market, for registration of medical devices referred to in paragraph (1).

Art. 7 - (1) Based on the documents provided for in Art. 6 paragraph (2), the ANMDMR shall register into the national database the information on medical devices placed on the market and the information on the manufacturer or the manufacturer's authorised representative located in Romania and shall inform the latter of the registration of medical devices through an information notification according to Annexes 2 and 3 to these Rules, as the case may be.

(2) The information notification regarding registration of medical devices includes data regarding the medical device and its manufacturer and/or authorised representative established in Romania and is issued in two original copies, one of which will remain in the records of the ANMDMR.

(3) The ANMDMR issues the information notification regarding registration of medical devices within a maximum period of 60 days from receipt of the notification form, provided for in Art. 6 paragraph (2), filled in with all data and accompanied by the corresponding documents.

Art. 8 - (1) The persons who have registered the medical devices referred to in Art. 6 paragraph (1) are obliged to communicate to the ANMDMR any change that occurs after receiving the notification of information on registration of medical devices, including the interruption/termination of placement on the market of the registered devices.

(2) The changes referred to in paragraph (1) shall be updated by the ANMDMR into the national database, which shall inform the persons referred to in paragraph (1) of this aspect by means of a notification within a maximum period of 60 days from receipt of the notification referred to in paragraph (1), according to Annex 4.

(3) The change of the registered office or the name of the manufacturer, the establishment/deletion of work points shall be updated into the national database by the ANMDMR, according to the certificate of verification issued by the trade register office.

Section IV
Exemption from compliance assessment procedures

Art. 9 - (1) Based on a justified request, the ANMDMR authorises the placement on the market or putting into service on the Romanian territory of a certain device for which the compliance assessment procedures have not been carried out, but whose use is in the interest of public health or patient health, in accordance with the provisions of Art. 59 paragraph (1) of the Regulation.

(2) The national exemption provided for in paragraph (1) shall apply for a limited period, 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 or initiating these procedures by exceptional and unforeseeable circumstances, in the event of unavailability of a notified body in the field of interest, of the long waiting until the application is accepted by the notified body, of the long time required for clinical testing/verification/investigation for the product in question, of a suspected epidemic or in the case of a confirmed epidemic with pathogens, toxins, as well as in the case of a suspected or confirmed spread of chemical agents or nuclear radiation which could endanger the health of the population or in other cases of health crisis which prevent the activity from being carried out under normal conditions.

(3) The validity period of the national waiver is limited to 6 months, with the possibility of extension, a period considered reasonable for the completion of the compliance assessment procedure or the necessity for use of the medical devices subject to the national waiver.

(4) The ANMDMR is not obliged to inform the European Commission and the other Member States of the European Union, in accordance with the provisions of Art. 59 paragraph (2) of the Regulation, in the case of the decision to authorise the placement on the market or putting into service of a medical device, granted for a product intended for a single patient.

Art. 10 - (1) To obtain the waiver provided for in Art. 9 paragraph (1), the economic operator shall submit to the ANMDMR 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 5 to these rules.

(2) The ANMDMR verifies the information filled in the form 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 ANMDMR.

(3) To solve the request provided for in paragraph (1), the ANMDMR 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 Emergency Government Emergency Ordinance no. 46/2021, the ANMDMR, as the competent authority in the field of medical devices, may advise that the information provided by the manufacturer together with the medical device be in English exclusively for healthcare professionals, based on their written agreement and on submission of the application filled in with the data requested therein and accompanied by the documents specified therein, as the case may be, according to Annex 6 to these rules.

(2) The ANMDMR verifies the information filled in the form 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 medical device, within maximum 30 days from the date of its registration with the ANMDMR.

(3) In order to resolve the request provided for in paragraph (1), the ANMDMR may additionally request documents provided for in the legislation applicable to the type of the 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 ANMDMR 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.

(5) To obtain this type of exception, the distributor or manufacturer must ensure the training of the healthcare professional who has given his consent to receive the medical device with information in English.

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 Article 16 paragraph (2) points (a) and (b) of the Regulation, they must inform the ANMDMR about making available on the market the relabelled or repackaged device, in line with the provisions of Article 16 paragraph (4) of the Regulation, by means of the form filled in with the data requested therein, attaching a copy or a mock-up of the relabelled or repackaged device, including any label and instructions for use of the device translated into Romanian, according to Annex 7 to these rules.

