# Decree No. 169/2018/ND-CP dated December 31, 2018 amendments to Decree No. 36/2016/ND-CP on medical device management

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**THE GOVERNMENT**
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**SOCIALIST REPUBLIC OF VIETNAM**
**Independence - Freedom - Happiness**
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No. 169/2018/ND-CP

*Hanoi, December 31, 2018*

**DECREE**

AMENDMENTS TO THE GOVERNMENT'S DECREE NO. 36/2016/ND-CP (/docs/go/348213/) DATED MAY 15, 2016 ON MEDICAL DEVICE MANAGEMENT

*Pursuant to the Law on Government Organization dated June 19, 2015;t*

*Pursuant to the Law on Investment dated November 26, 2014;*

*At the request of the Minister of Health;*

*The Government promulgates a Decree on amendments to the Government's Decree No. 36/2016/ND-CP (/docs/go/348213/) dated may 15, 2016 on medical equipment management.*

**Article 1. Amendments to some Articles of the Government's Decree No. 36/2016/ND-CP (/docs/go/348213/) dated may 15, 2016 on medical device management**

1. Clause 1 of Article 2 is amended as follows:

"1. "medical device" means any instrument, apparatus, material, implant, reagent for in vitro use, software that satisfy all of the following requirements:

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

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

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

- supporting or sustaining life;

- control of conception,

- disinfection of medical devices, including chemicals used in testing;

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

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

2. Clause 6 of Article 3 is amended as follows:

"6. The sale of medical devices and raw materials for production medical devices that contain narcotic substances and precursors, in addition to requirements of this Decree, shall comply with regulations of law on drug control."

3. Chapter II is amended as follows:

**"Chapter II**

**CLASSIFICATION OF MEDICAL DEVICES**

**Article 4. Classes and rules for classification of medical devices**

1. Medical devices are divided into 02 classes and 4 categories according to their potential risk level related to their designs and production:

a) Group 1 consists of Class A medical devices, which present low level of risk.

b) Group 2 consists of Class B, C, D medical devices. To be specific:

- Class B: Low–moderate risk.

- Class C: Moderate-high risk;

- Class D medical devices are those that present high level of risk.

2. Rules for classification of medical devices:

a) Classification of medical devices is risk based and implemented by an classifying organization that has declared its eligibility to categorize medical devices in accordance with this Decree;

b) In the cases where a medical device only has one purpose which present various levels of risks, the highest level of risk shall apply;

c) In the cases where a medical device has multiple purposes and each of which presents various levels of risks, the highest level of risk shall apply;

d) When a medical device is used in combination with another medical device, each of them may present a different level of risk but the classification shall be based upon the highest level of risk of the final purpose of such combination.

3. The Minister of Health shall specify classification of medical devices in accordance with ASEAN's treaties on

classification of medical devices to which Vietnam is a signatory.

**Article 5. Classifying organizations**

1. Classification of medical devices shall be implemented by organizations that satisfy the conditions specified in Article 7 of this Decree.

2. Classifying organizations shall categorize medical devices pursuant to the definition in Article 2 of this Decree, the rules in Article 4, the documents in Point e, g, h, t Clause 1 Article 26 of this Decree and the Ministry of Health's classification rules.

3. Classifying organizations are legally responsible for their classification results

4. In case of discrepancies between the classifying organizations, the Ministry of Health shall make the final decision.

**Article 6. Conditions, documents and procedures for issuance and adjustment of the medical device classification certificate**

1. A person will be granted the medical device classification certificate (hereinafter referred to as "practising certificate") if he/she:

a) has at least a bachelor's degree in technology, health or pharmacy;

b) has at least 24 month's experience of working with medical devices within the last 48 months before the application date; and

c) has completed the Ministry of Health's training course in classification of medical devices the Ministry of Health at a qualified health facility.

2. Application and procedures for issuance of a new practising certificate:

a) An application for issuance of a new practising certificate consists of

- a) The application form No. 17 in Appendix I hereof;

- The original copy or certified true copy of the applicant's degree in technology, health or pharmacy; If the degree is issued overseas, its equivalence must be certified by the Ministry of Education and Training;

- The original copy or certified true copy of an unexpired certificate of training in medical device classification (not exceeding 03 years from the day on which it is signed)

- Two color 4x6 cm picture on a white background taken in the last 6 months;

- The original copy or certified true copy of the applicant ID card or passport;

- The original copy or copy of the confirmation of working duration according to the form in Appendix III hereof. If the applicant works for multiple classifying organizations and the duration of working for each classifying organization is less than 24 months, he/she shall obtain the confirmation of working duration from each classifying organization to prove his/her experience mentioned in Point b Clause 1 of this Article.

b) Procedures for issuance of a new practising certificate:

- Within 20 days from the receipt of the application, the Ministry of Health shall finish processing it;

- If the application is satisfactory, within 10 working days from the day on which it is processed, the Ministry of Health shall issue the practising certificate according to form No. 10 in Appendix IV hereof and post the application and the practising certificate on its website.

- If the application is not satisfactory:

Within 05 working days from the completion of the processing, the Ministry of Health shall send a document requesting the applicant to supplement the application. The request shall specify necessary addition of documents or revision of information;

The applicant shall comply with the Ministry of Health' request and send the supplemented application to the Ministry of Health. After receiving the supplemented application, the Ministry of Health shall process it in accordance with regulations of this Clause;

If the supplemented application is satisfactory, the Ministry of Health shall issue the practising certificate in accordance with regulations of this Clause;

If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to keep supplementing it.

Within 60 working days from the receipt of the Ministry of Health's request, the applicant shall submit the supplemented the application. If the applicant fails to supplement the application by the aforementioned deadline or the application is still unsatisfactory after 03 months from the first date it was submitted, it will be rejected.

3. Documents and procedures for revising the practising certificate:

a) An application for revision of the practising certificate consists of:

- a) The application form No. 18 in Appendix I hereof;

- The original copies or copies of documents proving the change in the applicant's name, ID number or passport number;

- The original copy or certified true copy of an unexpired certificate of training in medical device classification in case the scope of practice is changed, or the updated certificate of training in medical device classification;

- The original copy or copy of the confirmation of working duration according to the form in Appendix III hereof. If the applicant works for multiple classifying organizations and the duration of working for each classifying organization is less than 24 months, he/she shall obtain the confirmation of working duration from each classifying organization to prove his/her experience mentioned in Point b Clause 1 of this Article.

b) Procedures:

- Within 10 days from the receipt of the application, the Ministry of Health shall finish processing it;

- If the application is satisfactory, the Ministry of Health shall issue the practising certificate according to form No. 11 in Appendix IV hereof and update the changes on its website within 03 working days.

- If the application is not satisfactory:

Within 05 working days from the completion of the processing, the Ministry of Health shall send a document requesting the applicant to supplement the application. The request shall specify necessary addition of documents or revision of information.

The applicant shall comply with the Ministry of Health' request and send the supplemented application to the Ministry of Health. After receiving the supplemented application, the Ministry of Health shall process it in accordance with regulations of this Clause.

If the supplemented application is satisfactory, the Ministry of Health shall revise the practising certificate within 03 working days.

If the supplemented application is still unsatisfactory, the Ministry of Health shall request the application to keep supplementing it.

