Ministry of Health

ORDER No. 3.876 of 16 November 2023

on amendment and supplementation of certain regulatory documents in the field of medical devices and in vitro diagnostic medical devices

Published in: The Official Gazette of Romania no. 1.061 of 24 November 2023

On seeing approval report no. AR 20.967 of 16.11.2023 of the Pharmaceutical and Medical Devices Directorate and the notification of the National Agency for Medicines and Medical Devices of Romania no. 100.422 of 10.01.2023, registered at the Ministry of Health with no. P 11 of 10.01.2023,

taking into account the provisions of:

- paragraph 8 of the preamble, of art. 1 paragraph (6) and of art. 2 points 1 - 8 and 10 - 11 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;
- paragraph 8 of the preamble, of art. 1 paragraph (3) and of art. 2 points 1 - 9 and 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;
- art. 6 paragraph (3) and of art. 9 paragraph (4) 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. 1 paragraphs (1) and (2), art. 2, 4 and of art. 7 paragraph (4) 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 18 and 30 - 31 of Law 134/2019 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. I - Order of the Minister of Health no. 2.882/2021 on the manner of reporting suspected serious incidents related to medical devices, published in the Official Gazette of Romania, Part I, no. 1.226 of 24 December 2021, is amended as follows:

1. The Order's title is amended and shall read as follows:

"ORDER
on amendment and supplementation of certain regulatory documents in the field of medical devices and in vitro diagnostic medical devices"

2. Article 1 is amended and shall read as follows:

"Art. 1 - This order establishes the manner of reporting suspected serious incidents related to medical devices and in vitro diagnostic medical devices, in line with the provisions of Art. 9 paragraph (4) 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, precum and of art. 7 paragraph (4) 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."

3. Article 2 is amended and shall read as follows:

"Art. 2 - The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the NAMMDR, is the competent authority in the field of medical devices and in vitro diagnostic medical devices, responsible for the centralised registration, at national level, of reports received from healthcare professionals, users and patients."

4. Article 3 is amended and shall read as follows:

"Art. 3 - 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 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 referred to as Regulation (EU) ***2017/746***."

5. The title of Section II is amended and shall read as follows:

"SECTION II
Reporting suspected serious incidents related to medical devices and in vitro diagnostic medical devices"

6. Article 4 is amended and shall read as follows:

"Art. 4 - Healthcare professionals, patients and users report to the NAMMDR any suspected serious incident related to the medical devices and in vitro diagnostic medical devices they handle, within a maximum of 15 days from the date of occurrence of the incident, depending on its consequences."

7. Article 5 is amended and shall read as follows:

"Art. 5 - Patients or, as the case may be, relatives or legal representatives of patients can inform their physician, the economic operator from whom they have purchased the medical device or the in vitro diagnostic medical device and the NAMMDR, when they suspect the occurrence of any serious incident, as a result of the use of the respective medical device or in vitro diagnostic medical device."

8. Article 6 is amended and shall read as follows:

"Art. 6 - In order to report suspected serious incidents related to medical devices and in vitro diagnostic medical devices, healthcare professionals, patients and users shall use the form provided in the Annex which is an integral part of this Order, which they shall afterwards submit to the NAMMDR, completed with the data requested therein, in electronic format or on paper, using the contact data available on the NAMMDR website, section "Medical devices" - Vigilance."

9. The title of Section III is amended and shall read as follows:

"SECTION III
Evaluation of forms for reporting suspected serious incidents related to medical devices and in vitro diagnostic medical devices"

10. Article 7 is amended and shall read as follows:

"Art. 7 - The NAMMDR submits to the manufacturers of the medical devices or in vitro diagnostic medical devices in question the forms received from healthcare professionals, users or patients, provided for in Art. 6, as soon as it is informed about them, 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.

