GOVERNMENT	**SOCIALIST REPUBLIC OF VIETNAM**
_ _ _ _ _ _ _ _ _ _	**Independence - Freedom - Happiness**
No: 07/2023/ND-CP	_ _
	Hanoi, March 3, 2023

DECREE
Amending and supplementing a number of articles of Decree No. 98/2021/ND-CP November 8, 2021 of the Government on the management of medical equipment

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Pursuant to the June 19, 2015 Law on Government Organization; The Law amending and supplementing a number of articles of the Law on Government Organization and the Law on Organization of Local Government dated November 22, 2019;

At the request of the Minister of Health,

The Government promulgates a Decree amending and supplementing a number of articles of Decree No 98/202 1 /ND-CP dated 8 January 1 202 1 of the Government on the management of medical equipment.

Article 1. Amending and supplementing a number of articles of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021 on management of medical equipment

1. To amend and supplement Clause 2, Article 21 as follows:

"2. The free-sale registration number holder is an organization that publishes standards applicable to medical equipment or an organization that has been granted a certificate of free sale for medical equipment in accordance with this Decree." .

2. To amend and supplement Article 22 as follows:

“Article 22. Circulation conditions for medical equipment

1 . When being circulated on the market, medical equipment must satisfy the following conditions:

a) Having obtained a free-sale registration number, a free-sale registration number, a certificate of circulation registration, or an import permit according to the regulations on management of medical equipment or the case specified at Point d, Clause 2 of this Article; 76 of this Decree, except for the following cases:

- Being liquidated in accordance with the law;

- Expiry date of the product;

- It is not possible to remedy the fault factor that adversely affects the user's health as prescribed in Clause 4, Article 34 of this Decree;

- When the competent state agency does not allow the use.

b) Having labels with full information according to current regulations of law on goods labels ;

c) There are instructions for use of the medical equipment in Vietnamese;

d) There is information about the warranty facility, warranty conditions and duration; except in the case of single-use medical equipment as specified by the owner of the medical equipment or with documents proving that there is no warranty.

2. In case an import license is obtained as prescribed at Points a, b, c, d and dd, Clause 1, Article 48 of this Decree, the conditions specified at Point d, Clause 1 of this Article are not required.

3. In case the information specified at Points c and d, Clause 1 of this Article is not attached to the medical equipment, it must be provided in the form of electronic information and must clearly show instructions on how to search for information on the website. medical device labels”.

3. To amend and supplement Point c, Clause 3 , Article 32 as follows:

“c) When receiving a request to amend and supplement the application file for a free-sale registration number, the organization applying for a free-sale registration number must amend and

supplement it according to the notified contents and send it to the Ministry of Health. .

In case the organization applying for a free-sale registration number has modified or supplemented its dossier but it is not in accordance with the requirements, the Ministry of Health will notify the organization requesting the issuance of a free-sale registration number to continue to complete the dossier according to regulations. at point b, clause 3 of this article.

After 90 days from the date on which the Ministry of Health issues a notice of the request, the organization requesting the issuance of a free-sale registration number does not amend or supplement the dossier, or if after 03 times of amending and supplementing the dossier from the date of If there is a request for amendment or supplementation for the first time but the dossier still does not meet the requirements, the procedure for applying for a free-sale registration number must be carried out from the beginning.

4. To amend and supplement Clause 6, Article 37 as follows:

"6. In case the Ministry of Health has issued a written permission not to continue the circulation of medical equipment as prescribed in Clause 5 of this Article, the owner of the free-sale registration number or the distribution establishment shall have to carry out the withdrawal of the medical equipment. medical equipment being circulated on the market, except for the case where medical equipment has been sold to medical facilities or users".

