THE GOVERNMENT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

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Hanoi, November 08, 2021

DECREE

PRESCRIBING MEDICAL DEVICE MANAGEMENT

Pursuant to the Law on Government Organization dated June 19, 2015; the Law on Amendments to the Law on Government Organization and the Law on Local Government Organization dated November 22, 2019;

Pursuant to the Law on Investment dated June 17, 2020;

At the request of the Minister of Health;

The Government promulgates a Decree prescribing medical device management.

Chapter I

GENERAL PROVISIONS

Article 1. Scope

1. This Decree deals with the management of medical devices, including: classification of medical devices; manufacture, placement on the market, trading, import, export and provision of services related to medical devices; medical device information and advertising; management of prices of medical devices, and management and use of medical devices in health facilities.

2. This Decree does not apply to:

a) Ingredients and semi-finished products used for manufacture of medical devices, except raw materials containing narcotic substances and precursors;

b) Raw materials for manufacture of medical devices, including samples of blood, serum, plasma, urine, fecal, body fluids or other human materials that are subject to biosafety requirements upon import/export as prescribed by law;

c) Medical gas;

d) Medical device accessories;

dd) Research Use Only (RUO) and Laboratory Use Only (LUO) products.

Article 2. Definitions

1. “medical device” means any instrument, implant, apparatus, material, in-vitro reagent or calibrator, or software that meets all of the following requirements:

a) It is intended, by the product owner, to be used, whether alone or in combination, for human beings for the purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease, or compensation for an injury or trauma;

- investigation, replacement, modification or support of the anatomy or of a physiological process;

- supporting or sustaining life;

- control of conception,

- disinfection of medical devices;

- providing information serving diagnosis, monitoring or treatment through examination of specimens derived from the human body.

b) The device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means to serve the purposes mentioned in Point a of this Clause.

2. “in vitro diagnostic (IVD) medical device” means a reagent, calibrator, control material, instrument, apparatus, equipment or system or other product, whether used alone or in combination, intended by the product owner, to be used in vitro for the examination of specimens derived from the human body.

3. “personalized medical device” means a medical device that is specifically made in accordance with a duly qualified medical practitioner’s written prescription, which gives, under his responsibility, specific design characteristics and intended for the sole use of a particular individual.

4. “accessory” means an article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose.

5. “product owner” means any organization or person that:

a) supplies the medical device under its/his own name, or under any trademark, design, trade name or other name or mark owned or controlled by it/him; and

b) is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose.

Article 3. Principles of management of medical devices

1. The quality, safety and efficacy of the medical device must be verified.

2. Adequate, accurate and timely information about specifications and intended purpose of the medical device and potential risks to the user must be provided.

3. The traceability of medical devices must be ensured.

4. Medical devices shall be managed in accordance with risk classification rules and relevant national technical regulations and/or national standards issued or recognized by competent regulatory authorities or announced standards applied by organizations/individuals in accordance with regulations of law.

5. Medical devices that are measuring devices or radiation equipment must be managed in accordance with regulations of the law on measurement, the law on atomic energy and regulations herein.

6. Chemicals and preparations intended solely for disinfection of medical devices shall be managed in accordance with regulations herein. Chemicals and preparations intended for other purposes, in addition to the disinfection of medical devices, shall be managed in accordance with regulations of law on insecticidal and germicidal chemicals and preparations for medical and household use.

7. Medical devices, raw materials or ingredients used for manufacturing of medical devices, and substances for external quality assessment that contain narcotic substances and precursors must be managed in accordance with regulations of law on drug control, if they are imported or exported, and regulations herein.

8. Regulations on classification, issuance of registration number, and eligibility requirements for trading of medical devices laid down herein shall not apply to:

a) Software used for medical devices;

b) Medical devices that are traded as normal goods and imported as gifts or presents given to individuals or organizations other than health facilities.

Chapter II

CLASSIFICATION OF MEDICAL DEVICES

Article 4. Classes of medical devices

Medical devices shall be classified into the following 4 classes according to their levels of potential risks related to their designs and manufacture:

1. Class A: Low risk.

2. Class B: Low-moderate risk.

3. Class C: Moderate-high risk.

4. Class D: High risk.

Article 5. Classification rules for medical devices

1. The classification of medical devices must be carried out in accordance with risk classification rules.

2. In the event that a medical device only has one intended purpose which is assigned into two or more risk levels, that medical device shall be assigned into the class representing the highest risk level.

3. In the event that a medical device has multiple intended purposes and each of which represents various risk levels, that medical device shall be assigned into the class representing the highest risk level.

4. In the event that a medical device is designed to be used in combination with another medical device, each of the medical devices shall be classified separately.

IVD medical devices that are equipment or systems used in testing process and reagents, titrants, calibrators or control materials may be assigned into various risk levels but assigned into the class representing the highest level of risks posed by the final purpose of that medical device as a whole. IVD medical devices that are other products used in or supporting testing process may be separately assigned into risk levels.

5. The Minister of Health shall provide detailed guidelines on classification of medical devices in accordance with ASEAN's treaties on classification of medical devices to which Vietnam is a signatory.

6. The classification of medical devices must be carried out by the classification body whose name is specified in the declaration of applied standards or certificate of registration of medical device.

Article 6. Cancellation of classification results

1. Classification results shall be cancelled in the following cases:

a) The incorrect classification result reduces the level of risk of the medical device;

b) The record of classification results is found fraudulent.

2. Procedures for cancellation:

a) Within 01 working day from the day on which a conclusion mentioned in Clause 1 of this Article is given, the Ministry of Health shall issue a decision to cancel classification result which request the classification body to implement remedial measures (if any) and remove the cancelled classification result from the Portal on management of medical devices.

The decision to cancel classification result shall be sent to the classification body, Provincial Departments of Health, General Department of Customs and border checkpoint customs authorities, and published on the Portal on management of medical devices.

b) After receiving the decision to cancel classification result, the classification body shall cancel all classification results specified in the decision and implement remedial measures against its violations (if any).

c) After receiving the decision to cancel classification result, the authority that has received the application for declaration of applied standards or application for registration number (hereinafter referred to as "application for registration number") shall review the registration numbers issued, and follow procedures for revoking the registration numbers of medical devices that have been issued using classification results specified in the Ministry of Health's decision to cancel classification results.

Article 7. Handling of medical devices whose classification results are cancelled

1. In case a medical device whose classification result is cancelled has not been granted the registration number:

a) The applicant for registration number shall send a written request to the receiving authority to suspend procedures for issuance of registration number.

b) After receiving the written request mentioned in Point a of this Clause or the decision to cancel classification result, the receiving authority shall refuse to issue the registration number.

2. In case a medical device whose classification result is cancelled has been granted the registration number but has not been granted customs clearance:

a) The registration number holder shall stop following procedures for customs clearance, request the checkpoint customs authority to suspend procedures for customs clearance, and request the registration number issuer to revoke the issued registration number.

b) After receiving the written request from the registration number holder or the decision to cancel classification result, the customs authority shall suspend procedures for customs clearance, and the registration number issuer shall follow procedures to revoke the issued registration number.

3. In case a medical device whose classification result is cancelled has been granted the registration number and customs clearance but has not been purchased:

a) The registration number holder shall:

- Stop placing on the market and recall the medical device granted the registration number using the classification result that has been cancelled;

- Send a report to the customs authority that granted customs clearance in which the quantity of medical device granted customs clearance must be specified, and do not follow procedures for import of the following shipments until the relevant medical device is granted a new registration number using the correct classification result;

- Send a report to the registration number issuer specifying the quantity of medical device granted customs clearance and the sale contracts (if any);

- Reapply for the registration number.

b) After receiving the registration number holder's written request or the decision to cancel classification result:

- The customs authority shall refuse to grant customs clearance;

- The registration number issuer shall revoke the issued registration number.

4. If the medical device has been sold to health facilities:

a) The registration number holder shall:

- Send a report to the registration number issuer specifying the quantity of medical device sold to health facilities;

- Send written notices to health facilities that purchased the medical device.

b) If the medical device granted the registration number using incorrect classification result does not pose threats to patients' heath, health facilities may keep using the medical device and the registration number holder shall supplement the documents about registration of the medical device after a new registration number is granted.

c) If the medical device granted the registration number using incorrect classification result is found to pose threats to patients' heath, health facilities shall stop using the medical device and the registration number holder shall implement necessary measures for ensuring normal operation of such health facilities.

Chapter III

MANUFACTURE OF MEDICAL DEVICES

Article 8. Requirements for quality control by medical device manufacturer

1. The manufacturer's quality control system must comply with ISO 13485.

2. A manufacturer of the medical device that contains narcotic substances and precursors shall, in addition to the requirements laid down in Clause 1 of this Article, also meet the following requirements:

a) It has a system for monitoring the dispatching, warehousing, inventory and use of narcotic substances and precursors, the medical devices and raw materials containing narcotic substances and precursors;

b) Medical devices and raw materials containing narcotic substances and precursors must be safely stored in a separate area or warehouse.

Article 9. Application for declaration of eligibility for manufacture of medical devices

An application for declaration of eligibility for manufacture of medical devices includes:

1. The declaration of eligibility for manufacture of medical devices.

2. Certificate of conformity with ISO 13485 quality control standards issued by the conformity assessment body in accordance with regulations of law.

3. The documents proving the satisfaction of eligibility requirements specified in Clause 2 Article 8 of this Decree.

Article 10. Requirements for application for declaration of eligibility for manufacture of medical devices

1. A set of application for declaration of eligibility for manufacture of medical devices shall be prepared. To be specific:

a) Documents included in the application must be clearly printed and arranged in the order prescribed in Article 9 of this Decree; space must be provided between content parts in a document; the application must have covers and a list of documents.

b) Documents in a language other than English and Vietnamese must be translated into Vietnamese. Vietnamese translations must be notarized in accordance with regulations of law.

2. Requirements for some documents in an application for declaration of eligibility for manufacture of medical devices:

a) The original or certified true copy or copy bearing the applicant's certification of the Certificate of conformity with quality control standards.

b) The originals bearing the applicant's certification of documents proving its satisfaction of eligibility requirements as set out in Clause 2 Article 8 of this Decree.

Article 11. Procedures for declaration of eligibility for manufacture of medical devices

1. Before initiating manufacture of medical devices, the manufacturer shall submit an application for declaration of eligibility for manufacture of medical devices to the Department of Health of province where its factory is located (the manufacturer's factory is specified in the certificate of quality control system). Where there are multiple factories located in different provinces, application for each province shall be submitted.

2. After receiving the application (including application fee receipt as prescribed by the Ministry of Finance), the Department of Health of province where the factory is located shall publish on the Portal on management of medical devices all information about and application for declaration of eligibility for manufacture of medical devices.

3. During its operation, the manufacturer shall prepare a notice of changes which is accompanied by supporting documents for such changes, and update such documents to its application for declaration of eligibility for manufacture of medical devices published on Portal on management of medical devices within 03 working days from the occurrence of such changes.

Chapter IV

CLINICAL STUDY ON MEDICAL DEVICES

Article 12. Clinical study stages for medical devices

1. Stage 1: preliminary study to determine the safety of medical device for patients and its usability for medical practitioners and healthcare workers.

2. Stage 2: confirmatory study to ascertain and establish evidence for the safety and efficacy of medical device.

3. Stage 3: post-market study conducted after the medical device is placed on market to assess the safety and efficacy of the medical device when used under the conditions in broader populations.