11. Article 8 is amended and shall read as follows:

"Art. 8 - (1) Within a maximum of 10 days after receiving the statement of reasons provided for in Art. 87 (11) paragraph 3 of the Regulation, the NAMMDR informs the manufacturer if it does not agree with the conclusion of the statement of reasons and may request the manufacturer to submit a report in accordance with the provisions of Art. 87 (1) - (5) of Regulation (EU) 2017/745 and to ensure that appropriate monitoring actions are undertaken in accordance with Art. 89 of Regulation (EU) 2017/745.

(2) In the case of in vitro diagnostic medical devices, in maximum of 10 days after receiving the exposure of the reasons provided in art. 82 Paragraph (11) Paragraph 3 of Regulation (EU) 2017/746, the NAMMDR informs the manufacturer if it does not agree with the conclusion of the exposure of reasons and may request the manufacturer to present a report in accordance with the provisions of art. 82 Paragraphs (1) - (5) of Regulation (EU) 2017/746 and to ensure that appropriate monitoring actions are taken according to art. 84 of Regulation (EU) 2017/746.

(3) In case the NAMMDR agrees with the exposure of reasons provided for in Paragraph (1) or (2), as the case may be, it shall inform the persons who reported the severely suspected incident, presenting the reasons of the manufacturer and the outcome of the final risk assessment."

12. The Annex is amended and replaced with Annex 1, which is an integral part of this Order.

Art. II - Order of the Minister of Health no. 2.242/2022 on approval of the procedure for grant of out-of-scope notices for products which do not fall under the scope 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, published in the Official Gazette of Romania, Part I, no 745 of 25 July 2022, is amended as follows:

1. The Order's title is amended and shall read as follows:

"ORDER
on approval of the procedure for granting out-of-scope notices by the National Agency for Medicines and Medical Devices of Romania"

2. Article 1 is amended and shall read as follows:

"Art. 1 - This order establishes the procedure for ***granting out-of-scope notices for medicinal products in extreme cases***, for which it is not clear whether or not they fall within the scope 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, hereinafter referred to as Regulation (EU) ***2017/745***, namely 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, hereinafter referred to as Regulation (EU) ***2017/746***."

3. Article 2 is amended and shall read as follows:

"Art. 2 - The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the NAMMDR, is the competent authority responsible for deciding, on a case-by-case basis, whether or not a product falls within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively, with the issuance of out-of-scope notices for products which do not fall within the scope of the aforementioned regulations, but for which, by virtue of the name and/or intended purpose of the products, it is not clear whether or not they fall within the scope of Regulation (EU) 2017/745 or Regulation (EU) 2017/746, respectively."

4. Article 3 is amended and shall read as follows:

"Art. 3 - The terms used in this Order have the significance established by Regulation (EU) 2017/745 and by Regulation (EU) 2017/746. "

5. Article 4 is amended and shall read as follows:

"Art. 4 – Upon request, the NAMMDR issues out-of-scope notices for the products which do not fall within the definitions provided in art. 2 Points 1 - 8; 10 and 11 of Regulation (EU) 2017/745, respectively art. 2 Points 1 - 9 and 11 of Regulation (EU) 2017/746, as the case may be, based on the information mentioned in the request for issuing out-of-scope notices, provided in the Annex. "

6. The Annex is amended and replaced with Annex 2 which is an integral part of this Order.

Art. III - Order of the Minister of Health no. 1.171/2022 on approval of the procedure for issuing a free-sale certificate for medical devices, published in the Official Gazette of Romania, Part I, no. 408 of 28 April 2022, is amended and supplemented as follows:

1. The Order's title is amended and shall read as follows:

"ORDER
on approval of the procedure for issuing a free-sale certificate for medical devices and in vitro diagnostic medical devices"

2. Article 1 is amended and shall read as follows:

"Art. 1 - This order establishes the procedure for issuing the certificate of free sale for medical devices and in vitro diagnostic medical devices, in line with the provisions of Art. 6 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, namely of art. 4 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."

