MINISTRY OF HEALTH OF VIETNAM

No. 10/2023/TT-BYT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

Hanoi, May 11, 2023

CIRCULAR

AMENDMENTS TO CERTAIN ARTICLES OF CIRCULAR NO. 19/2021/TT-BYT DATED NOVEMBER 16, 2021 OF THE MINISTER OF HEALTH ON TEMPLATES OF DOCUMENTS AND REPORTS ON IMPLEMENTATION OF DECREE NO. 98/2021/ND-CP DATED NOVEMBER 08, 2021 OF THE GOVERNMENT ON MANAGEMENT OF MEDICAL DEVICES

Pursuant to Decree No. 95/2022/ND-CP dated November 15, 2022 of the Government on functions, tasks, powers and organizational structure of the Ministry of Health of Vietnam;

Pursuant to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices;

Pursuant to Decree No. 07/2023/ND-CP dated March 03, 2023 of the Government on amendments to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices;

At the request of the Director of the Department of Medical Equipment and Construction;

The Minister of Health hereby promulgates a Circular on amendments to certain Articles of Circular No. 19/2021/TT-BYT dated November 16, 2021 of the Minister of Health on templates of documents and reports on implementation of Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices.

Article 1. Amendments to Article 3 of Circular No. 19/2021/TT-BYT dated November 16, 2021 of the Minister of Health on templates of documents and reports on implementation of Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices

1. Amendments to Clause 1 of Article 3 concerning regulations in Appendix I:

a) Template No. 02.01; Template No. 02.02; Template No. 03.01; Template No. 03.02; Template No. 03.03; Template No. 03.04 and Template No. 03.05 are amended.

b) Template No. 05.A and Template No. 05.B are added.

2. Amendments to Clause 4 of Article 3 concerning regulations in Appendix IV:

a) Template No. 02.01; Template No. 02.02; Template No. 03; Template No. 05; Template No. 07 are amended.

b) Template No. 05.A and Template No. 05.B are added.

3. Addition of Clause 6a to Article 3:

"6a. Appendix VI.A: Template of Letter of authorization of issuance of medical device import licences according to regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP."

4. Amendments to Clause 8 of Article 3 concerning regulations in Appendix VIII:

a) Template No. 04 is amended.

b) Template No. 06 is added.

Article 2. Transitional regulations

1. Documents contained in dossiers on declaration of applied standards or applications for certificates of marketing authorization or applications for import licences that are submitted before the day on which this Circular comes into force shall be continued to be applied to issue numbers of marketing authorization and import licences, unless amendments to such dossiers and applications are required.

2. If letters of authorization using the prescribed template are signed for promulgation by medical devices' owners before the day on which this Circular comes into force, they shall be continuously included in applications for medical device import licences.

Article 3. Implementation clauses

1. This Circular comes into force from the day on which it is signed.

2. Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Health for consideration and settlement./.

PP. MINISTER
DEPUTY MINISTER

Do Xuan Tuyen

APPENDIX I

TEMPLATE OF DECLARATION OF, DISCLOSURE OF, STATEMENT OF, NOTIFICATION OF AND APPLICATION FOR ISSUANCE OF MARKETING AUTHORIZATION NUMBER, IMPORT LICENCE AND CERTIFICATE OF FREE SALE
(enclosed with Circular No. 10/2023/TT-BYT dated May 11, 2023 of the Minister of Health)

Template No. 02.01	Declaration of applied standards of class A medical devices
Template No. 02.02	Declaration of applied standards of class B medical devices
Template No. 03.01	Application for issuance of marketing authorization numbers of class C and class D medical devices subject to national technical regulations
Template No. 03.02	Application for issuance of marketing authorization numbers of class C and class D medical devices which are measuring instruments subject to sample approval
Template No. 03.03	Application for issuance of marketing authorization numbers of class C and class D medical devices eligible for quick issuance
Template No. 03.04	Application for issuance of marketing authorization numbers of class C and class D medical devices eligible for emergency use authorization
Template No. 03.05	Application for issuance of marketing authorization numbers of other class C and class D medical devices
Template No. 05.A	Applications for medical device import licences serving the implementation of the regulations in Clause 8 Article 1 of Decree No. 07/2023/ND-CP dated March 03, 2023 of the Government on amendments to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices (hereinafter referred to as "Decree No. 07/2023/ND-CP")
Template No. 05.B	Orders for import of biological products for in vitro diagnostic tests serving the implementation of the regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP

Template No. 02.01

FACILITY'S NAME

No. ……..

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

…[1]……, day…….....month……..year 20……

DECLARATION OF APPLIED STANDARDS OF CLASS A MEDICAL DEVICES

To: ……[2]……

1. Name of declarant:……

TIN or number of Licence for representative office establishment: …….

Address:……..[3]…….

Landline: ……. Fax:……..

Email:……

2. Legal representative of the facility:

Full name:……..…….

ID/passport: ……..date of issue: ……. Place of issue: .....

Landline:…….Mobile phone: …….

3. Class A medical device:

General medical device[4]: * or IVD medical device: *

Name of the medical device[5]:……

Trade name[6] (if any):……..…….

Global Medical Device Nomenclature - GMDN code *(if any):* ……..

Model:……

Product code *(if any)*: ……..

Packing specification *(if any):* …….

Uses:……

Name of manufacturer:……

Address of manufacturer:……

Applied standard: .....

4. For medical device that contains narcotic or precursor:

Name of the narcotic or precursor: ……..Scientific name: ……

CAS Registry Number: ……..

Concentration and content of the narcotic or precursor: .....

Total content of narcotics and precursors in a smallest packing unit:

……
.

5. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

6. Information about warranty facility *(if any):*

Name of facility:……

Address:……

Landline:…….Mobile phone: ……

7. Number of declaration of eligibility for domestic production of medical devices:

……
.

Declaration of applied standards of class A medical device

Enclosures:

1.	ISO 13485 Certificate	*
2.	Letter of authorization of the owner of the medical device	*
3.	Confirmation of eligibility for warranty	*
4.	Documentation of brief technical description of the medical device in Vietnamese	*
5.	Technical documentation of functions and specifications of the medical device promulgated by its owner	*

6.	Technical documents in Vietnamese enclosed with documents on materials, product safety, manufacturing process and clinical and preclinical research reports including reports on the stability of reagents, calibrators and in vitro control materials.	*
7.	Standard version declared to be applied by the owner of the medical device	*
8.	Certificate of conformity with standards	*
9.	For a medical device manufactured in Vietnam: result of evaluating chemical, physical and microbiological parameters and other parameters granted by a qualified facility according to the provisions of law on conformity assessment, or Certificate of quality assessment issued by a competent authority of Vietnam for in vitro diagnostic medical devices	*
10.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese.	*
11.	Template of label on the medical device	*
12.	Certificate of free sale for the imported medical device	*

We hereby declare that:

1. The declared information is accurate and legal according to the regulations. We will wholly be responsible for any falsification and will face penalties according to regulations of law.

2. We ensure the quality of the medical device and trade thereof according to the declaration.

3. Any changes related to the declaration will be updated in accordance with regulations.

Legal representative of the facility
Signature (full name, title)
Confirmed by seal or signature

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[1] Geographic name

[2] Department of Health of the province where the facility is located

[3] The address written on the business registration certificate

[4] Non-IVD medical device

[5] Specify name of the medical device in Vietnamese in accordance with uses of the medical device, unless its name cannot be translated into Vietnamese.

[6] Specify the trade name given by the owner of the medical device.

Template No. 02.02

FACILITY'S NAME **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom – Happiness** **----------**
No. ……..	*…[1]……, day……..month……..year 20……*

DECLARATION OF APPLIED STANDARDS OF CLASS B MEDICAL DEVICES

To: ……[2]……

1. Name of declarant:……

TIN or number of Licence for representative office establishment: …….

Address:……..[3]…….

Landline: ……. Fax:……..

Email:……

2. Legal representative of the facility:

Full name:……..…….

ID/passport: ……..date of issue: …… Place of issue: .....

Landline:…….Mobile phone: …….

3. Class B medical device:

General medical device[4]: * or IVD medical device: *

Name of the medical device[5]:……

Trade name[6] (if any):……..…….

Global Medical Device Nomenclature - GMDN code *(if any):* ……..

Model:……

Product code *(if any):* ……..

Packing specification *(if any):* …….

Uses:……

Name of manufacturer:……

Address of
manufacturer:……

Applied standard: .....

4. For medical device that contains narcotic or precursor:

Name of the narcotic or precursor: ……..Scientific name: ……

CAS Registry Number: ……..

Concentration and content of the narcotic or precursor: .....

Total content of narcotics and precursors in a smallest packing unit: .....

……
..

5. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

6. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

7. Number of declaration of eligibility for domestic production of medical devices: …….

Declaration of applied standards of class B medical device

Enclosures:

1.	ISO 13485 Certificate	*
2.	Letter of authorization of the owner of the medical device	*
3.	Confirmation of eligibility for warranty	*
4.	Documentation of brief technical description of the medical device in Vietnamese	*
5.	Technical documentation of functions and specifications of the medical device promulgated by its owner	*
6.	Technical documents in Vietnamese enclosed with documents on materials, product safety, manufacturing process and clinical and preclinical research reports including reports on the stability of reagents, calibrators and in vitro control materials.	*
7.	Standard version declared to be applied by the owner of the medical device	*
8.	Certificate of conformity with standards	*
9.	For a medical device manufactured in Vietnam: result of evaluating chemical, physical and microbiological parameters and other parameters granted by a qualified facility according to the provisions of law on conformity assessment, or Certificate of quality assessment issued by a competent authority of Vietnam for in vitro diagnostic medical devices	*
10.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese.	*
11.	Template of label on the medical device	*
12.	Certificate of free sale for the imported medical device	*

We hereby declare that:

1. The declared information is accurate and legal according to the regulations. We will wholly be responsible for any falsification and will face penalties according to regulations of law.

2. We ensure the quality of the medical device and trade thereof according to the declaration.

3. Any changes related to the declaration will be updated in accordance with regulations.

Legal representative of the facility
Signature (full name, title)
Confirmed by seal or digital signature

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[1] Geographic name

[2] Department of Health of the province where the facility is located

[3] The address written on the business registration certificate

[4] A medical device, not an in vitro diagnostic medical device

[5] Specify name of the medical device in Vietnamese in accordance with uses of the medical device, unless its name cannot be translated into Vietnamese.

[6] Specify the trade name given by the owner of the medical device.

Template No. 03.01

NAME OF APPLICANT **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom – Happiness** **----------**
No. ……..	*…[1]……, day…….month……..year 20……*

APPLICATION FOR ISSUANCE OF NUMBERS OF MARKETING AUTHORIZATION OF CLASS C AND CLASS D MEDICAL DEVICES SUBJECT TO NATIONAL TECHNICAL REGULATIONS

To: The Ministry of Health

1. Name of the applicant:……

TIN or number of Licence for representative office establishment: …….

Address:……..[3]…….

Tel: …….Fax:……

Email:……

2. Legal representative of the applicant:

Full name:……..…….

ID/passport: ……..date of issue: …… Place of issue: .....

Landline:…….Mobile phone: …….

