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**	

Ministry of Health

ORDER No. 1171*)
of 18 April 2022
on approval of the procedure for grant of free-sale certificates for medical devices and in-vitro diagnostic 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 6.571 of 18.04.2022 of the Pharmaceutical, Medical Devices and Health Technologies Directorate and of the National Agency for Medicines and Medical Devices of Romania and notification no. 66.625E of 25.11.2021, registered at the Ministry of Health with no. 1/27.610 of 26.11.2021,

taking into account the provisions of:

- Art. 6 (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. 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 30 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 issuing the certificate for free sale of 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 with the provisions 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.*

Art. 2 - *The National Agency for Medicines and Medical Devices of Romania, hereinafter the ANMDMR, is the competent authority in the field of medical devices and in vitro diagnostic medical devices, responsible for issuance of the certificate for free sale of medical devices and in vitro diagnostic medical devices.*

Art. 3 - *The terms used in this Order 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 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.***

Section II
Export of medical devices and in vitro diagnostic medical devices by manufacturers and authorised representatives headquartered in Romania

Art. 4 - *For export purposes, upon request of the manufacturer of medical devices or in vitro diagnostic medical devices, as the case may be, or of their*

authorised representative, headquartered in Romania, the ANMDMR issues the certificate for free sale of medical devices, mentioned in Art. 6 of Emergency Government Ordinance no. 46/2021, namely the certificate for free sale of 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 application set out in Annex 1."

Art. 5 - *(1) For issuance of a certificate for free sale of medical devices and in vitro diagnostic medical devices, mentioned in Art. 4, the applicant submits to the ANMDMR the request for issuance of a certificate for free sale of medical devices and in vitro diagnostic medical devices, in line with Annex 1, filled in with the data requested herein, 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 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 receipt of the request, with acknowledgement of receipt.

Art. 6 - (1) Based on the documents provided in Annex 1, the ANMDMR issues the certificate for free sale of medical devices in English or Romanian, as requested by the medical device manufacturer or their authorised representative, in two original copies, one of which is issued to the applicant and the other is stored in the ANMDMR records, as follows:

a) certificate for free sale of class I medical devices in line with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as further amended and supplemented, in line with Annex 2;

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

c) certificate for free sale of class IIa, IIb or III medical devices, with valid CE certificate, issued in accordance with Directive 93/42/EEC of the Council, in line with Annex 4;

d) *certificate for free sale of class IIa, IIb or III medical devices, with valid certificate of conformity, issued in accordance with Regulation (EU) 2017/745, in line with Annex 5;*

e) certificate for free sale of active implantable medical devices, with valid certificate of conformity, issued in accordance with Directive 90/385/EEC, in line with Annex 6.

(2) The certificate for free sale mentions the following:

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

b) the unique device identification system of a medical device ***(UDI-DI)***, as the case may be;

c) the manufacturer’s name and address;

d) the number of the certificate of conformity, date of issue and expiry date;

e) the date until which the certificate for free sale of medical devices is valid.

(3) The certificate for free sale of medical devices is issued within maximum 30 days from submission of the application mentioned in Art. 5 paragraph (1), filled in and accompanied by the appropriate documents.

(4) If the application or documents mentioned in Art. 5 are not complete, within maximum 20 days from registration of the application for issuing the certificate for free sale of medical devices, the ANMDMR requests the manufacturer or their authorised representative to submit the missing information and documents.

(5) If the manufacturer or their authorised representative does not submit the information and documents requested under paragraph (4) within maximum 20 days, the application shall be dismissed.