Within 60 working days from the receipt of the Ministry of Health's request, the applicant shall submit the supplemented application to the Ministry of Health. If the applicant fails to supplement the application by the aforementioned deadline or the application is still unsatisfactory after 03 months from the first time it was submitted, it will be rejected.

**Article 7. Conditions, documents and procedures for declaration of eligibility for medical device classification**

1. Condition: at least 01 employee of the classifying organization has the practising certificate.

2. An application for declaration includes:

a) Form No. 01 in Appendix I hereof;

b) A list of personnel according to the form in Appendix II hereof enclosed with the original copy or certified true copy of the practising certificate of each person in charge of medical device classification on the list;

c) The original copy or certified true copy of the certificate of business registration of the classifying organization or the certificate of investment.

3. Procedures:

a) The classifying organization shall send the application specified in Clause 2 of this Article to the Ministry of Health;

b) After receiving the valid and satisfactory application, the Ministry of Health shall issue a Form No. 01 in Appendix IV hereof to certify the submission of the declaration of eligibility for medical device classification (hereinafter referred to as "certification of eligibility declaration");

c) Within 03 working days from the date written on the certification of eligibility declaration, the Ministry of Health shall post on its website the classifying organization's name, address, phone number, scope of operation and declaration of eligibility for medical device classification.

4. Revision of the declaration of eligibility for medical device classification:

a) The declaration of eligibility for medical device classification may be revised in the following cases:

- The person in charge of medical device classification is replaced by another person who has the same scope of

practice;

- Any of the following information is changed: the organization's address, phone number, legal representative.

b) An application for revision of the declaration of eligibility for medical device classification consists of:

- Form No. 19 in Appendix I hereof, which specifies the changes (including the case in which the person in charge of medical device classification no longer works at the classifying organization);

- The person in charge of medical device classification is replaced: the original copy or certified true copy of the replacing person's practising certificate which has the same scope of practice;

- In case of changes in the organization's address, phone number, legal representative: documents proving such changes.

c) Procedures:

- b) After receiving the valid and satisfactory application, the Ministry of Health shall issue a certification of eligibility declaration (Form No. 13 in Appendix IV hereof);

- Within 03 working days from the date written on the certification, the Ministry of Health shall update the changes on its website. The Ministry of Health shall respond and explain in writing in case of rejection.

5. The classifying organization may only carry out medical device classification after receiving the certification of eligibility declaration.

6. During its operation, the classifying organization shall resubmit the declaration of eligibility for medical device classification in chase of replacement of the person in charge of medical device classification with another person whose scope of practice is not covered by the previously submitted declaration.

**Article 8. Suspension of classification activities**

1. A classifying organization shall be suspended from medical device classification if it:

a) carries out medical device classification before submitting the declaration of eligibility for medical device classification;

b) uses untruthful or inaccurate documents to declare eligibility for medical device classification;

c) fails to satisfy the condition specified in Article 7 of this Decree;

d) gives an incorrect classification result that reduces the level of risk of the medical device;

dd) gives a classification result without signature of the person stated on the certification of eligibility declaration or the classifying organization's legal representative;

e) fails to implement or satisfactorily implement the remedial measures as requested by the supervisory body;

g) fails to publish the classification results in accordance with Point c Clause 5 Article 66 and Clause 8 Article 68 of this Decree.

2. Procedures for suspension:

a) During the inspection, if the classifying organization or the person in charge of medical device classification is found or suspected of committing any of the violations mentioned in Clause 1 of this Article, the inspecting authority shall issue an inspection record according to the form in Appendix XII hereof and request a competent authority to suspend the organization or the person in charge of medical device classification, and send the inspection record to the Ministry of Health within 24 hours after it is issued;

b) Within 24 hours from the receipt of the record, the Ministry of Health shall request the Department of Health, the General Department of Customs and border checkpoint customs to suspend the cases that involve the medical devices mentioned in the inspection record until an official conclusion is given by the Ministry of Health. The Ministry of Health shall also request the classifying organization to provide explanation for the issues written in the inspection record.

c) Within 03 working days from the receipt of the classifying organization's explanation, the Ministry of Health shall evaluate it;

d) If the explanation is acceptable and remedial measures are not required, the Ministry of Health shall issue a notice that the classifying organization is no longer suspended from medical device classification. The notice shall be sent to the suspended organization, the Department of Health, the General Department of Customs, border checkpoint customs and posted on the website of the Ministry of Health;

dd) If the explanation is acceptable and remedial measures are required, the Ministry of Health shall send a notice to the classifying organization, which has to subsequently implement the remedial measures. The notice shall be sent to the suspended organization, the Department of Health, the General Department of Customs, border checkpoint customs and posted on the website of the Ministry of Health;

The suspended organization shall submit a written report to the Ministry of Health after the remedial measures are implemented.

Within 03 working days from the receipt of the report, the Ministry of Health shall issue a notice that the classifying organization is no longer suspended from medical device classification, request the classifying organization to keep implementing the remedial measures, or revoke the confirmation according to Article 9 of this Decree. The notice shall be sent to the classifying organization, the Department of Health, the General Department of Customs, border checkpoint customs and posted on the website of the Ministry of Health;

e) If the classifying organization's explanation is deemed unacceptable, the Ministry of Health shall request the authority that received the declaration of eligibility for medical device classification to revoke the certification in accordance with Article 9 and handle the medical devices classified by such organization in accordance with Article 10.

**Article 9. Revocation of the certification of eligibility declaration, practising certificate and medical device classification result**

1. Revocation of the certification of eligibility declaration:

a) The certification of eligibility declaration shall be revoked in the following cases:

- Use of fraudulent documents in the application for declaration of eligibility for medical device classification;

- Failure to satisfy the condition specified in Article 7 of this Decree;

- Issuance of classification results during suspension period;

- Issuance of a classification result that reduces the level of risk of the medical device for the second time within 12 months;

- Failure to implement or satisfactorily implement the remedial measures as requested by the supervisory body.

b) Procedures:

- c) Within 01 working day after a conclusion that the classifying organization has committed a violation mentioned in Point a of this Clause is given, the Ministry of Health shall issue a revocation decision which specifies the remedial measures (if any), and remove information about the classifying organization from the Ministry of Health's website.

The revocation decision shall be sent to the classifying organization, the Department of Health, the General Department of Customs, border checkpoint customs and posted on the website of the Ministry of Health;

- After receiving the revocation decision, the classifying organization shall immediately stop classifying medical devices and implement remedial measures (if requested), and make compensation for the damage caused by its violations;

- If the classifying organization fails to comply or fully comply with the revocation decision, the Ministry of Health shall request a competent authority to handle the case.

2. Revocation of the practising certificate:

a) The practising certificate shall be revoked in the following cases:

- Use of fraudulent documents in the application for the practising certificate;

- Carrying out medical device classification without satisfying the conditions specified in this Decree;

- Carrying out medical device classification and issuing classification results while the certificate of training in medical device classification has expired;

- Giving an incorrect classification result that reduces the level of risk of the medical device for the second time within 12 months;

- Carrying out medical device classification and issuing classification result while being suspended, including the case in which the classifying organization employing the person is suspended or has the certification of eligibility declaration revoked.

b) Procedures for revocation of a practising certificate:

- Within 01 working day after a conclusion that the person in charge of medical device classification has committed a violation mentioned in Point a of this Clause is given, the Ministry of Health shall issue a revocation decision which requests the classifying employing that person to implement remedial measures (if any), and remove information about such person from the Ministry of Health's website.