3. Proposed medical device:

Name of the medical device:……

Trade name *(if any):*……..…….

Global Medical Device Nomenclature - GMDN code *(if any):* ……..

Model:……

Product code *(if any):* ……..

Packing specification *(if any):* ……

Type of the medical device:……

Uses:……

Name of manufacturer:……

Address of
manufacturer:……

4. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

5. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

6. Number of declaration of eligibility for domestic production of medical devices: …….

7. Effective periods of documents contained in the application[3]:

- ISO 13485 Certificate:……..

- Letter of authorization of the owner of the medical device:……

- Certificate of free sale for the imported medical device: ……..

Enclosures:

1.	ISO 13485 Certificate	*
2.	Letter of authorization of the owner of the medical device	*
3.	Confirmation of eligibility for warranty	*
4.	Certificate of free sale for the imported medical device	*
5.	Common Submission Dossier Template (CSDT)	*
6.	Certificate of conformity with regulations	*
7.	Documentation of brief technical description of the medical device in Vietnamese	*
8.	Technical documentation of functions and specifications of the medical device promulgated by its owner	*
9.	Technical documents in Vietnamese enclosed with documents on materials, product safety, product quality control and manufacturing process and clinical and preclinical research reports including reports on the stability of reagents, calibrators and in vitro control materials.	*
10.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese.	*
11.	Template of label on the medical device	*

The applicant hereby delares that:

1. The declared information is accurate and legal according to the regulations. The applicant will wholly be responsible for any falsification and will face penalties according to regulations of law.

2. The applicant ensures the quality of the medical device and trade thereof according to the application.

3. Any changes related to the application will be updated in accordance with regulations.

Legal representative of the applicant
(Signature (full name, title))
Confirmed by seal or digital signature

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[1] Geographic name

[2] The address written on the business registration certificate

[3] In case of multiple documents: Specify expiry date of the document whose effective period is shortest. In case of a document whose effective period is not specified, write "indefinite".

Template No. 03.02

NAME OF APPLICANT **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom – Happiness** **----------**
No. ……..	*…[1]……, day…….month……..year 20……*

APPLICATION FOR ISSUANCE OF MARKETING AUTHORIZATION NUMBERS OF CLASS C AND CLASS D MEDICAL DEVICES WHICH ARE MEASURING INSTRUMENTS SUBJECT TO SAMPLE APPROVAL

To: The Ministry of Health

1. Name of the applicant:……

TIN or number of Licence for representative office establishment: …….

Address:……[2]……..

Tel: ……Fax:……

Email:……

2. Legal representative of the applicant:

Full name:……..…….

ID/passport: ……..date of issue: …… Place of issue: .....

Landline:…….Mobile phone: …….

3. Proposed medical device

Name of the medical device:……

Trade name *(if any)*:……..…….

Global Medical Device Nomenclature - GMDN code *(if any):* ……..

Model:……

Product code *(if any):* ……..

Packing specification *(if any):* …….

Type of the medical device:……

Uses:……

Name of manufacturer:……

Address of
manufacturer:……

4. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

5. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

6. Number of declaration of eligibility for domestic production of medical devices: …….

7. Effective periods of documents contained in the application[3]:

- ISO 13485 Certificate: ……..

- Letter of authorization of the owner of the medical device:……

- Certificate of free sale for the imported medical device: ……..

Enclosures:

1.	ISO 13485 Certificate	*
2.	Letter of authorization of the owner of the medical device	*
3.	Confirmation of eligibility for warranty	*
4.	Certificate of free sale for the imported medical device	*
5.	Common Submission Dossier Template (CSDT)	*
6.	Decision on sample approval	*
7.	Documentation of brief technical description of the medical device in Vietnamese	*
8.	Technical documentation of functions and specifications of the medical device promulgated by its owner	*
9.	Technical documents in Vietnamese enclosed with documents on materials, product safety, product quality control and manufacturing process and clinical and preclinical research reports including reports on the stability of reagents, calibrators and in vitro control materials.	*
10.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese.	*
11.	Template of label on the medical device	*

The applicant hereby delares that:

1. The declared information is accurate and legal according to the regulations. The applicant will wholly be responsible for any falsification and will face penalties according to regulations of law.

2. The applicant ensures the quality of the medical device and trade thereof according to the application.

3. Any changes related to the application will be updated in accordance with regulations.

Legal representative of the applicant
(Signature (full name, title))
Confirmed by seal or digital signature

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[1] Geographic name

[2] The address written on the business registration certificate

[3] In case of multiple documents: Specify expiry date of the document whose effective period is shortest. In case of a document whose effective period is not specified, write "indefinite".

Template No. 03.03

NAME OF APPLICANT **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom – Happiness** **----------**
No. ……..	*…[1]……, day…….month……..year 20……*

APPLICATION FOR ISSUANCE OF MARKETING AUTHORIZATION NUMBERS OF CLASS C AND CLASS D MEDICAL DEVICES ELIGIBLE FOR QUICK ISSUANCE

To: The Ministry of Health

1. Name of the applicant:……

TIN or number of Licence for representative office establishment: …….

Address:……[2]……

Tel: …….Fax:……

Email:……

2. Legal representative of the applicant:

Full name:……..…….

ID/passport: ……..date of issue: ……. Place of issue: .....

Landline:…….Mobile phone: …….

3. Proposed medical device:

Name of the medical device:……

Trade name *(if any):*……..…….

Global Medical Device Nomenclature - GMDN code *(if any): …*……..

Model:……

Product code *(if any):* ……..

Packing specification *(if any):* …….