Art. 6[1]*)- *(1) Based on the documents provided in Annex 1, the ANMDMR issues the certificate for free sale of in vitro diagnostic medical devices, in English or Romanian, as requested by the manufacturer of in vitro diagnostic medical devices or their authorised representative, in two original copies, one of which is issued to the applicant and the other is stored in the ANMDMR records, as follows:*

a) certificate for free sale of in vitro diagnostic medical devices which do not have critical characteristics issued in accordance 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 Annex 7;

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

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

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

(2) *The certificate for free sale mentions the following:*

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

b) the unique device identification system of a medical device (UDI-DI), as the case may be;

c) the manufacturer's name and address;

d) the number of the certificate of conformity, date of issue and expiry date;

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

(3) *The certificate for free sale of in vitro diagnostic medical devices is issued within maximum 30 days from submission of the application mentioned in Art. 5 paragraph (1), filled in and accompanied by the appropriate documents.*

(4) *If the application or documents mentioned in Art. 5 are not complete, within maximum 20 days from registration of the application for issuing the certificate for free sale of in vitro diagnostic medical devices, the ANMDMR requests the manufacturer or their authorised representative to submit the missing information and documents.*

(5) *If the manufacturer or their authorised representative does not submit the information and documents requested under paragraph (4) within maximum 20 days, the application shall be dismissed.*

**) Art. 6[1] was introduced by Order of the Minister of Health no. 3.876/2023 of 24 November 2023*

Art. 7 - *(1) The certificate for free sale of medical devices is valid one year from the date of its issuance, for class I devices, and 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.*

(2) The certificate for free sale of 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, and for class 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.

Section III
Final provisions

Art. 8 – *Annexes 1 - 10 are integral parts of this Order.*
Art. 9 – The ANMDMR shall carry out the provisions of this Order.
Art. 10 - This Order shall be published in the Official Gazette of Romania, Part I.

On behalf of the minister of Health,
Romică-Andrei Baciu,
Secretary of state

Annex 1

APPLICATION
for issuance of a certificate for free sale of 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
.....
unique registration code..... , Trade Register Registration Number
.....
International Bank Account Number (IBAN)…. opened at
……,
represented by
.....,
occupation
.....
Single registration number (SRN) (as the case may be):
.....
Status: |_| manufacturer |_| manufacturer's authorised representative
……,
headquartered in
.....,
manufacturing site
.....,
I hereby require the issuance of a free sale certificate:
- In Romanian/English (please choose);
- For export to (The country to which medical devices/in vitro diagnostic medical devices are exported shall be mentioned.) .....;
- For the following medical devices:

No.	*Name of the medical device/*	*Name of the medical device/*	*Product code*	*UDI-DI*	*Unique identification number*	*Class*

	in vitro diagnostic medical device	*in vitro diagnostic medical device (English)*			*of the certificate issued by the notified body*	

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 certificate for free sale shall be forwarded (please choose one):
|_| by courier company
|_| by mail

Date ..... *Full name .....*
Signature .....

Annex 2

CERTIFICATE
for free sale of class I medical devices

..... [economic operator], headquartered in ....., Romania, having its outlet/manufacturing site in ....., Trade Register Registration Number ..... , unique registration code ..... , manufactures the following medical device(s), in line with their field of activity:

Product name and type	Class	Registration code
	I	

This/these product(s) is/are EC marked in line with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as further amended and supplemented, and complies with the provisions of Art. 120 paragraph (2) 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, through

the manufacturer's declaration that they have reclassified the device in line with Section III din Annex VIII la Regulation (EU) 2017/745.

Upon request of the.....[economic operator], **the National Agency for Medicines and Medical Devices of Romania** hereby certifies that that the aforementioned medical device(s) may be marketed without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation 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 proves that the manufacturer has issued a declaration of compliance in line with Directive 93/42/EEC, as further amended and supplemented, and that after the 26th of May 2021 the document continues to be compliant with the mentioned Directive and that no significant changes are made to the project or its intended purpose.

The requirements of Regulation (EU) 2017/745 on post-market surveillance, market surveillance, vigilance, registration of economic operators and devices apply in place of the corresponding requirements of Directive 93/42/EEC of the Council, as further amended and supplemented.

