GOVERNMENT

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SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, November 8, 2021

DECREE
About medical equipment management

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;

Pursuant to the June 17, 2020 Investment Law;

At the proposal of the Minister of Health;

The Government promulgates the Decree on the management of medical equipment.

Chapter I
GENERAL PROVISIONS

Article 1. Scope

1 . This Decree regulates the management of medical equipment, including: classification of medical equipment; production, clinical research, circulation, purchase and sale, export, import, and service provision of medical equipment; information, advertising medical equipment; price management of medical equipment and management and use of medical equipment at medical facilities.

2 . This Decree does not apply to:

a) Raw materials and semi-finished products for the production of medical equipment, except raw materials containing narcotics and precursors;

b) Raw materials for production of medical equipment are samples of blood, serum, plasma, urine, feces, human body secretions, and other samples from humans, which must ensure biosafety when imported or exported. according to regulations of the Law;

c) Medical gas;

d) Accessories used with medical equipment;

dd) Products used in medicine for research purposes (Research Use Only - RUO), products used in laboratories (Laboratory Use Only - LUO).

Article 2. Interpretation of terms

1 . Medical equipment means devices, implants, instruments, materials, reagents and in vitro calibrators, software that simultaneously satisfy the following requirements:

a) Used individually or in combination with each other as designated by the owner of the medical equipment to serve humans for one or more of the following purposes:

- Diagnose, prevent, monitor, treat and alleviate disease or compensate for injury or injury;

- examines, replaces, corrects or supports anatomical and physiological processes;

- support or sustain life;

- control of conception;

- Sterilization of medical equipment;

- Provide information for diagnosis, monitoring, and treatment through testing of specimens originating from the human body.

b) Do not use the mechanism of pharmacological, immunological or metabolic in or on the human body or if using this mechanism, only the nature of support to achieve the purposes specified in this clause.

2 . Equipment medical in vitro diagnostic (in vitro diagnostic medical device) including reagents, quality calibration, materials control, instruments, machines, devices or systems and other products to participate in or support the Procedure

tests are used separately or combined as designated by the owner to serve for the inspection of specimens derived from the human body.

3 . Personal-specific medical equipment is medical equipment that is specially manufactured according to the prescription of a doctor, with unique design features for use only by a specific individual.

4 . An accessory is a product designated by the owner of a medical device for a specific purpose in conjunction with a particular medical device in order to facilitate or assist the device in its intended use. its determination.

5 . Product owner includes organizations and individuals that:

a) Supply the medical device in its own name or by any trademark, design, trade name or other name or code owned or controlled by that individual or entity;

b) To be responsible for the design, manufacture, assembly, handling, labeling, packaging or repair of the medical equipment or for determining the intended use of such medical equipment.

Article 3. Principles of medical equipment management

1 . Ensure quality, safety and effective use of medical equipment.

2 . Adequate, accurate and timely information on technical characteristics, uses of medical equipment and possible risk factors for users.

3 . Ensure traceability of medical equipment.

4 . Management of equipment health should be based on the classification of the level of risk and national standards, technical regulations and their respective countries by the agency managing the state authority to issue, acknowledge or criteria set by organizations and individuals to publicize the application in accordance with the law.

5 . Medical equipment that is a measuring instrument, radiation equipment must be managed in accordance with the law on measurement, the law on atomic energy and this Decree.

6 . Chemicals and preparations that have only one purpose of disinfecting medical equipment are managed according to the provisions of this Decree. Chemicals and preparations for the purpose of sterilizing medical equipment but also having other uses shall be managed in accordance with the law on insecticidal and germicidal chemicals and preparations used in the medical field. household and medical.

7 . Medical equipment, raw materials for the production of medical equipment and controlled substances containing narcotics and precursors must be managed, imported and exported according to the provisions of the law on drug prevention and control, and managed according to regulations. specified in this Decree.

8 . The provisions of this Decree on classification, grant of free-sale registration numbers and announcement of eligibility for trading are not applied to:

a) Software (software) used for medical equipment;

b) Medical equipment is bought and sold like normal goods imported in the form of gifts or presents to individuals or organizations other than medical facilities.

chapter II
CLASSIFICATION OF MEDICAL DEVICES

Article 4. Types of medical equipment

Medical devices are classified into 4 categories based on the level of potential risks associated with the technical design and manufacture of such medical devices:

1 . Class A medical devices are low-risk medical devices.

2 . A Class B medical device is a medium-low-risk medical device.

3 . A Class C medical device is a medium-high-risk medical device.

4 . Class D medical devices are high-risk medical devices.

Article 5. Principles of classification of medical equipment

1 . The classification of medical equipment must be based on the classification rules for the level of risk.

2 . A medical device that has only one use but that use can be classified into two or more different levels of risk, the classification according to the highest level of risk applies.

3 . Medical devices have many uses, and each use has a different level of risk, the classification according to the highest level of risk applies.

4 . In the case of a medical device designed to be used in combination with another medical device, each medical device must be assigned a separate risk rating.

In the case of an in vitro diagnostic medical device, it is a device or system of equipment that participates in the testing process and the reagents, controls, standards, calibrators and control materials are analyzed. separate risk class, but the classification should be based on the highest level of risk for the end use of the combined medical device population. In vitro diagnostic medical devices are other products that participate in or assist in the performance of a test that are individually risk-classified.

5 . The Minister of Health shall detail the classification of medical equipment to ensure compliance with international treaties on classification of medical equipment of the Association of Southeast Asian Nations to which Vietnam is a member. .

6. The classification of medical equipment must be done by a classification establishment that declares applicable standards or registers circulation under its name.

Article 6. Withdrawal of results of classification of medical equipment

1 . Cases of withdrawal of classification results of medical equipment:

a) Misclassification results reduce the risk level of medical equipment;

b) The classification result is forged.

2 . Withdrawal procedure:

a) Within 01 working day from the date of conclusion that the classification results fall into one of the cases specified in Clause 1 of this Article, the Ministry of Health is responsible for issuing a document revoking the classification results. classification, which must request the classification establishment to take remedial measures caused by the violation (if any) and at the same time destroy information on the classification results of the confiscated medical equipment. feedback on the electronic portal on management of medical equipment.

The document on revocation of classification results shall be sent to the medical equipment classification establishment, the Department of Health, the General Department of Customs and Customs at border gates and publicly posted on the electronic portal on management of medical equipment. Medical equipment.

b) After receiving the document on revocation of classification results, the classification establishment is responsible for withdrawing all the classification results recorded in the recall document, and at the same time is responsible for dealing with the consequences. as a result of their illegal acts.

c) After receiving the document on revocation of classification results, the agency where the application for publication of applicable standards is received or the application for registration of circulation (hereinafter referred to as the application for free-sale registration number) is responsible for: check the circulation numbers that you have issued. In case it is discovered that a medical device that has been granted a free-sale registration number using a classification result and has been revoked by the Ministry of Health, the agency that has issued the free-sale registration number is responsible for carrying out the collection procedures. recall the free-sale registration number for that medical device.

Article 7. Handling of medical equipment using the recalled classification results

1 . In case the medical equipment is undergoing the procedures for applying for a free-sale registration number using the recalled classification results:

a) Organizations and individuals submitting dossiers of application for free-sale registration number shall report in writing to the agency receiving dossiers of application for free-sale registration number to stop the procedures for issuance of free-sale registration numbers.

b) After receiving the written request from the organization or individual specified at Point a of this Clause or after receiving the written withdrawal of the classification of medical equipment, the application-receiving agency shall refuse to issue a circulation number.

2 . Where health facilities have been granted circulation that use the classification results were recalled but not yet implemented procedures for clearance of goods:

a) The owner of the free-sale registration number is responsible for stopping the implementation of customs clearance procedures, report in writing to the customs at the border gate where the goods are expected to be cleared for customs clearance to stop and the agency where the goods have been cleared. issue a free-sale registration number to revoke the free-sale registration number.

b) After receiving the written request from the free-sale registration number owner or after receiving the written withdrawal of the classification of medical equipment, the customs authority shall stop the customs clearance procedures; The agency that has issued the free-sale registration book shall carry out the procedures for revocation of the free-sale registration number.

3 . In case of medical equipment that has been granted a free-sale registration number, which uses the recalled classification result and has undergone customs clearance procedures but has not yet been sold to users:

a) The circulation number holder is responsible for:

- Stop the circulation of medical equipment and the implementation of measures to recover the medical equipment had a circulation that record levels of circulation using the classification results have been revoked;

- Report in writing to the customs office where the goods have been cleared, which must clearly state the number of cleared medical equipment and do not carry out import procedures for the next shipment until medical equipment is granted a new free-sale registration number according to the adjusted classification results;

- Report in writing to the agency where the free-sale registration number has been issued, clearly stating the quantity of medical equipment that has been cleared and sales contracts (if any);

- Carry out the procedure for issuing a new circulation number again.

b) After receiving the written request from the registration number owner or after receiving the written withdrawal of the classification of medical equipment:

- Customs authorities are responsible for not handling customs clearance procedures;

- The agency that has issued the free-sale registration number is responsible for carrying out the procedures for revocation of the free-sale registration number.

4 . In case of medical equipment sold to medical facilities:

a) The circulation number holder is responsible for:

- Report in writing to the agency where the free-sale registration number has been issued, clearly stating the quantity of medical equipment sold to medical facilities;

- Notify in writing to medical facilities where medical equipment is being used.

b) In case the medical equipment that has been granted a free-sale registration number uses the wrong result in terms of classification but does not have the potential to affect the patient's health: the medical facility is allowed to continue using it. use such medical equipment and the free-sale registration number holder is responsible for completing the registration dossier for the medical equipment circulation at the medical facility after the new free-sale registration number is issued.

c) Where the equipment Medical has been granted circulation using the wrong results on the level of classification have the potential to influence patients' health: health facilities must not continue used medical equipment and owners are responsible for circulating the implementation of corrective measures to ensure the normal operation of the health facility.

Chapter III
MANUFACTURING MEDICAL EQUIPMENT

Article 8. Conditions for quality control of medical equipment manufacturers

1 . Meets ISO 13485 quality management system standards.

2 . For establishments manufacturing medical equipment containing narcotics and precursors, in addition to meeting the conditions specified in paragraph 1 of this Article, shall meet the following additional requirements:

a) Having a system to monitor and manage the process of export, import, inventory, use of narcotic ingredients and precursors, export, import, and inventory of medical equipment and drug-containing materials drugs and precursors;

b) medical equipment, materials containing narcotics and precursors are stored in a separate area in the warehouse or private warehouse, to ensure safety.

Article 9. Dossier of declaration of eligibility to manufacture medical equipment

A dossier of declaration of eligibility to manufacture medical equipment includes:

1 . Text announced eligible producer.

2 . The certificate of meeting the quality management standard ISO 13485 is issued by the conformity assessment organization in accordance with the law.

3 . The proof to meet the conditions specified in Clause 2, Article 8 of this Decree.

Article 10. Requirements for declaration of eligibility to manufacture medical equipment

1 . An application for declaration of eligibility to manufacture medical equipment shall be made in 1 set, in which:

a) Documents in the dossier are clearly printed and arranged in the order specified in Article 9 of this Decree; between sections with separation, cover page and document list.

b) If the document is not in English or in Vietnamese, it must be translated into Vietnamese. The translation must be certified according to the provisions of law.

2 . Requirements for some papers in the dossier of declaration of eligibility for production:

a) The original or a certified copy or copies certified by the proposal announced production eligible for the standard certificate of quality management.

b) The original certified by the establishment requesting declaration of eligibility for production, for documents proving the satisfaction of conditions specified in Clause 2, Article 8 of this Decree.

Article 11. Procedures for declaration of eligibility to manufacture medical equipment

1 . Before performing manufacturing equipment medical, manufacturing facility site medical device shall submit dossiers published on the Department of Health where production sites (determining location of production is based on place stated in the certificate of quality management system). Where there are multiple manufacturing locations in different provinces, they must make the announcement on the province.

2 . Upon receipt of the application (including a document confirming payment of fees as prescribed by the Ministry of Finance), the Department of Health in the locality where the medical equipment manufacturing facility is located shall publicly post it on the Electronic Portal. Information on medical equipment management information and declaration dossiers of eligibility to manufacture medical equipment.

3 . In the operation process production facilities are the responsibility of the written notice of the change together with the documents relating to the change and update the documents on record announced publicly on Portal electronic management of medical equipment within 03 working days from the date of change of information in the dossier published.

Chapter IV
CLINICAL RESEARCH MEDICAL DEVICES

Article 12. Stages of clinical research on medical equipment

1 . Phase 1: is the first stage to conduct preliminary research on the safety of medical equipment for humans and the ease of use of medical equipment for doctors and medical staff.

2 . Phase 2: is the research phase to determine and prove the safety and effectiveness of the medical device.

3 . Phase 3: is the stage conducted after the medical equipment has been circulated in order to continue to study the safety and effectiveness of the medical equipment after being widely used in the population according to the regulations. correct conditions of use.