3. Article 2 is amended and shall read as follows:

"Art. 2 - The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the ***NAMMDR***, is the competent authority in the field of medical devices and in vitro diagnostic medical devices, responsible for issuing a free-sale certificate for medical devices and in vitro diagnostic medical devices."

4. Article 3 is amended and shall read as follows:

"Art. 3 - The terms used in this Order have the significance 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/EE, hereinafter referred to as 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 referred to as Regulation (EU) ***2017/746."***

5. The title of Section II is amended and shall read as follows:

"SECTION II
The export of medical devices and in vitro diagnostic medical devices by authorised manufacturers and representatives in Romania"

6. Article 4 is amended and shall read as follows:

"Art. 4 - For the purpose of the export, at the request of the manufacturer of medical devices or in vitro diagnostic medical devices, as the case may be, or his authorised representative, based in Romania, the NAMMDR issues the free-sale certificate for medical devices, mentioned in Art. 6 of Emergency Government Ordinance no. 46/2021, respectively the certificate of free sale for in vitro diagnostic medical devices, mentioned in Art. 4 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, based on the information and documents mentioned in the request provided in Annex 1."

7. Article 5 is amended and shall read as follows:

"Art. 5 - (1) For issuing the free-sale certificate for medical devices or in vitro diagnostic medical devices, provided in art. 4, the applicant sends the NAMMDR the request for issuance of a free-sale certificate for medical devices or in vitro diagnostic medical devices, according to Annex 1, completed with the required data, together with the documents specified in its contents, as the case may be.

(2) At the justified request of the NAMMDR, the manufacturer submits additional compliance document, in addition to those provided in Annex 1, according to the legislation

applicable to medical devices or in vitro diagnostic medical devices, as the case may be, within maximum 15 days from the date of receipt of the request, with confirmation of receipt. "

8. Article 6 paragraph (1), points b) and d) are amended and shall read as follows:

"b) free-sale certificate for class I medical devices in line with Regulation (EU) 2017/745, in accordance with Annex 3;

.....

....

d) free-sale certificate for class I medical devices - Ia, IIb or III, with a valid compliance certificate, issued in line with Regulation (EU) 2017/745, in accordance with Annex 5;".

9. A new Article is introduced after Article 6, namely art. 6^{1}, which reads as follows:

"Art. 6^{1}- (1) Based on the documents provided in Annex 1, the NAMMDR issues the free-sale certificate for in vitro diagnostic medical devices, in English or in Romanian, according to the request of the manufacturer of in vitro diagnostic medical device or its authorised representative, in two original copies, one of which is issued to the applicant, and the other is kept in NAMMDR records, as follows:

a) Free-sale certificate for in vitro diagnosis medical devices which do not have critical characteristics issued according to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, in accordance with Annex 7;

b) free-sale certificate for class A in vitro diagnostic medical devices issued in line with Regulation (EU) 2017/746, in accordance with Annex 8;

c) free-sale certificate for medical devices for in vitro diagnostic medical devices with an EC compliance certificate, issued in line with Directive 98/79/EC, in accordance with Annex 9;

d) free-sale certificate for class A in vitro diagnostic medical devices placed on the market in sterile condition, B, C or D with a valid compliance certificate, issued in line with Regulation (EU) 2017/746, in accordance with Annex 10.

(2) The following shall be mentioned in the free-sale certificate:

a) the name, type and class of in vitro diagnostic medical devices;

b) the UDI device identifier – UDI-DI, as the case may be;

c) the manufacturer's name and address;

d) the number of the certificate of compliance, the date of issue and the expiration date;

e) the date by which the free-sale certificate for in vitro diagnostic medical devices is valid.

(3) The free-sale certificate for in vitro diagnostic medical devices shall be issued within maximum 30 days from the date of transmission of the request provided in art. 5 paragraph (1), completed and accompanied by the appropriate documents.

