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台灣醫療暨生技器材工業同業公會
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主旨：有關本組協查越南當地銷售輔具相關規定事，復如說明，請鑒參。

說明：

一、復貴局109年8月4日貿雙一字第1090451062號函。

二、經洽越南衛生部醫療器材司及本組自行查詢，貴局提問事項之相關規定如次：

(一)外國醫材及輔具在越南當地販售之經銷商資格與規定：

1、相關法規：越南36/2016/ND-CP議定及169/2018/ND-CP議定（英文譯本如附件）。

2、依前述法規，醫材分為2組、4種類型：

(1)第一組包括A類醫療器材，是低風險的醫療器材。

(2)第2組包括B、C和D類醫療器材，其中B類是平均風險較低的醫療器材；C類是平均風險較高的醫療器材；D類是高風險醫療器材。

3、經銷A類醫療器材：

(1)該醫療器材需先向衛生部登記並獲准在越南使用、經銷。

(2)公司的營業執照中有醫療器材交易者可執行經銷業務。

4、經銷B、C、D類醫療器材：

(1)該醫療器材需先向衛生部註冊並獲准在越南使用、經銷。

(2)經銷公司需有合格的技術人員，具有安裝或指導使用醫療器材的資格，其中至少1人具大學或更高水平的技術或醫學/藥學資格，或具有大專以上學歷，其職業符合公司所交易的醫療器材。

(3)經銷公司需依法規附件之申請表向當地衛生廳申請醫療器材買賣資格，批准後將頒發資格證明書，並於衛生部網站上公布該公司及有獲准經銷的醫療器材。

(二)越南公立醫院採購輔具之流程：本組參考胡志明市新平郡公立醫院的醫療器材採購流程如次：

1、醫院綜整院內科室需求，擬定醫療器材採購清單並編列預算。

2、院內科技委員會開會審核該清單及預算，並將結果通知院內科室。

3、倘採購獲准，科室需配合會計科提案選擇供應商，擬定招標計畫，由當地人委會常務單位審核通過後進行招標。倘採購金額5億越盾(約21,389美元)以上，將由當地省市衛生廳採購中心進行招標。

(三)當地已投資設廠生產輔具之外商是否仍需透過越籍經銷商以販售越南國內市場：此係依照外商之投資執照是否有包含經銷輔具之經營項目做判定，倘有則可經營。

正本：經濟部國際貿易局
副本：經濟部投資業務處 電子公文交換章 2020/08/20 17:38:47

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THE GOVERNMENT -------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No. 169/2018/ND-CP	*Hanoi, December 31, 2018*

DECREE

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

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

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 dated may 15, 2016 on medical equipment management.

Article 1. Amendments to some Articles of the Government's Decree No. 36/2016/ND-CP 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 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;

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;

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.

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 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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THE GOVERNMENT -------	SOCIALIST REPUBLIC OF VIETNAM Independence – Freedom - Happiness ----------
No. 36/2016/ND-CP	*Hanoi, May 15th, 2016*

DECREE

ON MEDICAL DEVICES MANAGEMENT

Pursuant to the Law on Government organization dated December 25, 2001;

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

At the request of the Minister of Health;

The Government hereby promulgates the Decree on medical devices management.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

This Decree provides for the management of medical devices, including the classification of medical devices; the manufacture, registration of medical devices and provision of services related to medical devices; information and label of medical devices and the management and use of medical devices at medical facility.

Article 2. Interpretation of terms

1. "Medical devices" includes devices, tools, materials for implanting activities, reagents and in vitro calibration solutions, software which are used separately or in association with each other according to the instruction of the product owner for human use for one or more of the following purposes:

a) To diagnose, prevent, supervise, treat and eliminate the illness or to make up for pains;

b) To examine, replace, adjust or assist surgery activities or physiology processes;

c) To support or sustain life;

d) To control the conception;

dd) To sterilize medical devices, including chemicals used in testing;

e) To serve the specialized transport or use for healthcare activities;

g) Provide information serving the diagnosis, supervision and treatment through the examination of samples taken from human body.

2. “In vitro diagnosis medical device” includes reagents, calibration solutions, control materials, tools, machinery, devices and systems which are used separately or together according to the instruction of their owners to serve the examination of samples taken from human body.

3. “Fittings” are products which are decided by the product owner to be used for a specific purpose together with a specific medical device to facilitate or assist such devices to be used for its intended use.

4. The product owner is an organization or an individual that:

a) Provide medical devices using its/his/her name or any label, design, trade name or other name or code within the possession of such individual/organization;

b) Take responsibility for the design, production, assembly, processing, labelling, packaging or the repair of medical devices or the determination of the use of such medical devices.

Article 3. Rules on management of medical devices

1. Assure the quality and safety of medical devices and assure the effective use thereof.

2. Promptly provide sufficient and accurate information about specifications and uses of medical devices and possible risks thereby to the users.

