Signed by: Office
Agency: Ministry of Health
Signed date: September 16, 2021
18:01:43 +07:00

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

Number: 12/2021/TT-BYT *Hanoi, September 16, 2021*

CIRCULARS

Regulations on issuance of free-sale registration numbers and importation of medical equipment for room service, fight against COVID-19 in urgent cases

Pursuant to Resolution No. 86/NQ-CP dated August 6, 2021 of the Government on the implementation of urgent measures to prevent and control the COVID-19 epidemic according to Resolution No. 30/2021/QH15 dated July 28, 2021 of the XV National Assembly;

Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government the Government shall prescribe the functions, tasks, powers and organizational structure of the Ministry of Health;

Pursuant to Decree No. 36/2016/ND-CP dated May 15, 2016 of Government on medical equipment management, as amended and supplemented by Decree No. 169/2018/ND-CP dated December 31, 2018 and Decree No. 03/2020/ND-CP dated May 15, 2016;

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

The Minister of Health promulgates a Circular providing for the issuance of circulation numbers and the import of Masks and medical equipment for the prevention and control of COVID-19 in case urgent.

Chapter I

GENERAL RULES

Article 1. Scope

This Circular provides:

1. Dossier and procedures for granting free-sale registration numbers for medical equipment, medical supplies, and biologic Testing products and chemicals used in the prevention and control of COVID-19 belong to The list is specified in Appendix 1 issued together with this Circular.

2. Import of medical equipment for the purpose of room service aid, fight against COVID-19.

Article 2. Conditions for application of the form of issuance of circulation numbers

Medical equipment may apply the form of fast issuance of free-sale registration numbers if it meets the requirements simultaneously meet the following conditions:

1. Belonging to the list specified in Appendix 1 issued together with this Circular;

2. In one of the following cases:

a) Has been allowed to circulate or use by one of the following organizations emergency: US Food and Drug Administration (FDA) - USA; Department Therapeutic Goods Administration (TGA) - Australia; Health Canada (Health .) Canada); Ministry of Health, Labor and Welfare (MHLW) or Agency Pharmaceuticals and Medical Devices (PMDA) - Japan;

b) It has been regulated by the competent authorities of the European countries specified in Appendix 2 to this Circular for permission for circulation and emergency use;

c) Belonging to the list of SARS-CoV-2 testing products that are used urgently issued by the World Health Organization (WHO) on its website at https://extranet.who.int (Coronavirus disease (COVID-19) Pandemic — Emergency Use Listing Procedure (EUL) open for IVDs | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Controls);

d) Belonging to the list of popular products for testing SARS-CoV-2 due to Issued by the European Health Security Committee (EUHSC) published on the website at https://ec.europa.eu (Technical working group on COVID-19 diagnostic tests | Public Health (europa.eu);

dd) Having been granted a commercial import license in Vietnam South before the effective date of this Circular;

e) Produced domestically in the form of technology transfer for medical equipment falling into one of the cases specified at points a, b, c, d or dd of this Clause;

g) Produced domestically in the form of processing for medical equipment economy in one of the cases specified at Points a, b, c, d or dd of this Clause.

Article 3. Regulations on circulation numbers

1. Form of registration for circulation:

a) Announcement of standards applicable to class B medical equipment;

b) Issuance of the certificate of registration of circulation for medical equipment of classes C, D.

2. Free-sale registration number of medical equipment issued in accordance with the provisions of this Circular This item includes:

a) Confirmation number of the Department of Medical Equipment and Construction on the public document Declaration of applicable standards according to the form No. 1 specified in Appendix 3 enclosed herewith This Circular applies to type B medical equipment;

b) The number of the certificate of circulation registration for medical equipment approved by the Department of Health Medical equipment and facilities issued according to the form specified in Appendix 4 issued

attached to this Circular for medical equipment of categories C and D.

3. The value of the free-sale number: The circulation number is issued according to the provisions of Circular

This Agreement is valid from the date of signing to December 31, 2022.