Article 13. Requirements for clinical research medical equipment

1 . Meets quality standards according to clinical research registration records.

2 . Tested and evaluated equipment specifications, quality assurance and safety.

3 . Labels of medical equipment for clinical research must have the words "Medical equipment used for clinical research, prohibited for other purposes". The labeling shall comply with the provisions of the law on goods labeling.

Article 14. Requirements for establishments receiving clinical research on medical equipment

Establishments that receive clinical research on medical equipment must meet the following requirements:

1 . As an establishment with the function of scientific research, independent of organizations and individuals that have medical equipment for clinical research.

2 . Having a location, clinical research room, quality management system, professional and technical documents that meet the principles of Good Clinical Practice under the guidance of the Minister of Health.

3 . There are enough research staff, including:

a) The main researcher in clinical research on medical equipment must have sufficient qualifications and professional capacity in the field of research, have experience in clinical practice and use of medical equipment, and have a firm grasp of the subject. regulations on management of science, technology and ethics in research, capable of conducting clinical research on medical equipment;

b) Researchers have qualified, professional capacity required matching research, receive training on knowledge and skills related to clinical studies of medical equipment.

Article 15. Dossier of clinical research on medical equipment

Dossier of clinical research on medical equipment, including application for approval of clinical research on medical equipment; Dossier of application for approval of changes to clinical research on medical equipment; Dossier of request for approval of clinical research results of medical equipment, specifically specified as follows:

1 . Dossier to request approval for clinical research on medical equipment includes:

a) A written request for approval of clinical trials of medical equipment.

b) Records of information about clinical research medical equipment include:

- Profile product information studies (general information on medical equipment and clinical studies: name, technical features, utilities and other related information);

- Preclinical research documents of medical devices that need clinical research: research reports on safety and effectiveness, recommendations on how to use and preserve them;

- Document clinical research site medical equipment phases (if recommended clinical research site medical device in the next stage and the equipment medical eligible for free clinical research the previous period).

c) Legal documents of clinical research medical equipment include:

- Technical documents of medical equipment;

- Technical standards and test sheets, medical equipment inspection by competent units;

- The instruction sheet has been licensed for circulation for medical devices that require phase 3 clinical research;

- Written confirmation of participation of research organizations for multi-center research in Vietnam;

- Contract of cooperation in clinical research on medical equipment between agencies, organizations and individuals having research medical equipment and medical equipment clinical research service business establishments; a cooperation contract between an organization or individual having medical equipment for clinical research and a research support organization (if any).

d) Outline of clinical research on medical equipment and explanations, including: Notes on clinical research of medical equipment and research information collection form or research medical record (Case Report Form - CRF)).

dd) Scientific curriculum vitae and a copy of the certificate of completion of the course Good practice in clinical research on medical equipment of the main investigator, issued by the Ministry of Health or by institutions with the function of training in practice. good clinical grade.

e) The research information supply and the research volunteer form of the participants in clinical research on medical equipment.

g) Minutes of evaluation on science and ethics in research by the Ethics Council in biomedical research at grassroots level.

h) Labels medical equipment according to Clause 3 of Article 13 of this Decree and manual medical equipment research.

2 . Profile approve changes proposed clinical studies of medical equipment include:

a) A written request for approval of changes to clinical research on medical equipment.

b) Updated versions of the respective documents specified in Clause 1 of this Article have been changed.

c) Minutes of appraisal of the Ethics Council in biomedical research at grassroots level for changes in clinical research of medical equipment that affect the health and interests of participants in the research. medical equipment or affect the study design, procedure, and procedure.

3 . Profile proposal to approve the results of clinical studies of medical equipment include:

a) A written request for approval of clinical research results for medical equipment;

b) Copy of the research proposal has been approved;

c) A copy of the Decision approving the research proposal has been approved;

d) Minutes of evaluation of clinical research results of medical equipment of the ethics committee in biomedical research at grassroots level;

dd) Full text report on clinical research results of medical equipment.

4 . Requirements for records:

a) Records of clinical research on medical equipment must be written in Vietnamese. In case the document cannot be expressed in Vietnamese, a notarized translation of that document into Vietnamese is required;

b) For papers by foreign regulatory agencies must be granted legalization under the provisions of the law on consular legalization, unless otherwise exempt under the provisions of law.

Article 16. Procedures and order for approval of clinical research on medical equipment

1 . Clinical research facility of medical equipment sent directly or by post 01 dossier requesting approval clinical studies of medical equipment to the Health Ministry.

2 . The Ministry of Health shall check the validity of the dossier within 05 working days from the date of receipt of the dossier. If the application is valid, within 02 working days, the Ministry of Health will transfer the dossier to the National Ethics Council in Biomedical Research (hereinafter referred to as the National Ethics Council) for evaluation. In case the dossier is invalid, a written notice and specific instructions must be given to the establishment to supplement the dossier.

The medical equipment clinical research facility is responsible for completing the dossier within a maximum of 60 days from the date of receipt of the written notice. Past this time limit, the research approval procedure must start from the beginning.

3 . Within 25 days from the date of receipt of complete and valid dossiers, the National Ethical Council shall hold a meeting and issue a minutes of evaluation of the clinical research protocol for medical equipment.

If the appraisal is satisfactory, the National Ethical Council will issue a Certificate of Approval of the research protocol.

In case the research proposal is not approved or needs correction, the National Ethics Council shall notify the research institution in writing and clearly state the reasons therefor. Within 90 days from the date of receiving the written notification of the clinical research facility of medical equipment, it is responsible to complete the dossier and send it to the National Ethics Council. Past this time limit, the research protocol approval procedure must start from the beginning.

Within 07 working days from the date of receipt of complete dossiers of amendments and supplements, the National Ethics Council must hold a meeting to consider. Where unsatisfactory, the national ethics council certificate approved research proposal. In case of disapproval, the National Ethical Council shall notify the clinical research facility in writing and clearly state the reason.

Dossier will only be considered for amendment and supplement no more than 03 times.

4 . Within 05 working days from the date of receiving the Certificate of Approval of the research protocol and accompanying documents, the Ministry of Health shall decide to approve the clinical research protocol for medical equipment.

Article 17. Procedures and order for approving changes to clinical research protocols for medical equipment

1 . A clinical research facility for medical equipment shall send, directly or by post, 01 set of dossiers of application for approval to change the clinical research protocol of medical equipment to the Ministry of Health.

2 . The Ministry of Health shall check the validity of the dossier within 05 working days from the date of receipt of the dossier. In case the dossier is invalid, there must be a written notice and specific instructions for the establishment to supplement the dossier until the dossier is valid. The medical equipment clinical research facility is responsible for completing the dossier within a maximum of 60 days from the date of receipt of the written notice. Past this time limit, the procedure for approving changes to the research protocol must start from the beginning.

If the application is valid, within 02 working days, the Ministry of Health will transfer the dossier to the National Ethics Council for evaluation and make a record of appraisal of the change of the clinical research protocol for medical equipment.

3 . Within 25 days from the date of receipt of complete and valid dossiers, the National Ethical Council shall hold a meeting of the Council and issue a minutes of appraisal of changes to the medical device clinical research protocol.

Where unsatisfactory evaluation, the National Council for ethical approval certificate change research proposal.

In case the research proposal is not approved or needs correction, the National Ethics Council shall notify the research institution in writing and clearly state the reasons therefor. Within 60 days from the date of receipt of the written notification of the clinical research facility of medical equipment, it is responsible to complete the dossier and send it to the National Ethics Council. Past this time limit, the procedure for approving changes to the research protocol must start from the beginning.

Within 07 working days from receipt of complete dossiers including amendments and supplements, the national ethics council for consideration. Where unsatisfactory, Council of national moral certificate of approval of the change research proposal, the case is not approved, the Council of national moral written notice to base clinical studies and stating the reasons.

Dossier will only be considered for modification and supplementation no more than 03 times.

4 . Within 05 working days from receipt of the certificate of approval of the change research proposal and accompanying documents, the Health Ministry decided to approve the change proposal clinical research site medical device.

Article 18. Procedures and order for approving clinical medical device research results

1 . A clinical research facility for medical equipment shall send, directly or by post, 01 set of application documents for approval of clinical research results of medical equipment in Vietnamese to the Ministry of Health.

2 . The Ministry of Health shall check the validity of the dossier within 05 working days from the date of receipt of the dossier. In case the application is valid, within 02 working days, the Ministry of Health will transfer the dossier to the National Ethics Council for appraisal. In case the dossier is invalid, a written notice and specific instructions must be given to the establishment to supplement the dossier.

The medical equipment clinical research facility is responsible for completing the dossier within a maximum of 60 days from the date of receipt of the written notice. Past this time limit, the procedure for approving research results must start from the beginning.

3 . Within 25 days from the date of receipt of a valid application, the national ethics council meetings and minutes of the Board of evaluation findings on medical equipment and clinical.

In case the appraisal is satisfactory, the National Ethical Council will issue a Certificate of Approval of the results of clinical medical device research.

In case the research results are not approved or need to be corrected, the National Ethics Council shall notify in writing the research institution and clearly state the reasons therefor. Within 60 days from the date of receipt of the written notification, the clinical research facility of medical equipment is responsible for completing the research dossier and results and sending it to the National Ethics Council. Past this time limit, the procedure for approving research results must start from the beginning.

Within 07 working days from the date of receipt of complete dossiers of amendments and supplements, the National Ethics Council will consider it. In case of meeting the requirements, the National Ethical Council will issue a Certificate of Approval of the research results, in the case of disapproval, the National Ethics Council will notify the clinical research facility in writing and state the following: clear reason.

Dossier will only be considered for amendment and supplement no more than 03 times.

4 . Within 05 working days from the date of receiving the Certificate of approval of research results and accompanying documents, the Ministry of Health shall decide to approve the results of clinical research on medical equipment.

Article 19. Responsibilities of organizations and individuals possessing clinical research medical equipment

1 . Compensation for damage to participants in clinical research on medical equipment if there is a risk caused by research on medical equipment in accordance with the law.

2 . Sign contracts on clinical research on medical equipment with medical equipment clinical research recipients.

3 . Responsible before law for the quality and safety of medical equipment supplied by them.

Article 20. Responsibilities of medical equipment clinical research recipients

1 . Responsible for the results of clinical research on medical equipment.

2 . Take responsibility for the safety and ensure the interests of participants in clinical research with medical equipment and compensate for damage to participants in clinical research with medical equipment if there is a risk caused by errors of the medical equipment clinical research facility in accordance with the law.

3 . Ensure honesty and objectivity in clinical research of medical equipment.

4 . Economic independence, organization and personnel for organizations and individuals that have medical equipment for clinical research.

Chapter V
CAREER OF MEDICAL DEVICES

Section 1
CLEANING NUMBER, CONDITIONS FOR TRADE AND CONDITIONS OF THE NAME OF THE ORGANIZATION ANNOUNCEMENT OF APPLIED STANDARDS OR SIGN UP FOR MARKET

Article 21. Circulation number of medical equipment

1 . The circulation number of the medical device is:

a) Number of published standards applicable to medical equipment of categories A and B;

b) The number of certificates of registration for circulation of medical equipment belonging to class C, D.

2 . The free-sale registration number holder is an organization that publishes standards applicable to medical equipment of categories A, B or an organization that has been granted a certificate of free sale for medical equipment of

class C, D.

3 . Validity of the free-sale registration number: the free-sale registration number of medical equipment is valid for an indefinite period, except for the case where the free-sale registration number for medical equipment is issued according to the regulations on emergency issuance of the free-sale registration number of medical equipment. health services for disease prevention and control, overcoming consequences of natural disasters. Based on the actual dossiers of the medical equipment requested for issuance of an urgent free-sale registration number, the Minister of Health shall decide the specific duration of the free-sale registration number.

Article 22. Conditions for sale of medical equipment

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

a) Having a free-sale registration number or an import permit as prescribed in this Decree, except for the cases specified in Clause 8 Article 3 and Article 24 of this Decree;

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, conditions and warranty period, except for the case of single-use medical equipment as prescribed by the owner of the medical equipment or there are documents to prove it is not there is a warranty.

2 . If 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 look up information on the label. medical equipment.

Article 23. Conditions for publication of applicable standards or issuance of circulation registration certificates for medical equipment

1 . Conditions for announcing applicable standards or granting circulation registration certificates for medical devices:

a) Produced at a manufacturing facility that has announced production conditions for domestically manufactured medical equipment;

b) Produced at a production facility that has been granted a certificate of ISO 13485 quality management standard and circulated in any country in the world for imported medical equipment;

c) Compliant with national technical regulations or standards announced by the manufacturer to apply.

2 . Do not allow to repeat procedures applicable standards published or registered for circulation for medical equipment in one of the following cases:

a) Medical equipment in the cases specified in Clause 1, Article 37 of this Decree;

b) medical equipment is recovered in cases stipulated in paragraphs 1 and 3 of Article 38 of this Decree.