The revocation decision shall be sent to its holder, the employing organization, the Department of Health, the General Department of Customs, border checkpoint customs and posted on the website of the Ministry of Health;

- After receiving the revocation decision, the person in charge of medical device classification and the employing organization shall immediately stop classifying medical devices and implement remedial measures (if requested), and make compensation for the damage caused by their violations;

- If the person in charge of medical device classification and the employing organization fails to comply or fully comply with the revocation decision, the Ministry of Health shall revoke the certification of eligibility declaration and transfer the case to a competent authority for handling.

3. Cancellation of classification results:

a) A classification result shall be cancelled in the following cases:

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

- The classification result bears the signature of a person other than that written on the certification of eligibility declaration or other than the classifying organization's legal representative;

- The classification result sheet is found fraudulent;

- The classification result is given while the classifying organization is being suspended or having its certification of eligibility declaration revoked.

b) Procedures for cancellation:

- Within 01 working day after a conclusion mentioned in Point a of this Clause is given, the Ministry of Health shall issue a cancellation decision which requests the classifying organization to implement remedial measures (if any), and remove the cancelled classification result from the Ministry of Health's website;

The cancellation decision shall be sent to the classifying organization, the Department of Health, the General Department of Customs, border checkpoint customs and posted on the website of the Ministry of Health;

- After receiving the cancellation decision, the classifying organization shall cancel the classification results specified therein and compensate for the damage caused by its violations;

If the classifying organization fails to comply or fully comply with the cancellation decision, the Ministry of Health shall revoke the certification of eligibility declaration and transfer the case to a competent authority for handling.

- After receiving the cancellation decision, the authority that received the application for declaration of applied standards or application for registration number (hereinafter referred to as "registration number issuer") shall review the registration numbers issued and revoke the registration numbers of medical devices that use the classification results that are cancelled under the decision of the Ministry of Health.

**Article 10. Disposal of medical devices whose classification results are cancelled**

1. In the cases where the medical device whose classification result is cancelled by the Ministry of Health has not been granted the registration number:

a) The applicant for registration number shall send a document to the receiving authority requesting suspension of the procedures for issuance of the registration number;

b) After receiving the document mentioned in Point a of this Clause or the cancellation decision, the receiving authority shall reject the application.

2. In the cases where the medical device whose classification result is cancelled by the Ministry of Health 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 to suspend the procedures for customs clearance and request the registration number issuer to revoke the registration number;

b) After receiving the registration number holder's document or the cancellation decision, the customs authority shall suspend the procedures for customs clearance and the registration number issuer shall revoke the registration number.

3. In the cases where the medical devices whose classification result is cancelled by the Ministry of Health has been granted the registration number and customs clearance but have not been purchased:

a) The registration number holder shall:

- Stop the sale of the medical devices and recall the medical devices classification result is cancelled by the Ministry of Health:

- Send a report to the customs authority that granted customs clearance specifying the quantity of medical devices granted customs clearance and do not follow procedures for import of the next shipments;

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

- Reapply for the registration number.

b) After receiving the registration number holder's document or the cancellation decision:

- The customs authority shall refuse to grant customs clearance;

- The registration number issuer shall revoke the registration number.

4. If the medical devices have been sold to health facilities:

a) The registration number holder shall:

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

- Send notices to the health facilities that purchased the medical devices.

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

c) If the incorrect classification of the medical devices poses a threat to patients' health, the health facilities shall stop using them and the registration number holder shall implement necessary measures for ensuring normal operation of such health facilities."

4. Point a Clause 1 Article 12 is amended as follows:

"a) have at least a college degree in medical devices or bachelor's degree in technology, health or pharmacy. The chief technician of a manufacturer of medical devices that contain narcotic substances and precursors shall have a bachelor's degree in medical devices, health, pharmacy, chemistry or biology;"

5. Article 13 is amended as follows:

**"Article 13. Requirements for quality control by medical device manufacturer**

1. The quality control system satisfies the standards specified in Clause 1 Article 68 of this Decree.

2. A manufacturer of medical devices containing narcotic substances and precursors, in addition to the standards mentioned in Clause 1 of this Article, shall have a system for monitoring the inventory of narcotic substances, precursors, medical devices that contain narcotic substances and precursors in accordance with Article 7 of the Government's Decree No. 80/2001/ND-CP (/docs/go/164780/) dated November 05, 2001 on control of legal drug-related activities in Vietnam (hereinafter referred to as "Decree No. 80/2001/ND-CP)."

6. Article 14 is amended as follows:

a) Clause 4 is amended as follows:

"4. A certificate of conformity with quality control standards recognized by a conformity assessment body as prescribed by law.

In case the manufacturer fails to conduct self-inspection of product quality, or the manufacturer does not have a warehouse or transport vehicle and signs a quality inspection, storage or transport contract with another establishment, storage and transport, documents proving that the hired establishment is capable of conducting quality inspection, storage or transport of the medical devices manufactured by the hirer are required."

b) Clause 5 below is added after Clause 4:

"5. Documents proving fulfilment of the requirements specified in Clause 2 Article 13 of this Decree."

7. Article 16 is amended as follows:

"1. A establishment may only produce medical devices after being granted a document certifying the submission of the declaration of production capability (hereinafter referred to as "certification of production capability declaration") by the Department of Health as prescribed in Point b Clause 2 of this Article.

2. Procedures for declaration of capability of medical device production (hereinafter referred to as "declaration of production capability"):

a) Before initiating the production, the manufacturer shall the application for declaration of production capability specified in Article 14 of this Decree to the Department of Health of the province where its factory is located;

b) After receiving the valid and satisfactory application, the Department of Health shall issue a certification of production capability declaration (Form No. 02 in Appendix IV hereof). In case of production of medical devices that contain narcotic substances and precursors, the Department of Health shall send a copy of the certification to the Ministry of Public Security.

3. Revision of the declaration of production capability:

a) Information in the declaration of production capability may be revised in the following cases:

- Change of the chief technician of the manufacturer;

- Change of the address or phone number.

b) An application for revision of the declaration of production capability consists of:

- a) Form No. 20 in Appendix I hereof which specifies the change;

- In case of change of the chief technician: the documents specified in Clause 3 Article 14 of this Decree;

- In case of change in the address or phone number: documents proving the change.

c) Procedures:

- b) After receiving the application, Department of Health shall issue form No. 14 in Appendix IV hereof;

- Within 03 working days from the date written on Form 14, Department of Health shall update the changes on its website. Department of Health shall respond and explain in writing in case of rejection.

4. During its operation, the manufacturer shall resubmit the declaration of production capability if there is any change to the previous declaration other than those mentioned in Point a Clause 3 of this Article.

5. If the factory is relocated to another province, a notice shall be sent to the Department of Health that received the declaration of production capability within 10 working days from the date of relocation.

Within 03 working days from the receipt of the relocation notice, the Department of Health shall stop posting information about the factory."

8. Point a and Point dd Clause 1 Article 17 are amended as follows:

"a) Having an unexpired registration number or an import license as prescribed in this Decree, except for medical gas;

dd) Having information about warranty center, conditions and time for warranty, except disposable medical devices defined by the product owner or there are documents proving that the device is not under warranty;"

9. Article 22 is amended as follows:

**"Article 22. Application for declaration of applied standards**

An application for declaration of applied standards of Class A medical devices consists of:

1. The declaration form No. 03 in Appendix I hereof;

2. The medical device classification form in Appendix V hereof.

3. An unexpired certificate of conformity with quality control standards. For domestically manufactured medical device, the certification of declaration of production capability.