Article 4. Competence to organize receipt, appraisal and issuance of circulation numbers

1. The Minister of Health assigns the Department of Medical Equipment and Construction to organize the next meeting Receive and appraise application for free-sale registration number for medical equipment in service COVID-19 prevention and control in urgent cases.

2. The Minister of Health authorizes the Director of the Department of Medical Equipment and Constructions

Issuance of circulation numbers for medical equipment serving the prevention and control of COVID-19 in case of emergency.

chapter II

ISSUANCE OF MARKETING NUMBERS OF MEDICAL DEVICES SERVICE FOR PREVENTION AND FIGHTING COVID-19

Section 1

ANNOUNCEMENT OF APPLICABLE STANDARDS FOR REMOVED MEDICAL DEVICES

Article 5. Dossier for publication of applicable standards

1. Document announcing applicable standards according to form No. 1 specified in Appendix 3 enclosed with this Circular: Number of 02 copies.

2. Papers specified in Clauses 4, 6, 7, 8, 9 Article 22 of Decree No. 36/2016/ND-CP dated May 15, 2016 of the Government is amended and supplemented by Decree No. 169/2018/ND-CP dated December 31, 2018 of the Government on management of medical equipment (hereinafter referred to as Decree No. 36/2016/ND-CP).

3. Documents proving that the medical equipment has been prescribed by a competent authority circulation permit, including one of the following papers:

a) Certificate of free sale of medical equipment;

b) The marketing authorization or emergency use authorization for with imported medical equipment.

4. Import license, for the case specified at Point dd, Clause 2, Article 2 of this Circular.

5. Technology transfer contract for the case specified at point e Clause 2, Article 2 of this Circular.

6. Processing contract, for the case specified at Point g, Clause 2, Article 2 of this Circular.

Article 6. Requirements for application standard announcement dossiers

An application for publication of applicable standards shall be made in 1 set. The paper The sheets in the dossier are arranged in the correct order as prescribed in Article 5 of this Circular and must meet the following requirements:

1. Papers issued by foreign countries must be legalized by consular offices or schools In the absence of consular legalization:

a) For the letter of authorization, the original must be provided;

b) For the papers specified in Clause 3, Article 5 of this Circular, it must be provided

Link to look up the circulation, allow the use of medical equipment from

website of the licensing authority, together with a document providing information about the road

search instructions of the establishment under the name of circulation registration. Level information lookup results
The circulation permit on the website must include at least the following information in English:

Name; species; manufacturer, country of manufacture; firm, owner country.

2. All documents in the dossier must be stamped for certification by the standing establishment

the name of the applicable standard publication. Documents with two or more pages must be closed

affixed seal.

Article 7. Procedures for publication of applicable standards

1. The establishment declaring the applicable standard directly submits a set of documents

publish the applicable standards in paper form as prescribed in Article 5 of this Circular
This is at the Department of Medical Equipment and Construction. For online submissions
Post offices comply with the provisions of Decision No. 45/2016/QD-TTg dated 19

October 2016 of the Prime Minister on the receipt of dossiers and return of results

results of administrative procedures through the public postal service.

2. After receiving a complete and valid dossier (including documents certifying that

pay fees for publication of applicable standards according to regulations of the Ministry of Finance), Department of Page
Medical equipment and works performed:

a) Stamp receipt of application on both documents announcing applicable standards

use and return 01 copy to the publishing establishment (the receipt must be fully displayed

time, date of receiving dossiers);

b) Direct confirmation on the publication of the applicable standard within the time limit

01 working day from the date of receipt of the dossier specified at Point a, Clause 2 of this Article.

3. Within a maximum of 02 working days from the date of issuance of the next number of votes

receive the application for publication of the applicable standard, the Department of Medical Equipment and Construction has
responsibility to publicize all application standards publication dossiers on the portal
electronic information Online public service system for managing medical equipment, at local

only: https://dmec.moh.gov.vn.

Section 2

ISSUANCE OF CERTIFICATE OF CAREER REGISTRATION FOR CLASS C, EASY MEDICAL DEVICES

Article 8. Dossier of application for a certificate of circulation registration

1. A written request for a certificate of circulation registration, made according to form No. 02
specified in Appendix 3 to this Circular: Number of 02 copies.