3 . Do not receive the application for publication of applicable standards or registration for free sale within 12 months from the date of issuance of a decision on revocation of the free-sale registration number for medical equipment falling into one of the cases specified in Clause 1 of this Article. Clause 2, Article 38 of this Decree.

Article 24. Cases exempt from publication of applicable standards and from registration of circulation

1 . Medical equipment is only for the purposes of research, testing, inspection, testing, testing, quality assessment, training in the use and repair of medical equipment.

2 . Site medical device imported into Vietnam for the purpose of aid or healthcare Humanitarian or service activities fairs, exhibitions, displays, product introduction or to use for the purpose of gifts gifts, gifts for the medical establishment or individual treatment, personal characteristics or special diagnostic needs of medical facilities.

3 . Medical equipment without a free-sale registration number imported to meet the urgent needs of disease prevention and control, and to overcome consequences of natural disasters and catastrophes, for which there are no other capable medical equipment available on the market. instead of, replace.

4 . Medical equipment manufactured in Vietnam for export purposes only or participating in exhibitions, fairs and exhibitions abroad.

Article 25. Conditions of organizations entitled to announce applicable standards or register for circulation of medical equipment

1 . Organization names are announced applicable standards or registration for distribution of medical equipment include:

a) enterprises, cooperatives, business households in Vietnam are owners of medical equipment;

b) Vietnamese enterprises, cooperatives and business households authorized by the owner of the medical equipment;

c) The representative office permanently residing in Vietnam of a foreign trader that is the owner of the medical equipment or authorized by the owner of the medical equipment.

2 . The organization declaring the applicable standards or registering the free sale of medical equipment must have a warranty facility in Vietnam or must have a contract with a qualified organization to provide warranty for medical equipment, except for the following cases: The case of single-use medical devices as specified by the owner of the medical device or with documents proving that there is no warranty.

In case the organization in whose name announces the applicable standards or registers the free sale of medical equipment specified at Point c, Clause 1 of this Article, the owner of the medical equipment must have a warranty facility in Vietnam. or have a contract with a qualified facility to provide warranty for medical equipment, except for the case of single-use medical equipment as prescribed by the owner of the medical equipment or with documents proving that no warranty.

The warranty facility must be certified by the medical equipment owner to be qualified to warrant the product.

Section 2
DISCLOSURE STANDARDS APPLICABLE TO EQUIPMENT UNDER MEDICAL CLASS A, B

Article 26. Dossier for publication of applicable standards

Dossier declaring standards applicable to medical equipment of categories A and B includes:

1 . Document announcing applicable standards of medical equipment of categories A, B.

2 . The certificate of ISO 13485 quality management standard is valid at the time of application.

3 . The power of attorney of the medical equipment owner for the organization declaring the applicable standard is still valid at the time of application, except for the case specified at Point a, Clause 1, Article 25 of this Decree.

4 . Certificate of eligibility for warranty issued by the owner of the medical equipment, unless the medical equipment is single-use according to the regulations of the owner of the medical equipment or has documents proving that it is not. there is a warranty.

5 . A brief technical description of the medical equipment in Vietnamese, accompanied by a technical document describing the functions and technical parameters of the medical equipment, issued by the owner of the medical equipment.

Particularly for reagents, calibrators, and in vitro control materials: technical documents in Vietnamese together with documents on materials, product safety, production process, and research reports Clinical and preclinical including stability reports.

6 . A certificate of conformity according to regulations or a copy of product standards announced by the owner of the medical equipment.

Particularly for domestically produced medical equipment, the results of assessment of chemical, physical, microbiological parameters and other parameters shall be added because the facility satisfies all conditions in accordance with the law on conformity assessment. or Certificate of quality assessment issued by a competent authority of Vietnam for in vitro diagnostic medical equipment. Evaluation results must be consistent with the standards announced by the owner of the medical device.

7 . User documentation of medical equipment.

8 . Sample labels will use when circulation in Vietnam of medical equipment.

9 . The certificate of free sale is still valid at the time of application for imported medical equipment.

Article 27. Requirements for application standard announcement dossiers

1 . Dossier for publication of applicable standards shall be made into 1 set.

2 . Requirements for a number of papers in the application for publication of applicable standards:

a) For the Certificate of satisfaction of quality management standards: Submit the original or a certified true copy or a copy certified by the organization declaring the applicable standard.

If the Certificate of satisfaction of quality management standards is not in English or in Vietnamese, it must be translated into Vietnamese. The translation must be certified according to the provisions of law.

b) For the power of attorney of the owner of the medical equipment and the certificate that the facility is eligible for warranty:

- For domestically produced medical equipment: Submit the original or a certified copy;

- For imported medical equipment: Submit the consularly legalized copy or a certified copy of the consularly legalized copy.

c) For the standard conformity certificates or written standards that owners of medical equipment announced apply: Submit originals or copies certified by the organization whose name announced applicable standards.

If the Standard is not in English or in Vietnamese, it must be translated into Vietnamese. The translation must be certified according to the provisions of law.

d) For the documentation of use of the equipment medical: Submit a Vietnamese version certified by the organization whose name announced applicable standards, together with the original in English by owners of equipment medical devices issued for medical equipment imports. Where documentation to use in English or Vietnamese language must be translated into Vietnamese. The translation must be certified according to the provisions of law.

dd) For label samples: Submit a sample label certified by the organization declaring the applicable standard. Label samples must meet the requirements of the law on goods labels.

e) For the certificate of free sale: Submit the consularly legalized copy or a certified copy of the consularly legalized copy.

If the certificate of free sale is not in English or in Vietnamese, it must be translated into Vietnamese. The translation must be certified according to the provisions of law.

g) For the results of evaluation of chemical, physical, microbiological parameters and other parameters, issued by an establishment that fully meets the conditions prescribed by the law on conformity assessment or the Certificate of quality assessment; issued by a competent Vietnamese authority for in vitro diagnostic medical equipment: Submit the original or a certified copy.

Article 28. Procedures for publication of applicable standards

1 . Before putting medical equipment of categories A and B into circulation on the market, the establishment announcing the applicable standards is responsible for submitting the declaration dossier to the Department of Health where its business is located.

2 . When receiving the application file (including the paper certifying that the fee has been paid according to regulations of the Ministry of Finance), the Department of Health in the area where the medical equipment business establishment is located shall upload the applicable standard publication number. for medical equipment of categories A and B, it shall be published on the electronic portal on management of medical equipment and the application for publication of applicable standards, except for the documents specified in Clause 5, Article 26 of the Decree. this.

3 . Where the site owners to change medical equipment, medical equipment categories, types and uses, specified use; Additional production facilities, product code owners responsible circulation retake the disclosure standards applicable under the provisions of this Decree.

4 . During the circulation of medical equipment, the owner of the applicable standard publication number is responsible for making a written notice of the change, enclosed with documents related to the change, and updating such documents on the website. application standard announcement dossiers have been published on the electronic portal on management of medical equipment within 05 working days from the date of one of the following changes:

a) Change of address of the owner of the medical equipment or the owner of the free sale number of the medical equipment;

b) Changing the name of the owner of the circulation or the name of the owner of medical equipment;

c) Change one of the information about the name and address of the manufacturing facility of medical equipment;

d) Change of packing specifications;

dd) Change of warranty facility;

e) Change the label, change the instructions for use but do not change the purpose of use, specify the use. Medical devices manufactured before the date the owner of the standard announcement number applies the notice of change of the label may be circulated with the published information at the time of manufacture;

g) Reducing production facilities, categories and product codes.

Section 3
REGISTRATION FOR CIRCULATION OF MEDICAL EQUIPMENT SUBJECT TO TYPE C, D

Article 29. Forms of registration for circulation

1 . The issuance of a new free-sale registration number applies to medical equipment in the following cases:

a) Medical equipment that is applied for a free-sale registration number for the first time.

b) Medical Equipment has been granted circulation but have one of the following changes:

- Owners of medical equipment; type of medical equipment; types, purposes of use, indications for use; quality standards; additional production facilities and product codes; manufacturing materials that affect the function of in vitro diagnostic medical devices and disposable medical devices; concentration, content and composition of ingredients that are pharmaceutical ingredients combined in a medical device with the role of supporting treatment purposes;

- Not falling into the cases specified in Clause 7 Article 32 of this Decree.

2 . Fast new level of circulation for medical equipment in one of the following cases:

a) Has been granted a certificate of free sale by one of the following organizations or countries or a market authorization (hereinafter referred to as the circulation certificate): United States Food and Drug Administration (FDA) - USA; Therapeutic Goods Administration (TGA) - Australia; Health Canada (Health Canada); Japan's Ministry of Health, Labor and Welfare (MHLW) or Medicines and Medical Devices Agency (PMDA) - Japan, EU member states, UK, Switzerland; National Medical Products Administration (NMPA) - China; The Ministry of Food and Drug Safety (MFDS) - Korea or on the list of marketing authorization organizations recognized by the competent authorities of Vietnam (hereinafter referred to as countries for short). reference);

b) has been granted import permits or certificates in circulation or registered for circulation in the form of trade in Vietnam, except for the cases was revoked before the date of effectiveness of this Decree;

3 . Urgently issue new free-sale registration numbers for medical equipment in service of epidemic prevention and control, and to overcome consequences of natural disasters and disasters in urgent cases on the List promulgated by the Minister of Health and belong to the Ministry of Health. one of the following cases:

a) Has been approved for circulation or emergency use by one of the reference countries;

b) on the list of products used by emergency World Health Organization (WHO) announced;

c) Belonging to the list of popular products announced by the European Health Security Committee (EUHSC);

d) Having been granted a free-sale registration number or granted a commercial import license in Vietnam, except for the cases in which it was revoked before the effective date of this Decree;

e) To be produced domestically in the form of technology transfer for medical equipment in one of the cases specified in points a, b, c or d of this paragraph;

e) Being domestically produced in the form of processing for medical equipment falling into one of the cases specified at Points a, b, c or d of this Clause.

Article 30. Dossier of application for a new free-sale registration number

1 . Records suggest new level of circulation for medical equipment with technical regulations and the respective countries:

a) A written request for a new circulation number.

b) Certificate standard ISO 13845 quality management in force at the time of filing.

c) The power of attorney of the owner of the medical equipment for the establishment conducting the free sale registration is still valid at the time of application submission, except for the case specified at Point a, Clause 1, Article 25 of this Decree.

d) A certificate of eligibility for warranty issued by the owner of the medical equipment, unless the medical equipment is for single use as prescribed by the owner of the medical equipment or there are documents proving it. I have no warranty.

dd) The certificate of free sale is valid at the time of submission of the application for imported medical equipment.

e) General technical dossiers on medical equipment according to ASEAN regulations (hereinafter referred to as CSDT dossiers).

g) Certificate of conformity.

2 . Dossier of application for a new free-sale registration number for medical equipment that is a measuring instrument subject to sample approval in accordance with the law on measurement:

a) A written request for a new circulation number.

b) Sample approval decision.

c) Papers prescribed at Points b, c, d, e and f, Clause 1 of this Article.

3 . Records suggest new level of circulation for medical equipment under emergency cases quickly prescribed in Clause 2, Article 29 of this Decree:

a) A written request for a new circulation number.

b) Papers prescribed at Points b, c and d, Clause 1 of this Article.

c) The circulation certificate is issued by one of the reference countries for the case specified at point a, clause 2, Article 29 of this Decree.

d) The certificate of free sale for imported medical equipment and the import license or the free-sale registration number or the certificate of free-sale registration for the case specified at Point b, Clause 2, Article 29 of this Decree.

dd) A quality assessment certificate issued by a competent Vietnamese authority for in vitro diagnostic medical equipment, except for the following cases:

- Belonging to lists A, B, Appendix 2 to the Agreement on in vitro diagnostic medical devices in Europe and have been granted a certificate of free sale (Certificate of Free Sale) of one of the EU member countries. , England, Switzerland;

- Belonging to lists A and B, Appendix 2 to the Agreement on in vitro diagnostic medical devices in Europe and have been granted a certificate of sale (Market Authorization) of one of the reference countries;

- Not on the list A, B, Appendix 2 to the Agreement on in vitro diagnostic medical devices in Europe but has been granted a certificate of sale (Market Authorization) of one of the reference countries;

- Belonging to the list announced by the Minister of Health.

e) CSDT file.

4 . Dossier of application for a new free-sale registration number for emergency medical equipment specified in Clause 3, Article 29 of this Decree:

a) A written request for a new circulation number.

b) Papers prescribed at Points b, c and d, Clause 1 of this Article.

c) Certificate of circulation or license for emergency use for imported medical equipment.

d) Technology transfer contract, for the case specified at point dd, clause 3, Article 29 of this Decree.

dd) Processing contract, for the case specified at Point e, Clause 3, Article 29 of this Decree.

e) A certificate of product quality inspection or assessment of one of the units on the list published on the website of the Ministry of Health if it falls into one of the following cases:

- Domestically produced medical equipment;

- Medical equipment that has been authorized by competent authorities in EU member states, the UK, and Switzerland for circulation and emergency use, but is not on the list of popular products issued by the Health Security Commission. published by the European Health Security Committee (EUHSC).

g) Dossier of CSDT.