5. Edit the title of Section 5 Chapter V as follows:

"Section 5. DISCLAIMER OF MEDICAL EQUIPMENT AND HANDLING OF MEDICAL DEVICES WITH RECOVERY RICE NUMBER "

6. To add Clause 14, Article 38 as follows:

"14. The document composition of the application for registration of circulation of medical equipment is concluded by the competent authority to be inconsistent with the provisions of law.".

7. To add Clause 6, Article 39 as follows:

"6. Upon receipt of a conclusion from a competent authority in the case specified in Clause 14, Article 38 of this Decree, within 5 working days from the date of receipt of the document from the competent authority, the issuing authority shall: circulation, consider and issue documents on revocation of the circulation number under its management.

After receiving a written revocation of the free-sale registration number, the competent authorities shall carry out the procedures prescribed in Clauses 3 and 4 of this Article.".

8. To add Article 39a as follows:

"Article 39a. Handling of equipment medical after revoking the circulation number

1. Medical equipment sold to medical facilities or users may continue to be used until it is liquidated in accordance with law or until the expiry date of the product, except for medical equipment. If the medical device cannot be remedied, the fault factor that adversely affects the user's health as prescribed in Clause 4, Article 34 of this Decree.

2. In case the medical equipment with the free-sale registration number is withdrawn but has not been sold to users or medical facilities, the owner of the free-sale registration number is responsible for stopping the circulation of the medical equipment and taking the following actions: measures to recall medical equipment".

9. To amend Article 44 as follows:

"Article 44. Listing of medical equipment prices

1. Organizations and individuals manufacturing and trading in medical equipment shall list prices of medical equipment at locations as prescribed in Article 17 of Decree No. 177/2013/ND-CP dated May 14th. November 2013 of the Government detailing and guiding the implementation of a number of articles of the Law on Prices or on the electronic portal of the Ministry of Health .

2. In case the price of medical equipment is listed on the website of the Ministry of Health, it must contain the following minimum information:

a) Name and type of medical equipment;

b) Manufacturer, country of manufacture; firm, owner country;

c) Unit of calculation;

d) Configuration, technical features of medical equipment;

dd) Listed price of medical equipment.”.

10. To amend Article 45 as follows:

“Article 45. Declaration of medical equipment prices

1. Production and business organizations and individuals must declare prices; Declaration contents, order and procedures for declaring prices of medical equipment comply with the provisions of the law on prices .

2. Based on the actual situation and when there is an abnormal fluctuation in price affecting the supply of medical equipment, the ability of the buyer to pay, and the solvency of the Health Insurance Fund, the Minister, the Minister The Ministry of Health shall issue, update, amend and supplement the list and guide information on medical equipment subject to price declaration.

3. Organizations and individuals manufacturing and trading in medical equipment shall declare prices of medical equipment in the forms prescribed by the law on prices or on the website of the Ministry of Health. .”.

11. Amend and supplement Article 46 as follows:

“Article 46. Principles of management of export and import of medical equipment

1. Organizations and individuals that export or import medical equipment must satisfy the conditions prescribed by the law on export and import and must take responsibility for ensuring the quality and quantity. , types and purposes of use of medical equipment that they export or import.

2. Medical equipment with a free-sale registration number in Vietnam may be exported or imported according to demand, without quantity limitation and without the approval of the Ministry of Health.

3. Medical equipment in the cases specified in Clause 1, Article 48 of this Decree, when imported for use in Vietnam, must have an import license.

4. Medical equipment that does not fall into the cases specified in Clauses 2 and 3 of this Article, when brought into Vietnam by other forms, must comply with the law on foreign trade management.

5. The issuance of the certificate of free sale applies to medical equipment in accordance with the provisions of the law on foreign trade management.