2. Papers specified at Points d, g, i, m, Clause 1, Article 26 of the Decree

No. 36/2016/ND-CP.

3. Documents proving that the medical equipment has been prescribed by a competent authority
circulation permit, including one of the following papers:

a) Certificate of free sale of medical equipment;

b) The marketing authorization or emergency use authorization for with imported medical equipment.

4. Import license, for the case specified at Point dd, Clause 2, Article 2 of this Circular.

5. Technology transfer contract for the case specified at point e Clause 2, Article 2 of this Circular.

6. Processing contract for the case specified at Point g, Clause 2, Article 2 This circular.

7. Certificate of product quality inspection/assessment of one of the units on the list published on the website of the Ministry of Health for chemicals (biological products) running the SARS-CoV-2 PCR machine, Test kit rapid test for antigens/antibodies against SARS-CoV-2 if belonging to one in the following cases:

a) Domestically produced medical equipment;

b) Medical equipment already prescribed by the competent authority at point b Clause 2, Article 2 of this Circular permits emergency circulation and use.

Article 9. Requirements for application for registration certificate circulate

A dossier of application for a certificate of circulation registration shall be made in 1 set. The papers in the dossier are arranged in the order specified in Article 8 of this Circular this, must meet the requirements specified in Clause 1, Article 6 of this Circular and stamped with certification of the establishment under the name of circulation registration. For documents with from two or more pages must have a cross border stamp.

Article 10. Procedures for issuance of circulation registration certificates

1. The applicant for the certificate of circulation registration shall submit the application directly according to the provisions of Article 8 of this Circular at the Department of Medical Equipment and Construction. For dossiers submitted by post, comply with the provisions of Decision No Decision No. 45/2016/QD-TTg dated October 19, 2016 of the Prime Minister about receiving dossiers, returning results of administrative procedures through services public postal service.

2. After receiving a complete and valid dossier (including documents certifying the pay the fee for appraisal and grant of a circulation permit in accordance with regulations of the Ministry of Finance), the Departm Equipment and medical works performed:

a) Stamp receipt of application on both documents of application for certificate receive circulation registration and return 01 copy to the requesting establishment (Receipt seal must fully show the time, date of receiving the dossier);

b) Carrying out the process of appraisal and issuance of circulation registration certificates as provided for in Clause 3 of this Article.

3. Evaluation and issuance of circulation registration certificates:

a) In case there is no request to amend or supplement the dossier: Department of Equipment and Medical works shall organize the appraisal of the papers specified in Clauses 1, 3, 4, 5, 6, Article 8 of this Circular and Point d, Clause 1, Article 26 of Decree No. 36/2016/ND-

CP to issue a new certificate of circulation registration within 10 working days
work, from the date of receipt of the application (the date of receipt of the application is calculated according to the date of recorc
on the seal of the incoming dispatch of the Department of Medical Equipment and Construction). Case
If the certificate of registration is not issued, a written response must be given and clearly stated
reason;

Within a maximum of 03 working days from the date of issuance of the certificate
registration of circulation, the Department of Medical Equipment and Construction is responsible for publicity
all registration documents for circulation on the web portal Service System
Online publicity for managing medical equipment, at the address: https://dmec.moh.gov.vn.

b) If the application for a certificate of circulation registration has not yet been submitted,
complete:

- The Department of Medical Equipment and Construction must notify in writing to the medical team
The applicant for the issuance of a free-sale registration number to supplement or amend the dossier within 03 days
working, from the date of receipt of the application for a certificate of registration
implementation, which must specify which documents are supplemented and which contents are needed
Revision;

- When receiving a written request to supplement or amend the application file for a license
certificate of registration of circulation, the establishment applying for a certificate of registration of circulation
The practice must supplement and amend in accordance with the contents stated in the document
and send it to the Ministry of Health.

c) In case the establishment applying for the certificate of circulation registration has supplemented
If the application is supplemented or amended but it is not in accordance with the requirements, the Ministry of Health will notify
the basis for further completing the dossier as prescribed at Point b, Clause 3 of this Article;

d) After 30 days, from the date on which the Department of Medical Equipment and Medical Works issues a document
request but the establishment does not supplement or amend the dossier or if after 03 times of amendment, supplement
supplementing dossiers from the date on which the Department of Medical Equipment and Construction requests to amend,
If the application is supplemented for the first time but still does not meet the requirements, it must be done again from
procedures for applying for a certificate of circulation registration.