5 . Dossier of application for a new free-sale registration number for other medical equipment:

a) A written request for a new circulation number.

b) Papers specified at Points b, c, d and dd Clause 1 of this Article.

c) Result of appraisal of medical records of the unit appointed by the Minister of Health together with the dossier of medical records.

d) For medical equipment in vitro diagnostic reagents, quality calibration, control materials must have more quality certificate issued by the competent authorities of Vietnam.

dd) For chemicals and preparations with only one purpose of sterilizing medical equipment, there must be an additional test sheet of ingredients and content of substances with disinfectant activity of the unit that has announced the eligibility for food. currently testing according to the provisions of the law on management of chemicals, insecticidal and germicidal preparations used in household and medical fields; Test sheet to evaluate the biological effectiveness of the product and the product's side effects for the test participants of the unit that has announced the eligibility to conduct the test in accordance with the law on chemical management , insecticidal and germicidal preparations used in household and medical fields.

Article 31. Requirements for application for a new free-sale registration number

1 . Requirements for some papers in the application for registration of circulation:

a) For the certification standards of quality management: Submit original or certified copy or copies certified by the proposals in circulation numbers.

In case the certificate of satisfaction of quality management standards is not in English or in Vietnamese, it must be translated into Vietnamese. The translation must be certified according to the provisions of law.

b) For the power of attorney of the owner of the medical equipment and the certificate that the facility is eligible for warranty:

- For domestically produced medical equipment: Submit the original or a certified copy;

- For imported medical equipment: Submit the consularly legalized copy or a certified copy of the consularly legalized copy.

c) For circulation papers: 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.

d) For the certificate of quality assessment, test sheet, test sheet and appraisal results of CSDT dossier: Submit the original or a certified true copy or a certified copy of the applicant establishment. circulate.

dd) For CSDT dossier: Submit a copy certified by the organization requesting the issuance of a free-sale registration number. In case the CSDT dossier 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.

2 . Requirements for some papers in the application for registration of circulation in case of emergency are specified in Clause 3, Article 29 of this Decree:

Documents issued by foreign countries must be consular legalized, in case there is no consular legalization:

a) For the letter of authorization, the original must be provided with confirmation information.

b) For the papers specified at Point c, Clause 4, Article 30 of this Decree, a link to search for the circulation and use of medical equipment must be provided from the website of the licensing agency, enclosed with the document. The copy provides information on the search link of the organization applying for the circulation number. The results of searching for information on the circulation license on the website must include at least the following information in English: name; species; manufacturer and country of manufacture.

Article 32. Receipt and evaluation of application for registration of free sale of medical equipment

1 . Organizations applying for free-sale registration numbers shall submit dossiers to the Ministry of Health through the electronic portal on management of medical equipment.

2 . For registration documents circulated medical equipment specified in paragraphs 1 and 2 of Article 30 of this Decree:

a) If there is no request to amend or supplement the application for registration of circulation, the Minister of Health is responsible for: Organize the appraisal to issue a free-sale registration number within 30 days from the date of receipt of the application. complete and valid documents (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.

b) Where the registration documents for circulation unfinished, the Ministry of Health must inform the organization applying for circulation to supplement or amend registration documents circulated, stating specifically the tonic supplementing these materials, the content need to be amended within 25 days from the date of receipt of complete documents, valid.

c) When receiving a request for addition or modification of the application file for a free-sale registration number, the applicant establishment must supplement or amend the information according to the notified information and send it to the Ministry of Health.

In case the establishment applying for a free-sale registration number has added or modified its dossier but it is not in accordance with the requirements, the Ministry of Health will notify the establishment to continue to complete the dossier according to the provisions of Point b, Clause 2 of this Article. this.

After 90 days from the date the Ministry of Health issues a notice of the request, but the establishment does not supplement or amend the dossier, or if after 05 times of amending and supplementing the dossier from the date the Ministry of Health requests the amendment, If the application is supplemented for the first time but still does not meet the requirements, the procedure for applying for a free-sale registration number must be repeated from the beginning.

3 . For registration documents circulated medical equipment specified in paragraph 3 of Article 30 of this Decree:

a) In case there is no request to amend or supplement the application for circulation registration, the Minister of Health is responsible for: Organize the appraisal to issue a free-sale registration number within 10 working days from the date of receipt of the registration number. complete and valid dossiers (including papers certifying payment of fees for assessment and issuance of circulation permits according to 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.

The Ministry of Health only appraises the legal documents specified at Points b, c, d and dd, Clause 1, Article 30 of this Decree. As for other contents, the organization applying for a free-sale registration number is responsible for the accuracy and legality of these documents. The Ministry of Health shall post-check these contents after the issuance of a free-sale registration number.

b) 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 registration of circulation, specifying the additional information. which documents and contents need to be amended within 10 working days from the date of receipt of a complete and valid dossier.

c) When receiving a request for addition or modification of the application file for a free-sale registration number, the applicant establishment must supplement or amend the information according to the notified information and send it to the Ministry of Health.

In case the establishment applying for a free-sale registration number has added or modified its dossier but it is not in accordance with the requirements, the Ministry of Health will notify the establishment to continue to complete the dossier according to the provisions of Point b, Clause 3 of this Article. this.

After 90 days from the date the Ministry of Health issues a notice of the request, but the establishment does not supplement or amend the dossier, or if after 05 times of amending and supplementing the dossier from the date the Ministry of Health requests the amendment, If the application is supplemented for the first time but still does not meet the requirements, the procedure for applying for a free-sale registration number must be repeated from the beginning.

4 . For the application for registration of free sale of medical equipment specified in Clause 4, Article 30 of this Decree:

a) In case there is no request to amend or supplement the application for circulation registration, the Minister of Health is responsible for: Organize the appraisal to issue a free-sale registration number within 10 working days from the date of receipt of the registration number. complete and valid dossiers (including papers certifying payment of fees for assessment and issuance of circulation permits according to 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.

The Ministry of Health only appraises legal documents specified at Points b, c, d, dd and e, Clause 4, Article 30 of this Decree. As for other contents, the organization applying for a free-sale registration number is responsible for the accuracy and legality of these documents. The Ministry of Health shall post-check these contents after the issuance of a free-sale registration number.

b) 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 registration of circulation, specifying the additional information. which documents and contents need to be amended within 08 working days from the date of receipt of complete and valid dossiers.

c) When receiving a request for addition or modification of the application file for a free-sale registration number, the applicant establishment must supplement or amend the information according to the notified information and send it to the Ministry of Health.

In case the establishment applying for a free-sale registration number has added or modified its dossier but it is not in accordance with the requirements, the Ministry of Health will notify the establishment to continue to complete the dossier according to the provisions of Point b, Clause 4 of this Article. this.

After 90 days from the date the Ministry of Health issues a notice of the request, if the establishment does not supplement or amend the dossier, it must repeat the procedure for applying for a free-sale registration number from the beginning.

5 . For registration documents circulated medical equipment specified in Clause 5 of Article 30 of this Decree:

a) 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 to issue a free-sale registration number within 45 days from the date of receipt of the application. complete and valid documents (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.

b) Where the registration documents for circulation unfinished, the Ministry of Health must inform the organization applying for circulation to supplement or amend registration documents circulated, stating specifically the tonic supplementing these materials, the content need to be amended within 40 days from the date of receipt of complete documents, valid.

c) When receiving a request for addition or modification of the application file for a free-sale registration number, the applicant establishment must supplement or amend the information according to the notified information and send it to the Ministry of Health.

In case the establishment applying for a free-sale registration number has added or modified its dossier but it is not in accordance with the requirements, the Ministry of Health will notify the establishment to continue to complete the dossier according to the provisions of Point b, Clause 5 of this Article. this.

After 90 days from the date the Ministry of Health issues a notice of the request, but the establishment does not supplement or amend the dossier, or if after 05 times of amending and supplementing the dossier from the date the Ministry of Health requests the amendment, If the application is supplemented for the first time but still does not meet the requirements, the procedure for applying for a free-sale registration number must be repeated from the beginning.

6 . Within 01 working day from the date of issuance of the free-sale registration number, the Ministry of Health is responsible for publishing on the electronic portal on management of medical equipment the following information:

a) The name, classification, production facilities, domestic production of medical equipment;

b) The circulation number of the medical equipment;

c) Name and address of the owner of the medical equipment;

d) The name and address of the owner of circulation;

dd) Name and address of the medical equipment warranty establishment;

e) The documents in circulation registration dossier of medical equipment, except for the documents specified at Point f, Clause 1 and Clause 5, Article 30 c;

g) Purpose of use of the medical equipment.

7 . During the circulation of medical equipment, the registration number holder is responsible for making a written notice of the change enclosed with documents related to the change and updating such documents in the registration file. circulated publicly on the Medical Equipment Management Portal within 10 working days from the date of one of the following changes:

a) Change of address of the owner of the medical equipment or the owner of the free sale number of the medical equipment;

b) Changing the name of the owner of the circulation or the name of the owner of medical equipment;

c) Change one of the information about: name, address of the medical equipment manufacturer;

d) Change of packing specifications;

dd) Change of warranty facility;

e) Change the label, change the instructions for use but do not change the purpose of use, indications for use, features and performance of the medical equipment. Medical devices manufactured before the date of notification of the change of label by the holder of the registration number shall be circulated with registered and updated information at the time of manufacture.

Section 4
AFTER-SALE MEDICAL DEVICE MANAGEMENT AND HANDLING OF MEDICAL DEVICES IN SOME READING CASE

Article 33. Requirements on records of after-sales medical equipment management

The registration number holder must establish, organize and manage the traceability of medical equipment on the market and keep a complete record of equipment management, including at least:

1 . A dossier for issuance of a free sale registration number of medical equipment, in which a paper copy must be kept, is required for the following papers:

a) Power of attorney from the owner of the medical equipment for the establishment to register for free sale, except for the case specified at Point a, Clause 1, Article 25 of this Decree;

b) A certificate of eligibility for warranty issued by the owner of the medical equipment, unless the medical equipment is for single use as prescribed by the owner of the medical equipment or there is a document certifying it. does not have a warranty;

c) Certificate of free sale or certificate of circulation.

2 . Distribution records (in case the owner of the circulation number is a representative office, it is not required to store it but must request the establishment that it authorizes to import to perform this responsibility).

3 . Track record of incidents, complaints and corrective measures, handling; which defines the name, type, quantity, batch number of medical equipment; especially for medical equipment fault or risk causing unsafe for the user.

4 . The medical equipment quality management dossier includes:

a) Certificate of origin shall comply with the provisions of law on origin of goods;

b) Quality certificate of each batch issued by the owner of the medical equipment or the manufacturer named in the application for registration of free sale of the medical equipment;

c) The test results of medical equipment for the medical equipment under the circumstances specified in Clause 1 of Article 55 of this Decree;

d) There are technical documents to serve the repair and maintenance of medical equipment, except for the case of single-use medical equipment as prescribed by the owner of the medical equipment or there are documents prove no warranty;

dd) There is information on the instructions for use of the medical equipment in Vietnamese;

e) There is information on the basis of the warranty conditions and the warranty period, unless the equipment medical disposable prescribed by the site owners of medical equipment or documents proving that no with warranty.

Article 34. Handling of medical equipment with warnings about potential risks seriously threatening public health or possibly leading to death for users

1 . In case the medical equipment has a warning from a Vietnamese or international competent authority about a potential risk that seriously threatens public health or can lead to death for the user, the owner will The circulation number holder is responsible for informing medical facilities that are using such medical equipment of the warning risk and conducting investigation and identification within 30 days from the date of receiving the warning. newspaper. In case the investigation and determination takes more than 30 days, a written report must be made to the Ministry of Health, clearly stating the cause and proposing solutions to ensure the safety of users.

2 . In case the medical equipment specified in Clause 1 of this Article is determined to be faulty medical equipment that affects the user's health, the free-sale registration number owner is responsible for:

a) Suspend the circulation of that batch of medical equipment.

b) There is a written notice to the Ministry of Health and other organizations and individuals are making the distribution and use of medical equipment there. In a written notice must specify the production batch, error factors adversely affecting the health as well as the user can or can not overcome such factors.

c) Make a plan to handle, remedy or recall the defective batch of medical equipment.

d) Report to the Ministry of Health after completing the remedy or withdrawing medical equipment.

3 . Where medical equipment can overcome the errors affect health of users:

a) Within 03 working days from the date of receipt of notice from the owner of the free-sale registration number of medical equipment, the Ministry of Health is responsible for issuing a decision on suspension of circulation for the batch of medical equipment. medican.