Article 13. Requirements for medical devices undergoing clinical study

1. The medical device meets quality standards specified in the clinical study application.

2. Technical parameters of the medical device have been duly inspected to ensure its quality and safety.

3. The medical device must be labeled as “for clinical study only - not for any other purposes”. The labeling of medical devices shall comply with regulations of law on labeling of goods.

Article 14. Requirements for organizations conducting clinical study on medical devices

An organization conducting clinical study on medical devices (hereinafter referred to as “clinical study institution”) is required to meet the following requirements:

1. It is a scientific research institution that is independent from the organization or individual whose medical device undergoes clinical study.

2. It must have clinical study laboratory or site, quality control system and technical documents that meet the Good Clinical Practice (GCP) guidelines adopted by the Minister of Health.

3. It has adequate human resources to conduct clinical studies, including:

a) Principal investigator who must have appropriate professional qualifications and competence in research, and experience in clinical practice and use of medical devices, have a thorough grasp of regulations on science and technology management and codes of ethics in research, and be capable of conducting clinical study on medical devices.

b) Researchers who must have professional qualifications and competence meeting research requirements, and have completed training courses in knowledge and skills in clinical study on medical devices.

Article 15. Clinical study dossiers

A clinical study dossier consists of the following application for approval to conduct clinical study, application for approval of changes to clinical study, and application for approval of clinical study results:

1. An application for approval to conduct clinical study consists of:

a) The application form for approval to conduct clinical study.

b) Documents about the medical device undergoing the clinical study, including:

- Description of the investigational product (general information about the investigational medical device, including: name, specifications, uses and other relevant information);

- Documents about pre-clinical study on the investigational medical device, including: study report on the safety and efficacy of the medical device, and recommendations for use and storage of the device;

- Documents about previous stages of the clinical study on the medical device (in case an application for following-stage clinical study is submitted and the medical device is not exempt from previous clinical study stages).

c) Legal documents about the medical device undergoing the clinical study, including:

- Technical documents for medical device;

- Technical standards and records of testing/inspection of the medical device issued by competent authorities;

- The user manual if the medical device undergoes stage-3 clinical study;

- Certifications of participation given by research institutions in a multi-center clinical study conducted in Vietnam;

- The cooperative agreement on clinical study between the authority, organization or individual whose medical device undergoes the clinical study and the clinical study service provider; the cooperative agreement between organization or individual whose medical device undergoes the clinical study and the sponsor of the clinical study (if any).

d) Clinical study protocol and protocol description, including: Description of the clinical study on medical device and questionnaires or CRFs (Case Report Forms).

dd) Scientific CV and copy of certificate of completion of GCP training course, issued by the Ministry of Health or qualified GCP training program provider, of the principal investigator.

e) Informed consent forms given by the clinical study volunteers.

g) The record of review of ethical and scientific aspects of the clinical study made by the Internal Ethics Committee.

h) Label of the medical device as prescribed in Clause 3 Article 13 of this Decree and instructions for use of the investigational medical device.

2. An application for approval of changes to clinical study consists of:

a) The application form for approval of changes to clinical study.

b) Updated versions of the corresponding documents specified in Clause 1 of this Article, as changed.

c) Review record made by the Internal Ethics Committee if changes to the clinical study may affect the health and benefits of the participants or the design, process and procedures of the clinical study.

3. An application for approval of clinical study results consists of:

a) The application form for approval of clinical study results.

b) The copy of the approved clinical study protocol;

c) The copy of the decision on approval of the clinical study protocol;

d) The record of review of clinical study results made by the Internal Ethics Committees;

dd) The full text of the report on clinical study results.

4. Requirements for documents:

a) Documents in the clinical study dossier must be made in Vietnamese. Documents in a language other than Vietnamese must be accompanied by their notarized Vietnamese translations.

b) Documents issued by foreign authorities require consular legalization in accordance with regulations of law on consular legalization, except for the case in which consular legalization is exempted in accordance with regulations of law.

Article 16. Procedures for approval of clinical study on medical devices

1. The clinical study institution (the applicant) shall send, directly or by post, an application for approval to conduct clinical study to the Ministry of Health.

2. The Ministry of Health shall check the validity of the application within 05 working days from the date of receipt. If the application is valid, within 02 working days, the Ministry of Health shall transfer it to the National Ethics Committee for review. If the application is not valid, a written notice of request for modification of the application shall be sent to the applicant.

The applicant must complete the application within 60 days from the receipt of the notice. After this period, the application shall be rejected.

3. Within 25 days from the receipt of the valid application, the National Ethics Committee shall hold a meeting to review the clinical study protocol which must be duly recorded.

If the clinical study protocol is satisfactory, the National Ethics Committee shall issue a Certificate of approval of the clinical study protocol.

If the clinical study protocol is refused or requires modification, the National Ethics Committee shall give a written notice in which reasons for such refusal or modification must be specified. The applicant shall complete and send the application to the National Ethics Committee within 90 days from the receipt of the notice. After this period, the application shall be rejected.

Within 07 working days from the receipt of the complete application, the National Ethics Committee shall hold a meeting to review the application. If the application is satisfactory, the National Ethics Committee shall issue a Certificate of approval of the clinical study protocol. If the application is refused, the National Ethics Committee shall give a written notice in which reasons for such refusal must be specified.

An application shall not be modified more than 03 times.

4. Within 05 working days from the receipt of the Certificate of approval of the clinical study protocol and accompanied documents, the Ministry of Health shall issue a decision to approve the clinical study protocol.

Article 17. Procedures for approval of changes to clinical study on medical devices

1. The clinical study institution (the applicant) shall send, directly or by post, an application for approval of changes to clinical study to the Ministry of Health.

2. The Ministry of Health shall check the validity of the application within 05 working days from the date of receipt. If the application is not valid, written notices of request for modification of the application shall be sent to the applicant until the application is considered valid. The applicant shall complete the application within 60 days from the receipt of the notice. After this period, the application shall be rejected.

If the application is valid, within 02 working days, the Ministry of Health shall transfer the application to the National Ethics Committee for review of changes to the clinical study protocol which must be duly recorded.

3. Within 25 days from the receipt of the valid application, the National Ethics Committee shall hold a meeting to review changes to the clinical study protocol which must be duly recorded.

If the clinical study protocol is satisfactory, the National Ethics Committee shall issue a Certificate of approval of changes to the clinical study protocol.

If the clinical study protocol is refused or requires modification, the National Ethics Committee shall give a written notice in which reasons for such refusal or modification must be specified. The applicant shall complete and send the application to the National Ethics Committee within 60 days from the receipt of the notice. After this period, the application shall be rejected.

Within 07 working days from the receipt of the complete application, the National Ethics Committee shall review the application. If the application is valid, the National Ethics Committee shall issue a Certificate of approval of changes to the clinical study protocol. If the application is refused, the National Ethics Committee shall give a written notice, in which reasons for such refusal must be specified, to the applicant.

An application shall not be modified more than 03 times.

4. Within 05 working days from the receipt of the Certificate of approval of changes to the clinical study protocol and accompanied documents, the Ministry of Health shall issue a decision to approve changes to the clinical study protocol.

Article 18. Procedures for approval of clinical study results for medical devices

1. The clinical study institution (the applicant) shall send, directly or by post, an application for approval of clinical study results that is made in Vietnamese to the Ministry of Health.

2. The Ministry of Health shall check the validity of the application within 05 working days from the date of receipt. If the application is valid, within 02 working days, the Ministry of Health shall transfer it to the National Ethics Committee for review. If the application is not valid, a written notice of request for modification of the application shall be sent to the applicant.

The applicant shall complete the application within 60 days from the receipt of the notice. After this period, the application shall be rejected.

3. Within 25 days from the receipt of the valid application, the National Ethics Committee shall hold a meeting to review clinical study results which must be duly recorded.

If the application is satisfactory, the National Ethics Committee shall issue a certificate of approval of clinical study results.

If clinical study results are refused or require modification, the National Ethics Committee shall give a written notice, in which reasons for such refusal or modification must be specified, to the applicant. The applicant shall complete and send the application to the National Ethics Committee within 60 days from the receipt of the notice. After this period, the application shall be rejected.

Within 07 working days from the receipt of the complete application, the National Ethics Committee shall review the application. If the application is valid, the National Ethics Committee shall issue a Certificate of approval of clinical study results. If the application is refused, the National Ethics Committee shall give a written notice, in which reasons for such refusal must be specified, to the applicant.

An application shall not be modified more than 03 times.

4. Within 05 working days from the receipt of the Certificate of approval of clinical study results and accompanied documents, the Ministry of Health shall issue a decision to approve clinical study results.

Article 19. Responsibilities of organizations or individuals whose medical devices undergo clinical study

1. Make compensation for clinical study participants for any risks incurred from the clinical study in accordance with regulations of law.

2. Conclude agreement on clinical study on medical device with the clinical study institution.

3. Assume legal responsibility for quality and safety of their medical devices.

Article 20. Responsibilities of clinical study institutions

1. Assume responsibility for their provided clinical study results.

2. Assume responsibility for safety and ensuring rights and benefits of clinical study participants, and make compensation for clinical study participants for damage caused by their mistakes in accordance with regulations of law.

3. Ensure the integrity and objectivity of conducted clinical studies.

4. Ensure that their economic benefits and personnel are independent from the organization or individual whose medical device undergoes clinical study.

Chapter V

PLACEMENT OF MEDICAL DEVICES ON MARKET

Section 1. REGISTRATION NUMBER, CONDITIONS FOR PLACEMENT ON THE MARKET AND REQUIREMENTS FOR ORGANIZATIONS DECLARING APPLIED STANDARDS OR APPLYING FOR REGISTRATION NUMBER

Article 21. Registration number of medical devices

1. Registration number of a medical device is:

a) The number of declaration of applied standards of Class-A or Class-B medical device;

b) The number of certificate of registration of Class-C or Class-D medical device.

2. Registration number holder is the organization that declares applied standards for Class-A or Class-B medical device or that is granted certificate of registration of Class-C or Class-D medical device.

3. Validity of registration number: The medical device registration number shall be valid for indefinite term, except cases where a registration number is issued according to regulations on issuance of emergency use registration number for medical devices to serve epidemic prevention and control, and disaster recovery purposes. Based on the application for issuance of emergency use registration number for the medical device, the Minister of Health shall decide specific period validity of the issued registration number.

Article 22. Conditions for placement of medical devices on the market

1. A medical device may be placed on the market if it meets the following conditions:

a) It has been granted registration number or import license in accordance with regulations laid down in this Decree, except the cases specified in Clause 8 Article 3 and Article 24 of this Decree;

b) Its label contains adequate information in accordance with regulations of law on labeling of goods;

c) Instructions for use of the medical device are given in Vietnamese;

d) Information about warranty center, conditions and time for warranty, except disposable medical devices defined by product owners or cases where there are documents proving that the medical device is not under warranty.

2. If the information specified in Point c and Point d Clause 1 of this Article is not provided upon the medical device itself, it must be provided in the form of electronic information for which instructions for search must be available on the label of the medical device.