Chapter III
REGULATIONS ON IMPORT OF MEDICAL DEVICES FOR THE PURPOSE AID FOR THE PREVENTION AND CONTROL OF COVID-19

Article 11. Management of medical equipment imported for aid purposes

1. Medical equipment without free-sale registration number imported for room service,
fighting against COVID-19 for the purpose of aid must be approved by the competent authority
approved according to current regulations of law on aid management and use
foreign.

The customs clearance must be based on the aid-receiving decision of the agency
has the authority and does not need a license to import medical equipment from the Ministry of Health.

2. Other cases specified in Article 42 of Decree No.
36/2016/ND-CP.

Article 12. Responsibilities of organizations and individuals receiving and using aid

1. Responsibilities of organizations and individuals requesting approval of the page aid amount
Medical equipment for the prevention and control of COVID-19:

a) Be responsible for checking the dossier of the medical equipment requested to be received aid;

b) Using the aid for the right purpose;

c) Actual inspection of quantity, type and quality of goods aid;

d) In case the examination on the application file is not enough grounds to allocate to the application Users, organizations and individuals requesting aid shall coordinate with organizations that have function of inspecting and evaluating the quality of medical equipment to assess the quality of medical equipment quality, ensure safety and effectiveness before being put into use;

dd) Hand over the received materials and equipment to the unit for use in accordance with the law Decision of the competent authority.

2. Responsibilities of the unit using the aid medical equipment:

a) Actual inspection of quantity, type, expiry date and quality aided goods;

b) Using the medical equipment for the right purpose;

c) During use, if the aid medical equipment is faulty, it is not guaranteed safety must stop using, must promptly report to the competent authority allow aid recipients to consider and settle.

Chapter IV
TERMS ENFORCEMENT

Article 13. Effect

The Circular takes effect from the date of signing until the end of December 31 year 2022.

Article 14. Terms of Reference

In the event that legal documents and regulations are referred to in this Circular, if there is a change, addition or replacement, the used in accordance with the new legal documents.

Article 15. Responsibilities for implementation

1. Responsibilities of the circulation number holder:

In addition to implementing the provisions on responsibility in Decree No 36/2016/ND-CP, the owner of the circulation number has the following additional responsibilities:

a) Take responsibility before law for the accuracy and truthfulness of the dossier application for issuance of a free-sale registration number;

b) Ensure that medical equipment is manufactured, imported, and guided for use used in accordance with the application for which the free-sale registration number has been issued;

c) Immediately publicize the price of medical equipment on the portal of the Ministry of Health before putting medical equipment on the market;

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d) Notify the Ministry of Health of cases of medical equipment specified in Article 2 of this Circular if there is any change in the circulation and use of products of the competent authority granting the license for circulation and use.

2. Responsibilities of Medical Equipment and Construction Department:

a) Based on the need for COVID-19 prevention and control in each period, the Department Medical equipment and facilities shall assume the prime responsibility for coordinating with relevant units study and submit to the Minister of Health for consideration and issue a decision on updating Update the list of medical equipment in the case of rapid circulation as prescribed in Appendix 01 issued together with this Circular;

b) Publicly announce the price of medical equipment and the list of medical equipment has been suspended and revoked the circulation number on the website of the Ministry of Health.

3. Inspector of the Ministry of Health shall assume the prime responsibility for, and coordinate with relevant agencies in, ins inspect and inspect the implementation of this Circular for business establishments, import masks and medical equipment nationwide.