6. The import of used medical equipment must comply with the law on foreign trade management.”.

12. To amend and supplement Article 48 as follows:

a) To amend Point e, Clause 1 , Article 48 as follows:

“e) Medical equipment without a free-sale registration number imported for use at medical facilities purchased from official development assistance (ODA) and concessional loans, non-refundable aid under official development assistance”.

b) B additional Point o, Clause 2, Article 48 is as follows:

“o) For import cases specified at Point e, Clause 1 of this Article, an application for an import license must contain the following additional documents:

- The original or a certified true copy of the decision approving the investment policy and the decision on investment, for investment projects, or the decision approving project documents, for technical assistance projects and project costs. or a grant that is not part of official development assistance, clearly stating the import of medical equipment;

- The original or certified true copy of the contract to provide medical equipment for the project;

- The power of attorney of the owner of the medical equipment for the organization applying

for an import license is still valid at the time of application submission. Submit a consularly legalized copy or a certified copy of the consularly legalized copy;

- Certificate of eligibility for warranty issued by the owner of the medical equipment, except for the case of single-use medical equipment as prescribed by the owner of the medical equipment or with documents proving it. no warranty. Submit the consularly legalized copy or the certified copy of the consularly legalized copy;

- The certificate of circulation is still valid at the time of application for imported medical equipment. Submit the consularly legalized copy or a certified copy of the consularly legalized copy. In case the circulation paper is not in English or not in Vietnamese, it must be translated into Vietnamese. The translation must be certified according to the provisions of law.".

13. Amendment 3 Article 52 as follows :

"3. List prices, declare prices of medical equipment according to the provisions of this Decree and the provisions of the law on prices.".

14. To add to inventory 12 Article 66 as follows:

"twelfth. If in the procedures specified in this Decree, a dossier component is classified as confidential as prescribed by law, confidential documents and contents related to the licensing procedure of such dossier component shall be submitted in the form of a dossier. directly and preserved in secret mode".

15. To amend and supplement Article 70 as follows:

a) To amend and supplement Clause 5, Article 70 as follows:

"5. Publish publicly on the website of the Ministry of Health information about:

a) The winning bid for medical equipment procurement from state medical facilities nationwide;

b) List of medical equipment whose circulation number has been revoked;

c) List of organizations and individuals that forge records, violate regulations on management of medical equipment as prescribed in this Decree.".

b) To amend and supplement Clause 7, Article 70 as follows:

"7. Assume the prime responsibility for, and coordinate with state management agencies in, inspecting, examining, settling complaints and denunciations, and handling violations of the law in the field of medical equipment in accordance with Decree No. this provision and in accordance with the law".

c) To add Clauses 13 and 14 to Article 70 as follows:

"13. Announce and adjust the list of medical equipment subject to price declaration according to management requirements and actual situation.

14. Issue instructions on information of medical equipment subject to price declaration.".

16. To amend and supplement Clause 5 , Article 73 as follows:

"5. To be responsible for organizing and implementing the procedures as prescribed in this Decree; organize the inspection, examination, settlement of complaints and denunciations and handle violations of the law in the field of medical equipment, the price of medical equipment in the province in accordance with regulations. provisions of the law".

17. To amend and supplement Article 74 as follows:

a) Amend point o, Clause 3, Article 74 as follows:

"o) List prices and declare prices of medical equipment in accordance with this Decree and the law on prices.".

b) To add Clause 5, Article 74 as follows:

"5. Responsibilities of organizations and individuals when submitting dossiers of application for implementation of the procedures specified in this Decree:

a) Take responsibility before law for the legality and accuracy of the submitted papers and documents in the application;

b) Ensure the conformity and consistency of information on medical equipment between the application and the application for the initial license with additional documents at the request of the competent authority;

c) Ensure that the papers and documents of the dossier are still valid throughout the implementation process;

d) Be responsible for keeping papers and documents in the submitted dossier.".