(4) If the request or documents provided in art. 5 are not complete, within maximum 20 days from registration of the request for issuing a free-sale certificate for in vitro diagnostic medical devices, the NAMMDR requests the manufacturer or authorised representative to transmit the missing information and documents.

(5) If the authorised manufacturer or representative does not send the information and documents requested in line with paragraph (4) within maximum 20 days, the request is dismissed. "

10. Article 7 is amended and shall read as follows:

"Art. 7 - (1) The free-sale certificate for medical devices is valid one year from the date of its issuance, for class I devices, except for the certificates mentioned in Art. 6 points c) and e), for class IIa, IIb or III medical devices of Regulation (EU) 2017/745, up to the term of validity stipulated in the certificates issued by notified bodies, except for the certificates mentioned in Art. 6 points c) and e), whose validity cannot exceed the 26th of May 2024.

(1) The free-sale certificate for in vitro diagnostic medical devices is valid one year from its date of issuance for class A devices, and in the case of class A in vitro diagnostic devices introduced on the market under sterile conditions, classes B, C and D of Regulation (EU) 2017/746, until the validity term provided in the certificates issued by the notified bodies, except for the certificates mentioned in Art. 6^{1} paragraph (1) point c), whose validity cannot

exceed the date corresponding to the risk class provided in art. 110 of Regulation (EU) 2017/746."

11. Annex 1 is amended and replaced with Annex 3 which is an integral part of this Order.

12. 4 new Annexes are introduced after Annex 6, namely Annexes 7 - 10 mentioned in Annexes 4 - 7 which are an integral part of this Order.

13. Article 8 is amended and shall read as follows:

"Art. 8 - Annexes 1 - 10 are an integral part of this Order."

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

Minister of health,
Alexandru Rafila

Annex 1*)
(Annex to Order of the Minister of Health no. 2.882/2021)

*) The Annex is reproduced in facsimile.

REPORTING FORM
of suspected serious incidents related to medical devices and in vitro diagnostic medical devices

AUTORITATEA COMPETENTĂ/COMPETENT AUTHORITY
THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA (ANMDMR)/NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA (NAMMDR)

RAPORTOR/RAPPORTEUR	
FORMULAR TRANSMIS DE:/FORM SUBMITTED BY:	
Profesionist din domeniul sănătăţii/Healthcare professional ⎕	
Utilizator/User ⎕	
Pacient/Patient ⎕	
Altul - vă rugăm specificaţi/Other - please specify ⎕	
NUME/NAME:	
ADRESA (strada, număr, oraş)/ADDRESS (street, number, city):	
TEL.	
FAX	
E-MAIL	
PERSOANA DE CONTACT/CONTACT PERSON:	
DATA TRANSMITERII/SUBMISSION DATE:	

INFORMAŢII DESPRE PRODUCĂTOR, DISPOZITIVUL MEDICAL SAU DISPOZITIVUL MEDICAL PENTRU DIAGNOSTIC IN VITRO ŞI ACCESORIILE ASOCIATE - DUPĂ CAZ/INFORMATION ABOUT THE MANUFACTURER, THE MEDICAL DEVICE OR IN VITRO DIAGNOSTIC MEDICAL DEVICE AND THE ASSOCIATED ACCESSORIES - AS THE CASE MAY BE
PRODUCĂTOR/MANUFACTURER:
ADRESA (strada, număr, oraş, ţară)/ADDRESS (street, number, city, country):
TIP DISPOZITIV MEDICAL (ex. seringă, stimulator cardiac, pompă de insulină, aparat auditiv, implanturi de diferite tipuri etc.) sau DISPOZITIV MEDICAL PENTRU DIAGNOSTIC IN VITRO (ex. dispozitiv autotestare glicemie, sarcină, test pentru detectarea SARS-COV-2, reactivi şi produşi de reacţie, inclusiv calibratori şi materiale de control pentru determinarea grupelor de sânge, pentru determinarea virusului hepatic, HIV etc.)/ ***TYPE OF MEDICAL DEVICE (e.g. syringe, peacemaker, insulin pump, hearing aid, various type of implants etc.) or in vitro diagnostic medical device (e.g. self-testing device for blood glucose, pregnancy, test for the detection of SARS-COV-2, reagents and reaction products, including calibrators and control materials for the determination of blood groups or determination of hepatitis, HIV etc.)***
DENUMIRE COMERCIALĂ DISPOZITIV MEDICAL sau DISPOZITIV MEDICAL PENTRU DIAGNOSTIC IN VITRO/TRADE NAME OF MEDICAL DEVICE or IN VITRO DIGNOSTIC MEDICAL DEVICE
MODEL SAU NR. CATALOG (DUPĂ CAZ)/MODEL OR CATALOGUE NUMBER (AS THE CASE MAY BE)
NR. SERIE SAU NR. LOT/SERIAL NUMBER OR LOT NUMBER ***SN -*** ***LOT -***