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 3

CERTIFICATE
for free sale of class I medical devices

..... [economic operator], headquartered in …..... , Romania, having its outlet/manufacturing site in ....., Trade Register Registration Number....., unique registration code . ....., manufactures the following medical device(s), in line with their field of activity:

Product name and type	Class	UDI -DI	Registration code
	I		

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

Upon request of the..... [economic operator],

The National Agency for Medicines and Medical Devices of Romania hereby certifies that that the aforementioned medical device(s) may be marketed

without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation 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 proves that the manufacturer has issued a declaration of compliance with Regulation (EU) 2017/745.

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 4

CERTIFICATE
for free sale of class IIa, IIb or III medical devices

..... [economic operator], headquartered in ..... , Romania, having its outlet/manufacturing site in ....., Trade Register Registration Number , unique registration code …….. , manufactures the following medical device(s), in line with their field of activity:

Product name and type	Risk class in line with MDD 93/42/EEC

This/these medical device(s) is/are certified in line with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as further amended and supplemented, in line with certificate(s) [number(s) of the certificate(s) of conformity] issued by [name and number of the notified body], issued on [date] and valid until [date]

Upon request of the……. [economic operator], **the National Agency for Medicines and Medical Devices of Romania** hereby certifies that that the aforementioned medical device(s) may be marketed without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation within the European Union, is/are the same product(s) exported and marketed in ……...[third country of the European Union].

During assessments, [applicant economic operator] proved that the aforementioned medical device(s), within their own production (regardless of the sales market), is/are designed and manufactured so that, whether used in accordance with their intended purpose, does/do not compromise the safety or clinical condition of the patient or the safety and health of users.

Bucharest, [date of issuance]

This document is valid until ..... [date] and proves that the medical device(s) is/are subject to a valid CE certificate issued in line with Directive 93/42/EEC of the Council before the 26th of May 2021 and complies with the provisions of Art. 120 paragraph (3) 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. The requirements of Regulation (EU) 2017/745 on post-market surveillance, market surveillance,
vigilance, registration of economic operators and devices apply in place of the corresponding requirements of Directive 93/42/EEC, as further amended and supplemented.

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

CERTIFICATE
for free sale of class IIa, IIb or III medical devices

..... [economic operator], headquartered in …..... , Romania, having its outlet/manufacturing site in ....., Trade Register Registration Number....., UNIQUE REGISTRATION CODE …..... , manufactures the following medical device(s), in line with their field of activity:

Product name and type	UDI - DI	Risk class in line with Regulation (EU) 2017/745

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

Upon request of the.....[economic operator],

The National Agency for Medicines and Medical Devices of Romania hereby certifies that that the aforementioned medical device(s) may be marketed
without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation within the European Union, is/are the same product(s) exported and marketed in
..... [third country of the European Union].

During assessments, [applicant economic operator] proved that the aforementioned medical device(s), within their own production (regardless of the sales market), is/are designed and manufactured so that, whether used in accordance with their intended purpose, does/do not compromise the safety or clinical condition of the patient or the safety and health of users.

Bucharest, [date of issuance]

This document is valid until [date] and proves that the medical device(s) is/are subject to a valid EU certificate issued in line with Regulation (EU) 2017/745.

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

CERTIFICATE
for free sale of active implantable medical devices

..... [economic operator], headquartered in …..... , Romania, having its outlet/manufacturing site in ....., Trade Register Registration Number ..... , unique registration code . ..... , manufactures the following medical device(s), in line with their field of activity:

Product name and type	Risk class in line with MDD 93/42/EEC

This/these medical device(s) is/are certified in line with Directive 90/385/EEC of the Council of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as further amended and supplemented, in line with certificate(s) [number(s) of the certificate(s) of conformity] issued by [name and number of the notified body], issued on [date] and valid until [date]

Upon request of the.....[economic operator],

The National Agency for Medicines and Medical Devices of Romania hereby certifies that that the aforementioned medical device(s) may be marketed without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation within the European Union, is/are the same product(s) exported and marketed in …….. [third country of the European Union].