Type of the medical device:……

Uses:……

Name of manufacturer:……

Address of
manufacturer:……

4. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

5. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

6. Information about the marketing authorization of the medical device:

- Document number:……

- Name of issuing
authority:……

- Date of issue:…….…….……..

- Expiry date:.....…….…….....

7. Number of declaration of eligibility for domestic production of medical devices:
…….

8. Effective periods of documents contained in the application[3]:

- ISO 13485 Certificate: ……..

- Letter of authorization of the owner of the medical device:……

- Certificate of free sale for the imported medical device: ……..

Enclosures:

1.	ISO 13485 Certificate	*
2.	Letter of authorization of the owner of the medical device	*
3.	Confirmation of eligibility for warranty	*
4.	Certificate of free sale for the imported medical device	*
5.	Common Submission Dossier Template (CSDT)	*
6.	Certificate of quality assessment issued by a competent authority of Vietnam for in vitro diagnostic medical devices	*
7.	Documentation of brief technical description of the medical device in Vietnamese	*
8.	Technical documentation of functions and specifications of the medical device promulgated by its owner	*
9.	Technical documents in Vietnamese enclosed with documents on materials, product safety, product quality control and manufacturing process and clinical and preclinical research reports including reports on the stability of reagents, calibrators and in vitro control materials.	*
10.	User manual of the medical device in Vietnamese; for an imported medical device,	*

	an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese.	
11.	Template of label on the medical device	*

The applicant hereby delares that:

1. The declared information is accurate and legal according to the regulations. The applicant will wholly be responsible for any falsification and will face penalties according to regulations of law.

2. The applicant ensures the quality of the medical device and trade thereof according to the application.

3. Any changes related to the application will be updated in accordance with regulations.

Legal representative of the applicant
Signature (full name, title)
Confirmed by seal or digital signature

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[1] Geographic name

[2] The address written on the business registration certificate

[3] In case of multiple documents: Specify expiry date of the document whose effective period is shortest. In case of a document whose effective period is not specified, write “indefinite”.

Template No. 03.04

NAME OF APPLICANT

No. ……..

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

…[1]……, day…….month……year 20……

APPLICATION FOR ISSUANCE OF MARKETING AUTHORIZATION NUMBERS OF CLASS C AND CLASS D MEDICAL DEVICES ELIGIBLE FOR EMERGENCY USE AUTHORIZATION

To: The Ministry of Health

1.

Name of the applicant:……

TIN or number of Licence for representative office establishment:

Address:……[2]……

Tel: ……Fax:……

Email:……

2. Legal representative of the applicant:

Full name:……..…….

ID/passport: ……..date of issue: ……. Place of issue: .....

Landline:…….Mobile phone: …….

3. Proposed medical device:

Name of the medical device:……

Trade name *(if any)*:……..…….

Global Medical Device Nomenclature - GMDN code *(if any): …*……..

Model:……

Product code *(if any):* ……..

Packing specification (if any): …….

Type of the medical device:……

Uses:……

Name of manufacturer:……

Address of
manufacturer:……

4. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

5. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

6. Information about circulation, emergency use authorization of medical devices (in case of technology transfer or processing where information about the transferred or processed products in circulation has to be provided):

- Document number:……

- Name of issuing
authority:……

- Date of issue:…….……..

- Expiry date:.....…….……....

- Links about permission for circulation and use of the medical device:

……
…

7. Number of declaration of eligibility for domestic production of medical devices:
…….

8. Effective periods of documents contained in the application[3]:

- ISO 13485 Certificate: ……..

- Letter of authorization of the owner of the medical device:……

- Certificate of free sale for the imported medical device: ……..

Enclosures:

1.	ISO 13485 Certificate	*
2.	Letter of authorization of the owner of the medical device	*
3.	Confirmation of eligibility for warranty	*
4.	Certificate of free sale or licence for emergency use authorization for the imported medical device.	*
5.	Document containing links of the applicant for issuance of marketing authorization numbers	*
6.	Common Submission Dossier Template (CSDT)	*
7.	Technology transfer contract	*
8.	Processing contract	*
9.	Certificate of product quality inspection or assessment	*
10.	Documentation of brief technical description of the medical device in Vietnamese	*
11.	Technical documentation of functions and specifications of the medical device promulgated by its owner	*
12.	Technical documents in Vietnamese enclosed with documents on materials, product safety, product quality control and manufacturing process and clinical and preclinical research reports including reports on the stability of reagents, calibrators and in vitro control materials.	*
13.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese.	*
14.	Template of label on the medical device	*

The applicant hereby delares that:

1. The declared information is accurate and legal according to the regulations. The applicant will wholly be responsible for any falsification and will face penalties according to regulations of law.

2. The applicant ensures the quality of the medical device and trade thereof according to the application.

3. Any changes related to the application will be updated in accordance with regulations.

Legal representative of the applicant

(Signature (full name, title))
Confirmed by seal or digital signature

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[1] Geographic name

[2] The address written on the business registration certificate

[3] In case of multiple documents: Specify expiry date of the document whose effective period is shortest. In case of a document whose effective period is not specified, write "indefinite".

Template No. 03.05

NAME OF APPLICANT **-------** No. ……..	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom – Happiness** **----------** *…[1]……, day……..month……..year 20……*

APPLICATION FOR ISSUANCE OF MARKETING AUTHORIZATION NUMBERS OF CLASS C AND CLASS D MEDICAL DEVICES ELIGIBLE FOR EMERGENCY USE AUTHORIZATION

To: The Ministry of Health

1. Name of the applicant:……

TIN or number of Licence for representative office establishment: …….

Address:……[2]……

Tel: …….Fax:……

Email:……

2. Legal representative of the applicant:

Full name:……..…….

ID/passport: ……..date of issue: ……. Place of issue: .....