ACCESORIILE ASOCIATE DISPOZITIVULUI MEDICAL SAU DISPOZITIVULUI MEDICAL PENTRU DIAGNOSTIC IN VITRO (DUPĂ CAZ) - VĂ RUGĂM PRECIZAŢI/ACCESSORIES ASSOCIATED WITH THE MEDICAL DEVICE OR IN VITRO DIAGNOSTIC MEDICAL DEVICE (AS THE CASE MAY BE) - PLEASE SPECIFY
PRODUCĂTOR/MANUFACTURER:
DENUMIRE COMERCIALĂ/TRADE NAME:
MODEL SAU NR. CATALOG (DUPĂ CAZ)/MODEL OR CATALOGUE NUMBER (AS THE CASE MAY BE):
NR. SERIE SAU NR. LOT/SERIAL NUMBER OR LOT NUMBER

INFORMAŢII DESPRE PERSOANA(ELE) AFECTATĂ(E) - VĂ RUGĂM SPECIFICAŢI DACĂ ESTE NECESAR PENTRU EVALUARE/INFORMATION ABOUT THE AFFECTED PERSON(S) - PLEASE SPECIFY IF NECESSARY FOR EVALUATION	
INIŢIALE PENTRU NUME ŞI PRENUME/INITIALS FOR NAME AND SURNAME	
GEN (M - MASCULIN/F - FEMININ)/GENDER (M - MALE/F - FEMALE)	
ANUL NAŞTERII/DATE OF BIRTH	

INFORMAŢII DESPRE INCIDENTUL GRAV SUSPECTAT/INFORMATION ABOUT THE SUSPECTED SERIOUS INCIDENT	
DATA PRODUCERII INCIDENTULUI/THE DATE THE INCIDENT OCCURRED	
LOCUL PRODUCERII INCIDENTULUI (spital, cabinet medical, azil de bătrâni, acasă, altul - vă rugăm precizaţi)/THE PLACE THE INCIDENT OCCURRED (hospital, medical cabinet, asylum for elderly, at home, other - please specify)	
Spital/Hospital	☐
Cabinet medical/Medical cabinet	☐
Azil de bătrâni/Asylum for elderly	☐
Acasă/At home	☐
Altul - vă rugăm specificaţi/Other - please specify	☐
DESCRIEREA INCIDENTULUI ŞI A URMĂRILOR PENTRU PACIENT (DACĂ ESTE NECESAR, VĂ RUGĂM UTILIZAŢI PAGINI SUPLIMENTARE)/DESCRIPTION OF THE INCIDENT AND OF THE CONSEQUENCES FOR THE PATIENT (IF NECESSARY, PLEASE USE SUPPLEMENTARY SHEET)	
VĂ RUGĂM SĂ PRECIZAŢI DACĂ AU FOST CONTACTAŢI PRODUCĂTORUL,REPREZENTANTUL AUTORIZAT ÎN UE AL PRODUCĂTORULUI SAU FURNIZORUL./PLEASE SPECIFY IF THE MANUFACTURER, THE EU AUTHORISED REPRESENTATIVE OF THE MANUFACTURER OR THE SUPPLIER HAVE BEEN CONTACTED.	
DA/YES ☐	
.....	