18. To amend and supplement Article 76 as follows:

" Article 76. Transfer Terms

1. The application for issuance of a free-sale registration number submitted under the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on management of medical equipment has been revised. Amended and supplemented by Decree No. 169/2018/ND-CP and Decree No. 03/2020/ND-CP (hereinafter referred to as Decree No. 36/2016/ND-CP) before January 1, 2022 By the time this Decree takes effect, but have not yet been granted a free-sale registration number, the following handling procedures shall be carried out:

a) For the application for registration of circulation of medical equipment of class B, the Ministry of Health shall guide the enterprises that have submitted the application to review to make the announcement of applicable standards according to regulations . in this Decree without having to re-pay the fee for assessment of the circulation permit;

b) For the application for registration of free sale of medical equipment of categories C , D, if the conditions specified in Clause 3, Article 30 of this Decree are satisfied , the Ministry of Health shall issue a free-sale registration number according to the procedures prescribed in Clause 1 of this Article. procedures specified in Article 32 of this Decree;

c) To use the results of classification of medical equipment announced by an organization eligible for classification of medical equipment before the effective date of this Decree in the application file for a free-sale registration number.

2. Q regulations on the value of import permits; regulations on the import of medical equipment that are not on the list of medical equipment subject to an import license:

a) Import permits for medical devices other than in vitro diagnostic biological products that have been issued from January 1, 2018 to December 31, 2021 may continue to be used until the end of December 31. year 2024;

b) The import license for medical equipment that is an in vitro diagnostic biological product that has been issued from January 1, 2018 to December 31, 2021, may continue to be used until the end of December 31, 2024. and no limit on the quantity of imports;

c) Organizations that have been granted import permits specified at Points a and b of this Clause must satisfy the conditions prescribed by law and have to take responsibility for ensuring the quality, quantity, types and purposes. intended use of the imported medical equipment. The Ministry of Health is responsible for inspecting, examining and withdrawing import permits for cases of violations against regulations on management of medical equipment;

d) For medical equipment not on the list of required import permits (except for chemicals, insecticidal and germicidal preparations used in household and medical fields with only one purpose: is the sterilization of medical equipment) and has a classification as medical equipment of categories C , D published information on the electronic portal of the Ministry of Health to continue importing until the end of the day. December 31, 2024 is not limited in quantity, does not need a document from the Ministry of Health to confirm that it is a medical device and does not depend on the time of information disclosure on the electronic portal of the Ministry of Health when implementing customs clearance procedures.

Importing organizations and individuals, when carrying out import procedures, must declare information about the number of documents promulgating results of classification of medical equipment made or requested by the organization that meets the requirements. classify, perform and be responsible for assuring the quality, quantity, type and use purposes of imported medical

equipment.

The customs authority shall check and compare the information in the document promulgating the results of classification of medical equipment of the importing organization or individual that has declared the information on the electronic portal of the Ministry of Health . .

3. Regulations on the value of free-sale registration numbers, circulation registration certificates, and circulation registration numbers:

a) The circulation number issued under the provisions of Decree No. 36/2016/ND-CP before January 1, 2022 is valid for an indefinite period;

b) The certificate of circulation registration for domestically produced medical equipment that has been issued before January 1, 2022 is valid until the end of the time stated on the certificate of circulation registration;

c) The circulation registration number for medical equipment being in vitro diagnostic biological products issued from January 1, 2014 to December 31, 2019 may continue to be used until the end of December 31, 2019. 2024;

d) For medical equipment that is an in vitro diagnostic biological product that has been granted a circulation registration number from January 1, 2020 to December 31, 2021, this circulation registration number is valid until the end of its use. the time limit stated on the circulation registration paper;

dd) Organizations that have been granted a certificate of circulation registration and circulation registration number specified at Points b, c and d of this Clause must satisfy the conditions prescribed by law and shall be responsible for ensuring that ensure the quality, quantity, type and purpose of use of the medical equipment. The Ministry of Health is responsible for inspecting, examining and withdrawing circulation registration certificates and circulation registration numbers in cases of violations against regulations on management of medical equipment.

4. For importing organizations that apply for a license to import medical equipment, which has submitted an application before January 1, 2022, but has not yet been granted an import license.