Landline:…….Mobile phone: …….

3. Proposed medical device:

Name of the medical device:……

Trade name *(if any):*……..…….

Global Medical Device Nomenclature - GMDN code *(if any):* ……..

Model:……

Product code *(if any):* ……..

Packing specification *(if any):* …….

Type of the medical device:……

Uses:……

Name of manufacturer:……

Address of
manufacturer:……

4. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

5. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

6. Number of declaration of eligibility for domestic production of medical devices:
…….

7. Effective periods of documents contained in the application[3]:

- ISO 13485 Certificate: ……..

- Letter of authorization of the owner of the medical device:……

- Certificate of free sale for the imported medical device: ……..

Enclosures:

1.	ISO 13485 Certificate	*
2.	Letter of authorization of the owner of the medical device	*
3.	Confirmation of eligibility for warranty	*
4.	Certificate of free sale for the imported medical device	*
5.	Common Submission Dossier Template (CSDT)	*
6.	Certificate of quality assessment issued by a competent authority of Vietnam for in vitro diagnostic medical devices	*
7.	Testing form for composition and content of substances with antibacterial activity; assessment form for bio-efficacy of products for chemicals and preparations serving the only purpose of sterilization.	*
8.	Documentation of brief technical description of the medical device in Vietnamese	*
9.	Technical documentation of functions and specifications of the medical device promulgated by its owner	*
10.	Technical documents in Vietnamese enclosed with documents on materials, product safety, product quality control and manufacturing process and clinical and preclinical research reports including reports on the stability of reagents, calibrators and in vitro control materials.	*
11.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese.	*
12.	Template of label on the medical device	

The applicant hereby delares that:

1. The declared information is accurate and legal according to the regulations. The applicant will wholly be responsible for any falsification and will face penalties according to regulations of law.

2. The applicant ensures the quality of the medical device and trade thereof according to the application.

3. Any changes related to the application will be updated in accordance with regulations.

Legal representative of the applicant
(Signature (full name, title))
Confirmed by seal or digital signature

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[1] Geographic name

[2] The address written on the business registration certificate

[3] In case of multiple documents: Specify expiry date of the document whose effective period is shortest. In case of a document whose effective period is not specified, write "indefinite".

Template No. 05.A

Application for medical device import licence serving the implementation of regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP

Name of importer **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom – Happiness** **----------**
No. ……../……[1]	*…[2]……, day…….month……..year 20……*

APPLICATION FOR IMPORT LICENCE

To: The Ministry of Health

Importer:

Address:

TIN:

Tel: Fax:

Legal representative:

Landline: Mobile phone:

Official being charged with import-related tasks:

Landline: Mobile phone:

We hereby apply for the licence to import the following medical devices:

No.	**Name of medical device**	**Model**	**Manufacturer, country of manufacture**	**Manufacturer, country of product owner**	**Distributor, country of distribution** *(if any)*	**Year of production**

1. Purpose of import:

2. Time limit of certificate of free sale:

3. Time limit of ISO certificate:

4. Time limit of letter of authorization:

5. We hereby declare that:

- We are responsible for the consistency of the quality, model, quantity and brand-newness of the imported medical devices with the application.

- We are responsible for warranty on medical devices and provision of chemicals, materials and spare parts during the use of such medical devices.

- We have qualified personnel in charge of effectiveness and safety of medical devices for users and environment, and ensure that the quality of the imported medical devices is not affected during transport and in our facilities. We fully comply with regulations on goods labeling.

- The imported medical devices are used in accordance with the application. We will facilitate inspection by competent authorities.

We will be responsible before law for breach of the above-mentioned commitments.

Importer

(Signature, full name and seal)

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[1] Abbreviation of the importer

[2] Name of province or city where the importer is located

Template No. 05.B

Order for import of biological products for in vitro diagnostic test serving the implementation of the regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP

NAME OF IMPORTER

No. ……..

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

ORDER FOR IMPORT

To: The Ministry of Health

(Name of importer) herein requests the Department of Medical Equipment and Works – of the Ministry of Health to consider granting an approval in order that (the importer) may import the following biological products for in vitro diagnostic test which are not registered:

Name of biological product for in vitro diagnostic test, composition, content, dosage form, packing specification	Unit	Import quantity	Date of production / expiry date	Use	Name and country of manufacturer	Name and country of supplier	Name of entrustor (if any) *

* If the import is not entrusted, specify “No entrustment”

……., day….month……. year
Director of the importer
(signature, seal)

APPENDIX IV

TEMPLATE OF MEDICAL DEVICE APPLICATION FOR DECLARATION, CERTIFICATE, IMPORT LICENCE
(enclosed with Circular No. 10/2023/TT-BYT dated May 11, 2023 of the Minister of Health)

Template No. 02.01	Template of application for declaration of applied standards of class A medical devices
Template No. 02.02	Template of application for declaration of applied standards of class B medical devices
Template No. 03	Certificate of marketing authorization of class C and class D medical devices
Template No. 05	Medical device import licence serving the implementation of regulations in Clause 2 Article 48 of Decree No. 98/2021/ND-CP and Clause 12 Article 1 of Decree No. 07/2023/ND-CP
Template No. 05.A	Import licence serving the implementation of regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP
Template No. 05.B	Licence to import biological products for in vitro diagnostic test serving the implementation of the regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP
Template No. 07	Certificate of free sale for the medical devices

Template No. 02.01

….[1]….

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

INFORMATION

Application for declaration of applied standards of class A medical devices

Declaration number.....

Declaration date:……

1. Name of declarant: .....

2. Address:……..

3. Document number of the declarant:…… Date:……..

4. Class A medical device:

Name of the medical device:……

Trade name *(if any):*……..……

Global Medical Device Nomenclature - GMDN code *(if any):* ……..