4. Departments of Health of provinces and centrally run cities are responsible for controlling inspect and inspect the implementation of this Circular for website business establishments medical equipment within the scope of management.

In the course of implementation, if there are difficulties or problems, agencies and organizations Organizations and individuals report to the Ministry of Health (Department of Medical Equipment and Construction) to consider resolution.

Recipients:
- Committee on social affairs of the National Assembly;
- Government Office (Cong Bao, CP e-Portal);
- Ministries, ministerial-level agencies, agencies attached to the Government;
- State audit;
- Ministry of Justice (Department for Examination of Legal Documents);
- Health Minister;
- The Deputy Ministers of Health;
- People's Committees of provinces and centrally run cities;
- Departments of Health of provinces and centrally run cities;
- Units under the Ministry;
- Departments, Departments, General Departments, Offices of the Ministry, Inspectors of the Ministry;
- Portal of the Ministry of Health;
- Save: VT, TB-CT, PC (05 copies).

KT. MINISTER
DEPUTY

Truong Quoc Cuong

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Appendix 1

LIST OF MEDICAL EQUIPMENT FOR PREVENTION AND CONTROL COVID-19 QUICK RANKING NUMBERS

(Issued together with Circular No./2021/TT-BYT dated September 2021 13 16

of the Minister of Health)

TT	Name of medical equipment
1.	Extraction machine
2.	PCR machine
3.	Chemicals (biological products) running the PCR machine to test for SARS-CoV-2
4.	Anti-SARS-CoV-2 . antigen/antibody rapid test kit
5.	High-function ventilators, invasive and non-invasive ventilators, ventilators non-invasive, high flow oxygen machine, portable ventilator
6.	Continuous dialysis machine
7.	Portable X-Ray Machine
8.	Color Doppler ultrasound machine 3 probes
9.	Blood gas meter (measuring electrolytes, lactate, hematocrite)
10.	Patient monitor 5 parameters
11.	Electric injection pump
12.	Infusion machine
13.	Pacemaker Defibrillator
14.	Electrocardiogram 6 channels
15.	Portable ultrasound machine
16.	Coagulation time meter
17.	Hemodynamic meter

Appendix 2

LIST OF EUROPEAN COUNTRIES

(Attached to Circular No./2021/TT-BYT dated September 2021 13 16

of the Minister of Health)

- Republic of Austria;
- Republic of Romania;
- Republic of Poland;
- Czech Republic;
- Portuguese Republic;
- Republic of Cyprus;
- Republic of Bulgaria;
- Slovak Republic;

- Republic of Croatia;
- Republic of Estonia;
- Republic of Hungary;
- Greek Republic;
- Republic of Ireland;
- Republic of Latvia;
- Germany;
- Republic of Lithuania;
- Republic of Malta;
- Republic of Finland;
- French Republic;
- Republic of Slovenia;
- Republic of Spain;
- Italian Republic;
- Grand Duchy of Luxembourg;
- Swiss Confederation;
- UK;
- The kingdom of Belgium;
- Kingdom of Denmark;
- Kingdom of the Netherlands;
- Kingdom of Sweden.

twelfth

Appendix 3

SAMPLE DOCUMENTATION OF ANNOUNCEMENT OF APPLICABLE STANDARDS AND RECOMMENDAT ISSUANCE CERTIFICATE OF REGISTRATION FOR CAREER OF MEDICAL DEVICES

(Issued together with Circular No./2021/TT-BYT dated September 15, 2021 of the Minister of Health)

Model number 01

Document announcing standards applicable to class B medical equipment Serving the prevention and control of COVID-19

Model number 02

A written request for a certificate of registration of circulation for the site Class C, D medical equipment for COVID-19 prevention and control

Model number 01

FACILITY NAME
___

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number: ……

…… [1] ……, date..... month..... year 20…

DISCLOSURE DOCUMENT

Applicable standards of class B medical devices
serve the prevention and control of COVID-19 in urgent cases

To: Ministry of Health (Department of Medical Equipment and Construction)

hungbm.ttbct_Bach Minh Hung_September 16, 2021 18:14:10

1. Name of the publishing establishment: …….

Tax code or Representative office establishment license number: ……

Address: …… [2]

Landline: .. ..Fax: ……..