3. Ensure the traceability of the origin of the medical devices.

4. The management of medical devices must be based on the classification according to levels of risks and the respective national standards and National technical regulations

which are issued or recognized by competent authorities or published and applied by organizations/individuals according to laws.

5. Medical devices being measurement instruments or radiological equipment must be managed according to laws on measuring and laws on atomic energy and the provisions of this Decree.

Chemicals and preparations which are used only for sterilizing medical devices shall be managed according to regulations in this Decree. Chemicals and preparations which are used not only for sterilizing medical devices but also for other purposes shall be managed according to laws pertaining to chemicals and/or preparations killing insects and bacteria for domestic and medical use.

Chapter II

CLASSIFICATION OF MEDICAL DEVICES

Article 4. Classes of medical devices

Medical devices shall be classified into 2 groups which are divided into 4 types depending on the possible levels of risks related to the design and production of such medical devices:

1. Group 1 comprises Class A medical devices which is medical devices with low level of risks.

2. Group 2 comprises Class B, C and D medical devices, where:

a) Class B medical devices are medical devices with lower average level of risks;

b) Class C medical devices are medical devices with upper average level of risks;

c) Medical devices of Class D are medical devices with high level of risks.

Article 5. Rules on classification of medical devices

1. The classification of medical devices must be based on the classification of levels of risks.

2. If medical devices can be classified into multiple levels of risks, its highest level of risks shall prevail.

3. If the medical devices are intended to be used together with other medical devices, such devices shall be classified separately.

4. If the medical devices are intended to be used together with other medical devices or the medical device has multiple uses, the classification must be based on its most important use.

5. The Minister of Health shall be responsible for detailing the classification of medical devices according to international treaties on classification of medical devices by Association of Southeast Asian Nations to which Vietnam is a signatory.

Article 6. Carrying out classification of medical devices

1. The classification of medical devices must be carried out by an organization satisfying the conditions specified in Article 7 of this Decree.

2. The organization classifying medical devices must take legal responsibility for the classification of such medical devices.

3. If there is difference in the classification of medical devices, such classification shall be decided by the Ministry of Health.

Article 7. Requirements to be satisfied by classifying organizations

1. Any organization must satisfy the following requirements to classify medical devices

a) Legally established as prescribed by laws;

b) Having qualified medical devices-classifying employees according to clause 2 of this Article.

2. Conditions of medical devices-classifying employees:

a) Having at least a bachelor's degree in technology or medicine/pharmacy;

b) Having at least 24 months' experience of working in the field of medical devices technologies at hospitals, medical facilities having beds, training institutions specified in

medical devices, facilities researching medical devices, establishments producing medical devices, classifying organizations, agencies managing medical devices (hereinafter referred to as “medical device facilities”);

c) Having been tested and recognized by a training institution as capable of classifying medical devices according to the training program issued by the Ministry of Health.

3. Such organizations may only carry out classification of medical devices when it has obtained the document certifying the declaration of eligibility for medical device classification (from the Ministry of Health according to provisions of point b clause 1 Article 9 of this Decree.

Article 8. Declaration of eligibility for medical device classification

1. A declaration of eligibility for medical device classification shall consist of:

a) A written document announcing the eligibility to classify medical devices using the form No. 01 specified in Annex I enclosed with this Decree;

b) A list of employees using the form specified in Annex II enclosed with this Decree; accompanied by a written certificate of working time using the form in Annex III enclosed with this Decree and qualifications of each employee conducting the classification of medical devices.

2. Requirements for documents in the declaration:

a) Original copies or certified true copies of the certificates of working time;

b) Certified true copies of qualifications of employees conducting the classification of medical devices.

Article 9. Procedures for declaring eligibility to classify medical devices

1. Procedures for declaring the eligibility to classify medical devices:

a) Before classifying medical devices, the classifying organization of medical devices shall send the declaration of eligibility for medical device classification specified in clause 1 Article 8 of this Decree to the Ministry of Health;

b) If the declaration is satisfactory, the Ministry of Health shall issue the classifying organization with the certification of declaration using the form No. 01 specified in Annex IV enclosed herewith;

c) Within 03 working days from the date written on the certification of declaration, the Ministry of Health shall publish the following information on its web portal: name, address, phone number of the classifying organization of medical devices and the declaration of eligibility for medical device classification.

2. If there is any modification in the declaration during its operation, the classifying organization of medical devices shall re-conduct the procedures for declaration of eligibility for medical device classification.

Article 10. Recognition of classification of medical devices

1. Medical devices are not required to be reclassified in Vietnam if it has been classified by a competent regulatory body of a country recognized by Vietnam on the basis of international treaties or international arrangements to which Vietnam is a party or of a country which adopts a medical devices classification system similar to that adopted by Vietnam.