Article 23. Requirements for declaration of applied standards or issuance of certificate of registration for medical devices

1. Requirements for declaration of applied standards or issuance of certificate of registration for medical devices:

a) The medical device is manufactured domestically by a manufacturer that has made declaration of eligibility for manufacture of medical devices;

b) If the medical device is imported, it has been manufactured by a manufacturer that is granted certificate of conformity with ISO 13485 quality control standards, and permitted to be sold in every country in the world;

c) The medical device comply with national technical regulations or standards declared by the manufacturer.

2. Applications for declaration of applied standards or registration of medical devices shall be rejected in the following cases:

a) The medical device falls in the case specified in Clause 1 Article 37 of this Decree;

b) The medical device is recalled under Clauses 1, 3 Article 38 of this Decree.

3. If a medical device registration number is revoked under Clause 2 Article 38 of this Decree, an application for declaration of applied standards or registration of that medical device submitted within 12 months from the date of the revocation decision shall be rejected.

Article 24. Cases of exemption from requirements for declaration of applied standards and registration

1. The medical device is used for research, testing, inspection, experiment, performance evaluation, instruction for use or device modification only.

2. The medical device is imported into Vietnam to serve the purposes of emergency aid or provision of humanitarian medical services or display at trade fair, exhibition or product launch event or use as gift given to a health facility or for medical treatment of a particular individual or to serve special diagnosis of a health facility.

3. Unregistered medical devices are imported to serve epidemic prevention and control, disaster recovery and cannot be replaced by any other medical devices sold on the market.

4. Medical devices are manufactured in Vietnam to serve the purposes of export or display at an overseas trade fair or exhibition only.

Article 25. Requirements for organizations declaring applied standards or applying for registration number for medical devices

1. Organizations that declare applied standards or apply for registration number for medical devices include:

a) Vietnamese enterprises, cooperatives or household businesses that are product owners;

b) Vietnamese enterprises, cooperatives or household businesses that are authorized by product owners;

c) Permanent representative offices in Vietnam of foreign traders that are product owners or authorized by product owners.

2. The organization declaring applied standards or applying for registration of a medical device must establish and maintain a warranty center in Vietnam or sign a contract with a qualified warranty center, except disposable medical devices as defined by product owners or cases where there are documents proving that the medical device is not under warranty.

Where the organization declaring applied standards or applying for registration of a medical device is the entity prescribed in Point c Clause 1 of this Article, the product owner must establish and maintain a warranty center in Vietnam or sign a contract with a qualified warranty center, except disposable medical devices as defined by product owners or cases where there are documents proving that the medical device is not under warranty.

The warranty center must be granted certificate of eligibility to provide warranty by the product owner.

Section 2. DECLARATION OF APPLIED STANDARDS FOR CLASS-A OR CLASS-B MEDICAL DEVICES

Article 26. Application for declaration of applied standards

An application for declaration of applied standards for Class-A or Class-B medical device consists of:

1. The declaration of applied standards for Class-A or Class-B medical device.

2. An unexpired certificate of conformity with ISO 13485 quality control standards.

3. The unexpired letter of authorization given by the product owner to the organization that applies for declaration of applied standards, except the case specified in Point a Clause 1 Article 25 of this Decree.

4. The certificate of eligibility to provide warranty services granted by the product owner, except disposable medical devices defined by product owners or cases where there are documents proving that the medical device is not under warranty.

5. A synopsis of technical description of the medical device in Vietnamese, accompanied by technical documents describing functions and specifications of the medical device issued by the product owner.

With regard to in-vitro reagents, calibrators and control materials, the synopsis of technical description in Vietnamese must be accompanied by documents on materials and safety of the product, manufacturing process, pre-clinical and clinical study reports including stability report.

6. The certificate of conformity or product standard sheet provided by the product owner.

With regard to domestically manufactured medical devices, the assessment record of chemical, physical and microbiological indicators and other indicators provided by a qualified conformity assessment body in accordance with regulations of law on conformity assessment is required; if it is an IVD medical device, certificate of quality assessment issued by a competent authority of Vietnam is required. The assessment result must be conformable with the standards declared by the product owner.

7. User manual of the medical device.

8. A sample of the label for the medical device sold in Vietnam.

9. The unexpired CFS (for imported medical devices).

Article 27. Requirements for application for declaration of applied standards

1. 01 set of application for declaration of applied standards shall be prepared.

2. Requirements for some documents included in the application:

a) Certificate of conformity with quality control standards: original copy or certified true copy or copy bearing certification of the declarant.

If the Certificate of conformity with quality control standards is not written in English or Vietnamese, it must be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.

b) Product owner's letter of authorization and certificate of eligibility to provide warranty:

- For a domestically manufactured medical device: original copy or certified true copy;

- For an imported medical device: consularly legalized copy or certified true copy thereof.

c) Certificate of conformity or product standard sheet provided by the product owner: original copy or copy bearing certification of the declarant.

If the product standard sheet is not written in English or Vietnamese, it must be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.

d) User manual of the medical device: Vietnamese copy bearing certification of the declarant, accompanied by English version issued by the product owner, in case of imported medical devices. If the user manual is not written in English or Vietnamese, it must be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.

dd) Sample label: the sample label bearing certification of the declarant. The sample label must meet requirements laid down in regulations of law on labeling of goods.

e) CFS: consularly legalized copy or certified true copy thereof.

If the CFS is not written in English or Vietnamese, it must be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.

g) Record of chemical, physical and microbiological indicators and other indicators provided by a qualified conformity assessment body in accordance with regulations of law on conformity assessment or certificate of quality assessment issued by regulatory authority of Vietnam (for an IVD medical device): original copy or certified true copy.

Article 28. Procedures for declaration of applied standards

1. Before placing Class-A or Class-B medical device on the market, the organization declaring applied standards (declarant) shall submit an application for declaration to the Department of Health of province where it is headquartered.

2. After receiving the application (including application fee receipt as prescribed by the Ministry of Finance), the Department of Health of province where the declarant is headquartered shall publish the number of declaration of applied standards for Class-A or Class-B medical device on the Portal on management of medical devices and applications for declaration of applied standards, except the documents specified in Clause 5 Article 26 of this Decree.

3. In case of changes in the product owner, class of the medical device, category, intended purposes or indications for use of the medical device, or provision of additional information about the manufacturer or product code, the registration number holder shall reapply for declaration of applied standards in accordance with regulations of this Decree.

4. During the placement of the medical device on the market, the product owner that has declared applied standards for the medical device shall prepare written notice of changes, accompanied by supporting documents, and update them to its application for declaration of applied standards published on the Portal on management of medical devices within 05 working days from the occurrence of any of the following changes:

a) Change in address of the product owner or registration number holder;

b) Change in name of the registration number holder or product owner;

c) Change in the medical device manufacturer's name or address;

d) Change in packaging specifications;

dd) Change in the warranty center;

e) Change in the label or user manual without changing intended purposes or indications for use. Where the medical device has been manufactured before the product owner makes a notice of change in the label, the device may be placed on the market with the information declared at the date of manufacture;

g) Reduction of factories, category or product code.

Section 3. REGISTRATION OF CLASS-C OR CLASS-D MEDICAL DEVICES

Article 29. Methods of registration

1. A new registration number shall be issued in the following cases:

a) The medical device does not have any registration number.

b) The medical device has been granted registration number but has any of the following changes:

- A change in the product owner; class of the medical device; category, intended purposes or indications for use; quality standards; addition of factory or product code; raw materials that affect the functions of IVD medical device or disposable medical device; concentration, content, composition of raw materials that are active ingredients incorporated in the medical device to support in medical treatment;

- A change other than those specified in Clause 7 Article 32 of this Decree.

2. Cases of quick issuance of a new registration number:

a) The medical device has been granted the CFS (Certificate of Free Sale) or marketing authorization by one of the following authorities or countries: U.S. Food and Drug Administration (FDA), Australian Therapeutic Goods Administration (TGA), Health Canada, Japanese Ministry of Health, Labour and Welfare (MHLW) or Pharmaceuticals and Medical Devices Agency, EU state members, UK, Switzerland, National Medical Products Administration (NMPA) - China, Ministry of Food & Drug Safety (MFDS) - Korea, or other CFS issuing authorities recognized by Vietnam (hereinafter referred to as "reference countries");

b) The medical device has been granted the import license or registration number or certificate of registration in the commercial form in Vietnam, unless revoked before the effective date of this Decree;

3. Issuance of emergency use registration number for medical devices to serve epidemic prevention and control, and disaster recovery purposes in emergency cases included in the relevant List issued by the Minister of Health and in one of the following cases:

a) The medical device has been placed on the market or granted registration number for emergency use in one of the reference countries;

b) The medical device is included in the list of products for emergency use announced by the World Health Organization (WHO);

c) The medical device is included in the list of common products announced by the EU Health Security Committee (EUHSC);

d) The medical device has been granted the registration number or import license in the commercial form in Vietnam, unless revoked before the effective date of this Decree;

dd) The medical device is domestically manufactured in the form of technology transfer in one of the cases specified in Points a, b, c or d of this Clause;

e) The medical device is domestically manufactured in the form of processing in one of the cases specified in Points a, b, c or d of this Clause.

Article 30. Application for issuance of a new registration number

1. An application for issuance of a new registration number of a medical device without a national technical regulation consists of:

a) The application form for issuance of a new registration number.

b) An unexpired certificate of conformity with ISO 13845 quality control standards.

c) The unexpired letter of authorization given by the product owner to the organization that applies for registration, except the case specified in Point a Clause 1 Article 25 of this Decree.

d) The certificate of eligibility to provide warranty granted by the product owner, except disposable medical devices defined by product owners or cases where there are documents proving that the medical device is not under warranty.

dd) The unexpired CFS (for imported medical devices).

e) ASEAN Common Submission Dossier Template (hereinafter referred to as "CSDT").

g) Certificate of conformity.

2. An application for issuance of a new registration number for the medical device that is a measuring device whose sample requires approval as prescribed by the law on measurement consists of:

a) The application form for issuance of a new registration number.

b) Decision on approval of the sample medical device.

c) The documents specified in Points b, c, d, dd and e Clause 1 of this Article.

3. An application for quick issuance of a new registration number for the medical device as prescribed in Clause 2 Article 29 of this Decree consists of:

a) The application form for issuance of a new registration number.

b) The documents specified in Points b, c, and d Clause 1 of this Article.

c) The CFS issued by one of the reference countries in the case prescribed in Point a Clause 2 Article 29 of this Decree.

d) The CFS of the imported medical device and import license or registration number or certificate of registration in the case prescribed in Point b Clause 2 Article 29 of this Decree.

dd) Certificate of quality assessment issued by a competent authority of Vietnam for IVD medical device, except the following cases:

- The medical device is included in List A or List B of Annex 2 of the European Union Regulation of In Vitro Diagnostic Medical Devices and has been granted CFS by one of EU Member States, UK or Switzerland;

- The medical device is included in List A or List B of Annex 2 of the European Union Regulation of In Vitro Diagnostic Medical Devices and has been granted the Marketing Authorization by one of the reference countries;

- The medical device is not included in List A or List B of Annex 2 of the European Union Regulation of In Vitro Diagnostic Medical Devices but has been granted the Marketing Authorization by one of the reference countries;

- The medical device is included in the list of medical devices announced by the Minister of Health.

e) The CSDT.