4. The product owner's document authorizing the organization to declare applied standards (the form in Appendix VI hereof) except for the case mentioned in Point a Clause 1 Article 32 of this Decree.

5. The certificate of warranty qualification issued by the product owner (the form in Appendix VII hereof), except for disposable medical devices defined by the product owner or there are documents proving that the device is not under warranty.

6. A document containing brief description of the medical device in Vietnam language according to form No. 01 in Appendix VIII hereof enclosed with the document containing description of functions and specifications of the medical device issued by the product owner.

For In vitro diagnostic reagents, calibrators and control materials: Vietnamese technical document according to form No. 02 in Appendix VIII hereof enclosed with the document about the raw materials and safety of the product, manufacturing process, pre-clinical and clinical study reports including stability report.

7. For domestically manufactured medical devices: The certificate of conformity or product standard sheet declared by the product owner enclosed with the chemical, physical, microbiological indicators and other indicators provided by a qualified conformity-assessing establishments. The assessment result shall be conformable with the standards declared by the product owner.

8. The instruction manual of the device.

9. A sample of the label for the devices sold in Vietnam.

10. An unexpired CFS (for imported medical devices)

10. Clause 2 of Article 23 is amended as follows:

a) Point b Clause 2 is amended as follows:

"b) The certificate of conformity with quality control standards: original copy or certified true copy or a copy certified by 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) Point g below is added to Clause 2:

"g) A consularly legalized CFS or a 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.

IF the CFS does not have an expiration date, it will expire in 36 months from its issuance date."

11. Clause 4 below is added to Article 24:

"4. During the sale of medical devices, their owner shall inform the registration number issuer within 10 days from the day on which any of the following changes occur:

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

b) Change in the registration number holder's name. The registration number holder shall send a notice and documents proving the change and the label sample as prescribed in Article 54 of this Decree;

c) Change in the medical device manufacturer's name or address. The registration number holder shall send a notice together with an unexpired CFS and an unexpired certificate of fulfillment of quality control standards;

d) Change in package contents of the in vitro diagnostic device. The registration number holder shall send a notice and the documents mentioned in Clause 6 and Clause 9 Article 22 of this Decree;

dd) Change in the warranty center. The registration number holder shall send a notice and the documents mentioned in Clause 5 Article 22 of this Decree;

e) Change in the label or instruction manual without changing the indications. The registration number holder shall send a notice and documents about the changes."

12. Article 25 is amended as follows:

**"Article 25. Methods of registration**

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

a) The medical device has not had any registration number;

b) The in vitro diagnostic device or disposable medical device already has a registration number but there is a change in its category or materials that affect its function.

b) The existing registration number of the medical device is not renewed by the deadline mentioned in Clause 3 Article 27 of this Decree.

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

a) The medical device has been placed on the market in at least 02 of the following countries: Japan, Canada, Australia, EU member states;

b) The medical device has placed on the market in Vietnam before December 31, 2018 and satisfies the following conditions:

- It has been placed on the market for at least 03 years in the last 05 years before the application date;

- There is no warning against its quality and safety.

3. Renewal of registration numbers shall comply with Clause 3 Article 27 of this Decree."

13. Article 26 is amended as follows:

a) Clause 1 is amended as follows:

"1. An application for issuance of a new registration number of a medical device without a National Technical Regulation:

a) Application form No. 04 in Appendix I hereof;

b) The medical device classification form in Appendix V hereof;

c) A certificate of conformity with quality control standards that is still unexpired when the application is submitted;

d) The product owner's document authorizing the establishment to apply for registration (the form in Appendix VI

hereof) except for the case mentioned in Point a Clause 1 Article 21 of this Decree;

dd) The certificate of warranty qualification issued by the product owner (the form in Appendix VII hereof), except for disposable medical devices defined by the product owner or there are documents proving that the device is not under warranty.

e) An unexpired CFS (for imported medical devices);

g) A document containing brief description of the medical device in Vietnam language according to form No. 01 in Appendix VIII hereof and the document containing description of functions and specifications of the medical device issued by the product owner;

For In vitro diagnostic reagents, calibrators and control materials: Vietnamese technical document according to form No. 02 in Appendix VIII hereof enclosed with the document about the raw materials and safety of the product, manufacturing process, pre-clinical and clinical study reports including stability report;

h) The common technical dossier shall comply with instructions in ASEAN Medical Device Directive;

i) The instruction manual of the device;

k) Regarding Class C and Class D medical devices: a brief description of the clinical trial data (the form in Appendix IX hereof) enclosed with the clinical trial result, except for the following cases:

- The medical device has been placed on the market and granted the CFS in any of the following countries: Japan, Canada, Australia (TGA), the United State (FDA), EU member states;

- The medical device has been granted registration before the effective date of this Decree;

- Other cases specified by the Minister of Health.

l) Regarding Class C and Class D in vitro diagnostic devices, it is required to provide the certificate of inspection as prescribed by the Minister of Health, except for the following cases:

- The medical device has been granted the CFS in any of the following countries: Japan, Canada, Australia (TGA), the United State (FDA), EU member states;

- The medical device has been granted registration before the effective date of this Decree;

m) A sample of the label for the devices when sold in Vietnam;

n) The certification of production capability declaration that is conformable with the product applying for registration number (for domestically manufactured devices);

g) The income statement (form No. 01 in Appendix X hereof) if the medical device was granted a registration number before the effective date of this Decree and exempt from submission of the brief description of clinical trial data or certificate of inspection."

b) Point c Clause 2 is amended as follows:

"c) The documents specified in Points b, c, d, dd, e, g, h, i, m, n and o Clause 1 of this Article."

c) Point c Clause 3 is amended as follows:

"c) The documents specified in Points b, c, d, dd, e, g, h, i, m, n and o Clause 1 of this Article."

d) Clause 5 below is added after Clause 4:

"5. Application for quick issuance of a registration number:

a) In the case mentioned in Point a Clause 2 Article 25:

The documents specified in Clause 1 of this Article and at least 01 unexpired CFS issued by the competent authority of any of the following countries: EU member states, Japan, Canada, Australia (TGA), the United State (FDA);

b) In the case mentioned in Point b Clause 2 Article 25:

The documents specified in Clause 1 of this Article and:

- At least 03 contracts with health facilities in Vietnam for supply of the medical devices;

- Documents of the health facilities certifying that there is no warning against the quality and safety of the medical devices during their use."

14. Clause 2 of Article 27 is amended as follows:

a) Point c Clause 2 is amended as follows:

"c) A certificate of conformity with quality control standards that is still unexpired when the application is submitted;"

b) Point g below is added to Clause 2:

"g) The common technical dossier shall comply with instructions in ASEAN Medical Device Directive if the registration number was issued before the ASEAN Common Technical Dossier (ACTD) is required by law.

15. Clause 2 of Article 28 is amended as follows:

a) Point a Clause 2 is amended as follows:

"a) The certificate of conformity with quality control standards: original copy or certified true copy or a copy certified by the applicant;

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) Point e Clause 2 is amended as follows:

"e) The certificate of inspection: original copy or certified true copy or a copy certified by the applicant."