2. The Minister of Health shall publish the list of countries whose medical devices classifications have been recognized by Vietnam.

Chapter III

PRODUCTION OF MEDICAL DEVICES

Article 11. Investment incentives for the production of medical devices

1. Reduction or exemption from rents for State owned land:

a) Any investor having a project of producing Class B medical devices that leases state-owned land shall be eligible for the rental rate prescribed by People's Committees of provinces/central-affiliated cities and shall be eligible for exemption from land rents according to laws;

b) Any investor having a project of producing Class C or D medical devices shall be eligible for exemption from land rents from the day on which the project is launched;

c) Any investor having a project of producing medical devices shall be eligible for exemption from rents for land used for the construction of accommodations for employees or for planting public trees.

2. Apart from investment incentives specified in clause 1 of this Article, the project of producing medical devices shall be eligible for other investment incentives as prescribed by laws on investment and science and technology.

Article 12. Requirements for employees of producers of medical devices

1. The professionals must:

a) Have qualifications specified in medical devices technology of college level or higher or having qualifications specified in technique or medicine of university level or higher;

b) Have at least 24 months experience of working in the field of technique of medical devices at a medical devices-providing facility for at least 24 months;

c) Be a full-time worker at the producer's factory. The assignment and appointment of professionals shall be made in writing.

2. Other employees must satisfy requirements for producing medical devices.

Article 13. Requirements for infrastructures, equipment and quality control of producers of medical devices

1. Having conditions of location, area and factory in conformity with the medical devices that such producer produces.

2. Having equipment and procedures of production and quality inspection in conformity with the medical devices that such producer produces. In case there is no equipment for quality inspection, a contract with an establishment capable of conducting quality inspection for the medical devices shall be concluded.

3. Having storage facilities at least conformable to the following conditions:

a) Having area in accordance with the type and the quantity of the medical devices to be stored;

b) Being airy, dry, clean, separate from sources of pollution;

c) Satisfying other storing requirements applicable to medical devices according to the instruction.

4. Having vehicles for delivering medical devices from producing establishments in accordance with the medical devices.

5. Applying the quality control system prescribed in clause 1 Article 68 of this Decree.

6. If the establishment does not have storage facilities and vehicles for transporting medical devices, a contract with an establishment satisfying requirements for storage facilities and transport of medical devices as prescribed in clauses 3 and 4 of this Article shall be concluded.

Article 14. Declaration of eligibility to produce medical devices

A declaration of eligibility to produce medical devices shall consist of the following documents:

1. A declaration of eligibility to produce medical devices using the form No. 02 specified in Annex I enclosed with this Decree.

2. A list of employees using the form specified in Annex II enclosed with this Decree.

3. A document on assignment/appointment of professionals of the producing establishment, enclosed with the certificates of working time using the form in Annex III enclosed with this Decree and qualifications of the professionals.

4. A certificate of conformity with quality control standards.

In case of unavailability of the certificate of conformity with quality control standards, documents proving facilities satisfying requirements specified in clauses 1, 2, 3 and 4 Article 13 of this Decree are required.

In case the establishment fails to conduct the product quality inspection itself, or in case the establishment does not have storage facilities or transport vehicle and sign a contract with another establishment for quality inspection, storage and transport, documents proving that such contracting establishment is capable of conducting quality inspection, storing and transporting medical devices produced by the producing establishment must be enclosed.

Article 15. Requirements for declaration of eligibility to produce medical devices

1. The declaration of eligibility to produce medical devices shall be made in 1 copy, where:

a) Documents shall be readable and arranged according to the order provided for in Article 14 of this Decree; there shall be separators between different parts, there shall be cover pages and the table of contents;

b) Documents must be made in either English or Vietnamese.

2. Requirements for documents in the declaration of eligibility to produce medical devices:

a) An original copy or a certified true copy of the written assignment/appointment or qualifications of professionals of the producing establishment;

b) The original copies or the certified true copies of documents proving that the establishment satisfying requirements specified in clauses 1, 2, 3 and 4 Article 13 of this Decree;

c) An original copy or a certified true copy or a copy certified by the applicant establishment of the Certificate of conformity with quality control standards.

Article 16. Procedures for making declaration of eligibility to produce medical devices

1. The establishment shall carry out the production of medical devices only when it has obtained the certification of declaration prescribed in point b clause 2 of this Article.

2. Procedures for making declaration of eligibility to produce medical devices:

a) Before producing medical devices, heads of medical devices producing establishments shall send a declaration of eligibility to produce medical devices specified in Article 14 of this Decree to the Department of Health of the area where the producing establishment is headquartered;

b) If the declaration is satisfactory, the Department of Health shall issue the establishment with the certification of declaration using the form No. 02 in Annex IV enclosed with this Decree;

c) Within 03 working days from the date written on the certification of declaration, the Department of Health shall publish the following information on its web portal: name of

the establishment; the professionals in charge; medical devices produced by the establishment; contact address and phone number and the declaration of eligibility to produce medical devices, except for the producing procedures and the quality inspection procedures.