Email: .....

2. Legal representative of the establishment:

First and last name: ……..

ID No./Identifier/Passport: ……. date and place of issue: …….

Landline: ..... Mobile: ……..

3. Medical equipment:

- Name of medical equipment: ……

- Product type/code: …….

- Type of medical equipment: …….

- Packing: …….

- Uses:

4. Information about the production facility

- Name of production establishment: ……..

- Address of production facility: …….

[1] Places

[2] Enter the address on the business registration certificate

- ISO 13485 quality management system standard of production facilities granted:

+ Text number: …….

+ Name of organization issuing ISO 13485: …….

+ The scope of activities granted: …….

+ Expiration date: …….

- Number of receipts for declaration of eligibility for production for establishments Domestic production: ……

5. Information about the owner of the medical device:

- Owner's name: ……..

- Owner's address: …….

- Webpage: ……..

- Email address: ……

- Telephone: ……..

6. Information on circulation of products declaring applicable standards (case Technology transfer or outsourcing must provide information about the product transferred or processed in circulation):

- Number of documents issued for circulation: ……

- Name of organization issuing circulation: ……..

- Date Range: …….

- Expiration date: …….

- Name and category granted: …….

- Link to look up information about circulation in case of license circulation without consular legalization: …….

7. Information about the warranty facility (except for medical equipment using one as prescribed by the owner of the medical device or with supporting documents no warranty):

- Name of establishment: ……

- Address: ……

- Landline phone: ..... Mobile phone: ……..

Attached documents include:

1. Power of attorney of the owner of the medical equipment
2. Brief technical description of medical equipment and technical documents

accompanying art

3. Certificate of conformity or Standard copy that the owner announced application of medical equipment
4. User manual of medical equipment
5. Sample label to be used when circulating in Vietnam
6. Import License
7. Technology transfer contract
8. Processing contract
9. Other documents to substantiate the information declared in the public records dad like:
   - Manufacturer's quality management system,
   - Documentation of circulation of medical equipment.

10. Other documents (if any)

The basis for announcing the applicable standard commits to:

1. The disclosed information content is accurate, truthful, lawful and according to regulations. If there is a forgery, untrue basis, please accept it completely responsible and will be handled according to the provisions of law.

2. Ensuring the quality and circulation of medical equipment in accordance with the approved documents announced.

3. Notify the Ministry of Health if there is one of the changes related to the records announced.

Hanoi, day ......month......year..... [1]

Number: ..../PTN-TTB [2]

TL. MINISTER
DEPARTMENT OF DEPARTMENT
DEPARTMENT OF EQUIPMENT AND MEDICAL WORKS

Legal representative of the establishment
Sign (insert full name, title)
Confirm with

[1] The section is only for the management agency, the publishing establishment is not allowed to fill in any information in this section

[2] The circulation number is valid from the date of signing to the date of the announcement of the end of the COVID-19 epidemic

Model number 02

NAME OF REGISTERED BUSINESS

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Number: ……

…… [1] ……, date..... month..... year 20…

PROPOSAL DOCUMENT

Issuance of certificates of registration of circulation of medical equipment of classes C, DI serve the prevention and control of COVID-19 in urgent cases

To: Ministry of Health (Department of Medical Equipment and Construction).

hungbm.ttbct Bach Minh Hung, September 16, 2021 18:14:10

1. Name of the registered establishment:

Tax code or Representative office establishment license number:

Address: …….. [2]

Telephone: Fax:

Email: .....

2. Legal representative of the establishment:

First and last name:

ID/Passport/citizen identification number: ……. date and place of issue: ….....

Landline: ..... Mobile phone:

3. Medical equipment:

- Name of medical equipment: ……
- Product type/code: …….
- Type of medical equipment: …….
- Packing: …….
- Uses: …….