16. Article 29 is amended as follows:

a) Point d below is added to Clause 3:

"d) An inspection shall be carried out for issuance of a new registration number within 30 days from the date written on the receipt note in the cases specified in Clause 2 Article 25 of this Decree."

b) Clause 5 is amended as follows:

"5. The applicant shall send the supplemented application to the Ministry of Health;

If the supplemented application is still unsatisfactory, the Ministry of Health shall send another document requesting the applicant to supplement it in accordance with Clause 4 of this Article;

If the Ministry of Health's request is not complied with within after 90 days or the application is still unsatisfactory after 05 supplementation times, the procedures shall be followed from the beginning.

If any of the documents mentioned in Point c, d and e Clause 1 Article 26 expire during the process of supplementation, the applicant shall submit the renewed ones. Such documents shall satisfy the requirements specified in Article 28 of this Decree."

c) Point c Clause 8 is amended as follows:

"c) Change in information about the medical device manufacturer's name or address. The registration number holder shall send a notice together with an CFS and a certificate of conformity with quality control standards that are still effective when the application is submitted;"

d) Point d Clause 8 is amended as follows:

"d) Change in package contents of the in vitro diagnostic device. The registration number holder shall send a notice and documents about the changes;"

dd) Point e below is added to Clause 8:

"e) Change in the label or instruction manual without changing the indications: the registration number holder shall send a notice and documents about the changes."

17. Article 30 is amended as follows:

**"Article 30. Documents for after-sale management of medical devices**

The registration number holder shall organize and manage the tracing of origins of medical devices on the market and retain documents for management of the medical devices. The following documents are mandatory:

1. The application for registration of medical devices. The following documents shall be retained in physical form:

a) The product owner's document authorizing the facility to apply for registration, except for the case mentioned in Point a Clause 1 Article 21 of this Decree;

b) The certificate of warranty qualification issued by the product owner, except for disposable medical devices defined by the product owner or there are documents proving that the device is not under warranty;

c) The CFS.

2. Distribution documents (the registration number holder that is a representative office is not required to retain these documents but has to request the authorized importer to retain them).

3. Logs of adverse events (AE), complaints and remedial measures therefore. The documents shall specify the names, categories, quantities and batch numbers of the medical devices involved, especially those that are defective or unsafe for users.

4. Medical device quality control documents include:

a) The Certificate of Origin prescribed in the Government's Decree No. 31/2018/ND-CP (/docs/go/395776/) ;

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

c) Result of inspection of medical devices in the cases specified in Clause 1 Article 49 of this Decree."

18. Article 31 is amended as follows:

**"Article 31. Handling of medical devices that pose a serious threat to public health or can cause death of users**

1. In the cases where a Vietnamese or international competent authority issues a warning against a medical device that poses a serious threat to public health or can cause death of users, the registration number holder shall inform the health facilities using such device of the warning and carry out an investigation within 30 days from the day on which the warning is received. If the investigation has to last for more than 30 days, a report specifying the reasons and solutions for ensuring safety of users shall be submitted to the Ministry of Health.

2. In the cases where the medical devices mentioned in Clause 1 of this Article have a defect is harmful to users' health, the registration number holder shall:

a) Suspend the sale of the batch of medical devices;

b) Send a notice to the Ministry of Health, distributors and users of the medical devices. The notice shall specify the batch number and the defect, and whether such defect can be repaired;

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

d) Send a report to the Ministry of Health after all of the defective devices are repaired or recalled.

3. If the defect can be repaired:

a) Within 03 working days from receipt of the owner's notice, the Ministry of Health shall issue a decision to suspend the batch of medical devices from sale.

A suspension decision shall contain the following information:

- Name of the medical devices suspended from sale;

- Batch number;

- Registration number of the devices.

h) After a suspension decision is issued, the registration number holder shall repair the defect;

c) After the defect is repaired, the registration number holder shall send a report to the Ministry of Health together with the inspection result (if the medical devices are those mentioned in Clause 1 Article 49 of this Decree), or a commitment to maintain quality of medical devices after the defect is repaired (for other medical devices);

d) Within 20 working days from receipt of the owner's report, the Ministry of Health shall issue a decision to lift the suspension. If the Ministry of Health refuses to lift the suspension, it will 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 devices.

A recall decision shall contain the following information:

- Name of the medical devices;

- Batch number;

- Registration number of the devices.

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

c) If the recall is not done by the deadline, the recall will be enforced in accordance with regulations of law on handling administrative violations."

19. Article 32 is amended as follows:

**"Article 32. Actions to be taken in case of an adverse event (AE) that has caused harm to users' health:**

1. In the cases where a medical device has an AE that poses 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 to the Ministry of Health, the traders and users of that batch of medical devices;

b) Suspend the sale of the batch of medical devices associated with 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 devices, the report shall describe the defect and whether it can be repaired. Repair the defect or recall the batch of defective devices, submit a report to the Ministry of Health after the defect is repaired or the batch is recalled.

2. If the AE does not cause death but has caused serious harm to a user's health, the registration number holder shall:

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

b) Initiate an investigation into the cause 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 devices, the report shall describe the defect and whether it can be repaired. Repair the defect or recall the batch of defective devices, submit a report to the Ministry of Health after the defect is repaired or the batch is recalled.

3. Medical devices that have a defect is harmful to users' health shall be handled in accordance with Clause 3 and Clause 4 Article 31 of this Decree."

20. Article 33 is amended as follows:

**"Article 33. 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 device with an equivalent device;

d) Recall for re-export or destruction.

2. Defective medical devices shall be recalled in the following manners:

a) Voluntary recall by the registration number holder;

b) Mandatory recall in the cases specified in Article 35 of this Decree."

21. Article 35 is amended as follows:

a) Clause 2 is amended as follows:

"2. 03 batches of the medical devices are recalled during the effective period of the registration number, unless the registration number holder voluntarily recalls the devices."

b) Clauses 10, 11 and 12 below are added to Article 33:

"10. The registration number holder fails to implement the provisions of Point I Clause 2 Article 66 of this Decree, except for the cases specified in Article 34 of this Decree.

11. The application for declaration is not conformable with provisions of Article 22 and Article 23 of this Decree or the documents therein are found fraudulent.

12. The medical devices are not classified in accordance with regulations on classification of medical devices after a conclusion is given by the Ministry of Health."

22. Point a Clause 3 Article 36 is amended as follows:

"a) Post the decision on revocation of the registration number on the website of the registration number issuer; send a copy of the decision to the registration number holder, the Ministry of Health, Departments of Health and customs authorities;"

23. Article 37 is amended as follows:

**"Article 37. Requirements for trading in Class B, C, D medical devices**

To be permitted to trade in type B, C, D medical equipment, an establishment must:

1. Have at least 01 employee who has at least a college degree in technology, health, pharmacy or medical devices or at least a college degree suitable for the medical devices sold by the establishment;

2. Have at least a warehouse and a vehicle that satisfy the following requirements:

a) The warehouse must:

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

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

- satisfy storage conditions of the medical devices according to their instructions manuals.

b) The vehicle for delivery of medical devices is suitable for the devices carried therein;

An establishment without 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, health, pharmacy, chemistry or biology;

b) There is a warehouse that satisfies the requirements specified in Article 7 of Decree No. 80/2001/ND-CP (/docs/go/164780/) ;

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

24. Article 38 is amended as follows:

**"Article 38. Conditions, documents and procedures for declaration of eligibility for medical device trading**

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

a) Form No. 07 in Appendix I hereof;

b) A personnel list form in Appendix II hereof;

c) Documents proving that the a warehouse and vehicle satisfy the requirements specified in Clause 2 Article 37 of this Decree. These documents must be certified by the declaring establishment;

d) Documents proving that the warehouse, the inventory monitoring system for medical devices containing narcotic substances and precursors comply with the requirements in Clause 3 Article 37 of this Decree. Such documents shall be certified by the facility making the declaration of eligibility for trading in medical devices that contain narcotic substances and precursors.