Contents of the decision to suspend circulation include:

- Name of medical equipment is suspended;

- Number of batches of suspended medical equipment;

- Circulation number of suspended medical equipment.

b) After a decision is issued to suspend the circulation of a batch of medical equipment, the owner of the free-sale registration number is responsible for remedying the faulty element that affects the user's health of the product.

c) After completing the remedy of faulty factors affecting the user's health, the circulation number holder is responsible for sending a written report to the Ministry of Health, together with the inspection results, for the following cases: medical equipment specified in Clause 1, Article 55 of this Decree, or must have a commitment to ensure the quality of medical equipment after correcting errors in the written report to the patient. other medical equipment.

d) Within 20 days from the date of receiving the report on remedying the error factors affecting the user's health of the batch of medical equipment sent by the registration number owner, the Ministry of Health shall have to is responsible for issuing a decision to terminate the circulation of a batch of medical equipment. In case the Ministry of Health does not agree to terminate the circulation suspension, a written response must be clearly stated, clearly stating the reason for the refusal.

4 . In case the medical equipment cannot fix the error factor that adversely affects the user's health:

a) The Ministry of Health is responsible for issuing a decision to recall the entire batch of defective medical equipment.

Contents of the recall decision include:

- Name of the recalled medical equipment;

- Lot number of medical equipment is acquired;

- The circulation number of the recalled medical equipment.

b) The owner of the free-sale registration number is responsible for recalling the entire batch of defective medical equipment within the time limit decided by the competent state agency and bear all costs for the recall of the batch of medical equipment. economics is at fault.

c) Past the time limit for recall under a decision of a competent state agency, but the owner of the free-sale registration number fails to recall the faulty batch of medical equipment, he/she will be forced to recall according to regulations. of the law on handling of administrative violations.

Article 35. Handling of medical equipment incidents that affect the user's health

1 . In case the medical equipment has an incident that seriously threatens public health or causes death to the user, the license number holder is responsible for:

a) Notify on the website of the registration number owner (if any) and concurrently issue a written notice of the incident to establishments that purchase, sell and use the batch of medical equipment and the Ministry of Health. ;

b) Suspend the batch circulating medical equipment-related incidents;

c) To investigate and verify the cause of the incident;

d) Report to the Ministry of Health after the investigation and verification results are available. Where it is determined that the problem is caused by a fault of the medical equipment, the fault factor as well as whether it is possible or impossible to fix that factor. Carry out the remedial work or recall the batch of medical equipment with errors, and report to the Ministry of Health after completing the remedial work or withdrawing the batch of medical equipment.

2 . Where medical equipment incident occurred not fatal but can seriously affect the health of users, owners of circulation shall:

a) Notify in writing to the Ministry of Health of the incident;

b) Conduct investigation and verify the cause of the incident;

c) Report to the Ministry of Health after the investigation and verification results are available. In case it is determined that the problem is caused by a fault of the medical equipment, the fault factor as well as the possibility or inability to overcome that factor must be specified. Carry out the remedial work or recall the batch of medical equipment with errors, and report to the Ministry of Health after completing the remedial work or withdrawing the batch of medical equipment.

3 . The handling of faulty medical equipment that affects the user's health shall comply with the provisions of Clauses 3 and 4, Article 34 of this Decree.

Article 36. Forms of handling, remedying and withdrawing faulty medical equipment

1 . Forms of handling defective medical equipment include:

a) Guide to remedy errors;

b) Correcting errors of medical equipment;

c) Replace faulty medical equipment with corresponding medical equipment;

d) Recall for re-export or destruction;

2 . Defective medical equipment is recalled in the following forms:

a) Voluntary withdrawal by the registration number holder;

b) Compulsory recall for the cases specified in Article 39 of this Decree.

Article 37. Handling of medical equipment when the owner of the medical equipment or the holder of the free-sale registration number of the medical equipment ceases to manufacture or is bankrupt or dissolved.

1 . Medical equipment that has been granted a free-sale registration number but the owner of the medical equipment declares that it is no longer manufacturing or is bankrupt or dissolved, and may continue to circulate it for a maximum period of not more than 24 months, counting from the date of issuance. From the time the owner of the medical equipment declares that he/she will no longer continue to produce or goes bankrupt or is dissolved, if the owner of the registration number in Vietnam has committed to be responsible for the warranty, maintenance and supply supplies to replace or serve the use of medical equipment for a period of 08 years, unless the owner of the free-sale registration number is a resident representative office in Vietnam of a foreign trader whose trade name is a foreign trader. that individual is the owner of the medical device.

2 . Medical equipment that has been issued a free-sale registration number but the holder of the free-sale registration number is bankrupt or dissolved may continue to circulate on the market for a maximum period of not more

than 24 months from the date of issuance. The point where the owner of the circulation number of medical equipment declares bankruptcy or dissolves if the distribution establishment commits to be responsible for warranty, maintenance as well as providing supplies to replace or serve the treatment. use medical equipment for a maximum period of 08 years.

3 . The registration number owner or distribution establishment is responsible for sending the commitment file to the Ministry of Health through the electronic portal on medical equipment management within 60 days from the date of registration. the owner of the medical equipment or the holder of the free sale of the medical equipment declares that it has ceased to produce or is bankrupt or dissolved.

4 . Profile commitments include the following documents:

a) Written commitment to be responsible for warranty, maintenance and supply of supplies for the use of medical equipment;

b) The list of medical equipment with the free-sale registration number that the establishment is keeping but the owner of the medical equipment or the owner of the free-sale registration number of the medical equipment declares that it is no longer producing or has been discontinued. bankruptcy, dissolution.

5 . Within 15 working days from the date of receipt of the commitment dossier as prescribed in Clause 4 of this Article, the Ministry of Health shall reply in writing whether or not to allow the continued circulation of the website. medical equipment. In case of disapproval, the reason must be clearly stated.

6 . In case the medical equipment prescribed in Clause 1 of this Article is not allowed to continue circulating by the Ministry of Health, the owner of the free-sale registration number or the distributor shall have to carry out the recall of the equipment. medical equipment being circulated on the market, except for medical equipment that has been sold to users.

Section 5
RECOVERY NUMBER OF PRACTICE NUMBER OF MEDICAL DEVICES

Article 38. Cases in which the circulation number is revoked

1 . The circulation registration organization forged registration dossiers.

2 . Medical equipment with 03 lots is recalled during the validity period of the free-sale registration number, unless the owner of the free-sale registration number voluntarily withdraws it.

3 . The circulation registration organization corrects, erases and changes the content of the circulation number.

4 . The free-sale registration number holder terminates its operation or is no longer authorized by the medical equipment owner without a replacement organization, except for the case specified in Article 37 of this Decree.

5 . Medical equipment circulating on the market does not guarantee the quality registered for circulation.

6 . The free-sale registration number is not issued according to the authority, dossier and procedures as prescribed in this Decree.

7 . Medical equipment for which the free-sale registration number owner or the distributor does not have the commitments specified in Clauses 1 and 2, Article 37 of this Decree.

8 . Medical equipment expires in circulation as prescribed in Clauses 1 and 2, Article 37 of this Decree.

9 . Medical equipment manufactured at establishments that do not satisfy the conditions specified in this Decree.

1. The owner of the free-sale registration number fails to comply with the provisions of Point k, Clause 3, Article 74 of this Decree, except for the case specified in Article 37 of this Decree.

1 1. Dossier of announcement, registration of circulation of the owner of the free-sale registration number does not comply with the provisions of this Decree.

1 2. Medical equipment is classified incorrectly according to regulations on classification of medical equipment.

1 3. The free-sale registration number owner voluntarily withdraws the free-sale registration number.

Article 39. Procedures for revocation of circulation number

1 . During the inspection and inspection, if detecting one of the cases specified in Clauses 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12, Article 38 of the Decree If this is the case, the agency performing the examination and inspection must make a record and send it to the Ministry of Health or the Department of Health where the free-sale registration number has been issued (hereinafter referred to as the circulation number-issuing agency).

2 . Within 05 working days from the date of receipt of the minutes as prescribed in Clause 1 of this Article, the circulation number-issuing agency shall consider and decide on the withdrawal of the free-sale registration number under its management.

3 . After issuing a decision on revocation of the free-sale registration number, the agency issuing the recall decision shall have to:

a) Upload your decision to withdraw the circulation on the portal's electronic level agency circulation, and send the decision to recover the amount in circulation to owners of circulation, the Ministry of Health, Department of Health provinces and cities under central authority and customs authorities.

b) Remove information related to medical equipment that has been posted on the web portal of the circulation number issuer.

4 . When receiving the circulation number revocation decision from the circulation number issuer, the Departments of Health are responsible for posting the full text of the decision on revocation of the circulation number on the portal, and at the same time directing the relevant authorities to expertise in overseeing the recall of medical devices.

5 . Where the owners of voluntary withdrawal from circulation of circulation, circulation owners send documents clearly stating the reason for withdrawal of circulation of the circulating level agency. After receiving a written request, the issuing agency shall recover circulated under paragraph 2 and 3 of this Article.

Chapter VI
MANAGEMENT PURCHASE OF MEDICAL EQUIPMENT
Section 1
CONDITIONS FOR BUYING AND SELLING MEDICAL DEVICES

Article 40. Conditions for establishments trading in medical equipment of categories B, C, and D

1 . Having at least 01 technical staff with a college degree in engineering, medicine, pharmacy, chemistry, biology or a college degree in medical equipment engineering or a college degree or higher. Specialized training is appropriate to the type of medical equipment that the establishment buys and sells.

2 . Having a storage warehouse and means of transport that satisfy the following minimum conditions:

a) The storage:

- Having an area suitable to the type and quantity of preserved medical equipment,

- Ensure ventilation, dry, clean, not near sources of pollution,

- Meet other storage requirements of medical equipment according to the instructions for use.

b) Means of transporting medical equipment from the trading establishment to the place of delivery are suitable for the type of medical equipment that the trading establishment buys and sells.

In case there is no warehouse or means to preserve medical equipment, a contract must be signed with a qualified facility to preserve and transport medical equipment.

3 . For establishments trading in medical equipment containing narcotics and precursors:

a) The person in charge of the specialty must have a university degree in medical equipment, medicine, pharmacy, pharmaceutical chemistry or biology.

b) Having a storage warehouse that meets the requirements of Article 7 of the Government's Decree No. 80/2001/ND-CP of November 5, 2001 guiding the control of drug-related activities in the country.

c) Having a system to monitor and manage the export, import and inventory of medical equipment containing narcotics and precursors.

Article 41. Dossiers and procedures for announcing eligibility to buy and sell medical equipment

1 . Profile eligible announced purchase of medical equipment shall be made in 01 sets including the following documents:

a) Written announcement of eligibility to purchase and sell medical equipment;

b) The declaration of human resources;

c) Papers proving that the storage warehouse and means of transport of medical equipment satisfy the requirements specified in Clause 2, Article 40 of this Decree. These papers must be certified by the establishment declaring the eligibility to trade;

d) The proof storage facilities, system monitoring and management process delivery, inventory page medical equipment containing narcotics and precursors meet the requirements as stipulated in Clause 3, Article 40 of this Decree. These documents must be confirmed by the facility announced eligible purchase medical equipment containing narcotics and precursors.

2 . Procedures for announcement of eligibility for trading:

a) Before carrying out the purchase and sale of medical equipment, the medical equipment trading establishment is responsible for submitting the announcement dossier to the Department of Health where the place of purchase and sale is located.

b) Upon receipt of the application (including documents certifying payment of fees as prescribed by the Ministry of Finance), the Department of Health in the area where the medical equipment trading establishment is located shall publicly post it on the portal. electronic information on the management of medical equipment, information and documents announcing eligibility to buy and sell medical equipment.

c) In the course of operation, the trading establishment is responsible for making a written notice of the change enclosed with documents related to the change and updating those documents into the published file on the portal. electronic information on the management of medical equipment within 03 working days from the date of change of information in the published dossier.

Article 42. Purchase and sale of medical equipment without having to meet conditions and without having to carry out procedures for announcing eligibility for trading

1 . Medical equipment belonging to class B, C, D on the list of medical equipment by the Minister of Health issued shall be traded like ordinary goods.

2 . The purchase and sale of medical equipment prescribed in Clause 1 of this Article is not required to satisfy the conditions specified in Article 40 of this Decree and is not required to declare eligibility for trading as prescribed in Article 41 of this Decree. but still must meet the conditions on preservation, storage and transportation as prescribed by the owner of the medical equipment.

Section 2
PRICE MANAGEMENT OF MEDICAL DEVICES

Article 43. Principles of state management of medical equipment prices

1 . Manage the price of medical equipment according to the market mechanism, respecting the right to self-determine and compete on prices of medical equipment trading organizations and individuals according to the provisions of law.

2 . Ensure publicity and transparency of medical equipment prices when circulating on the market.

3 . Protect the lawful rights and interests of organizations and individuals doing business, using and the interests of the State.