3. During its operation, if there is any change related to the accepted declaration, the producing establishment shall re-conduct the procedures for declaration of eligibility to produce medical devices.

4. If the producing establishment has its producing site relocated to another province, is must notify the Department of Health where it has make the declaration of eligibility to produce medical devices within 10 working days from the date of relocation.

Within 03 working days from the day on which the notification of the relocation of producing site is received, the Department of Health receiving the declaration of eligibility to produce medical devices shall terminate the publication of information relevant to such establishment.

Chapter IV

REGISTRATION OF MEDICAL DEVICES

Section 1. REQUIREMENTS FOR GRANT OF REGISTRATION, REGISTRATION NUMBER AND REQUIREMENTS APPLIED TO ORGANIZATIONS DECLARING APPLIED STANDARDS OR APPLYING FOR REGISTRATION

Article 17. Requirements for registration of medical devices

1. Any medical devices to be registered and placed on the market must satisfy the following requirements:

a) Having an effective registration number or having obtained permission for import according to provisions of this Decree;

b) Having label or supplementary label containing sufficiently information specified in Article 54 of this Decree;

c) Having technical documents serving the repair and maintenance of medical devices, excluding disposable medical devices prescribed by its owner;

d) Having Vietnamese instruction of how to use the medical devices;

dd) Having information about warranty establishments, conditions and duration, unless the device is disposable as decided by its owner.

2. The information specified in points c, d and dd clause 1 of this Article which is not enclosed with the device must be provided in form of electronic information; guidelines for accessing to such information must be clearly stated on the label of the medical devices.

Article 18. Conditions for declaring applied standards of application or issuance of certificate of free-sale registration for medical devices

1. Conditions for declaring the applied standards or the issuing the certificate of free-sale registration for medical devices

a) Such medical devices shall be manufactured at the producing establishment which has declared its eligibility to produce domestically produced medical devices;

b) Such medical devices shall be manufactured at an establishment which has been issued with the Certificate of conformity with quality control standards and granted registration in any country in the world, applicable to imported medical devices;

c) Such medical devices shall be conformable to National technical regulation or the standard that the producer has declared to be applied.

2. Re-application for applied standards or registration is not available to:

a) Medical devices specified in clause 1 Article 34 of this Decree;

b) Medical devices that are recalled according to regulations in clauses 1 and 3 Article 35 of this Decree.

3. The declaration of applied standards or the application for registration of medical devices of any of cases specified in clauses 2 and 8 Article 35 of this Decree shall not be accepted for 12 months from the day on which the decision to revoke the registration number is issued.

Article 19. Medical devices exempt from declaring applied standards and free-sale registration

1. Medical devices that is used solely for researching, testing or repairing medical devices or guiding the use thereof.

2. Medical devices imported into Vietnam for assisting purpose or for displaying at a fair, exhibition or for product introduction or as a gift.

3. Medical devices produced in Vietnam solely for export or for displaying at an overseas fair or exhibition.

Article 20. Registration number of medical devices

1. Registration number of medical devices means:

a) The number of the certification of declaration of applied standards, applicable to Class A medical devices, using the form No. 03 provided in Annex IV enclosed with this Decree;

b) The number of the certificate of registration, applicable to Class B, C or D medical devices, using the form No. 09 provided in Annex IV enclosed with this Decree.

2. The registration number of medical devices may be issued to one or a group of medical devices type.

3. The registration number holder is the organization declaring the applied standards, applicable to Class A medical devices, or the organization obtaining the registration number, applicable to Class B, C or D medical devices.

4. Effect of the registration number:

a) The registration number of Class A medical devices shall be permanently effective;

b) The registration number of Class B, C or D medical devices shall be effective for 05 years from the date of issue. In case where the effect of the registration number is extended, the registration number shall be retained.

Article 21. Requirements for organizations declaring applied standards or applying for registration of medical devices

1. The following organizations are allowed to declare the applied standards or applying for the registration of medical devices:

a) Vietnamese enterprises, cooperatives or business households that are in possession of medical devices;

b) Vietnamese enterprises, cooperatives or business households trading medical devices that are authorized by medical devices' owners to follow the registration procedures;

c) Standing representative offices in Vietnam of foreign traders who are the owners of the medical devices or who are authorized by the owners of the medical devices.

2. Any organization declaring the applied standards or carrying out registration of medical devices must have warranty establishments in Vietnam or sign a contract with an organization capable of providing warranty services on medical devices which is registered by its name, except for disposable medical devices as prescribed by the owners of such medical devices.