2. Procedures for declaration of trading capability:

a) Before trading Class B, C or D medical devices, the head of the trading establishment shall send a declaration of capability of trading in medical devices (hereinafter referred to as "declaration of trading capability") specified in Clause 1 of this Article to the Department of Health of the province where the trading establishment is located;

b) When receiving the declaration, the Department of Health shall issue a document certifying the submission of the declaration of trading capability (hereinafter referred to as "certification of trading capability declaration") according to Form No. 05 in Appendix IV hereof;

c) Within 03 working days from the receipt of the declaration, the Department of Health shall post on its website the trading establishment's name, address, phone number, scope of operation and the declaration of trading capability.

3. Class B, C or D medical devices may only be traded after the declaration of trading capability is submitted as prescribed in Clause 2 of this Article, except for the case mentioned in Article 39 of this Decree.

4. Revision of the declaration of trading capability:

a) Information in the declaration of trading capability may be revised in the following cases:

- Change of the trading establishment's technician;

- Change of the address or phone number.

b) An application for revision of the declaration of trading capability:

- a) Application form No. 21 in Appendix I hereof which specifies the changes;

- In case of change of the technician: the personnel declaration form in Appendix II hereof which specifies the change;

- In case of changes in the establishment's address, phone number: documents proving such changes.

c) Procedures:

- After receiving the application, the Department of Health shall issue form No. 15 in Appendix IV hereof;

- Within 03 working days from the date written on Form No. 15, the Department of Health shall update the changes on its website, or respond and explain in writing in case of rejection.

5. During its operation, the trading establishment shall resubmit the declaration of trading capability if there is any change to the previous declaration other than those mentioned in Point a Clause 4 of this Article."

25. Clause 2 of Article 40 is amended as follows:

"2. Medical devices that have been granted registration numbers in Vietnam may be exported and imported without limits on quantities and are exempt from approval by the Ministry of Health, except for those that contain narcotic substances or precursors."

26. Clause 2 of Article 41 is amended as follows:

"2. An organization or individual that wishes to import medical devices that already have a registration number shall:

a) be the registration number holder or 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) has a warehouse and vehicles satisfying the requirements specified in Clause 2 Article 37 of this Article or has a medical device storage and transport contract with a capable service provider;

c) has a warehouse and an inventory monitoring system for medical devices containing narcotic substances and precursors that satisfy the requirements in Clause 3 Article 37 of this Decree."

27. Article 42 is amended as follows:

**"Article 42. Export license and import license**

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

a) Unregistered medical devices are imported to serve scientific research, inspection or training in use or repair of such devices;

b) Unregistered medical devices are imported as assistance or humanitarian aid;

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

d) Unregistered medical devices are imported for personal treatment of illness, including those specifically manufactured under prescription for treatment of a patient or under a health facility's request to serve its diagnosis works;

dd) Registered medical devices contain narcotic substances or precursors; the materials for manufacture of medical devices are narcotic substances or precursors;

e) Medical devices containing narcotic substances or precursors are imported for scientific research or inspection;

g) Used medical devices are imported to serve research or training (no use on humans or for diagnostic or treatment purposes). Import of medical devices in this case shall be decided by the Prime Minister;

h) Raw materials for manufacture of medical devices are narcotic substances or precursors and imported for scientific research or inspection.

2. An export license is required in the following cases:

a) Medical devices contain narcotic substances or precursors;

b) Raw materials for manufacture of medical devices are narcotic substances or precursors.

3. An application for the import license consists of:

a) Application form No. 08 in Appendix I hereof;

b) A document containing brief description of the medical device in Vietnam language according to form No. 01 in Appendix VIII hereof;

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

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

dd) If the medical devices are imported to serve training purposes: original copy of the training program and documents proving the devices are granted marketing authorization by a competent authority, bearing the applicant's certification;

e) If the medical devices are imported for inspection: The inspecting unit's certification which specifies the quantity of devices;

d) If the medical devices are imported as aid: a copy of the decision to approve the aid and documents proving the devices are granted marketing authorization by a competent authority, bearing the applicant's certification;

h) If the medical devices are imported to serve charitable medical examination and treatment: original copy of the training program and documents proving the devices are granted marketing authorization by a competent authority, bearing the applicant's certification;

i) If the medical devices are imported to serve special diagnostic purposes of the health facility: documents proving that the medical devices have been granted marketing authorization by a competent authority, bearing the applicant's certification;

k) If the medical devices are imported for personal treatment: copies of the doctor's prescription which is consistent with the applicant's diseases.

4. Application for import of medical devices that contain narcotic substances or precursors:

a) An application for import of medical devices that contain narcotic substances or precursors that already have a registration number consists of:

- a) The application form No. 13 in Appendix I hereof which specifies the reasons if the quantity of medical devices pending permission for import exceeds 150% of the quantity of the preceding import;

- The sales report of the medical devices containing narcotic substances and precursors according to form No. 02 in Appendix X hereof;

b) An application for import of medical devices containing narcotic substances or precursors serving scientific research or inspection consists of:

- a) Application form No. 13 in Appendix I hereof;

- The documents specified in Points b, c, d, e Clause 3 Article 42 of this Decree.

5. An application for import of medical devices that contain narcotic substances or precursors for production consists of:

a) Application form No. 14 in Appendix I hereof;

b) Copies of the importer's documents about the quality standards and methods for quality inspection of narcotic substances and precursors bearing the importer's seal;

c) A certified true copy of the raw material producer's license for production issued by a competent authority of the exporting country. The license for production shall be consularly legalized, except for the cases in which consular legalization is not required by law;

If any of the documents mentioned in Point b and Point c of this Clause is not written in Vietnamese or English, a certified Vietnamese or English translation shall be provided.

d) The report on use of raw materials for production of the medical devices containing narcotic substances and precursors according to form No. 03 in Appendix X hereof;

dd) The sales report of raw materials for production of medical devices containing narcotic substances and precursors according to form No. 02 in Appendix X hereof;

e) The plan for manufacture and use of imported raw materials and plan for sale of products expected to be obtained from the raw materials pending permission for import.

6. An application for import of raw materials for production of medical devices that contain narcotic substances or precursors for research or inspection consists of:

a) The application form No. 14 in Appendix I hereof;

b) If the raw materials are imported to serve research into production of medical devices: copies of documents to proving the research bearing the applicant's certification;

c) If the raw materials are imported for inspection: The inspecting unit's certification which specifies the quantity of raw materials expected to undergo inspection.