NU/NO ☐

DESCRIEREA MĂSURILOR CORECTIVE ÎNTREPRINSE - SE COMPLETEAZĂ ÎN CAZUL INCIDENTELOR GRAVE CARE IMPLICĂ UTILIZAREA UNUI DISPOZITIV MEDICAL SAU A UNUI DISPOZITIV MEDICAL PENTRU DIAGNOSTIC IN VITRO FABRICAT ÎN CADRUL UNEI INSTITUŢII SANITARE PUBLICE ŞI PRIVATE DIN ROMÂNIA/DESCRIPTION OF THE CORRECTIVE MEASURES TAKEN - IS COMPLETED IN THE CASE OF SERIOUS INCIDENTS THAT INVOLVE THE USE OF A MEDICAL DEVICE OR AN IN VITRO DIAGNOSTIC MEDICAL DEVICE WITHIN A PUBLIC AND PRIVATE HEALTH INSTITUTION IN ROMANIA

Signature electronică (opţional)/***Digital signature (optional)***

Vă rugăm să aveţi în vedere că ANMDMR vă poate contacta în vederea obţinerii de informaţii suplimentare privind prezentul incident, dacă va fi necesar./***Please be aware that the NAMMDR can contact you in order to obtain supplementary information regarding this incident, if this will be necessary.***

Vă rugăm să aveţi în vedere că prin completarea şi transmiterea acestui formular de raportare vă exprimaţi acordul privind stocarea în siguranţă de către ANMDMR a informaţiilor, inclusiv datelor de contact furnizate în formular. În scopul îndeplinirii cerinţelor legale şi de raportare ale ANMDMR, detalii din acest raport pot fi distribuite şi altor entităţi implicate în activităţi de monitorizare, în conformitate cu cerinţele de protecţie a datelor. În acest fel informaţiile vor fi disponibile tuturor părţilor interesate. Aveţi dreptul de a cere o copie a datelor personale deţinute de ANMDMR şi a corecta sau elimina orice inexactităţi prezente în acestea./

Please be aware that by completing and submitting this reporting form you express the agreement regarding the safe storage by NAMMDR of the information, including the contact details provided in the form. In order to fulfil the legal and reporting requirements, details from this report may be distributed to other entities involved in monitoring activities, in accordance with the data protection requirements. This way, the information will be available to all interested parties. You have the right to request a copy of the personal data held by the NAMMDR and to correct or eliminate any inaccuracies.

Annex 2
(Annex to Order of the Minister of Health no. 2.242/2022)

REQUEST FOR ISSUANCE OF AN OUT-OF-SCOPE NOTICE

To:

The National Agency for Medicines and Medical Devices of Romania

Applicant (economic operator)
.....,
Headquartered in
.....
.....
Telephone number ....., fax number....., e-mail address
.....

Fiscal code ..... , Trade Register Registration Number

.....
IBAN account ..... opened at
.....,
Represented by
.....,
position
.....,

I request the evaluation of the attached documentation in order to establish that the following product does not fall into the category of medical devices/in vitro diagnostic medical devices, as well as the issuance of a denial in this regard:

No.	Product description (name, type)	Manufacturer/ country	Attached documents
			☐ declaration of compliance ☐ EC compliance certificate ☐ manual/user instructions ☐ copy of the label or packaging ☐ any other document that shows the intended purpose of the product ☐ proof of payment of the fee for issuance of the out-of-scope notice

I mention that I need this out-of-scope notice for:
[...] completion of customs formalities
[...] other cases (Please fill in.) .....