4 . Implement measures to manage medical equipment prices in accordance with socio-economic development conditions in each period.

Article 44. Measures to control medical equipment prices

1 . Declare the price of medical equipment before being circulated in Vietnam and update when the declared medical equipment price changes according to the provisions of this Decree.

2 . Posting the wholesale and retail prices of medical equipment in Vietnam dong at the place of transaction or the place of sale of medical equipment of the medical equipment trading establishment; publicly announced on the board, on paper or in other forms.

3 . Publicize the winning bids for medical equipment of public medical facilities.

4 . Not to purchase medical equipment without value declaration and not traded higher than declared on the electronic portal of the Ministry of Health at the time of purchase.

Article 45. Contents and responsibilities for declaring prices of medical equipment

1 . Contents of declaration of prices of medical equipment:

a) Name and type of medical equipment;

b) Country of production;

c) Unit of calculation;

d) Import cost price for imported medical equipment or production cost for domestically produced medical equipment ;

d) Expected profit;

e) The maximum selling price of medical equipment corresponding to each configuration, technical features in units of calculation;

g) The price of components and accessories (if any);

h) Cost of warranty, maintenance and maintenance (if any);

i) Training costs (if any);

k) Other expenses (if any);

2 . Contents of publicizing prices of medical equipment:

a) Name and type of medical equipment;

b) The company, producer; carriers, water holder;

c) Unit of calculation;

d) the maximum selling price of medical equipment corresponding to each configuration, technical features in unit;

dd) Price of components and accessories (if any);

e) Cost of warranty, maintenance and maintenance (if any);

g) Training costs (if any);

h) Other expenses (if any);

3 . The price of medical equipment is calculated in Vietnamese Dong.

4 . The holder of the free-sale registration number of the medical device is responsible for:

a) Make a price declaration that includes all the information specified in Clause 1 of this Article and post the information on the website of the Ministry of Health before putting the first medical device on the market. Vietnam;

b) Update the price of medical equipment when there is a change;

c) Designate a distributor to comply with the provisions of Points a and b of this Article for the case specified at Point c, Clause 1, Article 25 of this Decree. In case there are many distributors distributing the same item, the holder of the medical device registration number must designate a distributor to make the price declaration. Other distributors are not required to declare prices but may not sell more than the price declared by the designated distributor;

d) To declare and explain price constituents to tax administration agencies or at the request of state management agencies.

5 . Publicly on the portal of the Ministry of Health include the full information specified in paragraph 2 of this Article.

Section 3
EXPORT AND IMPORT OF EQUIPMENT HEALTH

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, quantity and variety. types and purposes 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 . The issuance of certificates of acceptance for free sale applies to medical equipment in accordance with the provisions of the law on foreign trade management.

4 . The temporary import for re-export, temporary export for re-import or border-gate transfer or transit of medical equipment shall comply with the provisions of law.

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

Article 47. Export and import of medical equipment

1 . Encourage domestic enterprises to produce for export.

2 . Organizations and individuals that import medical equipment has had a circulation must meet the following conditions:

a) As the owner of circulating or written authorization of the owner of circulation. Owners of circulation when authorized for import facility performing the import of medical equipment must simultaneously send a written authorization to the issuing agency and the circulation of the customs office;

b) Having a warehouse and means of transportation that meet the requirements specified in Clause 2, Article 40 of this Decree, or having a contract with a capable facility to preserve and transport medical equipment;

c) Having a storage warehouse and a system to monitor and manage the export, import and inventory of medical equipment containing narcotics and precursors that meet the requirements specified in Clause 3, Article 40 of this Decree.
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3 . The order and procedures for export and import of medical equipment and comply with the law on customs. Organized import of medical equipment not prove the satisfaction of the conditions stipulated in paragraph 2 of this article

when making customs procedures.

Article 48. Import permits

1 . Cases requiring an import license:

a) Medical equipment without a free-sale registration number imported only to serve scientific research, inspection, testing, testing, quality assessment, or training in the use and repair of equipment. medical equipment;

b) Imported medical equipment without a free-sale registration number to meet urgent needs for disease prevention and control, and to overcome consequences of natural disasters;

c) Medical equipment without a free-sale registration number imported for aid or humanitarian aid purposes; gifts and presents for medical establishments; serving fairs, exhibitions, display or product introduction;

d) medical facilities have not had a circulation of import operations to serve medical, humanitarian medical;

dd) Medical equipment without a free-sale registration number imported for use for personal treatment, including specific medical equipment or according to the special diagnostic needs of a medical establishment;

e) Used medical equipment:

- Imported for research and training purposes (do not practice on humans and do not use these medical devices for diagnostic and therapeutic purposes);

- Temporarily imported for re-export for display, introduction, participation in trade fairs and exhibitions.

Dossier, order and procedures for import, temporary import and re-export of medical equipment comply with the law on foreign trade management.

2 . An import license application dossier includes:

a) A written request for an import license;

b) Document briefly describing the technique of medical equipment in Vietnamese;

c) The certificate of satisfaction of quality control standards of that medical equipment manufacturer, certified by the organization or individual applying for the import license;

d) In case of imported for research purposes must include copies certified decision approving research projects and documents proving the page medical equipment import request was authority competent for circulation certified by organizations and individuals applying for import licenses;

e) In case of import to training must be more original training programs and documents proving the pages of medical devices import request was the agency authorized for circulation certified by the organization individuals applying for import licenses;

e) In case of import for the purpose of inspection, testing, testing and quality assessment, there must be a written certification from the unit competent to carry out the inspection, testing and inspection. testing and evaluating quality, clearly stating the quantity;

g) In case of import for aid, there must be a copy of the competent agency's decision approving the receipt of aid and documents proving that the medical equipment requested for import has been approved by the competent authority. the right to permit circulation, certified by the organization or individual applying for an import license;

h) In case of import of gifts and gifts for health facilities to obtain additional copies of documents showing content for gifted and documents proving the page medical equipment import request was competent authority for circulation certified by organizations and individuals applying for import licenses;

i) In case of import to serve active examination and treatment humane to have more documents to prove page medical equipment import request was the agency authorized for circulation certified of organizations and individuals applying for import licenses;

k) In case of import for special diagnostic needs of a medical facility, there must be additional documents proving that the medical equipment requested for import has been approved by a competent authority for circulation. of organizations or individuals applying for import permits;

l) In case of import for personal medical use, including personal-specific medical equipment, there must be a copy of the doctor's order in accordance with the individual's disease. import;

m) In case of import for use in trade fairs, exhibitions, display or product introduction, a copy of the program documents, invitation and performance contract is required;

n) In case of import to meet urgent needs of disease prevention and control, and to overcome consequences of natural disasters, the following documents are required:

- The written approval of the competent authority for the urgent needs in disease prevention and overcoming consequences of natural disasters or catastrophes;

- Documents proving that the medical equipment to be imported has been allowed to be circulated or used urgently by a competent authority, certified by the organization or individual applying for the import license.

3 . Procedures for considering the application for a license to import medical equipment:

a) If there is no request to amend or supplement the application for a license to import medical equipment, the Ministry of Health is responsible for: Organize the appraisal for import license within 15 working days. and 02 working days for medical equipment without a free-sale registration number imported to meet urgent needs of combating epidemics and overcoming consequences of natural disasters, from the date of receipt of complete and valid dossiers. (including documents certifying that the fee for assessment and grant of import permits has been paid in accordance with regulations of the Ministry of Finance). In case of refusal, there must be a written reply clearly stating the reason.

The import permit is sent to the organization or individual requesting the import, to the customs office.

b) In case the application for a license to import medical equipment is incomplete, the Ministry of Health must notify the organization or individual applying for a license to import medical equipment for supplementation or modification. The dossier must specify which documents to supplement, which contents need to be amended within 10 working days and 02 working days for medical equipment that does not have a free-for-sale registration number and meets the requirements. urgent need for disease prevention and control, and to overcome consequences of natural disasters or catastrophes, from the date of receipt of complete and valid dossiers.

c) When receiving a written request for supplementation or modification of the import dossier, the organization applying for an import license must supplement or amend it in accordance with the contents recorded in the document and send it to the Ministry of Health. .

In case the organization or individual applying for an import license has supplemented or modified the dossier but it is not in accordance with the requirements, the Ministry of Health will notify such organization or individual to continue to complete the dossier.

d) After 30 days from the date of the Ministry of Health's written request, if the organization or individual applying for the import license fails to supplement or amend the dossier, it must start over.

dd) If there are no additional or modification requests, the Ministry of Health is responsible for granting import permits as prescribed at Point a of this Clause. Import permits are sent to the organizations or individuals that request the import and to the customs offices.

Article 49. Dossier of application for a certificate of free sale for medical equipment

1 . Dossier of application for a certificate of free sale of medical equipment:

a) A written request for a certificate of free sale.

b) Submit a certified true copy of the certificate of satisfaction of quality standards issued by the conformity assessment organization in accordance with the law, which is still valid at the time of application submission.

2 . Procedures for granting a Certificate of Free Sale shall comply with the Government's Decree No. 69/2018/ND-CP dated May 15, 2018 detailing a number of articles of the Law on Foreign Trade Management.

Article 50. Competence and procedures for granting, re-issuing and revoking the certificate of free sale

1 . The Minister of Health is responsible for the renewal, re-issuance and revocation of certificates of free sale for medical equipment.

2 . Procedures for new issuance, re-issuance and revocation of the certificate of free sale shall comply with the Prime Minister's regulations on the issuance of the certificate of free sale.

Section 4
RIGHTS AND OBLIGATIONS OF ORGANIZATIONS AND INDIVIDUALS PARTICIPATING IN MEDICAL EQUIPMENT ACTIVITIES

Article 51. Rights of medical equipment trading establishments

1 . Request the seller of medical equipment to provide complete information, records of traceability and warranty of medical equipment.

2 . Requesting organizations and individuals importing, distributing and using products to cooperate in the recall and handling of defective medical equipment.

3 . Require owners circulation of medical equipment or facility maintenance are certified by the owner of medical equipment warranty obligations of medical equipment.

4 . To be notified by the registration number holder about the defective medical equipment.

5 . Other rights as provided for by law.

Article 52. Obligations of medical equipment trading establishments

1 . Implement internal control measures to maintain the quality of medical equipment as specified by the registration number holder.

2 . Provide adequate and timely for the user information about:

a) Instructions on the use of medical equipment; conditions for ensuring safety, preservation, calibration, inspection, maintenance and repair of medical equipment;

b) Notice of defective medical equipment.

3 . Publicize and post prices according to the provisions of law. Medical equipment may not be purchased or sold without a declared price and must not be purchased or sold at a price higher than the published price on the website of the Ministry of Health at the time of purchase and sale.

4 . Maintain records tracking medical equipment and implementation of traceability, withdrawal of medical equipment under the provisions of this Decree.

5 . Timely notify the owner of the circulation number and the State management agency about the cases of medical equipment with errors.

6 . Comply with legal regulations and decisions on inspection and examination of competent state agencies.

7 . Other obligations as prescribed by law.

Chapter VII
MEDICAL DEVICE SERVICES
Section 1
TECHNICAL CONSULTATION OF MEDICAL EQUIPMENT

Article 53. Conditions for consultancy services for technical medical equipment

1 . The performance of consulting services on cataloging and building configurations and technical features of medical equipment must be performed by individuals who have been granted certificates of training in equipment technical consulting. get medical.

2 . Conditions of the individual implementation of technical consultants Medical equipment:

a) Having a university degree in engineering or medicine or pharmacy or higher;

b) Having worked directly in the field of medical equipment engineering at a medical facility for 5 years or more;

c) Having been tested and recognized by a training institution as being capable of providing technical advice on medical equipment according to the training program promulgated by the Ministry of Health.

3 . The consultant may only consult on medical equipment technology after the Ministry of Health has publicized the information and announced the dossier of eligibility for consulting on medical equipment technology as prescribed at Point b. Clause 2, Article 54 of this Decree.

Article 54. Dossier and procedures for announcing eligibility for consulting on medical equipment technology

1 . Profile eligible published technical advice on medical equipment, including:

a) written proposal announced qualified consultants;

b) Certified copies of diplomas and certificates as prescribed at Points a and c, Clause 2, Article 53 of this Decree;

c) Confirmation of working time.

2 . Procedures for declaration of eligibility for consultancy on medical equipment technology:

a) Before providing technical advice on medical equipment, the person requesting the announcement of eligibility for consulting on medical equipment technology is responsible for submitting the application for announcement to the Ministry of Health.

b) Upon receipt of the application file (including the paper certifying the payment of fees as prescribed by the Ministry of Finance), the Ministry of Health shall publicly post information on the electronic portal on medical equipment management. and dossiers of declaration of eligibility for consultancy on technical medical equipment.

c) During operation, the consultant shall make written notice of the change together with the documents relating to the change and update the documents on records published publicly on the portal electronic management of medical equipment within 03 days to change the information in the dossier published.