7. An application for export of medical devices containing narcotic substances and precursors or raw materials for production thereof:

a) The application form No. 15 or No. 16 in Appendix I hereof;

b) A report on quantity and origins of medical devices containing narcotic substances and precursors or raw materials for production thereof according to form No. 04 in Appendix X hereof;

c) A document permitting the import of the medical devices containing narcotic substances and precursors or raw materials for production thereof issued by a competent authority of the importing country. If such document is not written in Vietnamese or English, a certified Vietnamese or English translation shall be provided. The import permit shall be consularly legalized, except for the cases in which consular legalization is not required by law.

8. Procedures for processing an application for the license to import or export medical devices containing narcotic substances and precursors or raw materials for production thereof:

a) After receiving the application, the Ministry of Health shall send a receipt note (form No. 06 in Appendix IV hereof) to the applicant;

b) If the application is satisfactory, the Ministry of Health shall process it within 15 working days from the date written on the receipt note. If the application is rejected, a written response and explanation shall be provided.

The Ministry of Health shall process an application for the license to export medical devices or raw materials containing narcotic substances or precursors within 15 working days from the day on which the Ministry of Public Security issues a notice. If the application is rejected, a written response and explanation shall be provided;

The export or import license shall be sent to the applicant and customs authorities. In case of medical devices or raw materials containing narcotic substances or precursors, the export or import license shall also be sent to the Ministry of Public Security and the Ministry of Finance;

A license to export or import medical devices containing narcotic substances and precursors or raw materials for production thereof is only valid for a single export or import and will expire on the date written thereon.

c) If the application is not satisfactory, within 05 working days from the date written on the receipt note, the Ministry of Health shall request the applicant to supplement it. The request shall specify necessary addition of documents or revision of information.

d) The applicant shall comply with the request and send the supplemented application to the Ministry of Health;

If the supplemented application is still unsatisfactory, the Ministry of Health shall request the applicant to supplement it.

dd) If the applicant fails to submit the supplemented application within 60 days, the application will be rejected.

e) If the supplemented application is satisfactory, the Ministry of Health shall issue the import or export license in accordance with Point b of this Clause. The export or import license shall be sent to the applicant and customs authorities."

28. Article 43 is amended as follows:

**"Article 43.App for the Certificate of Free Sale (CFS) of domestically manufactured medical devices**

The Ministry of Health only issues the CFS to medical devices that have been granted registration numbers.

1. An application for the CFS consists of:

a) The application form No. 12 in Appendix I hereof;

b) A certified true copy of an unexpired certificate of conformity with quality control standards recognized by a conformity assessment body as prescribed by law;

c) The original copy or photocopy of the unexpired registration number;

2. Procedures for issuance of the CFS are specified in the Government's Decree No. 69/2018/ND-CP (/docs/go/395755/) .

3. The specimen of the CFS is form No. 12 in Appendix IV hereof."

29. Section 2 of Chapter VI is amended as follows:

**"Section 2. INSPECTION AND CALIBRATION OF MEDICAL DEVICES**

**Article 49. Rules for inspection and calibration of medical devices**

1. Medical devices on the Minister of Health's list shall undergo safety and function inspection before use (except for the cases in Article 51 of this Decree), periodically and after overhaul. Inspection of medical devices that are measurement devices and radiological equipment shall be carried out in accordance with Clause 2 of this Article.

2. Medical devices that are measurement devices and radiological equipment shall undergo inspection and calibration in accordance with regulations of law on measurement and atomic energy.

**Article 50. Requirements for provision of medical device inspection services**

Requirements in terms of equipment, personnel, preparation and submission of the application for the certificate of registration of medical device inspection services; issuance, revision, reissuance and revocation of the certificate 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 training in such process.

**Article 51. Exemption of first inspection before use**

First inspection before use of medical devices shall be exempted in the following cases:

1. The medical devices already have the Certificate of conformity;

2. a) The unregistered medical devices are imported to serve scientific research or training in use, maintenance or repair of such devices;

3. The unregistered medical devices are imported for the importer's personal treatment or charitable medical examination and treatment or serving special diagnostic purposes;

4. The unregistered medical devices are imported for display at an exhibition or introduction event.

**Article 52. Handling unqualified medical devices**

1. In the cases where the result of inspection before use is not satisfactory:

a) Health facilities must not receive or use the medical devices;

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

c) If 03 medical devices in the same batch fails the safety and function inspection, the Ministry of Health shall request the registration number holders to send reports on the quantity of medical devices being sold on the market and those being used by health facilities;

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

On the basis of the re-inspection result, the Ministry of Health shall decide whether to carry out another re-inspection, the quantity of medical devices that have to undergo another re-inspection, or request the registration number holder to recall the whole batch;

In the cases where 03 batches of medical devices are recalled during the effective period of the registration number, the registration number will 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 the cases where the result of a periodic inspection or post-overhaul inspection is not satisfactory:

a) Health facilities must stop using the medical devices;

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 re-inspection.

d) Only use the medical devices if the re-inspection result is satisfactory."

30. Clause 1 of Article 54 is amended as follows:

"1. Medical devices shall be labeled in accordance with applicable regulations of law on goods labels."

31. Clause 2 of Article 55 is amended as follows:

"2. Medical devices shall be stored, maintained, used in accordance with the manufacturer's instructions and inspected in accordance with this Decree.

Regarding medical devices with strict occupational hygiene and safety requirements, regulations of law on occupational hygiene and safety shall be complied with in addition to the quality assurance requirements specified in this Decree."

32. Article 56 is amended as follows:

**"Article 56. Management and use of medical devices by state-owned health facilities**

In addition to provisions of Article 55 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."

33. Point dd below is added to Clause 2 or Article 57:

"dd) Health facilities shall inspect the quality control documents when receiving medical devices; the test result of every batch of medical gas must be stored and updated."

34. Article 58 is amended as follows:

a) Clause 7 is amended as follows:

"7. Application for the certificate of registration of medical device inspection services."

b) Clause 10 below is added to Article 58:

"10. Issuance of the practising certificate for medical device classification."

35. Clause 5 below is added to Article 60:

"5. During operation, the registration number holder may retain the number of the receipt note of the previous declaration in case of change mentioned in Clause 4 Article 24 of this Decree;" Article."

36. Clause 1 of Article 61 is amended as follows:

"1. In case of online registration, the applicant shall retain the application in accordance with Clause 2 Article 30 of this Decree."

37. Clause 8, Clause 9 and Clause 10 below are added to Article 62:

"8. Provide for classification of medical devices conformably with ASEAN's treaties on medical device classification to which Vietnam is a signatory; introduce training program for medical device classification practice.

9. Publish a list of medical devices that have to undergo inspection and inspection process for each of the medical devices on the list.

10. Provide specific instructions on how to prepare the ASEAN common technical document."

38. Article 66 is amended as follows:

a) Clause 2 is amended as follows:

"2. The registration number holder shall:

a) Declare the applied standards or apply for registration of medical devices in accordance with this Decree;

b) Establish and maintain a warranty center for medical devices or sign a contract with a warranty center;

c) Prepare and retain documents for monitoring medical devices and trace origins of medical devices in accordance with this Decree, except for disposable medical devices defined by the product owners; inform Departments of Health and police authorities of any confusion or loss of medical devices containing narcotic substances and precursors or raw materials for production thereof.