The Ministry of Health is responsible for notifying and guiding enterprises to complete dossiers for issuance of circulation numbers according to the provisions of Decree No. 98/2021/ND-CP and to be considered for priority processing; In case of continuing to have the need to apply for an import license according to the submitted dossier, the Ministry of Health shall issue an import license according to the order and procedures specified at Point c of this Clause if the submitted dossier has sufficient components. and satisfy the requirements specified at Point a or Point b of this Clause.

a) An application for a license to import medical equipment on the list of which an import permit is required, issued by the Minister of Health, includes:

- A written request for an import license;

- The certificate of free sale for imported medical equipment is still valid (the original or a certified copy);

- The manufacturer's valid certificate of meeting ISO 13485 quality management standards (the original or a copy certified by the organization requesting the import);

- A valid authorization letter from the owner of the medical equipment for the organization or individual that imports medical equipment (the original or a certified true copy);

- Technical documents describing types of imported medical equipment in Vietnamese (certified by the organization requesting the import);

- Technical documents (catalogue) describing the functions and specifications of imported medical equipment;

- Clinical evaluation documents and user manuals of the owner or manufacturer for medical devices that are types of devices and materials that interfere with the body in cardiology, neurology skull.

b) An application for a license to import in vitro diagnostic biological products includes:

- Import orders;

- A valid certificate of free sale (original or certified copy);

- The manufacturer's valid certificate of meeting ISO 13485 quality management standards (the original or a copy certified by the organization requesting the import);

- Standards and methods of quality inspection of medical equipment (certified by the organization requesting the import);

- Label and instruction sheet in Vietnamese together with the original label and user manual (certified by the organization requesting the import).

c) Order and procedures for granting an import license:

- If the application file for an import license does not require modification or supplementation, the Ministry of Health shall issue an import license. In case of refusal to issue an import permit, a written reply must be given clearly stating the reason;

- In case the application for an import license is incomplete, the Ministry of Health shall notify the organization requesting the import to supplement or amend the application for an import license, which must specify the following: documents and contents that need to be amended or supplemented;

- When receiving a request to amend or supplement the dossier, the organization requesting the import must amend and supplement it as required and take responsibility for ensuring the conformity and consistency of the revised content with the dossier. previously submitted and sent to the Ministry of Health within 60 days from the date of the Ministry of Health's notice.

If more than 60 days from the date of the Ministry of Health's request for amendment and supplement, the import-requesting organization fails to submit the application for amendment or supplement or after 03 amendments and supplements, the dossier still fails to apply. satisfying the requirements, the Ministry of Health shall refuse to grant the license to import medical equipment;

d) Import permits issued under this Clause are valid until December 31, 2024.

5. Regulations on the application of the Common Technical Dossier on medical equipment according to ASEAN regulations (Common Submission Dossier Template - CSDT): Compulsory application of the CSDT dossier from January 1, 2024.

6. For the dossiers of application for a new free-sale registration number submitted before January 1, 2024 as prescribed in Article 30 of this Decree:

a) The application for a new registration number includes the papers specified in Article 30 of this Decree, in which the data collection dossier and the results of the appraisal of the data collection dossier specified at Point c, Clause 5, Article 30 of this Decree are replaced. with the following documents:

- Documentation of technical brief description of medical equipment: Submit the Vietnamese version, enclosed with a technical document describing the functions and technical parameters of the medical equipment provided by the owner of the medical device. promulgated, certified by the organization requesting the issuance of the free-sale registration number. Particularly for reagents, calibrators, and in vitro control materials: technical documents in Vietnamese together with documents on materials, product safety, production process and product quality control products, clinical and preclinical research reports including stability reports;

- Documentation on the use of medical equipment: Submit the Vietnamese version certified by the organization applying for the free-sale registration number, enclosed with the original in English issued by the owner of the medical equipment. with imported medical equipment;