Section 2
INSPECTION, CALIBRATION OF MEDICAL DEVICES

Article 55. Principles of inspection and calibration of medical equipment

1 . Medical equipment on the list announced by the Minister of Health must be inspected for safety and technical features before being put into use (except for the case specified in Article 57 of this Decree), periodically, after major repair. The inspection of medical equipment being measuring instruments and radiation equipment shall comply with the provisions of Clause 2 of this Article.

2 . Medical equipment is the measuring device or radiation equipment to make testing and calibration in accordance with the law on measurement and atomic energy.

Article 56. Conditions for providing medical equipment inspection services

Conditions on facilities and personnel; application file for the Certificate; Process of submitting paperwork; The order of issuing new, supplementing, re-issuing and withdrawing the Certificate of registration of inspection of medical equipment shall comply with current regulations of law on business conditions for conformity assessment service business. fit.

In which, the satisfaction of professional requirements in the field of medical equipment inspection is regulated as follows: for each inspection process that a registered accrediting organization performs, there must be at least 02 qualified auditors. certificate of training in that accreditation process.

Article 57. Exemption from the first inspection before being put into use for medical equipment

Medical equipment is exempt from first inspection before being put into use if it falls into one of the following cases:

1 . Medical equipment has a certificate of conformity.

2 . Medical equipment not had a circulation of imported for the purpose of scientific research for or used for training manuals, maintenance and repair of medical equipment.

3 . Medical equipment without a free-sale registration number is imported to be used for personal treatment by the importer or for humanitarian medical examination or treatment or for special diagnostic needs.

4 . Medical equipment without circulation number imported to serve the activities of fairs, exhibitions, display and product introduction.

Article 58. Handling of medical equipment that fails to meet inspection requirements

1 . In case the medical equipment fails to pass the inspection results before being put into use:

a) Medical facilities are not allowed to receive and use medical equipment;

b) The accrediting organization sends a written notice of the unsuccessful inspection results to the Ministry of Health;

c) In case there are 03 medical devices in the same batch with unsatisfactory test results in terms of safety and performance, the Ministry of Health shall request in writing the owners of the registration number to report the quantity medical equipment being circulated on the market and being used at medical facilities.

Based on the owner's report and the unsatisfactory test results, the Ministry of Health shall decide on the re-inspection, the number of samples that must be re-inspected or suspend the use of the medical equipment.

Based on the results of re-inspection, the Ministry of Health will decide to continue re-inspection, supplement the number of samples subject to re-inspection or request the owners of the circulation registration number to withdraw the entire page. medical equipment in that lot.

In case there are 03 batches of medical equipment that are recalled within the validity period of the free-sale registration number, the free-sale registration number shall be revoked for such medical equipment. Medical equipment that has been used at medical facilities before the time of issuance of the decision to revoke the free-sale registration number will continue to be used if the test results are satisfactory.

2 . In case the medical equipment has results of periodic inspection, inspection after major repair fails:

a) The medical facility is not allowed to continue using the medical equipment;

b) Remove the old inspection status sign;

c) To coordinate with the owner of the circulation in the conduct of the remedies and perform retest;

d) Equipment can only be used when there are satisfactory test results.

Chapter VIII

MANAGEMENT OF MEDICAL DEVICES AND MEDICAL DEVICES PRODUCTION MEDICAL DEVICES MANAGEMENT, EXTERNAL Substances containing DRUG substances and precursors

Article 59. Principles of management of raw materials for the production of medical equipment and controlled substances containing narcotics and precursors

1 . Raw materials for the production of medical equipment and controlled substances containing narcotics and precursors must be announced before being exported or imported in Vietnam.

2 . The clearance must be based on the published number and does not require an import permit from the Ministry of Health.

Article 60. Dossiers and procedures for publication of raw materials for the production of medical equipment and controlled substances containing narcotics and precursors

1 . Publication profile:

a) A document published materials for production of medical equipment, check the foreign substance containing narcotics and precursors;

b) Certificate of quality management;

c) Technical documents.

2 . Procedures for announcing concentration, content of drugs and precursors:

a) Before importing raw materials for the production of medical equipment and controlled substances containing narcotics and precursors, the importing establishment is responsible for posting complete and valid declaration documents according to regulations. specified in Clause 1 of this Article on the electronic portal on management of medical equipment;

b) After receiving a complete and valid dossier, the Ministry of Health shall publicly post on the electronic portal on medical equipment management information and announced dossiers for raw materials for medical equipment production. medical devices and controlled substances containing narcotics and precursors.

3 . Import and export establishments are responsible for re-announcing the concentration, content of drugs and precursors when there is any change in the published dossier.

Chapter IX
MEDICAL DEVICE INFORMATION

Article 61. Information about medical equipment

1 . Information on medical equipment is intended to guide the rational and safe use of medical equipment for medical staff and users of medical equipment.

2 . Information on medical equipment must be complete, objective, accurate, truthful, easy to understand, and must not be misleading.

3 . Responsibility for information about medical equipment is specified as follows:

a) Owners of circulation, the basis of purchasing medical equipment public shall have information on the risk level and the information relating to the use of medical equipment;

b) The medical facility is responsible for disseminating information about medical equipment within the facility;

c) Medical officers and employees are responsible for providing information on the level of risk of using medical equipment of categories C and D to patients;

d) The medical equipment management agency is responsible for disclosing information about medical equipment.

4 . Organizations and individuals providing information on medical equipment must be responsible for the information they provide.

5 . The Minister of Health is responsible for organizing the information system of medical equipment.

Article 62. Advertising of medical equipment

1 . Medical device advertising content must conform to one of the following documents:

a) Dossier for publication of standards applicable to medical equipment of categories A and B;

b) Application for registration of circulation for medical equipment of categories C, D.

2 . Advertising Medical equipment must contain the following:

a) Name of medical equipment, type, product code, manufacturer, manufacturing country;

b) Circulation number;

c) feature, the effect;

d) Name and address of the holder of the free-sale registration number of medical equipment or the organization authorized by the holder of the free-sale registration number of the medical equipment;

d) Warnings related to users' health and storage conditions (if any).

3 . Advertisements for medical equipment in audio and video newspapers must read or clearly display the content specified in Clause 2 of this Article.

4 . Before advertising, the holder of the free-sale registration number of medical equipment or the organization authorized in writing by the holder of the free-sale registration number of medical equipment shall publicly post it on the electronic portal. on the management of medical equipment, the content and form of the intended advertisement.

5 . The holder of the registration number of medical equipment or the organization authorized by the holder of the registration number of medical equipment shall be responsible before law for the conformity of the advertisement contents with the intended content. Advertisements posted and dossiers of announcement of standards applicable to medical equipment of categories A, B or dossiers of registration of circulation for medical devices of categories C and D.

6 . Materials or items that do not refer to the medical device name; documents or items that only list names and technical specifications of medical equipment but have no information on features and effects; scientific research papers; clinical documentation; Training materials supporting product manuals should not be considered promotional materials.

Chapter X
MANAGEMENT AND USE OF MEDICAL EQUIPMENT AT MEDICAL FACILITIES

Article 63. Principles of management and use of medical equipment

1 . The management and use of medical equipment must comply with the right purposes, functions and regimes, ensuring thrift and efficiency.

2 . Equipment health must be preserved, maintenance, maintenance, use and adhere to the technical instructions prescribed by the manufacturer and must be tested under the provisions of this Decree to ensure quality amount.

For pages of medical devices with stringent requirements for safety and labor sanitation in addition to compliance with regulations on quality assurance under the provisions of this Decree shall also comply with the provisions of law on labor safety and hygiene.

3 . To make, manage and store full dossiers on medical equipment; make timely and complete accounting of medical equipment in kind and its value according to current regulations of law on accounting, statistics and other relevant laws; ensure funding to perform the tasks specified in Clause 2 of this Article.

4 . To submit to the inspection, examination and supervision of the competent management agency in charge of medical equipment management.

Article 64. Management and use of medical equipment in state medical facilities

State-owned medical facilities, in addition to managing and using medical equipment as prescribed in Article 63 of this Decree, must manage medical equipment according to the following provisions:

1 . The investment, procurement, management and use of medical equipment must comply with the law on management and use of public property.

2 . Encourage the use of domestically produced medical equipment.

Article 65. Rights and responsibilities of medical facilities in the management and use of medical equipment

1 . Medical facilities have the right to:

a) Request the registration number owner or the warranty facility certified by the medical equipment owner to perform periodic maintenance during the warranty period;

b) Request the seller to provide technical documents of the medical equipment;

c) To receive the medical equipment used for the purpose of scientific research and manual, repair of medical equipment.

2 . Medical facilities are responsible for:

a) Use and operate medical equipment strictly according to the instructions of the owner of the medical equipment;

b) Periodically maintain, inspect and calibrate according to the instructions of the owner of the medical equipment or the provisions of law;

c) To participate in the trial, assessing the quality of medical equipment;

d) Report on the case of medical equipment fault and other information as required by the state agency having jurisdiction.

Chapter XI
ANNOUNCEMENT AND ONLINE REGISTRATION

Article 66. Online procedures

1 . Announcement of eligibility to manufacture medical equipment.

2 . Announcement of standards for medical equipment application.

3 . Registration of circulation of medical equipment.

4 . Announcement of eligibility to purchase and sell medical equipment.

5 . Announced qualified technical advice on medical equipment.

6 . Apply for a certificate of registration of medical equipment inspection activities.

7 . Apply for a license to import medical equipment.

8 . Apply for a certificate of free sale for domestically produced medical equipment.

9 . Price declaration medical equipment.

1 0. Announcement of concentrations and contents in raw materials for the production of medical equipment, externally controlled substances containing narcotics and precursors.

1 1. Publicize the content and form of advertising for medical equipment.

Article 67. Requirements for online application files

An online application for publication, registration, application for a license or a certificate of free sale (hereinafter referred to as registration dossier) is considered valid when it fully meets the following requirements:

1 . Full of papers and content of such papers are full declaration prescribed as records on paper and transferred into electronic text. The name of the electronic document must correspond to the name of the document in the paper file.

2 . Publication, registration and licensing information is entered completely and accurately according to information in electronic documents.

Article 68. Procedures for online publication

1 . The legal representative or the person authorized by the legal representative declares information, downloads electronic documents, confirms by digital signature (if any) and pays fees online according to the above process. Electronic portal on management of medical equipment.

2 . The agency that receives the online registration dossier shall carry out the administrative procedures corresponding to the registration dossier as prescribed in this Decree.

3 . The results of online administrative procedures have the same legal value as the results of administrative procedures handled by normal methods.

Article 69. Storage of online registration documents

1 . In case of online registration, the registration establishment must keep a paper copy of the registration dossier as prescribed in Clause 1, Article 33 of this Decree.

2 . In case the papers in the registration dossier specified in Clause 1 of this Article are lost or damaged, the registration establishment shall notify in writing the application-receiving agency, must complete the dossier and must notify in writing the application-receiving agency after completing the application, and update the dossier after obtaining the consent of the dossier-receiving agency.

3 . Within 35 days from the date of receipt of the notice of the loss of the dossier, if the establishment does not notify in writing that the dossier has been re-completed, the dossier-receiving agency shall:

a) Remove information posted on the web portal related to medical equipment manufacturers, medical equipment trading establishments, medical equipment technical consultants , medical equipment production materials, externally controlled substances containing narcotics and precursors, medical equipment inspection establishments, equipment's circulation number;

b) Revoking the free-sale registration number and the license to import medical equipment.

4 . The registration establishment may not continue to operate and the medical equipment shall not be circulated from the time the application-receiving agency cancels the information as prescribed in Clause 3 of this Article.

Chapter XII
ORGANIZATION OF IMPLEMENTATION

Article 70. Responsibilities of the Ministry of Health

The Ministry of Health is responsible before the Government for performing the state management of medical equipment and has the following tasks and powers:

1 . To submit to the Government and Prime Minister for promulgation or promulgate according to its competence legal documents, national technical regulations, strategies, policies and plans on medical equipment.

2 . Directing and organizing the implementation of legal documents, strategies, policies and plans on medical equipment.

3 . Organize information and communication about medical equipment.

4 . Organize training and retraining of human resources to work with medical equipment.

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

a) Price of medical equipment declared by the enterprise;

b) The winning bid for medical equipment procurement from State medical facilities nationwide;

c) List of medical equipment whose circulation number has been revoked.

6 . To decide on the application or exemption of the provisions of this Decree to the case that products and goods managed by some countries are medical equipment but not managed by other countries are medical equipment.

7 . Inspect, examine, settle complaints and denunciations and handle violations of the law in the field of medical equipment. During the course of inspection and control of medical equipment prices, if detecting that the price declarer does not publish sufficient information related to the price of medical equipment, the competent state management agency shall of the Ministry of Health to notify the price declarer to review the information related to the declaration and clearly state the reason.