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

dd) 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 the medical devices;

e) Stop circulating and take corrective actions or recall defective medical devices in accordance with this Decree, and inform relevant parties. Destruction of defective medical devices shall comply with regulations of law on environmental protection, relevant laws; the destruction cost shall be paid by the registration number holder;

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

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

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

- The CFS (for imported medical devices);

- The authorization letter in the case specified in Point a Clause 1 Article 21 of this Decree;

- The certification of warranty qualification or documents proving 57]]]]]]]]

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

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

m) Provide every health facility that buys the medical devices with 01 set of quality control documents specified in Clause 4 Article 30 of this Decree;

n) Fulfill other obligations prescribed by law."

b) Clause 4 below is added after Clause 4:

"4. Responsibility of establishments that trade in, export, import or transfer medical devices containing narcotic substances and precursors, or raw materials for production thereof:

a) Submit reports on sale, export, import and transfer of medical devices containing narcotic substances and precursors, or raw materials for production thereof (form No. 05 and form No. 06 in Appendix X hereof) to the Ministry of Health and the Ministry of Public Security within 10 days from the date of sale, export, import or transfer;

b) Submit biannual reports on receipt, delivery, inventory and use of medical devices containing narcotic substances and precursors and raw materials for production thereof (form No. 03 in Appendix X hereof) to the Ministry of Health by July 15 and January 15;

c) Submit reports according to form 07 in Appendix X hereof to the Department of Health within 48 hours from the discovery of confusion or loss of medical devices containing narcotic substances and precursors or raw materials for production thereof."

c) Clause 5 below is added after Clause 4:

"5. Organization of medical device classification:

a) An classifying organization, throughout its operation, shall satisfy all of the requirements specified in Article 7 of this Decree;

b) Assume responsibility and implement corrective measures for incorrect result in terms of risks of the medical devices or authority specified in this Decree;

c) Post the classification result on the Ministry of Health within 05 raw materials after it is available."

d) Clause 6 below is added after Clause 5:

"6. Manufacturers of medical devices may import active ingredients to produce medical devices. The imported active ingredients may only be used for production of medical devices and not for any other purpose, unless they are sold to another manufacturer for production of the same medical devices. Documents and procedures for import of active ingredient for production of medical devices shall comply with regulations of law on pharmacy."

39. Article 68 is amended as follows:

a) Clause 5 is amended as follows:

"a) The licenses to import Class B, C D medical devices that are issued in 2018 expire on December 31, 2018; import licenses issued in 2019 will expire after December 31, 2019, except for the cases specified in Clause 1 Article 42 and Point d of this Clause;

The licenses to import in vitro diagnostic reagents issued in 2018 and 2019 are effective until the end of December 31, 2019 without limited import quantity. The customs shall not impose any limits on import quantity in these cases;

Traders of medical devices shall ensure that the documents specified in Point I Clause 2 Article 66 of this Decree are effective throughout the effective period of the import license. If any of the aforementioned documents expires, the trader shall inform the Ministry of Health, which will subsequently revoke the import license.

b) Class A medical devices of the Ministry of Health that already have the certification of declaration of applied standards issued by a Department of Health may be imported without limits;

Medical devices that do not require the import license and have been classified as B, C or D by a classifying organization posted on the website of the Ministry of Health may be imported until the end of December 31, 2019 without limits and without the confirmation that they belong to the Ministry of Health.

c) Registration numbers of medical devices that are in vitro diagnostic reagents and granted the certificate of registration in accordance with the 2005's Law on Pharmacy and its instructional documents will be effective until the expiration date on their certificate of registration. The registration numbers of in vitro diagnostic reagents issued that expire after January 01, 2019 and before December 31, 2019 will be effective until the end of December 31, 2019;

Medical devices that are in vitro diagnostic reagents whose applications for registration are submitted before January 01, 2019 in accordance with the 2005's Law on Pharmacy shall be processed in accordance with the 2005's Law on Pharmacy;

Applications for the license to import in vitro diagnostic reagents that are submitted during the period from January 01, 2019 to December 31, 2019 shall be granted in accordance with the 2005's Law on Pharmacy; such import licenses shall be effective until the end of December 31, 2019;

Applications for registration of domestically manufactured in vitro diagnostic devices can be submitted from January 01, 2019.

d) Certificates of registration of insecticides and germicides for the sole purpose of sterilization of medical devices whose expires after July 01, 2016 and before January 01, 2019 will be effective until the end of December 31, 2019;

Applications for registration of insecticides and germicides for the sole purpose of sterilization of medical devices may be submitted from January 01, 2019.

dd) Registration numbers of domestically manufactured medical devices are effective until the expiration date written on the certificate of registration. The certificates of registration that expire after the effective date of this Decree and before December 31, 2019 will be effective until the end of December 31, 2019."

b) Clause 6 is amended as follows:

"6. Declarations of applied standards of Class A medical devices may be submitted from January 01, 2017; certifications of declaration of applied standards shall come into effect from July 01, 2017; applications for registration of Class B, C, D medical devices may be submitted from July 01, 2017; registration numbers of medical devices shall come into effect from January 01, 2020, except for the cases specified in Point c and Point d Clause 5 of this Article."

c) Clause 8 below is added after Clause 7:

"8. Organizations classifying medical devices shall publish the classification results that are issued before December 31, 2018 on the website of the Ministry of Health before April 01, 2019.

Documents proving the classification results in the form of recognition that have been submitted to supervisory authorities before December 31, 2018 may be used for applying for registration of the corresponding medical devices."

d) Clause 9 below is added after Clause 8:

"9. A certificate of completion of training in medical device classification that is issued before December 31, 2018 is effective for 03 years from the day on which it is signed."

dd) Clause 10 below is added after Clause 9:

"10. Every registration number holder shall review the medical device classification results in accordance with Clause 2 Article 4 of this Decree and submit a report to the Ministry of Health before July 01, 2019.

If the level of risk is changed after the review, the registration number holder shall reapply for registration with the new level of risk. Imported medical devices that have been granted customs clearance and domestically manufactured medical devices that are finished before December 31, 2020 in the cases specified in this Clause may be placed on the market until their expiration dates."

e) Clause 11 below is added after Clause 10:

"11. The ASEAN's CSDT may be applied from July 01, 2020, from which date applicants for registration are not required to provide the documents mentioned in Point g, Point i and Point m Clause 1 Article 26 of this Decree."

g) Clause 12 below is added after Clause 11:

"12. Manufacturers of medical gas shall apply ISO 9001 or an equivalent quality control system from January 01, 2020. The Minister of Health shall promulgate specific regulations on medical gas quality control."

h) Clause 13 below is added after Clause 12:

"13. Raw materials, software, accessories and medical gas are exempt from registration and import licensing under this Decree."

**Article 2. Effect**

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

2. The following regulations of Decree No. 36/2016/ND-CP (/docs/go/348213/) are annulled from the effective date of this Decree:

a) Clause 2 of Article 12;

b) Point b Clause 2 of Article 15;

c) Form No. 10 in Appendix I;

d) Form No. 11 in Appendix I;

dd) Form No. 08 in Appendix IV.

**Article 3. Responsibility for implementation organization**

1. The Minister of Health shall provide guidelines for, organize and inspect the implementation of this Decree.

2. Other Ministers, Heads of ministerial agencies, Heads of Governmental agencies, President of the People's Committees of provinces, relevant organizations and individuals are responsible for the implementation of this Decree.

**ON BEHALF OF THE GOVERNMENT**
**THE PRIME MINISTER**

**Nguyen Xuan Phuc**

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