During assessments, [applicant economic operator] proved that the aforementioned medical device(s), within their own production (regardless of the sales market), is/are designed and manufactured so that, whether used in accordance with their intended purpose, does/do not compromise the safety or clinical condition of the patient or the safety and health of users.

Bucharest, [date of issuance]

This document is valid until .....[date] and proves that the medical device(s) is/are subject to a valid CE certificate issued in line with Directive 90/385/EEC before the 26th of May 2021 and complies with the provisions of Art. 120 paragraph (3) 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. The requirements 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, as further amended and supplemented.

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 7 was added through Order of the Minister of Health no. 3.876/2023 of 24 November 2023.*

CERTIFICATE
for free sale of in vitro diagnostic medical devices which do not have critical characteristics, issued in accordance 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 having its outlet/manufacturing site in ....., Trade Register Registration Number....., unique registration code ....., 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 complies/comply with the provisions of Art. 110 paragraph (2) din Regulation (EU) 2017/746, through the manufacturer's declaration that they have reclassified the device in line 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 the.....(economic operator),

The National Agency for Medicines and Medical Devices of Romania hereby certifies that that the aforementioned medical device(s) may be marketed without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation 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.....and proves that the

manufacturer has issued a declaration of compliance in line with Directive 98/79/EC and that after the 26th of May 2022 the document continues to be compliant with the mentioned Directive and that no significant changes are made to the project or its intended purpose.

The requirements of Regulation (EU) 2017/746 on post-market surveillance, market surveillance, vigilance, registration of economic operators and devices apply in place of the 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 8*)

**) Annex 8 was added through Order of the Minister of Health no. 3.876/2023 of 24 November 2023.*

CERTIFICATE
for free sale of in class A vitro diagnostic medical devices, issued in accordance 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 having its outlet/manufacturing site in ....., Trade Register Registration Number....., UNIQUE REGISTRATION CODE ..... , 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 the.....(economic operator),

the National Agency for Medicines and Medical Devices of Romania hereby certifies that that the aforementioned medical device(s) may be marketed without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation 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 and proves that the manufacturer has issued a declaration of compliance 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 9*)

**) Annex 9 was added through Order of the Minister of Health no. 3.876/2023 of 24 November 2023.*

CERTIFICATE
for free sale of in vitro diagnostic medical devices with valid CE certificate, issued in accordance 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 having its outlet/manufacturing site in ....., Trade Register Registration Number....., UNIQUE REGISTRATION CODE……, is engaged in the manufacture of the following in vitro diagnostic medical device(s):

Product name and type	*Registration code*

This/these medical 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 certificate(s) [number(s) of the certificate(s) of conformity] issued by [name and number of the notified body], issued on (date) and valid until (date).

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

the National Agency for Medicines and Medical Devices of Romania hereby certifies that that the aforementioned medical device(s) may be marketed without restrictions in Romania, EU member states and other states which have signed a framework agreement with the European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation 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..... and proves that the medical device(s) is/are subject to a valid CE certificate issued in line with Directive 98/79/EC before the 26th of May 2022 and complies/comply 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 the 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 10*)

**) Annex 10 was added through Order of the Minister of Health no. 3.876/2023 of 24 November 2023.*

CERTIFICATE

for free sale of class A, B, C or D in vitro diagnostic medical devices placed on the market in sterile state, with valid certificate of conformity, issued in accordance 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 having its outlet/manufacturing site in ....., Trade Register Registration Number....., UNIQUE REGISTRATION CODE……, is engaged in the manufacture of the following in vitro diagnostic medical device(s):

Product name and type	*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 certificate(s) [number(s) of the certificate(s) of conformity] issued by [name and number of the notified body], issued on (date) and valid until (date)

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

The National Agency for Medicines and Medical Devices of Romania hereby certifies that that the aforementioned medical device(s) may be marketed without restrictions in Romania, EU member states and other states which have signed framework agreements with European Economic Area.

This certificate was issued to confirm that the aforementioned medical device(s), which is/are subject to the declaration of compliance allowing free circulation 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 and proves that the medical 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,

.....