I hereby attach the documents mentioned in the table above (last column). The out-of-

scope notice shall be transmitted (please check one):
☐ by courier company
☐ by mail

Date .....

Full name .....
Signature .....

Annex 3
(Annex 1 to Order of the Minister of Health no. 1.171/2022)

APPLICATION
For issuance of a free-sale certificate for medical devices/in vitro diagnostic medical devices

To:

The National Agency for Medicines and Medical Devices of Romania

Applicant (economic operator)
.....,
headquartered in
.....
.....
Telephone number....., fax number..... , e-mail address
.....
Fiscal code ..... , Trade Register Registration Number
.....
IBAN account ..... opened at
.....,
Represented by
.....
,
position
.....
SRN (as the case may be):
.....
Position: |_| manufacturer |_| manufacturer's authorised representative
.....,
headquartered in
.....
.....,
manufacturing site
.....,
I hereby request the issuance of a free-sale certificate:
- In Romanian/English (Please choose.);
- For export in (The country where medical devices/in vitro diagnostic medical devices are exported shall be mentioned.) .....;
- For the following medical devices:

No.	Name of medical device/in vitro diagnostic medical device	Name of medical device/in vitro diagnostic medical device (English)	Product code	UDI-DI	Unique identification number of the certificate issued by the notified body	Class

I hereby attach the following documents to this application:

☐ declaration of compliance (copy);
☐ certificate of compliance (copy);
☐ company identification documents (registration certificate) (copy);
☐ other.....(Please state the documents.)
.....
.....
The free-sale certificate shall be forwarded (Please choose one.):
☐ by courier company
☐ by mail

Date .....

Full name .....
Signature .....

Annex 4
(Annex 7 to Order of the Minister of Health no. 1.171/2022)

FREE-SALE CERTIFICATE
for in vitro diagnostic medical devices which do not present critical characteristics, issued in line with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

.....(economic operator), headquartered in ....., Romania and the work point/production site in ....., Trade Register Registration Number ..... , UNIQUE FISCAL REGISTRATION CODE (CUI) , is engaged in the manufacture of the following in vitro diagnostic medical device(s):

Name and type of product	Class	Registration code

This/these product(s) is/are EC marked in line with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and is compliant with the provisions of art. 110 paragraph (2) of Regulation (EU) 2017/746, by the manufacturer's declaration that it has reclassified the device in accordance with Annex VIII la 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.

Upon request of..... (economic operator),

The National Agency for Medicines and Medical Devices of Romania

hereby certifies that the above-mentioned device(s) can be marketed without restrictions in Romania, the member states of the European Union and other states which have concluded framework agreements with the European Economic Area.

This certificate has been issued to confirm that the above-mentioned device(s), subject to the declaration of compliance which allows free movement within the European Union, is/are the same product(s) exported and marketed in
.....(third country of the European Union).

Bucharest, (date of issuance)

This document is valid until.....(date) and certifies that the manufacturer has issued a declaration of compliance in line with Directive 98/79/EC and that, following 26 May 2022, it continues to be compliant with the specified Directive and that significant changes to the project or the proposed purpose are not carried out.

The requirements of Regulation (EU) 2017/746 on post-market surveillance, market surveillance, vigilance, registration of economic operators and devices apply in place of corresponding requirements of Directive 98/79/EC of the Council.

This free-sale certificate can only be used for export from the European Union.

President of the National Agency for Medicines and Medical Devices of Romania,
.....

Annex 5
(Annex 8 to Order of the Minister of Health no. 1.171/2022)

FREE-SALE CERTIFICATE
for class A in vitro diagnostic medical devices, issued in line with 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

.....(economic operator), headquartered in ....., Romania and the work point/production site in ....., Trade Register Registration Number ..... , unique fiscal registration code (CUI) ....., is engaged in the manufacture of the following in vitro diagnostic medical device(s) :

Name and type of product	Class	UDI-DI	Registration code

This/these product(s) is/are EC marked in line with 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.