4. An application for issuance of a new registration number for the medical device in an emergency case prescribed in Clause 3 Article 29 of this Decree consists of:

a) The application form for issuance of a new registration number.

b) The documents specified in Points b, c, and d Clause 1 of this Article.

c) The CFS or license for emergency use of the imported medical device.

d) The contract for technology transfer in the case prescribed in Point dd Clause 3 Article 29 of this Decree.

dd) The processing contract in the case prescribed in Point e Clause 3 Article 29 of this Decree.

e) Certificate of inspection or certificate of quality assessment issued by one of the inspection/assessment bodies in the list published on the Ministry of Health's website if the medical device falls in one of the following cases:

- a) The medical device is domestically manufactured;

- The medical device has been granted permit for placement on the market or emergency use by a competent authority of one of EU Member States, UK or Switzerland but is not included in the EUHSC's list of common products.

g) The CSDT.

5. An application for issuance of a new registration number for another medical device consists of:

a) The application form for issuance of a new registration number.

b) The documents specified in Points b, c, d and dd Clause 1 of this Article.

c) The CSDT inspection record given by the authority designated by the Minister of Health, accompanied by the CSDT.

d) With regard to IVD medical device that is reagent, calibrator or control material: certificate of quality issued by a competent authority of Vietnam.

dd) With regard to chemicals or preparations only used for disinfection of medical devices: Report on testing for active ingredients for disinfection given by the entity that has declared its eligibility to provide testing services in accordance with regulations of law on management of insecticidal and germicidal chemicals and preparations for medical and household use; report on trials to evaluate biological efficacy and side effects of product on trial participants given by the entity that has declared its eligibility to conduct trial in accordance with regulations of law on management of insecticidal and germicidal chemicals and preparations for medical and household use.

Article 31. Requirements for application for issuance of a new registration number

1. Requirements for some documents included in the application for registration:

a) Certificate of conformity with quality control standards: original copy or certified true copy or copy bearing the applicant's certification.

If the Certificate of conformity with quality control standards is not written in English or Vietnamese, it must be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.

b) Product owner's letter of authorization and certificate of eligibility to provide warranty:

- For a domestically manufactured medical device: original copy or certified true copy;

- For an imported medical device: consularly legalized copy or certified true copy thereof.

c) CFS: consularly legalized copy or certified true copy thereof.

If the CFS is not written in English or Vietnamese, it must be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.

d) Certificate of quality assessment, testing report, trial report and CSDT inspection record: original copy or certified true copy or copy bearing the applicant's certification.

dd) CSDT: copy bearing the applicant's certification. If the CSDT is not written in English or Vietnamese, it must be translated into Vietnamese. The Vietnamese translation must be certified as prescribed by law.

2. Requirements for some documents included in an application for registration of medical device for emergency use as prescribed in Clause 3 Article 29 of this Decree:

Documents issued by foreign competent authorities must be consularly legalized. Where a document does not bear consular legalization:

a) With regard to the letter of authorization: its original copy accompanied by certification shall be submitted.

b) With regard to the document specified in Point c Clause 4 Article 30 of this Decree: it must indicate the link for searching information on placement on the market or license for use of the medical device on the licensing authority's website and be accompanied by a document providing the link for searching information of the applicant. Information on placement of the device on the market found on the website must include at least the following information in English: name, category, manufacturer and manufacturing country.

Article 32. Receipt and processing of application for registration of medical devices

1. The applicant shall submit an application for registration number to the Ministry of Health through the Portal on management of medical devices.

2. With regard to an application for registration number for the medical device in the case prescribed in Clause 1 or Clause 2 Article 30 of this Decree:

a) If the application is satisfactory, the Minister of Health shall process it within 30 days from the receipt of the adequate and valid application (including the application fee receipt as prescribed by the Ministry of Finance). If an application is refused, a written response indicating reasons for such refusal shall be provided.

b) If the application is not satisfactory, the Ministry of Health shall send a request for modification, in which such documents and contents requiring modification must be specified, to the applicant within 25 days from the receipt of the application.

c) The applicant shall comply with the request for modification and send modified documents to the Ministry of Health as requested.

If the modified application is still unsatisfactory, the Ministry of Health shall continue sending a request for modification to the applicant as prescribed in Point b Clause 2 of this Article.

If the applicant fails to provide the modified application within 90 days from the receipt of the Ministry of Health's request for modification or the application is still unsatisfactory after 05 modification times, the application shall be rejected.

3. With regard to an application for registration number for the medical device in the case prescribed in Clause 3 Article 30 of this Decree:

a) If the application is satisfactory, the Minister of Health shall process it within 10 days from the receipt of the adequate and valid application (including the application fee receipt as prescribed by the Ministry of Finance). If an application is refused, a written response indicating reasons for such refusal shall be provided.

The Ministry of Health shall only appraise the legal documents specified in Points b, c, d and dd Clause 1 Article 30 of this Decree. The applicant shall assume responsibility for the accuracy and legitimacy of other documents included in the application which may be inspected by the Ministry of Health after issuing the registration number.

b) If the application for registration number is not satisfactory, the Ministry of Health shall send a request for modification, in which such documents and contents requiring modification must be specified, to the applicant within 10 days from the receipt of the application.

c) The applicant shall comply with the request for modification and send modified documents to the Ministry of Health as requested.

If the modified application is still unsatisfactory, the Ministry of Health shall continue sending another request for modification to the applicant as prescribed in Point b Clause 3 of this Article.

If the applicant fails to provide the modified application within 90 days from the receipt of the Ministry of Health's request for modification or the application is still unsatisfactory after 05 modification times, the application shall be rejected.

4. With regard to an application for registration number for the medical device in the case prescribed in Clause 4 Article 30 of this Decree:

a) If the application is satisfactory, the Minister of Health shall process it within 10 days from the receipt of the adequate and valid application (including the application fee receipt as prescribed by the Ministry of Finance). If an application is refused, a written response indicating reasons for such refusal shall be provided.

The Ministry of Health shall only appraise the legal documents specified in Points b, c, d, dd and e Clause 4 Article 30 of this Decree. The applicant shall assume responsibility for the accuracy and legitimacy of other documents included in the application which may be inspected by the Ministry of Health after issuing the registration number.

b) If the application for registration number is not satisfactory, the Ministry of Health shall send a request for modification, in which such documents and contents requiring modification must be specified, to the applicant within 08 days from the receipt of the application.

c) The applicant shall comply with the request for modification and send modified documents to the Ministry of Health as requested.

If the modified application is still unsatisfactory, the Ministry of Health shall continue sending another request for modification to the applicant as prescribed in Point b Clause 4 of this Article.

If the applicant fails to provide the modified application within 90 days from the receipt of the Ministry of Health's request for modification, the application shall be rejected.

5. With regard to an application for registration number for the medical device in the case prescribed in Clause 5 Article 30 of this Decree:

a) If the application is satisfactory, the Minister of Health shall process it within 45 days from the receipt of the adequate and valid application (including the application fee receipt as prescribed by the Ministry of Finance). If an application is refused, a written response indicating reasons for such refusal shall be provided.

b) If the application for registration number is not satisfactory, the Ministry of Health shall send a request for modification, in which such documents and contents requiring modification must be specified, to the applicant within 40 days from the receipt of the application.

c) The applicant shall comply with the request for modification and send modified documents to the Ministry of Health as requested.

If the modified application is still unsatisfactory, the Ministry of Health shall continue sending another request for modification to the applicant as prescribed in Point b Clause 5 of this Article.

If the applicant fails to provide the modified application within 90 days from the receipt of the Ministry of Health's request for modification or the application is still unsatisfactory after 05 modification times, the application shall be rejected.

6. Within 01 working day from the issuance of the registration number, the Ministry of Health shall publish the following information on the Portal on management of medical devices, including:

a) Name, category, manufacturer and manufacturing country of the medical device;

b) Registration number of the medical device;

c) Name and address of the product owner;

d) Name and address of the registration number holder;

dd) Name and address of the warranty center;

e) The documents included in the application for registration of the medical device, except the documents specified in Point e Clause 1 and Point c Clause 5 of Article 30;

g) Intended purposes of the medical device.

7. During the placement of the medical device on the market, the registration number holder shall prepare written notice of changes, accompanied by supporting documents, and update them to its application for registration number published on the Portal on management of medical devices within 10 working days from the occurrence of any of the following changes:

a) Change in address of the product owner or registration number holder;

b) Change in name of the registration number holder or product owner;

c) Change in the medical device manufacturer's name or address;

d) Change in packaging specifications;

dd) Change in the warranty center;

e) Change in the label or user manual without changing intended purposes, indications for use, functions or performance of the medical device. Where the medical device has been manufactured before the registration number holder makes a notice of change in the label, the device may be placed on the market with information registered and updated at the date of manufacture.

Section 4. POST-MARKET MANAGEMENT OF MEDICAL DEVICES AND HANDLING OF MEDICAL DEVICES IN SOME SPECIFIC CASES

Article 33. Documents for post-market management of medical devices

The registration number holder shall organize and manage the tracing of origin of medical devices placed on the market and fully retain at least the following documents to serve its management of medical devices:

1. The application for issuance of registration number for medical device of which the following documents shall be retained in physical form:

a) The letter of authorization given by the product owner to the organization that applies for registration, except the case specified in Point a Clause 1 Article 25 of this Decree;

b) The certificate of eligibility to provide warranty granted by the product owner, except disposable medical devices defined by product owners or cases where there are documents proving that the medical device is not under warranty;

c) The CFS or marketing authorization.

2. Distribution records (if the registration number holder is a representative office, it shall not be required to retain these records but must request the entity that it authorizes to import the medical device to perform this responsibility).

3. Records of adverse events, complaints and corrective actions that indicate name, category, quantity and batch number of the medical device, especially those that are defective or unsafe for users.

4. Medical device quality management documents, including:

a) The Certificate of Origin made in accordance with regulations of law on origin of goods;

b) The certificate of quality of each medical device batch issued by the product owner or manufacturer whose name is specified in the application for registration of the medical device;

c) Record of inspection of medical device in the case specified in Clause 1 Article 55 of this Decree;

d) Technical documents serving the repair and maintenance of the medical device, except disposable medical devices defined by product owners or cases where there are documents proving that the medical device is not under warranty;

dd) Instructions for use of the medical device are given in Vietnamese;

e) Information about warranty center, conditions and time for warranty, except disposable medical devices defined by the product owner or cases where there are documents proving that the medical device is not under warranty.

Article 34. Handling of medical devices that pose a serious threat to public health or may cause death of users

1. In case where a Vietnamese or international competent authority issues a warning against a medical device that poses a serious threat to public health or may cause death of users, the registration number holder shall inform health facilities using such device of the warning and carry out investigations within 30 days from the receipt of such warning. If the investigation cannot be finished within 30 days, a report specifying reasons and solutions for ensuring safety of users shall be submitted to the Ministry of Health.

2. In case the medical device specified in Clause 1 of this Article is found to have a defect which may affect the health of users, the registration number holder shall:

a) Suspend the placement of the batch of medical devices on the market.

b) Send a written notice to the Ministry of Health, distributors and users of such medical device. The notice shall specify the batch number and the defect, and whether or not such defect can be repaired.

c) Establish a plan for repairing or recalling the batch of defective medical device.

d) Send a report to the Ministry of Health after the repair or recall of defective medical devices is completed.

3. If the defect can be repaired:

a) Within 03 working days from the receipt of the notice from the registration number holder, the Ministry of Health shall issue a decision to suspend the placement of the batch of defective medical devices on the market.