4. For Chemicals (biological products) running a PCR machine to test for SARS-CoV-2 or Test kit for rapid antigen/antibody against SARS-CoV-2 must have more information:

- Type of test sample: ……
- Performance parameters and evaluated sample size for each type of test sample:

[1] Places

[2] Enter the address on the business registration certificate

+ Detection limit:…… /Sample size:……..

+ Sensitivity: ……. /Sample size: ……Control product: ……

+ Specificity: …….. /Sample size: ……Control product: ……

5. Information about the production facility

- Name of production establishment: ……..

- Address of production facility: …….

- ISO 13485 quality management system standard of production facilities granted:

+ Text number: …….

+ Name of organization issuing ISO 13485: …….

+ The scope of activities granted: …….

+ Expiration date: …….

- Number of receipts for declaration of eligibility for production for establishments Domestic production: ……

6. Information about the owner of the medical device:

- Owner's name: ……..

- Owner's address: …….

- Webpage: ……..

- Email address: …….

- Telephone: ……..

7. Information on circulation of products registered for circulation (in case of transfer technology transfer or processing must provide information about the transferred product delivery or processing has been circulated):

- Number of documents issued for circulation: ……

- Name of organization issuing circulation: ……..

- Date Range: …….

- Expiration date: …….

- Name and category granted: …….

- Link to look up information about circulation in case of license circulation without consular legalization: …….

8. Information about the warranty facility (except in the case of medical equipment using one as prescribed by the owner of the medical device or with supporting documents no warranty):

- Name of establishment: ……

- Address: ……

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- Landline phone: ..... Mobile phone: ……..

Attached documents include:

1. Power of attorney of the owner of the medical equipment
2. Medical device technical brief and technical documentation accompanying art
3. User manual of medical equipment
4. Sample label to be used when circulating in Vietnam
5. Import License

6. Technology transfer contract
7. Processing contract
8. Certificate of inspection/quality assessment for equipment medical in vitro diagnostic testing for SARS-CoV-2 (except for machines and equipment)
9. Other documents to prove the information declared in the application file circulation as:
- Manufacturer's quality management system,
- Documentation of circulation of medical equipment.
10. Other documents (if any)

The establishment applying for the certificate of registration of circulation of medical equipment conclude:

1. Information on circulation registration is accurate, lawful and according to regulations. If there is a forgery, untrue basis, please accept it completely responsible and will be handled according to the provisions of law.

2. Ensuring the quality and circulation of medical equipment in accordance with the registration dossier circulation registration.

3. Notify the Ministry of Health if there is one of the changes related to the records register.

Legal representative of the establishment

(Signature, full name, title)

Confirm with

Appendix 4

FORM OF CERTIFICATE OF CAREER OF SALE

(Issued together with Circular No./2021/TT-BYT dated September 2021 of the Minister of Health)

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

Number: …….. *Hanoi, date…. month…. years 20…*

CERTIFICATE OF REGISTRATION FOR MARKET OF MEDICAL DEVICES SERVICE FOR PREVENTION AND CONTROL OF COVID-19 IN EMERGENCY CASE

Pursuant to Circular No…./2021/TT-BYT dated …month…year…

The Ministry of Health issues a certificate of registration for medical equipment (new) (CV) as follows:

1. Name of medical equipment:
2. Categories:
3. Product code:
3. Packing (if any):

4. Purpose of use:

5. Type of medical equipment:

6. Name and address of the production establishment:

7. Name and address of the owner of the medical equipment:

8. Name and address of the owner of the circulation number:

9. Name and address of warranty facility:

10. For Chemicals (biological products) run the Realtime RT PCR test machine SARS-CoV-2 or SARS-CoV-2 antigen/antibody test kit:

- Performance parameters and evaluated sample size announced by the manufacturer:

+ Detection limit:…… /Sample size:……..

+ Sensitivity: ……. /Sample size: ……Control product: ……

+ Specificity: …….. /Sample size: …….Control product: ……

The circulation number is valid from the date of signing to the date of publication end the COVID-19 pandemic.

Recipients:
.....

POINT OF THE SIGNATURER
Sign (insert full name, title)
Confirmation by stamp or digital signature