8 . Update and publish the list of organizations specified at Point a, Clause 2, Article 29 of this Decree.

9 . Detailed regulations on the classification of medical equipment to ensure compliance with international treaties on classification of medical equipment of the Association of Southeast Asian Nations to which Vietnam is a member; promulgating a practical training program on classification of medical equipment.

1. Promulgate a list of medical equipment that must be inspected and the inspection process for each type of medical equipment in the list.

1 1. Specific guidance on how to record the common technical dossier of medical equipment prescribed by the ASEAN.

1 2. Specifying forms to guide the implementation of this Decree.

Article 71. Responsibilities of the Ministry of Science and Technology

1 . Promulgate a list of medical equipment that is a measuring instrument subject to sample approval, inspection and calibration after obtaining the consent of the Ministry of Health.

2 . To assume the prime responsibility for or coordinate with the Ministry of Health in formulating national standards on medical equipment; inspect and examine the quality of medical equipment that is measuring means and radiation equipment.

Article 72. Responsibilities of the Ministry of Finance

1 . To guide the management of public property being medical equipment for state-owned medical facilities after consulting the Ministry of Health.

2 . Specifying the management and use of fees and charges in the field of medical equipment in accordance with the law on fees and charges.

3 . Test, inspection and sanction laws on medical equipment price.

Article 73. Responsibilities of the Provincial People's Committee

1 . Responsible for managing activities related to the business and use of medical equipment in the province.

2 . Organize information and communication about medical equipment in the province.

3 . Organization fostering human resources working in health facilities in the province.

4 . Publicly post on the web portal of the Provincial People's Committee and send information to the Ministry of Health about:

a) Winning bid for procurement of medical equipment from state medical facilities in the province.

b) The list of medical equipment have been withdrawn from circulation numbers in the province.

5 . Inspect, examine, settle complaints and denunciations and handle violations of the law in the field of medical equipment in the province.

Article 74. Responsibilities of organizations and individuals trading in medical equipment

1 . Organizations and individuals trading in medical equipment must take responsibility for the safety and quality of the medical equipment they trade.

2 . Domestic medical equipment manufacturers are responsible for managing the quality of medical equipment in the process of manufacturing, transporting and preserving medical equipment in accordance with the dossiers issued with free-sale registration numbers.

3 . The circulation number holder is responsible for:

a) Carry out the classification, publish on the web portal of the Ministry of Health and take responsibility before law for the classification results for the medical equipment that they have classified;

Take remedial measures in cases of issuing false classification results to reduce the risk level of medical equipment or issuing results of misclassification according to authority specified in this Decree.

b) Make the announcement of applicable standards or register the free sale of medical equipment in accordance with this Decree. To take responsibility before law for the accuracy and truthfulness of the application file for a free-sale registration number;

c) Establish, maintain establishments inventory of medical equipment or contracting with base warranty page medical devices, unless the equipment medical disposable prescribed by owners Friendly medical equipment or documents proving no warranty;

d) Prepare and maintain medical equipment monitoring records and trace the origin of medical equipment according to the provisions of this Decree, except for the case of single-use medical equipment according to regulations. designation of the owner of the medical device; report to the police agency when detecting the loss of medical equipment containing narcotics and precursors, raw materials for production of medical equipment containing narcotic substances and precursors;

e) adequate information, accurate product labels, in documents accompanying medical equipment prescribed by legislation on labeling and the provisions of this Decree;

e) Warning timeliness, completeness and accuracy of the risk of adversely affecting the health of the user and the environment; precautions for sellers and consumers; provide information about the requirements for the transportation, storage, preservation and use of medical equipment;

g) Promptly stop circulation, notify relevant parties and take measures to handle, remedy or recall defective medical equipment as prescribed in this Decree. In case of disposal by destruction, the destruction of medical equipment must comply with the provisions of the law on environmental protection and relevant laws and must bear all costs for the treatment. destroy it;

h) Comply with legal regulations and decisions on inspection and examination by state agencies authorized;

i) Compensation for damage as prescribed by law when the medical equipment is faulty;

k) Responsible for ensuring the following papers are always in effect during the circulation value:

- Paper circulated for medical equipment imports;

- Power of attorney, except for the case specified at Point a, Clause 1, Article 25 of this Decree;

- Certificate of eligibility for warranty, except for the case of single-use medical equipment as specified by the owner of the medical equipment, or documents proving that there is no warranty.

l) Be responsible for ensuring that the medical equipment is only manufactured during the validity period of the manufacturer's certificate of meeting quality management standards;

m) To take responsibility before law for the legality and accuracy of the document was published when performing the procedures in this Decree;

n) Provide medical facility where medical equipment purchase 01 sets of records management stipulated in paragraph 4 of Article 33 of this Decree of medical equipment including;

o) Declare and update the selling price of medical equipment or appoint an organization to declare and update the selling price of medical equipment;

p) Other obligations as prescribed by law.

4 . Basis trading, export, import and transfer of equipment and medicine, material production, the foreign substance inspection containing narcotic substances and precursors are responsible for reporting to the Ministry of Health and to the Ministry of Public Security in annually before 15 June of the following year 01.

Chapter XIII
IMPLEMENTATION PROVISIONS

Article 75. Effect

1 . This Decree takes effect from January 1, 2022.

2 . The following Decrees cease to be effective from the effective date of this Decree:

a) Decree No. 36/2016/ND-CP dated May 15, 2016 of the Government on management of medical equipment;

b) Decree No. 169/2018/ND-CP dated December 31, 2018 of the Government amending and supplementing a number of articles of the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on medical equipment management;

c) Decree No. 03/2020/ND-CP dated January 1, 2020 of the Government amending and supplementing Article 68 of Decree No. 36/2016/ND-CP dated May 15, 2016 of the Government on management medical equipment has been amended and supplemented in Decree No. 169/2018/ND-CP dated December 31, 2018 of the Government amending and supplementing a number of articles of Decree No. 36/2016/ND-CP. CP dated May 15, 2016 of the Government on management of medical equipment.

3 . The provisions of Article 7 of Decree No. 181/2013/ND-CP dated November 14, 2013 of the Government detailing the implementation of a number of articles of the Law on Advertising are annulled from July 1, 2022.

Article 76. Transitional provisions

1 . The pages of medical devices were manufactured in Vietnam or were imported Vietnam before this Decree takes effect shall continue to circulate until being liquidated in accordance with the law on management and use use public property or until the expiry indicated on the certificate of registration for circulation or to the expiry date of the product.

2 . Regulations on the value of circulation numbers and import permits issued before January 1, 2022:

a) Medical equipment that has been granted a free-sale registration number in accordance with the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on the management of medical equipment has been amended and supplemented. 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), this circulation number is valid for an indefinite period. term;

b) For domestically-manufactured medical equipment that has been granted a certificate of free sale, the certificate of registration is valid until the expiration of the time indicated on the certificate of registration of circulation;

c) medical equipment is not biological in vitro diagnostic have been granted import licenses from 01 January 01 2018, the import license is valid until December 31, 2022;

d) For medical equipment that is not on the list of required import permits (except for chemicals, insecticidal and germicidal preparations used in the household and medical fields that have only one purpose of disinfecting the equipment). medical equipment) and has been classified as medical equipment of categories C, D and announced by the Ministry of Health on the electronic portal to continue to be imported until the end of December 31, 2022 according to the regulations of the Ministry of Health. demand, unlimited quantity without a written certification of medical equipment by the Ministry of Health when carrying out customs clearance procedures;

e) Home medical equipment is biological in vitro diagnostic have granted registration numbers from 01 January 01 2014 to December 31, 2017, the registration numbers for circulation are valid for use until the end December 31, 2022;

e) For medical equipment that is an in vitro diagnostic biological product, which has been granted a free-sale registration number from January 1, 2018, this free-sale registration number is valid until the expiry date indicated on the registration paper. circulate;

g) Imported medical equipment that is an in vitro diagnostic biological product that has been granted an import license since January 1, 2018, this import license is valid until the end of December 31, 2022 and There is no limit on the number of imports. The Customs authority does not control the quantity of imports in this case.

3 . The application for issuance of a circulation registration number submitted under the provisions of Decree No. 36/2016/ND-CP before January 1, 2022 up to the effective date of the Decree has not yet been granted a free-sale registration number. is handled as follows:

a) For registration documents circulation of equipment health of type B, the Health Ministry guiding businesses have filed conduct a review to implement the announced criteria applied under the provisions of this Decree shall return without appraisal licensing fees for circulation;

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

c) To use classification results issued by the classification organization that have been issued with the receipt of the application for declaration of eligibility for classification of medical equipment before the effective date of this Decree in the application file for issuance. circulation number.

4 . Dossier of application for an import license for medical equipment submitted before January 1, 2022 will continue to be processed according to the provisions of legal documents issued by the Minister of Health. promulgated before the effective date of this Decree. Import permits issued under this Clause are valid until the end of December 31, 2022.

5 . Labels of medical equipment that have been manufactured in Vietnam or imported into Vietnam before the date specified in Clauses 2 and 4 of this Article may continue to be used until the end of the useful life of the equipment. medicine or until it is liquidated in accordance with the law on management and use of public property, or until the expiry date indicated on the certificate of circulation registration or the expiry date of the product.

6 . Regulations on application of CSDT dossiers:

a) Compulsory application of CSDT dossiers from January 1, 2023.

b) Dossier for new issuance of a free-sale registration number submitted before December 31, 2022; a new application for a free-sale registration number shall include the papers specified at Points a, b, d, and dd, Clause 1, Article 30 of this Decree and other relevant documents. following documents:

- A brief technical description of the medical equipment in Vietnamese, enclosed with a technical document describing the functions and technical parameters of the medical equipment, issued by the owner of the medical equipment. .

Particularly for reagents, calibrators, in vitro control materials: technical documents in Vietnamese together with documents on materials, product safety, production process and product quality control product, clinical and preclinical study reports including stability reports.

- Documentation of use of medical equipment.

- Sample label to be used when circulating in Vietnam of medical equipment.

The above documents must meet the following requirements:

- For technical documentation of medical equipment: Submit copies certified by the organization applying for the circulation.

- For user manuals of medical equipment: Submit a copy in Vietnamese certified by the organization applying for the free sale number, enclosed with the original in English, issued by the owner of the medical device. promulgated for imported medical equipment.

- For label samples: Submit a sample label certified by the organization applying for a free-sale registration number. Label samples must meet the requirements of the law on goods labels.

c) The receipt and appraisal of the application for registration of free sale of medical equipment specified at Point b of this Clause shall be as follows:

- In case there is no request to amend or supplement the application for circulation registration, the Minister of Health is responsible for: Organize the appraisal to issue a free-sale registration number within 90 days from the date of receipt of the application. complete and valid (including documents 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;

- Where registration dossiers circulation unfinished, the Ministry of Health must inform the organization applying for circulation to supplement or amend registration documents circulated, stating the specific complementary what documents, content needs to be modified for a period of 70 days from the date of receipt of complete documents, valid;

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

In case the establishment applying for a free-sale registration number has added or modified its dossier but it is not in accordance with the requirements, the Ministry of Health shall notify the establishment to continue to complete the dossier according to the provisions of Point b, Clause 6 of this Article. this.

After 90 days from the date the Ministry of Health issues a notice of the request, but the establishment does not supplement or amend the dossier, or if after 05 times of amending and supplementing the dossier from the date the Ministry of Health requests the amendment, If the application is supplemented for the first time but still does not meet the requirements, the procedure for applying for a free-sale registration number must be repeated from the beginning.

7 . Disclosure of content and advertising of medical equipment will be applied from July 1, 2022.

8 . The owner of the free-sale registration number or the establishment named in the license to import medical equipment issued before the effective date of this Decree must comply with the provisions of Clause 4, Article 45 of this Decree before January 1. April 2022 for medical equipment circulating on the Vietnamese market and before the first medical equipment is circulated on the Vietnamese market.

Article 77. Responsibility for guidance and 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 related agencies, organizations and individuals are responsible for the implementation. this Decree.

Recipients:
- Secretariat of the Party Central Committee;
- Prime Minister, Deputy Prime Ministers;
- Ministries, ministerial-level agencies, agencies attached to the Government;
- People's Councils and People's Committees of provinces and centrally run cities;
- Central Office and Party Committees;
- Office of the General Secretary;
- Office of the President;
- Nationalities Council and the Committees of the National Assembly;
- Congress office;
- Supreme People's Court;
- People's Procuratorate of the Supreme;
- State audit;
- National Financial Supervisory Commission;
- Bank of Social Policy;
- Vietnam Development Bank;
- Central Committee of the Vietnam Fatherland Front;
- Central body of unions;
- Office of Government: BTCN, PCNs, Assistant to TTg, General Director of e-portal portal, Departments, Departments, affiliated units, Official Gazette;
- Save: VT, KGVX (2).

TM. GOVERNMENT
KT. PRIME MINISTER
VICE PRIME MINISTER

Vu Duc Dam

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