A suspension decision shall contain the following information:

- Name of the medical device suspended from placement on the market;

- Batch number of the medical device;

- Registration number of the medical device.

b) After a suspension decision is issued, the registration number holder shall repair the defect, which causes adverse effects to the health of users.

c) After completing the repair of the defect, the registration number holder shall send a report accompanied by the inspection record (for the medical device specified in Clause 1 Article 55 of this Decree) or commitment to maintain quality of the medical device after the defect has been repaired (for other medical device) to the Ministry of Health.

d) Within 20 working days from the receipt of the report for the registration number holder, the Ministry of Health shall issue a decision to lift the suspension. If the Ministry of Health refuses to lift the suspension, it shall respond and explain in writing.

4. If the defect cannot be repaired:

a) The Ministry of Health shall issue a decision to recall the entire batch of defective medical devices.

A recall decision shall contain the following information:

- Name of the medical device to be recalled;

- Batch number;

- Registration number of the medical device.

b) The registration number holder shall recall the entire batch of defective medical devices by the deadline imposed by a competent authority and pay the cost of recall.

c) If the registration number holder fails to complete the recall by the deadline imposed by the competent authority, the recall will be enforced in accordance with regulations of law on handling of administrative violations.

Article 35. Actions to be taken in case of an adverse event (AE) that has caused harm to health of users

1. In case where a medical device has an AE that pose a serious threat to public health or has caused death of a user, the registration number holder shall:

a) Post a notice of the AE on the registration number holder's website (if any) and send written notices of the AE to the Ministry of Health, traders and users of that batch of medical devices;

b) Suspend the placement on the market of the batch of medical devices involving the AE;

c) Initiate an investigation into the causes of the AE;

d) Send a report to the Ministry of Health after the investigation result is available. If the AE is caused by a defect in the medical device, the report shall describe the defect and whether it can be repaired. Carry out repair of the defect or recall of the batch of defective medical devices, submit a report to the Ministry of Health after completing the repair or recall.

2. In case the AE does not cause death but has caused serious harm to the health of users, the registration number holder shall:

a) Send a notice of the AE to the Ministry of Health;

b) Initiate an investigation into the causes of the AE;

c) Send a report to the Ministry of Health after the investigation result is available. If the AE is caused by a defect in the medical device, the report shall describe the defect and whether it can be repaired. Carry out repair of the defect or recall of the batch of defective medical devices, submit a report to the Ministry of Health after completing the repair or recall.

3. The medical device that has a defect that causes harm to health of users shall be handled in accordance with Clause 3 and Clause 4 Article 34 of this Decree.

Article 36. Handling, repair and recall of defective medical devices

1. Methods for handling defective medical devices:

a) Providing instructions on how to fix the defect;

b) Fixing the defect;

c) Replace the defective medical device with an equivalent device;

d) Recall the defective medical device for re-export or destruction;

2. Methods for recall of the defective medical devices:

a) Voluntary recall by the registration number holder;

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

Article 37. Handling of medical devices in case product owner or registration number holder no longer carries out manufacturing or goes bankrupt or is dissolved

1. If the product owner declares termination of manufacturing of a medical device which has been granted the registration number or goes bankrupt or is dissolved, the medical device may be placed on the market for a maximum period of 24 months from the date of the product owner's declaration of manufacturing termination, bankruptcy or dissolution provided that the registration number holder in Vietnam provides a commitment to provide warranty or materials for replacing or serving the use of the medical device for 08 years, unless the registration number holder is a permanent representative office in Vietnam of a foreign trader that is the product owner.

2. If the registration number holder of a medical device goes bankrupt or is dissolved, the medical device may be placed on the market for a maximum period of 24 months from the date of the registration number holder's declaration of bankruptcy or dissolution provided that the distributor provides a commitment to provide warranty or materials for replacing or serving the use of the medical device for 08 years.

3. The registration number holder or distributor shall send their commitments to the Ministry of Health through the Portal on management of medical devices within 60 days from the day on which the product owner or registration number holder declares termination of manufacturing or goes bankrupt or is dissolved.

4. The commitment shall include the following documents:

a) The written commitment to provide warranty and materials serving the use of the medical devices;

b) The list of medical devices of which it is the registration number holder but the product owner or registration number holder declares termination of manufacturing or goes bankrupt or is dissolved.

5. Within 15 working days from the receipt of the commitment as prescribed in Clause 4 of this Article, the Ministry of Health shall give a written response indicating whether or not the medical device may be placed on the market. If the placement of the medical device on the market is not approved, reasons for such refusal shall be given.

6. If the Ministry of Health refuses to permit the placement of the medical device specified in Clause 1 of this Article on the market, the registration number holder or distributor shall recall all medical devices placed on the market, except those sold to users.

Section 5. REVOCATION OF REGISTRATION NUMBER OF MEDICAL DEVICES

Article 38. Cases where registration number is revoked

1. The application for registration number is forged.

2. In case where 03 batches of the medical device are recalled during the validity of the registration number, except registration number holder's voluntary recall of the medical device.

3. The applicant deliberately alters or erasures the contents of the registration number.

4. The registration number holder shuts down or is no longer authorized by the product owner and no substitute is appointed, except the case specified in Article 37 of this Decree.

5. Quality of the medical device placed on the market is not consistent with the registered quality.

6. The registration number has been issued against regulations of this Decree.

7. The registration number holder or distributor has not provided commitment for the medical device as prescribed in Clause 1 and Clause 2 Article 37 of this Decree.

8. The period for placing the medical device on the market expires as prescribed in Clause 1 or Clause 2 Article 37 of this Decree.

9. The medical device has been manufactured at a factory that fails to satisfy eligibility requirements laid down in this Decree.

10. The registration number holder fails to comply with the provision of Point k Clause 3 Article 74 of this Decree, except the case specified in Article 37 of this Decree.

11. The application for declaration or issuance of registration number is found to not comply with regulations of this Decree.

12. The medical device has been classified against regulations on classification of medical devices.

13. The registration number holder applies for voluntary revocation of the registration number.

Article 39. Procedures for revocation of registration number

1. If any of the cases specified in Clauses 1 through 12 Article 38 of this Decree is discovered during the inspection, the inspecting agency shall prepare and send an inspection record to the Ministry of Health or Provincial Department of Health that has issued the registration number (hereinafter referred to as "registration number issuer").

2. Within 05 working days from the receipt of the inspection record specified in Clause 1 of this Article, the registration number issuer shall consider issuing a decision to revoke registration number under their management.

3. After issuing the decision to revoke registration number, the registration number issuer shall:

a) Publish the decision to revoke registration number on its website and send it to the registration number holder, Ministry of Health, Provincial Departments of Health and customs authorities.

b) Remove all information related to the medical device published on its website.

4. When receiving the decision to revoke registration number of the registration number issuer, Provincial Departments of Health shall publish the full text of the decision on their websites and direct specialized agencies to supervise the recall of relevant medical devices.

5. Where the registration number holder applies for revocation of registration number, an application indicating reasons for such revocation shall be submitted to the registration number issuer. After receiving the application, the registration number issuer shall carry out procedures for revocation of registration number as prescribed in Clause 2 and Clause 3 of this Article.

Chapter VI

MANAGEMENT OF TRADING OF MEDICAL DEVICES

Section 1. ELIGIBILITY REQUIREMENTS TO BE SATISFIED BY TRADING ESTABLISHMENTS

Article 40. Requirements for trading in Class-B, C, D medical devices

To be permitted to trade in Class-B, C, D medical devices, an establishment must:

1. Have at least 01 employee who has an associate degree, or higher, in technology, medicine, pharmacy, chemistry, biology or medical devices, or an associate degree, or higher, suitable for the medical devices sold by the establishment.

2. Have warehouse and vehicles that satisfy the following requirements:

a) The warehouse must:

- have an area suitable for the categories and quantities of medical devices stored therein;

- be well ventilated, dry and clean, and separated from sources of pollution;

- satisfy storage requirements for the medical devices laid down in their user manuals.

b) The vehicle used for transporting medical devices to buyers must be suitable for categories of such medical devices;

A trading establishment that does not have a warehouse or vehicle may sign a contract with a qualified storage or transport service provider.

3. Requirements for trading in medical devices that contain narcotic substances or precursors:

a) The chief technician has a bachelor's degree in medical devices, medicine, pharmacy, pharmaceutical chemistry or biology.

b) The trading establishment must have a warehouse that satisfies the requirements laid down in Article 7 of the Government's Decree No. 80/2001/ND-CP dated November 05, 2001.

c) There is an inventory monitoring system for medical devices containing narcotic substances and precursors.

Article 41. Application and procedures for declaration of eligibility for medical device trading

1. An application for declaration of eligibility for medical device trading consists of:

a) The declaration of eligibility for medical device trading;

b) A personnel list;

c) Documents proving that the warehouse and vehicle satisfy the requirements specified in Clause 2 Article 40 of this Decree. These documents must be certified by the applicant;

d) Documents proving that the warehouse and inventory monitoring system for medical devices containing narcotic substances and precursors comply with the requirements laid down in Clause 3 Article 40 of this Decree. Such documents shall be certified by the establishment making declaration of eligibility for trading in medical devices that contain narcotic substances and precursors.

2. Procedures for declaration of eligibility for medical device trading:

a) Before trading medical devices, the trading establishment shall submit an application for declaration of eligibility for medical device trading to the Department of Health of province where the trading establishment is located.

b) After receiving the application (including the application fee payment as prescribed by the Ministry of Finance), the Department of Health of province where the trading establishment is headquartered shall publish on the Portal on management of medical devices all information about and application for declaration of eligibility for medical device trading.

c) During its operation, the trading establishment shall prepare a notice of changes which is accompanied by supporting documents for such changes, and update such documents to its application for declaration of eligibility for medical device trading published on the Portal on management of medical devices within 03 working days from the occurrence of such changes.

Article 42. Trading in medical devices without satisfying eligibility requirements and following procedures for declaration of eligibility for medical device trading

1. Class-B, C, D medical devices included in the list of medical devices promulgated by the Minister of Health shall be traded as normal goods.

2. Establishments trading in the medical devices prescribed in Clause 1 of this Article shall not be required to satisfy eligibility requirements laid down in Article 40 of this Decree and follow procedures for declaration of eligibility for medical device trading as prescribed in Article 41 of this Article but must still meet the storage and transport requirements as prescribed by product owners.

Section 2. MANAGEMENT OF PRICES OF MEDICAL DEVICES

Article 43. Rules for state management of medical device prices

1. Manage prices of medical devices according to the market mechanism; respect the right to pricing and price competition of entities trading in medical devices in accordance with regulations of law.

2. Ensure transparency of prices of medical devices placed on the market.

3. Protect lawful rights and interests of medical device traders and users, and of the State.

4. Take measures for ensuring management of medical device prices appropriate for socio-economic development in each period.

Article 44. Measures for management of medical device prices

1. Prices of medical devices must be declared in accordance with regulations of this Decree before they are placed on the market in Vietnam, and declared again whenever they are changed.

2. Wholesale and retail prices in VND of medical devices shall be posted at transaction or selling locations of medical device trading establishments; such prices shall be publicly posted on a board, paper or otherwise posted.