Model:……

Product code *(if any):* ……..

Packing specification *(if any):* ……

Uses:……

Name of manufacturer:……

Address of manufacturer:……

Applied standard: .....

5. For medical device that contains narcotic or precursor *(if any):*

Name of the narcotic or precursor: ……..Scientific name: ……

CAS Registry Number: ……..

Concentration and content of the narcotic or precursor: .....

Total content of narcotics and precursors in a smallest packing unit: .....

6. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

7. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

8. Number of declaration of eligibility for domestic production of medical devices: …….

9. Enclosures:

1.	Application form	*
2.	ISO 13485 Certificate	*
3.	Letter of authorization of the owner of the medical device	*
4.	Confirmation of eligibility for warranty	*
5.	Standard version declared to be applied by the owner of the medical device	*
6.	Certificate of conformity with standards	*
7.	For a medical device manufactured in Vietnam: adding result of evaluating chemical, physical and microbiological parameters and other parameters granted by a qualified facility according to the provisions of law on conformity assessment, or Certificate of quality assessment issued by a competent authority of Vietnam for in vitro diagnostic medical devices	*
8.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese	*
9.	Template of label on the medical device	*
10.	Certificate of free sale for the imported medical device	*

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[1] Department of Health of the province where the applicant is located

Template No. 02.02

...[1]…

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

INFORMATION

Application for declaration of applied standards of class B medical devices

Declaration number:……

Declaration date:……

1. Name of the declarant:……

2. Address:……

3. Document number of the declarant:……Date:……..

4. Class B medical device:

Name of the medical device:……

Trade name *(if any):*……..…….

Global Medical Device Nomenclature - GMDN code *(if any):* ……..

Model:……

Product code *(if any):* ……..

Packing specification: …….

Uses:……

Name of manufacturer:……

Address of manufacturer:……

Applied standard: .....

5. For medical device that contains narcotic or precursor *(if any):*

Name of the narcotic or precursor: ……..Scientific name: ……

CAS Registry Number: ……..

Concentration, content: .....

Total content of narcotics and precursors in a smallest packing unit: .....

6. Information about the owner of the medical device:

Owner's name:……

Owner's address:……

7. Information about warranty facility *(if any):*

Name of the facility:……

Address:……

Landline:…….Mobile phone: …….

8. Number of declaration of eligibility for domestic production of medical devices: …….

9. Enclosures:

1.	Application for declaration of applied standards of class B medical devices	*
2.	ISO 13485 Certificate	*
3.	Letter of authorization of the owner of the medical device	*
4.	Confirmation of eligibility for warranty	*
5	Standard version declared to be applied by the owner of the medical device	*
6.	Certificate of conformity with standards	*
7.	For a medical device manufactured in Vietnam: adding result of evaluating chemical, physical and microbiological parameters and other parameters granted by a qualified facility according to the provisions of law on conformity assessment, or Certificate of quality assessment issued by a competent authority of Vietnam for in vitro diagnostic medical devices	*
8.	User manual of the medical device in Vietnamese; for an imported medical device, an original in English, issued by the owner of the medical device, will be enclosed with the user manual in Vietnamese	*
9.	Template of label on the medical device	*
10.	Certificate of free sale for the imported medical device	*

[1] Ministry of Health/ Department of Health of the province where the applicant is located

Template No. 03

MINISTRY OF HEALTH OF VIETNAM	**SOCIALIST REPUBLIC OF VIETNAM**
-------	**Independence - Freedom – Happiness**

No. ……..	*Hanoi, …….(date)…….*

CERTIFICATE OF MARKETING AUTHORIZATION OF CLASS C AND CLASS D MEDICAL DEVICES

Pursuant to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices;

Pursuant to Decree No. 07/2023/ND-CP dated March 03, 2023 of the Government on amendments to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices.

The Ministry of Health hereby grants a certificate of marketing authorization to the following brand-new medical device:

1. Name of medical device:

2. Trade name (if any):

3. Global Medical Device Nomenclature - GMDN code (if any):

4. Type of medical device:

5. Name and address of owner of medical device:

6. Name and address of holder of marketing authorization number:

7. Uses; name and address of warranty facility: *See attached annex.*

8. Detail on medical device (model; product code; packing specification; name of manufacturer; address of manufacturer and country of production): *See attached annex.*

This Certificate is granted in accordance with Decision No……

AUTHORITY AND POSITION OF SIGNER
(signature of competent person, seal of issuer)

Full name

ATTACHED ANNEX

1. Uses:

2. Name, address of warranty facility:

3. Details on medical device:

No	Name of medical device	Model	Product code (if any)	Packing specification (if any)	Name of manufacturer	Address of manufacturer	Country of production

Template No. 05

TEMPLATE OF MEDICAL DEVICE IMPORT LICENCE

Serving the implementation of the regulations in Clause 2 Article 48 of Decree No. 98/2021/ND-CP and Clause 12 Article 1 of Decree No. 07/2023/ND-CP

MINISTRY OF HEALTH OF VIETNAM

No. ……..

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

Hanoi, ……(date)……

To: ……

Pursuant to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices;

Pursuant to Decree No. 07/2023/ND-CP dated March 03, 2023 of the Government on amendments to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices.

Considering the request in Official Dispatch No. ……. dated…… on …….. The Ministry of Health hereby comes to an agreement with the request of (the applicant) on import of consignment of brand-new medical devices. To be specific:

No.	**Name of medical device**	**Model/ Product code**	**Manufacturer, country of manufacture**	**Manufacturer, country of product owner**	**Distributor, country of distribution** *(if any)*	**Quantity**	**Unit**

……. [1] …… shall be responsible for site inspection of goods quality before receipt, cooperate with Customs authority in solving import-related issues in accordance with regulations, be responsible for quality and safety of such goods, and use for intended puposes.