If the organization declaring the applied standards or applying for registration of medical devices is one of those specified in point c clause 1 of this Article, the owners of the medical devices sign a contract with an organization capable of providing warranty services on medical devices which is declared by its name, except for disposable medical devices as prescribed by the owners of such medical devices.

The warranty establishment shall be certified by the product owner to be capable of providing warranty on products which are registered by such organization.

Section 2. PUBLICATION OF APPLIED STANDARDS OF TYPE A MEDICAL DEVICES

Article 22. Declaration of applied standards

The declaration of applied standards for Class A medical devices shall consist of:

1. A declaration of the applied standards of Class A medical devices using the form No. 03 provided in Annex I enclosed with this Decree.

2. A classification table using the form in Annex V enclosed with this Decree.

3. A certification of declaration of eligibility to produce medical devices, applicable to domestically produced medical devices, or the Certificate of conformity with quality control standards which is effective by the time of declaration, applicable to imported devices.

4. The power of attorney by the product owner for the organization declaring the applied standards using the form in Annex VI enclosed with this Decree which is effective by the time of declaration, except for cases specified in point a clause 1 Article 21 of this Decree.

5. The certificate of eligibility to provide warranty issued by the product owner using the form provided in Annex II enclosed with this Decree, excluding disposable medical devices prescribed by its owner.

6. Documents that give brief description of medical devices technology using the form No. 01 in Annex VIII enclosed with this Decree.

7. The standard which the product owner declares to apply or the Certificate of conformity.

8. Written instruction for the medical devices.

9. The label of the medical devices which is intended to be used when it is sold in Vietnam.

Article 23. Requirements for declaration of applied standards

1. The declaration of applied standards shall be made in 01 dossier.

2. Requirements for a number of documents in the declaration of applied standards:

a) Regarding the certification of declaration of eligibility to produce medical devices: a copy which is certified by the organization declaring the applied standards is required.

b) Regarding the Certificate of conformity with quality control standard: an original copy or a certified true copy or a copy certified by the establishment declaring the applied standards is required;

If the copy certified by the organization declaring the applied standards is used, at the time of submission of the declaration, the original copy shall be presented for comparison or data sources shall be provided so that the receiving body checks the validity of such documents;

Any Certificate of conformity with quality control standard which is not made in English or Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

c) Regarding the power of attorney of the owner of medical devices and the Certificate of eligibility to provide warranty:

- Regarding domestically produced medical devices: an original copy of a certified true copy is required;

- Regarding imported medical devices: a consularly legalized copy or a certified true copy of the consularly legalized copy is required.

d) Regarding the Certificate of conformity or the standard declared by the product owner: a copy certified by the organization declaring the applied standards is required.

Any Standard which is not made in English or Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws;

dd) Regarding the instructions for the medical devices: a Vietnamese copy certified by the organization declaring the applied standards is required;

e) Regarding the label model: a copy which is certified by the organization declaring the applied standards is required. The label model must satisfy requirements specified in Article 54 of this Decree.

Article 24. Procedures for declaring applied standards

1. Class A medical devices shall only be placed on the market when the certification of declaration of applied standards has been issued by the Department of Health as prescribed in point b clause 2 of this Article.

2. Procedures for declaring applied standards:

a) Before releasing Class A medical devices, the establishment in charge of selling medical devices shall send the declaration of applied standards specified in Article 22 of this Decree to the Department of Health of the area where such establishment is headquartered;

b) If the declaration is satisfactory, the Department of Health shall issue the establishment with the certification of declaration using the form No. 03 in Annex IV enclosed with this Decree;

c) Within 03 working days from the date written on the certification of declaration, the Ministry of Health shall publish the following information on its web portal: name,

classification, producer, country of origin of medical devices; registration number of the medical devices; name, address of the product owner; name, address of the holder of the registration number; name, address of the establishment providing warranty services on medical devices and the declaration of applied standards for medical devices.

3. If the product owner or the producer is changed, the registration number holder shall re-conduct the procedures for declaration of the applied standards according to provisions of this Decree.

Section 3. REGISTRATION OF TYPE B, C OR D MEDICAL DEVICES

Article 25. Forms of registration

1. A new registration number shall be issued to the following medical devices:

a) Medical devices applying for registration number for the first time;

b) Medical devices which has been issued with the registration number and has been modified in type or producing materials (that affects its functions, applicable to in vitro diagnosis device and disposable medical devices);

c) Medical devices which has been issued with registration number and its owner fails to apply for extension of its registration number within the time specified in clause 3 Article 27 of this Decree.

2. The registration number shall be re-issued if the Certificate of registration is lost or damaged.

3. The time limit of the registration number shall be extended of the registration number nearly expires as prescribed in clause 3 Article 27 of this Decree.