3. Successful bids for medical devices of public health facilities must be made publicly available.

4. Trading establishments shall not be allowed to trade medical devices before their prices are declared or at prices higher than those available on the Ministry of Health's Portal on management of medical devices at the time of trading.

Article 45. Contents and responsibility for declaration of medical device prices

1. Contents of declaration of medical device prices:

a) Name and category of the medical device;

b) Manufacturing country;

c) Unit;

d) Import cost price of the imported medical device or manufacturing cost of the domestically manufactured medical device;

dd) Expected profits;

e) The highest price of the medical device determined according to its design configurations, technical functions and unit;

g) Prices of accessories and parts (if any);

h) Warranty or maintenance costs (if any);

i) Training costs (if any);

k) Other costs (if any);

2. Contents about medical device prices to be publicly posted:

a) Name and category of the medical device;

b) Manufacturer and manufacturing country; product owner and country of product owner;

c) Unit;

d) The highest price of the medical device determined according to its design configurations, technical functions and unit;

dd) Prices of accessories and parts (if any);

e) Warranty or maintenance costs (if any);

g) Training costs (if any);

h) Other costs (if any);

3. Prices of medical devices shall be expressed in VND.

4. Registration number holders shall:

a) Make declaration of prices of their medical devices according to the declaration contents specified in Clause 1 of this Article and publish information on the Ministry of Health's portal before such medical devices are placed on the market of Vietnam;

b) Update prices of medical devices whenever they are changed;

c) Request distributors to comply with the provisions of Points a and b of this Article in the case prescribed in Point c Clause 1 Article 25 of this Decree. In case of multiple distributors of the same medical device, one distributor shall be appointed to declare the medical device price. Other distributors shall not be required to make price declaration but shall not sell the medical device at a price higher than that declared by the appointed distributor;

d) Make declaration and explain elements constituting the medical device price to tax authorities or at the request of regulatory authorities.

5. A price posted on the Ministry of Health's portal must include adequate information prescribed in Clause 2 of this Article.

Section 3. EXPORT AND IMPORT OF MEDICAL DEVICES

Article 46. Rules for management of import and export of medical devices

1. Importers and exporters of medical devices must satisfy eligibility requirements laid down in the law on import and export and assume responsibility to ensure quality, quantities, categories and intended purposes of their imported/exported medical devices.

2. Medical devices that have been granted registration numbers in Vietnam may be exported and imported without limits on quantities and are exempt from the Ministry of Health's approval.

3. Issuance of CFS for medical devices shall comply with regulations of the law on foreign trade management.

4. Temporary import for re-export, temporary export for re-import, or transit of medical devices shall comply with regulations of law.

5. Import of used medical devices shall comply with regulations of the law on foreign trade management.

Article 47. Export and import of medical devices

1. Domestic enterprises are encouraged to manufacture medical devices for export.

2. An organization or individual that wishes to import the medical device that has been granted registration number shall:

a) be the registration number holder or be authorized in writing by the registration number holder. When authorizing import of medical devices, the registration number holder shall send a copy of the authorization letter to the registration number issuer and the customs authority;

b) have a warehouse and vehicles satisfying the requirements laid down in Clause 2 Article 40 of this Decree or have entered into a contract with a qualified storage and transport service provider;

c) have a warehouse and an inventory monitoring system for medical devices containing narcotic substances and precursors that meet the requirements laid down in Clause 3 Article 40 of this Decree.

3. Procedures for import and export of medical devices shall comply with regulations of the law on customs. Importers of medical devices shall not be required to prove their satisfaction of the requirements laid down in Clause 2 of this Article when following customs procedures.

Article 48. Import license

1. An import license is required in the following cases:

a) Unregistered medical devices are imported to serve scientific research, testing, inspection, experiment, performance evaluation, or instruction for use or device modification only;

b) Unregistered medical devices are imported to serve epidemic prevention and control, or disaster recovery;

c) Unregistered medical devices are imported as assistance or humanitarian aid; gifts or presents given to health facilities; or to serve display at trade fair, exhibition or product launch event;

d) Unregistered medical devices are imported to serve charitable medical examination and treatment;

dd) Unregistered medical devices are imported for personal treatment of illness, including personalized medical devices, or to serve a health facility’s special diagnosis demand;

e) Used medical devices:

- are imported to serve research or training (no use on humans and for diagnostic and treatment purposes); or

- are temporarily imported for re-export to serve display, product launch event, trade fair or exhibition.

Procedures for import, temporary import for re-export of medical devices shall comply with regulations of the law on foreign trade management.

2. An application for the import license consists of:

a) The application form for import license;

b) A synopsis of the technical description of the medical device in Vietnamese;

c) Certificate of conformity with quality control standards of the manufacturer bearing the applicant's certification;

d) If the medical device is imported to serve research: a certified true copy of the decision to approve the research and documents bearing the applicant's certification proving that the device has been granted marketing authorization by a competent authority;

dd) If the medical device is imported to serve training purposes: the original copy of the training program and documents bearing the applicant's certification proving that the device has been granted marketing authorization by a competent authority;

e) If the medical device is imported to serve testing, inspection, experiment, or performance evaluation: the certification indicating the quantity of the imported device given by the agency competent to carry out such testing, inspection, experiment, or performance evaluation;

g) If the medical device is imported as aid: a copy of the decision to approve the aid and documents bearing the applicant's certification proving that the device has been granted marketing authorization by a competent authority;

h) If the medical device is imported as gift or present given to a health facility: the original copy of the training program and documents bearing the applicant's certification proving that the device has been granted marketing authorization by a competent authority;

i) If the medical device is imported to serve charitable medical examination and treatment: documents bearing the applicant's certification proving that the device has been granted marketing authorization by a competent authority;

k) If the medical device is imported to serve a health facility's special diagnosis demand: documents bearing the applicant's certification proving that the device has been granted marketing authorization by a competent authority;

l) If the medical device is imported to serve personal treatment of illness, including personalized medical devices: a copy of the physician's prescription which is consistent with the applicant's illness;

m) If the medical device is imported to serve a trade fair, exhibition, display or product launch event: copies of documents on the program, invitation letter and service contract;

n) If the medical device is imported to serve the purposes of epidemic prevention and control or disaster recovery, the following documents are required:

- A competent authority's approval for import of the medical device to serve epidemic prevention and control or disaster recovery;

- Documents bearing the applicant's certification proving that the device has been granted marketing authorization or license for emergency use by a competent authority.

3. Procedures for processing an application for license to import medical devices:

a) If the application is satisfactory, the Ministry of Health shall process it within 15 working days, or 02 working days with respect to an unregistered medical device that is imported to serve epidemic prevention and control or disaster recovery, from the receipt of the adequate and valid application (including the application fee receipt as prescribed by the Ministry of Finance). If an application is refused, a written response indicating reasons for such refusal shall be provided.

The import license shall be sent to the applicant and customs authorities.

b) If the application is not satisfactory, the Ministry of Health shall send a request for modification, in which such documents and contents requiring modification must be specified, to the applicant within 10 days, or 02 working days with respect to an unregistered medical device that is imported to serve epidemic prevention and control or disaster recovery, from the receipt of the application.

c) The applicant shall comply with the request for modification and send modified documents to the Ministry of Health as requested.

If the modified application is still unsatisfactory, the Ministry of Health shall continue sending another request for modification of the application to the applicant.

d) If the applicant fails to provide the modified application within 30 days from the receipt of the Ministry of Health's request for modification, the application shall be rejected.

dd) If the modified application is satisfactory, the Ministry of Health shall issue an import license in accordance with Point a of this Clause. The import license shall be sent to the applicant and customs authorities.

Article 49. Application for Certificate of Free Sale (CFS) for medical devices

1. An application for CFS for a medical device consists of:

a) The application form for CFS.

b) A certified true copy of the unexpired certificate of conformity with quality control standards issued by a conformity assessment body as prescribed by law.

2. Procedures for the CFS shall comply with the Government's Decree No. 69/2018/ND-CP dated May 15, 2018.

Article 50. Authority and procedures for issuance, re-issuance and revocation of CFS

1. The Minister of Health shall consider issuing, re-issuing and revoking CFS for medical devices.

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

Section 4. RIGHTS AND OBLIGATIONS OF ORGANIZATIONS AND INDIVIDUALS ENGAGED IN TRADING OF MEDICAL DEVICES

Article 51. Rights of medical device trading establishments

1. Request the medical device seller to provide adequate information and documents serving the tracing of origin and warranty on the medical device.

2. Request importers, distributors and users to cooperate in recalling and handling defective medical devices.

3. Request the registration number holder or warranty center that is recognized by the product owner to provide warranty on the medical device.

4. Receive notice of defective medical device from the registration number holder.

5. Exercise other rights as prescribed by laws.

Article 52. Obligations of medical device trading establishments

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

2. Provide users with adequate and timely information about:

a) Instructions for use of medical devices; conditions for ensuring safety, storage, calibration, inspection and maintenance of medical devices;

b) Notices of defective medical devices.

3. Declare and post medical device prices in accordance with regulations of law. Do not trade medical devices before their prices are declared or at prices higher than those available on the Ministry of Health's Portal on management of medical devices at the time of trading.

4. Keep documents on management of medical devices and carry out tracing of origin and recall of medical devices in accordance with regulations of this Decree.

5. Promptly notify registration number holders and state regulatory authorities of defective medical devices.

6. Comply with regulations of law and inspection decisions issued by competent authorities.

7. Perform other obligations as prescribed by law.

Chapter VII

MEDICAL DEVICE-RELATED SERVICES

Section 1. MEDICAL DEVICE TECHNICAL CONSULTING

Article 53. Eligibility requirements to provide medical device technical consulting

1. Consulting on listing and formulation of technical configuration and functions of medical devices must be provided by individuals who have certificates of completion of training course in technical consulting on medical devices.

2. An individual who provides medical device technical consulting is required to:

a) have a bachelor's degree, or higher, in technology, medicine or pharmacy;

b) have at least 05 years' experience of working in medical device technology in health facilities;

c) have been examined and recognized by the training institution to be capable of providing medical device technical consulting according to the training program issued by the Ministry of Health.

3. A consultant shall only provide medical device technical consulting after the Ministry of Health publishes his/her information and application for declaration of eligibility to provide medical device technical consulting as prescribed in Point b Clause 2 Article 54 of this Decree.

Article 54. Application and procedures for declaration of eligibility to provide medical device technical consulting

1. An application for declaration of eligibility to provide medical device technical consulting consists of:

a) The application form for declaration of eligibility to provide medical device technical consulting;

b) Certified true copies of qualifications/certificates as prescribed in Point a and Point c Clause 2 Article 53 of this Decree;

c) Certificate of working period.

2. Procedures for declaration of eligibility to provide medical device technical consulting:

a) Before providing medical device technical consulting, the applicant shall send an application for declaration of eligibility to provide medical device technical consulting to the Ministry of Health.

b) After receiving the application (including application fee receipt as prescribed by the Ministry of Finance), the Ministry of Health shall publish on the Portal on management of medical devices all information about and application for declaration of eligibility to provide medical device technical consulting.

c) During its operation, the consultant shall prepare a notice of changes which is accompanied by supporting documents for such changes, and update such documents to his/her application for declaration of eligibility to provide medical device technical consulting published on the Portal on management of medical devices within 03 working days from the occurrence of such changes.

