MINISTRY OF HEALTH

ORDER No. 2.845
of 29 September 2022
on approval of the Methodological rules for approval of provisions of Article 13 of Emergency Government Ordinance no. 46/2021 on the establishment of the institutional framework and the measures necessary to ensure the direct application of the provisions 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 registration of custom-made devices placed on the market under their own name by manufacturers based in Romania

Published in: the Official Gazette no. 977 of 7 October 2022

On seeing Approval Report no. AR 20.535/2022 of the Pharmaceutical and Medical Devices Directorate and the notification of the National Agency for Medicines and Medical Devices of Romania no. 59.637E of 19.07.2021 registered at the Ministry of Health with no. P990 din 20.07.2021,

Considering the provisions of:

- Art. 13 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. 932 (1) and (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;
- Art. 4 (4) points 1 and 10 of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended, based on Art. 7 (4) of Government Decision no. 144/2010 on the organisation and functioning of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. 1 – The Methodological rules for enforcement of provisions of Art. 13 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, regarding the registration of custom-made devices introduced on the market under their own name by manufacturers based in Romania, mentioned in the Annex which is an integral part of this Order, are approved.

Art. 2 - This Order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Alexandru Rafila

Annex

METHODOLOGICAL RULES

for enforcement of provisions of Art. 13 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, regarding the registration of custom-made devices introduced on the market under their own name by manufacturers based in Romania

Section I
General provisions

Art. 1 - (1) The terms used in these methodological rules 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 the Regulation.

(2) A mass-produced medical device that needs to be adapted in order to meet certain requirements of a specific user and, respectively, a device which was mass-produced by industrial means of production manufactured in accordance with the prescription of a physician or an authorised person are not considered custom-made devices.

Art. 2 - The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the NAMMDR, registers custom-made devices into the national database of medical devices.

Section II
Registration of custom-made devices on the market

Art. 3 - The manufacturer based in Romania has the obligation to register with the NAMMDR when introducing custom-made devices on the market under its own name, providing data regarding the address of the registered office and the description of the medical devices which are the object of its activity.

Art. 4 - (1) For the registration of medical devices provided for in Art. 3, the manufacturer submits to the NAMMDR the notification form in line with the Annex, completed with the data requested therein, together with the documents specified therein, depending on the class of the medical device, as the case may be.

(2) Upon the justified request of the NAMMDR, the manufacturer shall submit additional documents to those provided in the notification form, according to the legislation applicable to the type of the medical device introduced on the market, in within maximum 15 days from the date of receipt of the request, with confirmation of receipt.

Art. 5 - (1) Based on the documents provided for in Art. 4, the NAMMDR registers into the national database the information regarding the identification of custom-made devices introduced on the market and the information regarding the identification and contact details of the manufacturer, respectively the registered office, telephone number, fax number, e-mail address, contact person, and informs the manufacturer, through an address, about the registration of the custom-made devices. The national database is available on the NAMMDR website: https://www.anm.ro/dispozitive-medicale/baza-nationalade-date-cu-dispozitivemedicale/.

(2) The address provided for in paragraph (1) includes data regarding the identification of the medical device and is forwarded to the manufacturer within a maximum of 60 days from the receipt of the notification form completed with all the data and accompanied by the appropriate documents.

(3) If for a custom-made device, the NAMMDR has issued a registration certificate prior to the entry into force of these methodological rules, based on the provisions of Order of the Minister of Health no. 1.009/2016 regarding the registration of medical devices into the national database, with further amendments and supplementations, the certificate is valid 24 months from the date of publication in the European Journal of the announcement that the European database of medical devices (Eudamed) has become fully operational according to the provisions of Art. 34 (3) of the Regulation.

(4) Manufacturers for whom a registration certificate was issued prior to the entry into force of these methodological rules are obliged to comply with the provisions of Art. 4 (1).

Art. 6 - (1) Manufacturers who have registered the medical devices provided for in Art. 3, as well as those provided for in Art. 5 (4) have the obligation to notify the NAMMDR of any change that occurs after the registration of custom-made devices, including the suspension or termination of introduction on the market of custom-made devices.

(2) The amendments provided for in paragraph (1) is updated by the NAMMDR into the national database. The NAMMDR informs the manufacturer, via an address regarding the update of information concerning any amendment that occurs after the registration of custom-made devices, including the suspension or termination of the introduction on the market of custom-made devices, within a maximum of 60 days from the receipt of the notification provided in paragraph (1).

(3) The change of the headquarters or the name of the manufacturer, the establishment/deletion of work points is updated by the NAMMDR into the national database, in line with the ascertaining certificate issued by the trade registry office.

Art. 7 - This Annex is an integral part of these methodological rules.

Annex
to the methodological rules

F.CMD – Form for notification of introduction on the market of custom-made devices in line with the provisions of Art. 13 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

To
The Ministry of Health
The National Agency for Medicines and Medical Devices of Romania

1. Identification data for the notice
Date:
Please specify whether this is the first notice or a change:
|¯| first notice
|¯| change
|¯|suspension of introduction on the market
|¯| termination of introduction on the market
If this is a change, suspension or termination, please state the previously assigned number:
Number of pages of the notice:

2. Manufacturer identification data
Full name of the manufacturer:
Manufacturer's abbreviated name:
Address of the manufacturer's registered office:
Postal code: District/County:
City/Town: Street no.:
Telephone/Fax number:
E-mail address:
Contact person:
The person responsible for compliance with regulations specific to the field of medical devices:
Work/activity points: .....

3. Identification data of the custom-made device
Full name of the custom-made device:
Device type:
|¯| custom-made device
|¯| class IIa custom-made device
|¯| class IIb custom-made device
|¯| class III custom-made device
The generic category of the custom-made device and/or a brief description of the 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 ascertaining certificate issued by the trade register office, demonstrating the object of the company's activity, for the applicant units which have the obligation to register at the trade registry office

|¯| declaration issued by the manufacturer in accordance with Annex XIII of Regulation (UE) 2017/745

|¯| declaration issued by the manufacturer in accordance with Annex IX section I of Regulation (EU) 2017/745

|¯| declaration issued by the manufacturer in accordance with Annex XI part A of Regulation (EU) 2017/745

|¯| copy of the certificate of compliance issued by a notified body (for custom implantable medical devices)

The information provided in this notice is correct and the custom-made devices identified in section 3 meet the applicable requirements set forth in 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.

Name, first name and function

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Signature and stamp

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