- Sample label to be used when circulating in Vietnam of medical equipment: Submit a sample label certified by the organization applying for the free sale number . Label samples must meet the requirements of the law on goods labels.

b) The receipt and evaluation of application for registration of free sale of medical equipment specified in Clauses 1, 2, 3 and 4, Article 30 of this Decree shall comply with the provisions of Article 32 of this Decree.

c) The receipt and appraisal of the application for registration of free sale of medical equipment specified in Clause 5, Article 30 of this Decree shall be carried out as follows:

- In case there is no request to amend or supplement the application for registration of

circulation, the Minister of Health is responsible for: Organize the appraisal and issue the free-sale registration number within 90 days from the date of receipt of the application. complete and valid (including papers certifying that the fee for assessment and issuance of a circulation permit has been paid in accordance with regulations of the Ministry of Finance); in case of refusal to issue a free-sale registration number, there must be a written reply clearly stating the reason;

- In case the application for registration of circulation is incomplete, the Ministry of Health must notify the organization requesting the issuance of a free-sale registration number to supplement or amend the application for circulation registration. which documents and contents need to be modified and sent to the Ministry of Health within 60 days from the date the Ministry of Health issues a notice;

- When receiving a request to supplement or amend the application file for a free-sale registration number, the applicant organization must amend and supplement according to the notified contents and send it to the Ministry of Health.

In case the organization applying for a free-sale registration number has modified or supplemented its dossier but it is not in accordance with the requirements, the Ministry of Health will notify the applicant organization for further completion of the dossier in accordance with regulations . specified in this paragraph.

After 90 days from the date of the Ministry of Health's notification of the request, the organization applying for the free-sale registration number does not amend or supplement the dossier, or if after 03 times of amending and supplementing the dossier from the date of If the health care provider requires the first amendment or supplement, but the dossier still does not meet the requirements, it must repeat the procedure for applying for a free-sale registration number from the beginning.

7. It is not mandatory to apply the regulation “Do not buy or sell medical equipment without the declared price and must not buy or sell higher than the public price on the website of the Ministry of Health at the time of purchase and sale ” for bidding packages opened before April 1, 2022.

8. For medical equipment procurement bidding packages that have approved the contractor selection plan before the effective date of this Decree but have not yet posted the notice or issued the bidding documents, in case it is necessary to When adjusting the contents related to the price declaration, the contractor selection plan shall be adjusted according to the provisions of the law on bidding.”.

Article 2. Terms of implementation

This Decree takes effect from the date of signing for promulgation.

Article 3. Responsibilities for implementation

1. The Minister of Health shall have to guide, organize and inspect the implementation of this Decree.

2. The ministers, the heads of the ministerial-level agencies, the heads of the agencies attached to the Government, the presidents of the People's Committees of the provinces and centrally-run cities and the relevant agencies, organizations and individuals shall have to take responsibility. implementation of this Decree.

Place of multiplication:
- Secretariat of the Party Central Committee;
- Prime Minister, Deputy Prime Ministers;
- Ministries, ministerial-level agencies, agencies attached to the Government;
- People's Councils, People's Committees of provinces and centrally run cities;
- Central Office and Party Committees ;
- Office of the General Secretary;
- Office of the President;
- Council for Ethnic Minorities and Committees of the National Assembly;
- Office of the National Assembly;

TM. GOVERNMENT
KT. PRIME MINISTER
DEPUTY PRIME MINISTER

Tran Hong Ha

- Supreme People's Court;
- The Supreme People's Procuracy;
- State audit;
- National Financial Supervisory Commission;
- Bank for Social Policies;
- Vietnam Development Bank;
- Central Committee of the Vietnam Fatherland Front;
- Central body of unions;
- Government Office: BTCN, PCNs, Assistant TTg, General Director of e-portal portal, Departments, Departments, affiliated units, Official Gazette;
- Save: VT, KGVX (2).