Section 2. INSPECTION AND CALIBRATION OF MEDICAL DEVICES

Article 55. Rules for inspection and calibration of medical devices

1. Medical devices included in the Minister of Health's list shall undergo safety and function inspection before use (except for the cases in Article 57 of this Decree), periodically and after overhaul. Inspection of medical devices that are measuring devices or radiation equipment shall be carried out in accordance with Clause 2 of this Article.

2. Medical devices that are measuring devices or radiation equipment shall undergo inspection and calibration in accordance with regulations of laws on measurement and atomic energy.

Article 56. Requirements for provision of medical device inspection services

Facilities and personnel requirements, preparation and submission of application for certificate of registration of medical device inspection services, issuance, revision, re-issuance and revocation of certificate of registration of medical device inspection services are the same as those for provision of conformity assessment services.

Each inspection process registered must be handled by at least 02 inspectors who have certificates of completion of training program in such process.

Article 57. Exemption from first inspection before putting medical devices into service

A medical device shall be exempted from the first inspection before it is put into service in one of the following cases:

1. The certificate of conformity for the medical device is available.

2. The unregistered medical device is imported to serve scientific research or training in use, maintenance or repair of such medical device.

3. The unregistered medical device is imported to serve the importer's personal treatment of illness or charitable medical examination and treatment or special diagnostic purposes.

4. The unregistered medical device is imported for display at a trade fair, exhibition or product launch event.

Article 58. Handling of unqualified medical devices

1. In case the result of the inspection conducted before putting the medical device into service is not satisfactory:

a) Health facilities shall not receive and use that medical device;

b) The inspecting organization shall send a written notice of unsatisfactory inspection result to the Ministry of Health;

c) If 03 medical devices of the same batch fail to meet the safety and function inspection requirements, the Ministry of Health shall request the registration number holders in writing to send reports on the quantity of medical devices being placed on the market and those being used in health facilities.

Registration number holders' reports and the unsatisfactory inspection result are the basis for the Ministry of Health to decide whether to carry out a reinspection, the quantity of medical devices that have to undergo reinspection, or suspend the use of such medical devices.

The Ministry of Health shall, based on the reinspection result, decide whether to carry out another reinspection, the quantity of medical devices that have to undergo another reinspection, or request the registration number holders to recall the entire batch of medical devices.

In case 03 batches of medical devices are recalled during the validity of the registration number, the registration number of the medical device shall be revoked. Medical devices that have been used by health facilities before the issuance of the decision to revoke the registration number may be used if they pass the inspection.

2. In case the result of a periodic inspection or post-overhaul inspection is not satisfactory:

a) Health facilities must stop using that medical device;

b) The marking of the previous inspection result shall be removed;

c) Health facilities shall cooperate with the registration number holder in implementing corrective measures and carrying out a reinspection;

d) Only the medical device that passes the reinspection may be used.

Chapter VIII

MANAGEMENT OF RAW MATERIALS FOR MANUFACTURE OF MEDICAL DEVICES, SUBSTANCES FOR EXTERNAL QUALITY ASSESSMENT THAT CONTAIN NARCOTIC SUBSTANCES AND PRECURSORS

Article 59. Rules for management of raw materials for manufacture of medical devices, substances for external quality assessment that contain narcotic substances and precursors

1. Concentration and content of raw materials used for manufacture of medical devices and substances for external quality assessment that contain narcotic substances and precursors must be declared before they are imported to or exported from Vietnam.

2. Customs clearance shall be granted according to declaration number and does not require the import license issued by the Ministry of Health.

Article 60. Application and procedures for declaration of raw materials for manufacture of medical devices, substances for external quality assessment that contain narcotic substances and precursors

1. An application for declaration consists of:

a) Declaration form;

b) Certificate of conformity with quality control standards;

c) Technical documents.

2. Procedures for declaration of concentration/content of narcotic substances and precursors:

a) Before importing raw materials for manufacture of medical devices and substances for external quality assessment that contain narcotic substances and precursors, the importer is required to publish an adequate and valid application for declaration as prescribed in Clause 1 of this Article on the Portal on management of medical devices;

b) After receiving an adequate and valid application, the Ministry of Health shall publish on the Portal on management of medical devices all information and the application for declaration of

raw materials for manufacture of medical devices and substances for external quality assessment that contain narcotic substances and precursors.

3. Importers/exporters shall reapply for declaration of concentration/content of narcotic substances and precursors whenever there are any changes to their declaration.

Chapter IX

INFORMATION ON MEDICAL DEVICES

Article 61. Information on medical devices

1. Information on a medical device is meant to provide medical practitioners and medical device users with instructions on how to use the medical device reasonably and safely.

2. Information on a medical device must be adequate, objective, accurate, truthful and easily understandable and must not cause misunderstanding.

3. Responsibility to provide information on medical devices:

a) Registration number holders and trading establishments shall publish information on levels of risks and other information related to the use of medical devices;

b) Health facilities shall internally disseminate information on medical devices;

c) Health workers shall disseminate information on levels of risks of Class-C, D medical devices to patients;

d) Authorities in charge of managing medical devices shall make information on medical devices publicly available.

4. Providers of information on medical devices shall assume responsibility for their provided information.

5. The Minister of Health shall organize a medical device information system.

Article 62. Advertising of medical devices

1. Contents of an advertisement for a medical device must be consistent with one of the following documents:

a) The application for declaration of applied standards of Class-A or Class-B medical device;

b) The application for registration of Class-C or Class-D medical device.

2. An advertisement for a medical device shall, inter alia, have the following information:

a) Name, category, product code, manufacturer and manufacturing country of the medical device;

b) Registration number;

c) Functions and uses;

d) Name and address of the registration number holder or the entity authorized by the registration number holder;

dd) Warnings for medical device users and storage conditions (if any).

3. Audio or video advertisement must contain sufficient information specified in Clause 2 of this Article which must be read or displayed clearly.

4. Before carrying out the advertising of a medical device, the registration number holder or the entity authorized in writing by the registration number holder shall publish on the Portal on management of medical devices planned contents and form of advertising.

5. The registration number holder or the entity authorized in writing by the registration number holder shall assume legal responsibility for the conformity of advertisement contents with the published ones and the application for declaration of applied standards of Class-A or Class-B medical device or the application for registration of Class-C or Class-D medical device.

6. Documents or materials that do not contain name of a medical device, those that contain name and technical specifications of the medical device but do not contain functions or uses of the medical device, scientific research documents, clinical documents, and documents used for training in use of a medical device shall not be considered as advertising documents.

Chapter X

MANAGEMENT AND USE OF MEDICAL DEVICES BY HEALTH FACILITIES

Article 63. Rules for management and use of medical devices

1. Medical devices must be properly managed and used to ensure their functions as well as economical and effective use.

2. Medical devices shall be stored, maintained and used in accordance with the manufacturer's instructions, and must undergo quality in accordance with regulations of this Decree.

With regard to medical devices subject to strict occupational safety and health requirements, regulations of the Law on occupational safety and health must be strictly complied in addition to regulations on quality control laid down in this Decree.

3. Documents on medical devices must be adequately prepared, managed and retained; medical devices shall be sufficiently and punctually recorded according to their actual state and values in accordance with regulations of laws on accounting and statistics and other relevant laws; funding for performing tasks prescribed in Clause 2 of this Article must be ensured.

4. Health facilities shall bear inspection of regulatory authorities in charge of managing medical devices.

Article 64. Management and use of medical devices by State-owned health facilities

In addition to the provisions of Article 63 of this Decree, State-owned health facilities shall comply with the following provisions:

1. Investment in, purchase, management and use of medical devices shall comply with regulations of law on management and use of public assets.

2. Use of domestically manufactured medical devices is encouraged.

Article 65. Rights and responsibilities of health facilities for management and use of medical devices

1. Each health facility shall have the following rights:

a) Request the registration number holder or the warranty center recognized by the product owner to provide periodical maintenance of medical device during the warranty period;

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

c) Receive the used medical devices to serve their scientific research and training in use and repair of medical devices.

2. Each health facility shall have the following responsibilities:

a) Use and operate the medical device according to instructions of the product owner;

b) Carry out periodical maintenance, inspection and calibration according to instructions of the product owner or as prescribed by law;

c) Participate in testing for and assessment of quality of medical devices;

d) Submit reports on defective medical devices and provide other information at the request of competent authorities.

Chapter XI

ONLINE DECLARATION AND REGISTRATION

Article 66. Online procedures

1. Declaration of eligibility for manufacture of medical devices.

2. Declaration of applied standards for medical devices.

3. Application for registration of medical device.

4. Declaration of eligibility for medical device trading.

5. Declaration of eligibility to provide medical device technical consulting.

6. Application for certificate of registration of medical device inspection services.

7. Application for license to import medical devices.

8. Application for Certificate of Free Sale for domestically manufactured medical device.

9. Declaration of prices of medical devices.

10. Declaration of concentration/content of raw materials for manufacture of medical devices and substances for external quality assessment that contain narcotic substances and precursors.

11. Declaration of contents and form of advertising of medical device.

Article 67. Requirements for online application

An application for declaration, registration, and issuance of license or CFS submitted online (hereinafter referred to as “online application”) shall be considered valid when it meets the following requirements:

1. It contains adequate documents which are prepared according to regulations applicable to a physical application and converted into electronic documents. The name of an electronic document must be relevant to the name of the physical document.

2. Information on declaration, application for registration or license is complete and accurate.

Article 68. Procedures for online declaration

1. The legal representative or his/her authorized person shall declare information, upload electronic documents, make certification using digital signature (if any) and make online application fee payment according to procedures on the Portal on management of medical devices.

2. The online application receiving authority shall carry out administrative procedures relevant to the application in accordance with regulations of this Decree.

3. Results of online administrative procedures shall have the same legal effect as those of normal administrative procedures.

Article 69. Retention of online application

1. When submitting an online application, the applicant is required to retain physical documents of that application in accordance with Clause 1 Article 33 of this Decree.

2. In case any physical document included in the application specified in Clause 1 of this Article is lost or damaged, the applicant shall give a written notice to the receiving authority, reprepare that document and notify the receiving authority in writing of their completion of application, and then follow procedures for updating their application after obtaining an approval from the receiving authority.

3. Within 35 days from the receipt of the written notice of the loss of document, if the applicant fails to give a written notice of their completion of application, the receiving authority shall:

a) Remove all information published on the Portal about the medical device manufacturer, trading establishment or consultant, raw materials for manufacture of medical devices, substances for external quality assessment that contain narcotic substances and precursors, medical device inspection service provider, and registration number of the medical device;

b) Revoke the registration number and license to import medical devices.

4. The applicant shall stop their operation and placement of the relevant medical device on the market from the day on which the information is removed as prescribed in Clause 3 of this Article.

Chapter XII

ORGANIZATION OF IMPLEMENTATION

Article 70. Responsibilities of Ministry of Health

The Ministry of Health shall assume responsibility before the Government for state management of medical devices and have the following tasks and powers:

1. Submit to the Government or Prime Minister to promulgate, or promulgate within their jurisdiction, legislative documents, national technical regulations, strategies, policies and plans on medical devices.

2. Direct and organize the implementation of legislative documents, national technical regulations, strategies, policies and plans on medical devices.

3. Organize information dissemination and communication on medical devices.

4. Provide training for human resources in the field of medical devices.

5. Publish the following information on the Ministry of Health's Portal:

a) Prices of medical devices declared by enterprises;

b) Successful bids for medical devices of State-owned health facilities nationwide;

c) List of medical devices whose registration number has been revoked.