(2) Based on the form provided for in paragraph (2) and the documents related to it, if the relabelled or repackaged medical device complies with the requirements of the Regulation, the ANMDMR 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 8 to these Rules.

Annex 1
to the methodological rules

*) Annex 1 is reproduced in facsimile.

F.l - Notification form for placing medical devices on the market

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 class I medical devices ⎕ manufacturer of class IIa medical devices ⎕ manufacturer of class IIb medical devices ⎕ manufacturer of class III medical devices ⎕ manufacturer of systems and procedure packages ⎕ manufacturer of active implantable medical devices	Authorised representative of a: ⎕ manufacturer of class I medical devices ⎕ manufacturer of class IIa medical devices ⎕ manufacturer of class IIb medical devices ⎕ manufacturer of class III medical devices ⎕ manufacturer of systems and procedure packages ⎕ manufacturer of active implantable 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 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 ⎕ active implantable medical device	
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)	
⎕ document by which the manufacturer nominates you as an authorised representative pursuant to Art. 11 din 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	

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) 2017/745.

Full name and position
.....
Signature and stamp

Annex 2
to the methodological rules

NOTIFICATION
on registration of medical devices 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 point 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, of Art. 31 paragraph (1) of Government Decision no. 54/2009 on conditions for placing on the market of medical devices, as amended, and of Art. 29 - 33 of Government Decision no. 55/2009 on active implantable medical devices, as 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 (***ANMDMR***) with no. ...../..... and its related documentation, the ANMDMR has registered the following medical device into 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 ANMDMR 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

NOTIFICATION
on registration of medical devices 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 point 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, of Art. 31 paragraph (1) of Government Decision no. 54/2009 on conditions for placing on the market of medical devices, as amended, and of Art. 29 - 33 of Government Decision no. 55/2009 on active implantable medical devices, as 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 (***ANMDMR***) with no...../..... and its related documentation, the ANMDMR has registered the following medical device into the national database for medical devices, medical device class .....:

Name of the medical device	Type	Code	Registration code	Class

Manufacturer: ....., headquartered in..... , placed on the market by authorised manufacturer .....,
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 ANMDMR any change in the registered data, including the suspension/termination of the placement on the market of the device.

Annex 4
to the methodological rules

Annex ...../.....
to the Information regarding registration of medical devices 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 point 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, of Art. 31 paragraph (1) of Government Decision no. 54/2009 on conditions for placing on the market of medical devices, as amended, and of Art. 29 - 33 of Government Decision no. 55/2009 on active implantable medical devices, as 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 (***ANMDMR***) with no.. ...../..... and its related documentation, the ANMDMR modified the records into the national database for class ..... medical devices, 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 ANMDMR any change in the registered data, including the suspension/termination of the device's placement on the market.

Annex 5
to the methodological rules

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

To,

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

Applicant identification data
Society 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:
☐ I ☐ Is ☐ Im
☐ IIa ☐ IIb ☐ III
☐ 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 exemption
☐ Other certificates/approvals/authorisations obtained

Applicant's last and first name:
.....
Date:
.....
Applicant's signature
.....

Annex 6
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 medical device

To,

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

Applicant identification data
Society 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:
I Is Im
IIa IIb III
|¯| EU declaration of compliance
|¯| Compliance certificate issued by a notified body
|¯| Instructions for use
|¯| Label
|¯| Justification for the lack of translation:
|¯| Written agreement of the professional

Applicant's last and first name:
.....
Date:
.....
Applicant's signature
.....

Annex 7
to the methodological rules

F.5 - Information form based on Art. 16 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

To,

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

Applicant identification data
Society 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:
|¯| I |¯| Is |¯| Im
|¯| IIa |¯| IIb |¯| III
|¯| 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

Applicant's last and first name:
.....
Date:
.....
Applicant's signature
.....

Annex 8
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) 2017/745 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.

Following this notification, in line with the provisions of Regulation (EU) 2017/745, the following information:

Activity type	Certificate number for the quality management system issued by	Medical device name and type	Medical device class	Manufacturer's name

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.