Upon request of..... (economic operator),

The National Agency for Medicines and Medical Devices of Romania hereby

certifies that the above-mentioned device(s) can be marketed without restrictions in Romania, the member states of the European Union and other states which have concluded framework agreements with the European Economic Area.

This certificate has been issued to confirm that the above-mentioned device(s), subject to the declaration of compliance which allows free movement within the European Union, is/are the same product(s) exported and marketed in ..... (third country of the European Union).

Bucharest, (date of issuance)

This document is valid until (date) and certifies that the manufacturer has issued a declaration of compliance in line with Regulation (EU) 2017/746.

This free-sale certificate can only be used for export from the European Union.

President of the National Agency for Medicines and Medical Devices of Romania,
.....

Annex 6
(Annex 9 to Order of the Minister of Health no. 1.171/2022)

FREE-SALE CERTIFICATE
for in vitro diagnostic medical devices with an EC compliance certificate, issued in line with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

.....(economic operator), headquartered in ....., Romania and the work point/production site in ....., Trade Register Registration Number ..... , UNIQUE FISCAL REGISTRATION CODE (CUI) , is engaged in the manufacture of the following in vitro diagnostic medical device(s):

Name and type of product(s)	Registration code

This/these device(s) is/are certified in line with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, in line with the certificate(s) [number(s) of compliance certificate(s)] issued by [name and number of the notified body], issued on (date) and valid until (date).

Upon request of..... (economic operator),

The National Agency for Medicines and Medical Devices of Romania hereby certifies that the above-mentioned device(s) can be marketed without restrictions in Romania, the member states of the European Union and other states which have concluded framework agreements with the European Economic Area.

This certificate has been issued to confirm that the above-mentioned device(s), subject to the declaration of compliance which allows free movement within the European Union, is/are the same product(s) exported and marketed in ..... (third country of the European Union).

Bucharest, (date of issuance)

This document is valid until.....(date) and certifies that the device(s) is/are subject to a valid EC certificate issued in line with Directive 98/79/EC prior to 26 May 2022 and is compliant with the provisions of art. 110 paragraph (3) 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 requirements of Regulation (EU) 2017/746 on post-market surveillance, market surveillance, vigilance, registration of economic operators and devices apply in place of corresponding requirements of Directive 98/79/EC.

This free-sale certificate can only be used for export from the European Union.

President of the National Agency for Medicines and Medical Devices of Romania,

.....

Annex 7
(Annex 10 to Order of the Minister of Health no. 1.171/2022)

FREE-SALE CERTIFICATE
for class A in vitro diagnostic medical devices placed on the market in sterile condition, class B, C or D with a valid compliance certificate, issued in line with 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

.....(economic operator), headquartered in ....., Romania and the work point/production site in ....., Trade Register Registration Number ..... , unique fiscal registration code (CUI) , has in its field of activity the manufacture of the following in vitro diagnostic medical device(s):

Name and type of product(s)	UDI-DI	Risk class in line with Regulation (EU) 2017/746

This/these device(s) is/are certified in line with 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, in line with the certificate(s) [number(s) of compliance certificate(s)] issued by [name and number of the notified body], issued on (date) and valid until
(date)

Upon request of..... (economic operator),

The National Agency for Medicines and Medical Devices of Romania hereby

certifies that the above-mentioned device(s) can be marketed without restrictions in Romania, in the member states of the European Union and in other countries which have concluded framework agreements with the European Economic Area.

This certificate has been issued to confirm that the above-mentioned device(s), subject to the declaration of compliance which allows free movement within the European Union, is/are the same product(s) exported and marketed in .....(third country of the European Union).

Bucharest, (date of issuance)

This document is valid until (date) and certifies that the device(s) is/are subject to a valid EU certificate issued in line with Regulation (EU) 2017/746.

This free-sale certificate can only be used for export from the European Union.

President of the National Agency for Medicines and Medical Devices of Romania,
.....