6. Decide whether or not to apply provisions of this Decree to products or goods are considered as medical devices in some countries but may not be considered as such in other countries.

7. Carry out inspection and settle complaints, denunciations and take actions against violations in the field of medical devices. During inspection of medical device prices, if any establishment is found to inadequately declare medical device prices, the competent authority affiliated to the Ministry of Health shall request the subject establishment to review their price information and provide explanations.

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

9. Provide detailed regulations on classification of medical devices which must be conformable with ASEAN's treaties on classification of medical devices to which Vietnam is a signatory; issue practical training programs in classification of medical devices.

10. Issue the list of medical devices subject to inspection and class-based inspection procedures for listed medical devices.

11. Provide guidelines for preparation of ASEAN Common Submission Dossier Template (CSDT).

12. Provide specific provisions on templates used during the implementation of this Decree.

Article 71. Responsibilities of Ministry of Science and Technology

1. Issue the list of medical devices which are measuring devices subject to sample approval, inspection and calibration after obtaining the consent from the Ministry of Health.

2. Play the leading role and cooperate with the Ministry of Health in formulating national standards for medical devices; quality inspection of medical devices that are measuring devices and radiation equipment.

Article 72. Responsibilities of Ministry of Finance

1. Provide guidelines for management of public assets that are medical devices by State-owned health facilities after obtaining opinions from the Ministry of Health.

2. Provide specific provisions on management and use of fees and charges in the field of medical devices in accordance with regulations of law on fees and charges.

3. Carry out inspection and take actions against violations in the field of medical devices.

Article 73. Responsibilities of provincial People's Committees

1. Bear responsibility to manage activities relating to trading and use of medical devices in the province.

2. Organize information dissemination and communication on medical devices in the province.

3. Provide training for human resources in the field of medical devices in the province.

4. Publish on the Portal of the provincial People's Committee and send to the Ministry of Health the following information:

a) Successful bids for medical devices of State-owned health facilities in the province.

b) List of medical devices whose registration number has been revoked in the province.

5. Carry out inspection and settle complaints, denunciations and take actions against violations in the field of medical devices in the province.

Article 74. Responsibilities of medical device traders

1. Medical device traders shall assume responsibility for safety and quality of their medical devices.

2. Domestic medical device manufacturers shall assume responsibility to manage quality of medical devices during manufacture, transport and storage of medical devices according to their applications for registration number.

3. Registration number holders shall:

a) Carry out classification of medical devices, publish on the Ministry of Health’s Portal and assume legal responsibility for their classification results;

Take correction measures for incorrect classification results that reduce the level of risks of classified medical devices or in term of authority specified in this Decree.

b) Follow procedures for declaration of applied standards or application for registration of medical devices in accordance with this Decree. Assume legal responsibility for the accuracy and truthfulness of their applications for registration number;

c) Establish and maintain operation of warranty centers for medical devices or enter in service contracts with qualified warranty service providers, except disposable medical devices as defined by product owners or cases where there are documents proving that the medical device is not under warranty;

d) Prepare and keep documents on management of medical devices and carry out tracing of origin of medical devices as prescribed in this Decree, except disposable medical devices as defined by product owners; submit reports to police authorities on loss of medical devices or raw materials for manufacture of medical devices that contain narcotic substances and precursors;

dd) Provide adequate and accurate information about the product on the label and user manual of the medical devices in accordance with regulations of law on goods labels and provisions of this Decree;

e) Issue prompt, adequate and accurate warnings about risks to users' health and the environment; instructions for sellers and users on how to minimize the risks; provide information about requirements for transport, storage and use of medical devices;

g) Promptly stop placement on the market, take corrective actions against or recall defective medical devices in accordance with this Decree, and notify relevant parties. Destruction of defective medical devices shall comply with regulations of law on environmental protection and relevant laws; the destruction costs shall be paid by the registration number holder;

h) Comply with regulations of law and inspection decisions issued by competent authorities;

i) Pay compensation for damage caused by defective medical devices as prescribed by law;

k) Ensure that the following documents are effective during the effective period of the registration number:

- The CFS (for imported medical devices);

- The authorization letter, except the case specified in Point a Clause 1 Article 25 of this Decree;

- Certificate of eligibility to provide warranty services, except disposable medical devices defined by product owners or cases where there are documents proving that the medical device is not under warranty.

l) Ensure that the medical devices are only manufactured during the effective period of the certificate of conformity with quality control standards;

m) Take legal responsibility for the legitimacy and accuracy of the documents posted while following the procedures specified in this Decree;

n) Provide every health facility that buys the medical devices with 01 set of quality control documents specified in Clause 4 Article 33 of this Decree;

o) Directly or designate an organization to declare and update selling prices of medical devices;

p) Perform other obligations as prescribed by law.

4. Traders, exporters, importers and transferors of medical devices, raw materials, or substances for external quality assessment that contain narcotic substances and precursors shall submit annual reports to the Ministry of Health and Ministry of Public Security by January 15 of the following year.

Chapter XIII

IMPLEMENTATION

Article 75. Effect

1. This Decree comes into force from January 01, 2022.

2. The following Decrees cease to have effect from the effective date of this Decree, including:

a) Government's Decree No. 36/2016/ND-CP dated May 15, 2016;

b) Government's Decree No. 169/2018/ND-CP dated December 31, 2018;

c) Government's Decree No. 03/2020/ND-CP dated January 01, 2020.

3. Article 7 of the Government's Decree No. 181/2013/ND-CP dated November 14, 2013 shall be abrogated from July 01, 2022.

Article 76. Transition

1. The medical devices which have been manufactured in Vietnam or imported into Vietnam before the effective date of this Decree shall continue to be placed on the market until they are liquidated in accordance with regulations of law on management and use of public assets or the expiry date specified on the certificate of registration or expiry date of the product.

2. Regulations on validity of the registration number or import license issued before January 01, 2022:

a) Registration numbers of medical devices which have been issued in accordance with the Government's Decree No. 36/2016/ND-CP dated May 15, 2016, as amended in Decree No.

169/2018/ND-CP and Decree No. 03/2020/ND-CP (hereinafter referred to as "Decree No. 36/2016/ND-CP") shall be valid for indefinite term;

b) If domestically manufactured medical devices have been issued certificates of registration, these certificates of registration shall be valid until the expiry dates thereon;

c) Import licenses issued to medical devices other than IVD reagents on January 01, 2018 onwards shall be valid until December 31, 2022 inclusively;

d) Medical devices which are not subject to import license requirements (except insecticidal and germicidal chemicals and preparations for medical and household use which are used for disinfection of medical devices) and have been classified as Class-C or D medical devices as published on the Ministry of Health's Portal may continue to be imported until December 31, 2022 without limits on quantities and confirmation as medical devices from the Ministry of Health;

dd) Medical devices that are IVD reagents and have been granted registration number within the period from January 01, 2014 to December 31, 2017, these registration numbers shall be valid until December 31, 2022;

e) Medical devices that are IVD reagents and have been granted registration number within the period on January 01, 2018 onwards, these registration numbers shall be valid until the expiry dates thereon;

g) Import licenses issued to medical devices that are IVD reagents on January 01, 2018 onwards shall be valid until December 31, 2022 inclusively without limits on quantities. Customs authorities shall not control import quantities in this case.

3. Applications for registration number which are submitted in accordance with the Decree No. 36/2016/ND-CP before January 01, 2022 but have been not yet processed before the effective date of this Decree shall be processed as follows:

a) With regard to an application for registration of Class-B medical device, the Ministry of Health shall instruct the applicant to review the application and follow procedures for declaration of applied standards in accordance with this Decree without paying application fee.

b) With regard to an application for registration of Class-C or D medical device, the Ministry of Health shall issue registration number according to Article 32 of this Decree if it meets the requirements laid down in Clause 3 Article 30 of this Decree;

c) Classification result given by the classification body that has been granted certification of declaration of eligibility to classify medical devices before the effective date of this Decree may be used.

4. Applications for license to import medical devices submitted before January 01, 2022 shall be processed in accordance with legislative documents promulgated by the Minister of Health

before the effective date of this Decree. An import license issued according to the provisions of this Clause shall be valid until December 31, 2022.

5. Labels of medical devices which have been manufactured in Vietnam or imported into Vietnam before the dates specified in Clause 2 and Clause 4 of this Article shall continue to be used until the expiry date of medical device or the medical device is liquidated in accordance with regulations of law on management and use of public assets or until the expiry date specified on the certificate of registration or expiry date of the product.

6. Regulations on application of CSDT:

a) CSDT is compulsory from January 01, 2023.

b) With regard to applications for issuance of registration number submitted before December 31, 2022, an application shall consist of the documents specified in Points a, b, d, dd Clause 1 Article 30 of this Decree and the following documents:

- A synopsis of technical description of the medical device in Vietnamese, accompanied by technical documents describing functions and specifications of the medical device issued by the product owner.

With regard to in-vitro reagents, calibrators and control materials, the synopsis of technical description in Vietnamese must be accompanied by documents on materials and safety of the product, manufacturing process, pre-clinical and clinical study reports including stability report.

- User manual of the medical device.

- Sample of the label for the medical device sold in Vietnam.

Such documents must meet the following requirements:

- Technical documents of the medical device: copy bearing the applicant’s certification.

- User manual of the medical device: copy in Vietnamese bearing the applicant’s certification, accompanied by the original copy in English issued by the product owner in case of imported medical device.

- Sample label: the sample label bearing the applicant’s certification. The sample label must meet requirements laid down in regulations of law on labeling of goods.

c) An application for registration of a medical device prescribed in Point b of this Clause shall be received and processed as follows:

- If the application is satisfactory, the Minister of Health shall consider issuing the registration number within 90 days from the receipt of the adequate and valid application (including

application fee receipt as prescribed by the Ministry of Finance). If an application is refused, reasons for such refusal must be given in writing.

- If the application is not satisfactory, the Ministry of Health shall send a request for modification, in which such documents and contents requiring modification must be specified, to the applicant within 70 days from the receipt of the application;

- The applicant shall comply with the request for modification and send modified documents to the Ministry of Health as requested.

If the modified application is still unsatisfactory, the Ministry of Health shall continue sending a request for modification to the applicant as prescribed in Point b Clause 6 of this Article.

If the applicant fails to provide the modified application within 90 days from the receipt of the Ministry of Health's request for modification or the application is still unsatisfactory after 05 modification times, the application shall be rejected.

7. Declaration of contents and form of advertising of medical devices shall be applied from July 01, 2022.

8. Holders of registration numbers or licenses to import medical devices issued before the effective date of this Decree are required to comply with the provisions of Clause 4 Article 45 of this Decree before April 01, 2022 for their medical devices placed on the market of Vietnam and before placing their imported medical devices on the market of Vietnam.

Article 77. Responsibility for guidance and implementation

1. The Minister of Health shall instruct, organize and inspect the implementation of this Decree.

2. Ministers, heads of ministerial agencies, heads of Governmental agencies, Chairpersons of Provincial People's Committees and relevant authorities, organizations and individuals are responsible for the implementation of this Decree.

ON BEHALF OF THE GOVERNMENT
PP. PRIME MINISTER
DEPUTY PRIME MINISTER

Vu Duc Dam