Article 26. Application for new registration number

1. An application for the registration number of medical devices for which there is no applicable National technical regulation:

a) A written application form for a new registration number using the form No. 04 provided in Annex I enclosed with this Decree;

b) A classification table using the form in Annex V enclosed with this Decree;

c) The certificate of conformity with quality control standards which is effective at the time of application, unless the medical devices has been issued with the Certificate of Free sale (CFS) by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, Therapeutic Goods Administration (TGA) of Australia, Food and Drug Administration (FDA) of America;

d) The power of attorney by the product owner for the establishment conducting the free-sale registration using the form in Annex VI enclosed with this Decree which is effective by the time of application, except for cases specified in point a clause 1 Article 21 of this Decree;

dd) The certificate of eligibility to provide warranty issued by the product owner using the form provided in Annex II enclosed with this Decree, excluding disposable medical devices prescribed by its owner;

e) The CFS which is effective at the time of application, applicable to imported medical devices;

g) Vietnamese documents that give brief description of medical devices using the form No. 01 in Annex VIII enclosed with this Decree;

h) A catalogue describing functions and specifications of medical devices; technical information on reagents, calibration solutions, in vitro control materials using the form No. 02 provided in Annex VIII enclosed with this Decree;

i) Written instruction for the medical devices;

k) Regarding Class C or D medical devices which is used by putting into human body: the summary of clinically testing data using the form in Annex IX enclosed with this Decree together with the clinical trial results are required, unless:

- Medical devices are manufactured or processed in Vietnam solely for export and the importing country does not request clinical testing;

- Such medical devices have permitted been placed on the market and granted the CFS by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, TGA of Australia, FDA of America;

- Other cases specified by the Minister of Health.

l) Class C or D medical devices for in vitro diagnosis must have the certificate of inspection as prescribed by the Minister of Health, unless the medical devices has been

issued with the CFS by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, TGA of Australia, FDA of America;

m) The label of the medical devices which is intended to be used when such medical devices are placed on the market in Vietnam.

2. Regarding the application for the registration number of medical devices with applicable National technical regulations:

a) A written application form for a new registration number using the form No. 04 provided in Annex I enclosed with this Decree;

b) The certificate of conformity;

c) Papers specified in points b, c, d, dd, e, g, h, i and m clause 1 of this Article.

3. Regarding the application for a new registration number of medical devices being measurement instruments subject to obtaining the approval of the model according to laws on measuring:

a) A written application form for a new registration number using the form No. 04 provided in Annex I enclosed with this Decree;

b) The decision to approve the model;

c) Papers specified in points b, c, d, dd, e, g, h, i and m clause 1 of this Article.

4. Regarding the application for a new registration number of medical devices being measurement instruments which is not required to obtain the approval for the model as prescribed in laws on measuring, regulations in clause 1 of this Article shall be complied with.

Article 27. Application for reissuance/extension of registration number

1. The application for reissuance of the registration number which is lost or damaged shall include an application form using the form No. 05 provided in Annex I enclosed with this Decree.

2. An application for extension of the registration number shall consist of:

a) A written application form for extension of registration number using the form No. 06 provided in Annex I enclosed with this Decree;

b) A copy of the obtained certificate of registration;

c) The certificate of conformity with quality control standards which is effective at the time of application, unless the medical devices has been issued with the Certificate of Free sale by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, Therapeutic Goods Administration (TGA) of Australia, Food and Drug Administration (FDA) of America;

d) The power of attorney by the product owner for the establishment applying for registration using the form in Annex VI enclosed with this Decree, except for cases specified in point a clause 1 Article 21 of this Decree;

dd) The CFS which is effective at the time of application, applicable to imported medical devices;

e) The income statement for the period when the registration number is obtained using the form in Annex X enclosed with this Decree.

3. Time limit for applying for extension of the registration number shall be at least 60 days before it expires.

Article 28. Requirements for application for new issuance/extension of registration number

1. An application for new issuance or extension of the registration number of medical devices shall be made in 01 dossier and documents in such dossier shall be readable and shall be arranged according to the order specified in Article 26 of this Decree, applicable to applications for new issuance of the registration number, or in clause 2 Article 27 of this Decree, applicable to applications for extension of the registration number; there shall be separators between different parts, there shall be cover pages and the table of contents.

2. Required documents in the application for new issuance/extension of registration number:

a) Regarding the Certificate of conformity with quality control standards: the original copy or a certified true copy or a copy certified by the applicant establishment is required.

In case of including the copy certified by the applicant establishment, the original copy shall be presented for comparison or data sources shall be provided for checking the validity of such documents, at the time of submission of the application.