AUTHORITY AND POSITION OF SIGNER
(signature of competent person, seal of issuer)

Full name

---

[1] Name of importer

Template No. 05.A

TEMPLATE OF MEDICAL DEVICE IMPORT LICENCE

Serving the implementation of the regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP

MINISTRY OF HEALTH OF VIETNAM **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom – Happiness** **----------**
No. issuing medical device import licence	*Hanoi,….date……*

To: …….. Name of importer……

Pursuant to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices

Pursuant to Decree No. 07/2023/ND-CP dated March 03, 2023 of the Government on amendments to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices.

Considering the request in Official Dispatch No. ……. dated……of the importer on import of medical devices. The Ministry of Health hereby grants a licence to import the following brand-new medical devices:

No.	**NAME OF THE MEDICAL DEVICE**	**MODEL**	**MANUFACTURER, COUNTRY OF MANUFACTURE**	**MANUFACTURER, COUNTRY OF PRODUCT OWNER**	**DISTRIBUTOR, COUNTRY OF DISTRIBUTION** (if any)

The importer must comply with the applicable regulations on import of medical devices. The importer must comply with regulations on labeling, and take responsibility for quantity, value and quality of the imported medical devices in accordance with regulations of law.

This document comes into force from December 31, 2024.

AUTHORITY AND POSITION OF SIGNER
(signature of competent person, seal of issuer)

Full name

Template No. 05.B

LICENCE TO IMPORT BIOLOGICAL PRODUCTS FOR IN VITRO DIAGNOSTIC TEST

Serving the implementation of the regulations in Clause 18 Article 1 of Decree No. 07/2023/ND-CP

MINISTRY OF HEALTH OF VIETNAM	**SOCIALIST REPUBLIC OF VIETNAM**
-------	**Independence - Freedom – Happiness**

No. *Hanoi,….date.…..*
importing biological products for
in vitro diagnostic test

To: Importer …….

Pursuant to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices;

Pursuant to Decree No. 07/2023/ND-CP dated March 03, 2023 of the Government on amendments to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices.

Considering the request in Order No. …….……of the importer on import. The Ministry of Health hereby grants a licence to import the following brand-new biological products for in vitro diagnostic test:

Name of biological product for in vitro diagnostic test, composition, content, dosage form, packing specification	Unit	Date of production / expiry date	Use	Name and country of manufacturer	Name and country of supplier	Name of entrustor (if any)

The importer must comply with the applicable regulations on import of biological products for in vitro diagnostic test. The importer must comply with regulations on labeling, and concurrently take responsibility for quantity, value and quality of the imported biological products in accordance with regulations of law.

This document comes into force from December 31, 2024.

AUTHORITY AND POSITION OF SIGNER
(signature of competent person, seal of issuer)

Full name

Template No. 07

VIETNAM MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, date... month... year ...

CERTIFICATE OF FREE SALE

Certificate No: …… /CFS/BYT-TB-CT

Product Owner:

Address:

Information of medical devices: (Product name; Model; Product code; Market Authorization number in Vietnam and Manufacturing site): *See attached annex.*

This is to certify that the above product(s) complies with the Medical Device regulations of Vietnam and is (are) allowed to be sold in Vietnam.

This certificate is issued according to Decision No: ……

AUTHORITY AND POSITION OF SIGNER
(signature of competent person, seal of issuer)

Full name

ATTACHED ANNEX

Certificate of Free sale No: …… CFS/BYT-TB-CT

I. Manufacturing site(s):

1.

Name of Manufacturer:

Address:

2.

Name of Manufacturer:

Address:

II. Name of Product(s):

1.

Product name:

Model:

Product code:

Market Authorization number in Vietnam:

Name of Manufacturer

2.

Product name:

Model:

Product code:

Market Authorization number in Vietnam:

Name of Manufacturer:

APPENDIX VI.A

LETTER OF AUTHORIZATION TEMPLATE[1]
SERVING THE ISSUANCE OF MEDICAL DEVICE IMPORT LICENCE ACCORDING TO REGULATIONS IN CLAUSE 18 ARTICLE 1 OF DECREE NO. 07/2023/ND-CP
(enclosed with Circular No. 10/2023/TT-BYT dated May 11, 2023 of the Ministry of Health)

……[2] …….

Day ……month……..year

LETTER OF AUTHORISATION

To: ……

We, *(Name and address of product owner)*, as the legal manufacturer *(product owner)* do hereby authorize *(Name and address of the importer)* to apply for import licence, import the following medical devices:

(Products list: name of medical devices)

We commit to provide and support all information concerning product information, product quality upon request by Vietnam Ministry of Health (Department of Medical Equipment and Constructions) for medical devices mentioned above.

This authorization letter is valid until: ……. date (dd/mm/yy)

Legitimate representative of legal manufacturer (product owner)

Signature

(Full name and title)

_____

[1] Written in both Vietnamese and English (except for medical devices produced domestically), and other languages (if any).

[2] Information about the owner of the medical device (the product owner)

APPENDIX VIII

TEMPLATES OF TECHNICAL DOCUMENTS FOR MEDICAL DEVICES
(enclosed with Circular No. 10/2023/TT-BYT dated May 11, 2023 of the Minister of Health)

As for medical devices which are neither reagents, calibration substances, in vitro control materials nor chemicals and preparations serving the only purpose of disinfecting medical devices	
Template No. 04	Documentation of brief technical description of imported medical devices serving the issuance of marketing authorization numbers
Template No. 06	Technical description of models of imported medical devices serving the issuance of import licences

Template No. 04

DOCUMENTATION OF BRIEF TECHNICAL DESCRIPTION OF IMPORTED MEDICAL DEVICES

Name and address of facility registering for circulation of medical device

Day……month……year 20……..

