Documents whose amendment is included in updated form

Type	Number	Date of issuance	Date of application	Approved / Rejected
Order	3876	16.11.2023	24.11.2023	

Minister of Health

ORDER No. 2.242*)
of 20 July 2022
on approval of the procedure for grant of out-of-scope notices by the National Agency for Medicines and Medical Devices

***) Note:**
Includes all changes made to the official document, published in the Official Gazette of Romania, mentioned in:
Order of the Minister of Health no. 3.876/16.11.2023 Published in the Official Gazette of Romania no. 1.061/24.11.2023

On seeing common approval report no. AR 12.268 of 18.07.2022 of the Pharmaceutical and Medical Devices Directorate and of the National Agency for Medicines and Medical Devices of Romania and the notification of the National Agency for Medicines and Medical Devices of Romania no. 52.469E of 22.02.2022, registered at the Ministry of Health with no. P 0285 of 23.02.2022,

taking into account the provisions of:

- 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 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:

Section I
General provisions

Art. 1 - *This Order establishes the procedure for grant of out-of-scope notices for products in borderline cases, for which it is not clear whether 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****, or of the 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****.*

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 grant of out-of-scope notices for products*

which do not fall within the scope of the aforementioned regulations, but for which, by virtue of their name and/or intended purpose, it is unclear whether or not they fall within the scope of Regulation (EU) 2017/745 or Regulation (EU) 2017/746, respectively.

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

Section II
Procedure for grant of out-of-scope notices

Art. 4 - *The NAMMDR grants, upon request, out-of-scope notices for products which do not fall within the definitions set out in Article 2(1) - (8); (10) and (11) of Regulation (EU) 2017/745, and Article 2(1) - (9) and (11) of Regulation (EU) 2017/746, as the case may be, according to the information specified in the request for grant of an out-of-scope notice, set out in the Annex.*

Art. 5 - (1) To issue the out-of-scope notice provided for in Art. 4, the applicant shall submit to the NAMMDR the request for grant of an out-of-scope notice, according to the annex which is an integral part of this Order, supplemented with the data requested therein, together with the documents specified therein, as the case may be.

(2) Upon justified request of the NAMMDR, the applicant shall submit additional documents in addition to those provided in the Annex, within maximum 15 days from receipt of the request.

Art. 6 - (1) Based on the documents provided for in Art. 5 and only after receiving proof of payment of the fee, the NAMMDR grants the out-of-scope notice for products which do not fall within the scope of the Regulation. If the products for which the out-of-scope notice is requested fall within the scope of the Regulation, the NAMMDR sends the applicant a notice rejecting the application, specifying the grounds for its issuance.

(2) The out-of-scope notice for each product mentioned in the application provided for in Art. 5 par. (1) shall be issued by the NAMMDR, in two original copies, one of which shall be issued to the applicant and the other shall be kept in the records of the NAMMDR. The out-of-scope notice shall specify the following:

a) name/type and brand of the product;

b) name and address of the manufacturer;

c) number of the certificate of compliance, date of issue and expiry date, as applicable;

d) any other documents indicating the product's intended purpose.

(3) The out-of-scope notice shall be issued within maximum 30 days from the date of submission of the application provided for in Art. 5 paragraph (1), completed and accompanied by the appropriate documents.

(4) If the application or documents provided for in Article 5 are not complete, within maximum 20 days from registration of the application for grant of an out-of-scope notice, the NAMMDR shall request the applicant (namely the economic operator) to submit the missing information and documents.

(5) If the applicant does not submit the information and documents requested according to paragraph (4) within maximum 30 days from receipt of the request by the NAMMDR, the application shall be dismissed, without refund of the fee paid for grant of an out-of-scope notice.

Art. 7 – The Annex is an integral part of this Order.

Section III
Final provisions

Art. 8 - This Order shall be published in the Official Gazette of Romania, Part I.

On behalf of the minister of Health,
Adriana Pistol,
Secretary of state

Annex

APLICATION FOR GRANT 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
.....
Unique registration code ..... , Trade Register Registration Number
.....
International Bank Account Number (IBAN)..... opened at
.....,
represented by
.....,
occupation
.....,

I hereby 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 grant of an out-of-scope notice in this regard:

No.	*Product description (name, type)*	*Manufacturer/ country*	*Attached documents*
			|_| *declaration of conformity* |_| *CE Certificate of Conformity (CoC)* |_| *manual/instructions for use* |_| *copy of the label or packaging* |_| *any other document which shows the intended purpose of the product* |_| *proof of payment of the fee for grant of an out-of-scope notice*

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

I hereby attach to this application the documents mentioned in the table above (last column).

The out-of-scope notice will be transmitted (One option will be chosen.):
|_| by courier company
|_| by mail

Date .....

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