Any Certificate of conformity with quality control standard which is not made in English or Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

b) Regarding the power of attorney of the owner of medical devices and the Certificate of eligibility to provide warranty:

- Regarding medical devices manufactured in Vietnam: an original copy of a certified true copy is required;

- Regarding imported medical devices: a consularly legalized copy or a certified true copy of the consularly legalized copy is required.

c) Regarding the Certificate of Free sale: a consularly legalized copy or a certified true copy of the consularly legalized copy is required.

Any CFS which is not made in English or Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

If the CFS does not specify the date of expiry, it shall expire after 36 months counted from the date of issue.

d) Regarding catalogue of the medical devices: the copy certified by the applicant is required.

Any catalogue which is not made in English or Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws;

dd) Regarding the instructions for the medical devices: a Vietnamese copy certified by the applicant establishment is required.

e) Regarding the certificate of inspection: the original copy or a certified true copy or a copy certified by the applicant establishment is required.

In case of including the copy certified by the applicant, the original copy shall be presented at the time of submitting the application for comparison.

g) Regarding the label model: a copy which is certified by the applicant for registration of medical devices. The label model must satisfy requirements specified in Article 54 of this Decree.

Article 29. Receipt and inspection of application for registration number of medical devices

1. Any establishment applying for the registration number shall submit the application at the Ministry of Health.

2. When receiving satisfactory application, the Ministry of Health shall issue the applicant establishment with the certification of declaration using the form No. 04 provided in Annex IV enclosed with this Decree.

3. In case the application is satisfactory and not any modification is required, the Minister of Health shall:

a) Regarding medical devices for which there is no applicable National technical regulation: Conduct inspection for new issuance of the registration number within 60 days or for extension of the registration number within 30 days from the date written on the certification of declaration. In case of refusal to issue or grant extension of the registration number, a written response containing explanation shall be made;

b) Regarding medical devices with applicable National technical regulation: Conduct inspection for new issuance of the registration number within 15 days or for extension of the registration number within 10 days from the date written on the certification of declaration. In case of refusal to issue or grant extension for the registration number, a written response containing explanation shall be made;

c) The re-issuance of the registration number shall be carried out within 05 working days from the date written on the certification of declaration. In case of refusal to re-issue the registration number, a written response containing explanation shall be made.

4. If the application for the registration number is not satisfactory, the Ministry of Health shall send a written notification to the establishment applying for new issuance, re-issuance or extension of the registration requesting the modification, detailing documents and information subject to modification within the periods specified as follows:

a) 15 working days from the date written on the certification of declaration, applicable to applications for new issuance or extension of the registration;

b) 05 working days from the date written on the certification of declaration, applicable to applications for re-issuance of the registration.

5. After receiving the request for modification of the application for the registration number, the applicant establishment shall complete the documents according to the written notification and send them to the Ministry of Health. The date of receipt of the completed application shall be written on the certification of declaration.

In case where the applicant fails to comply with the request, the Ministry of Health shall request the applicant establishment to continue completing the application according to regulations in clause 4 of this Article.

After 60 days from the day on which the written notification by the Ministry of Health is received, if the applicant establishment fails to complete its application, it shall re-conduct the procedures for applying for the registration number.

6. If the inspection council requests the modification of the application, within 10 working days from the day on which the meeting minute of the council is made, the Ministry of Health shall send a written notification to the applicant establishment for modification of the application. The notification shall specify the information to be supplemented and the information to be adjusted.

After receiving the request for modification of the application for the registration number, the applicant establishment shall modify the documents according to the written notification and re-send the application to the Ministry of Health. The date of receipt of the completed application shall be written on the certification of declaration.

In case where the applicant fails to fully comply with the request, the Ministry of Health shall request the applicant establishment to continue completing the application according to regulations in clauses 4 and 5 of this Article.

7. Within 03 working days from the day on which the registration number is issued, the Ministry of Health shall publish on its web portal the following information:

a) Name, classification, producer and country of origin of the medical devices;

b) Registration number of the medical devices;

c) Name and address of the product owner;

d) Name and address of the registration number holder;

dd) Name and address of the warranty provider of the medical devices;

e) The application for registration number of the medical devices, except for information specified in points g and h clause 1 Article 26 of this Decree.

8. During the period of registration of medical devices, the holder of the registration number shall send a written notification to the Ministry of Health within 10 working days from the day on which any of the following activities is conducted:

a) The address of the product owner or of the holder of the registration number of the medical devices is changed;

b) Name of the registration number holder is changed. The holder of the registration number shall enclose with the written notification documents proving the ownership towards the medical devices of the new owner and the label model prescribed in Article 54 of this Decree;

c) Information about name or address of the producer of the medical devices is modified. The registration number holder shall enclose with the written notification of modification the following documents: the Certificate of Free sale and the Certificate of conformity with quality control standards which are effective at the time of application, unless the medical devices has been issued with the Certificate of Free sale by the competent body of any of the following countries and organizations: EU member countries, Japan, Canada, TGA of Australia, FDA of America;

d) The packing specifications are changed, applicable to in vitro diagnosis medical devices. The registration number holder shall enclose with the written notification documents specified in points h and m clause 1 Article 26 of this Decree;

dd) The warranty provider is changed. The registration number holder shall enclose with the written notification documents specified in points dd clause 1 Article 26 of this Decree.