No	Heading	Brief description
1	Product description of the medical device	
1.1	Prescription of the medical device	Brief prescription of operating principles and features and technical parameters of the medical device; specify that if the device uses new technologies, a description of such new technologies (e.g. nanotechnology) should be provided.
1.2	Catalog of parts and accessories	List of parts and accessories of the medical device
1.3	Purposes/Indications	List of purposes/indications of the medical device
1.4	Instructions for use	Brief instructions for use of the medical device as prescribed in the Instruction sheet or Information sheet of the medical device

1.5	Contraindication	Information on the contraindication – means that cases in which the use of the medical device must not be used for reasons of patient safety, for example due to the patient's medical history, physiological characteristics, etc., is in accordance with the approved content in the country in which marketing authorization is granted and is stated on the label of the medical device
1.6	Warnings and cautions	Warnings and cautions when using the medical device, including preventive measures to protect patients from risks caused by the use of the medical device. They can be warnings about adverse effects or misuse and precautions
1.7	Adverse effects	Adverse effects related to the use of the medical device is recorded through clinical tests and after-sales service which have been previously performed for the medical device
2	Information of the product circulated in countries (if any) Information on the countries in which the certificate of marketing authorization of the product is granted, or the first country in which the certificate of marketing authorization of the medical device is granted	
3	Indications that have been registered in other countries (if any) List of countries in which certificates of marketing authorization attached with the indications approved in these countries are granted; dates of issue of these certificates	
4	Notable information about the safety/operation of the medical device - Information on the number of reports on adverse effects related to the use of the medical device; measures for recall/adjustment of after-sales services implemented at the request of regulatory authorities of some countries; - Information about the following components of the medical device is mandatory: ● Human or animal cells or tissues or their derivatives intended for use in a non-viable form – e.g. artificial heart valves from pig or cat intestines, etc.; ● Cells, tissues and/or derivatives of microbial or recombinant origin – e.g. hyaluronic acid-based dermal fillers obtained by bacterial fermentation, etc.; Contain allergic or ionizing ingredients – e.g. X-ray; or non-ionizing - E.g. laser, ultrasound, etc.	
5	**Reports on clinical assessment of class C and D medical devices which are not in vitro diagnostic medical devices**	
5.1	Clinical assessment	Reports on clinical assessment of the owners of the medical devices in Vietnamese or English
5.2	References of the clinical	List of references (if any)

	assessment	

We certify that the above information is true. We will be responsible before law for the above-mentioned information.

Legal representative of the facility
Signature (full name, title)
Confirmed by seal or signature

Template No. 06

TEMPLATE OF TECHNICAL DESCRIPTION OF MODELS OF IMPORTED MEDICAL DEVICES

Name of importer

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom – Happiness

No. ……..

…….(location), day…… month……year…….

TECHNICAL DESCRIPTION OF MODELS OF IMPORTED MEDICAL DEVICES

No	Heading	Brief description
1	**Description of model of medical device**	
1.1	Prescription of the medical device	*Brief prescription of operating principles and features and technical parameters of the medical device; specify that if the device uses new technologies, a description of such new technologies (e.g. nanotechnology) should be provided.*
1.2	Catalog of parts and accessories (including added chemicals)	*List of parts and accessories of the medical device; As for medical devices for which chemicals and special reagents are provided, list of such chemicals and special reagents is required.*
1.3	Purposes/ Indications	*List of purposes/indications intended to be written on the label of the imported medical device*
1.4	Instructions for use	*Brief instructions for use of the medical device is in accordance with the instructions for use or information sheet of the imported medical device*

1.5	Contraindication	*Information on the contraindication – means that cases in which the use of the medical device must not be used for reasons of patient safety, for example due to the patient's medical history, physiological characteristics, etc., is in accordance with the approved content in the country of production and is stated on the label of the imported medical device*
1.6	Warnings and cautions	*Warnings and cautions when using the medical device, including preventive measures to protect patients from risks caused by the use of the medical device. They can be warnings about adverse effects or misuse and precautions*
1.7	Adverse effects	*Adverse effects related to the use of the medical device is recorded through clinical tests and after-sales service which have been previously performed for the imported medical device*
2	**Information of the product circulated in countries (if any)** *Information on the countries in which the certificate of marketing authorization of the product is granted, or the first country in which the certificate of marketing authorization of the medical device is granted*	
3	**Indications that have been registered in other countries (if any)** *List of countries in which certificates of marketing authorization attached with the indications approved in these countries are granted; dates of issue of these certificates*	
4	**Notable information about the safety/operation of the medical device:** *- (Information on the number of reports on adverse effects related to the use of the medical device; measures for recall/adjustment of after-sales services implemented at the request of regulatory authorities of some countries)* *- (Information about the following components of the medical device is mandatory:* ● *Human or animal cells or tissues or their derivatives intended for use in a non-viable form – e.g. artificial heart valves from pig or cat intestines, etc.;* ● *Cells, tissues and/or derivatives of microbial or recombinant origin – e.g. hyaluronic acid-based dermal fillers obtained by bacterial fermentation, etc.; Contain allergic or ionizing ingredients – e.g. X-ray; or non-ionizing - E.g. laser, ultrasound, etc.*	

Legal representative of the facility
Signature (full name, title)
Confirmed by seal or signature

MEDGATE
Connection to success