9. Within 03 working days from the day on which the notification by the registration number holder is issued, the Ministry of Health shall update the modified information on its web portal the following information.

10. The Minister of Health shall issue regulations on the inspection of the application for registration number.

Section 4. TRACING ORIGIN AND HANDLING DEFECTIVE MEDICAL DEVICES, SUSPENSION OF SALE OR RECALLING OF DEFECTIVE

MEDICAL DEVICES AND HANDLING OF MEDICAL DEVICES IN SPECIFIC CASES

Article 30. Tracing the origin of defective medical devices

1. Regarding defective medical devices, the registration number holder shall trace the origin, including:

a) Determining name, type and amount of medical devices in the defective batch;

b) Publishing on the web portal of the owner (if any) and the web portal of the Ministry of Health, and requesting establishments producing, trading or using such medical devices in writing to provide information on name, type and the amount of medical devices in the defective batch, the actual amount remained in the storage and the actual amount being on market;

c) Formulating plans on measures to be taken or on the recall of defective medical devices;

d) Report to a competent agency the plans specified in point c of this Clause.

2. The competent agency shall conduct inspection and monitor the tracing of the origin of the defective medical devices within its management.

Article 31. Handling and recalling defective medical devices

1. Measures to be taken for defective medical devices:

a) Providing guidelines on remedial measures;

b) Eliminating defects of the medical devices;

c) Replacing the defective medical devices with the equivalent one;

d) Recalling for re-exporting or destruction.

2. Defective medical devices shall be recalled as follows:

a) Voluntary recalling conducted by the registration number holder;

b) Compulsory recalling, for cases specified in Article 35 of this Decree.

3. The registration number holder of the defective medical devices shall recall and take measures for defective medical devices within a period specified by the competent agency and shall pay all the cost for the recall and handling of the defective medical devices.

If the registration number holder fails to recall the defective medical devices within the time limit specified by the competent agency, the recall shall be enforced as prescribed legislation on penalties for administrative violations.

Article 32. Procedures for suspension of sale of defective medical devices against which a warning has been issued by owner of medical devices

1. If the medical devices are found to be defective and have bad effect on users' health, the registration number holder shall:

a) Suspend such medical devices from sale;

b) Send a written notification to the Ministry of Health and organizations and persons that are selling or using such medical devices. The notification shall specify the manufacture batch, the factor causing bad effect on users' health and the statement whether such factor can be eliminated.

2. In case the defect of the medical devices that causes bad effect on users' health can be eliminated:

a) Within 03 working days from the day on which the notification by the product owner is received, the Ministry of Health shall issue a decision to suspend the sale of such medical devices;

b) When the decision to suspend the sale of the medical devices has been issued, the registration number holder in Vietnam shall take measures to eliminate the factor that causes bad effect on users' health;

c) After completing the elimination of the factor that causes bad effect on users' health, the registration number holder shall send a written report to the Ministry of Health which contains the undertaking to assure the quality of the medical devices after the elimination or the inspection result by a laboratory which is conformable to the TCVN ISO/IEC 17025 national standard or the ISO/IEC 17025 international standard or a equivalent standard;

d) Within 20 days as from the day on which the report specified in point c of this Clause is received, the Ministry of Health shall issue a decision to terminate the suspension of the medical devices If the Ministry of Health refuse to terminate the suspension, a written response containing explanation shall be made.

3. If the defect of the medical devices that causes bad effect on users' health cannot be eliminated, the Ministry of Health shall issue a decision to recall all the devices of the batch of medical devices which incurs the suspension.

4. The decision to suspend the sale shall consist of:

a) Name of medical devices to incur the suspension;

b) The number of the batch of medical devices to incur the suspension;

c) The registration number of the medical devices to incur the suspension;

Article 33. Procedures for suspension of sale of defective medical devices against which a warning has been issued by a competent

1. Within 05 working days as from the day on which the notification of the defect that causes bad effect on users' health made by a medical facility of another country where the medical devices are being sold or to which they are sent by World Health Organization, the Ministry of Health shall send a written request to the registration number holder for explanatory report.

2. Within 05 working days from the day on which the written response by the Ministry of Health is received, the registration number holder shall send a written report to the Ministry of Health.

3. Within 5 working days from the day on which the report made by the registration number holder of medical devices in Vietnam is received, the Ministry of Health shall establish a scientific council for assessing the defect that causes bad effect on users' health.

4. If it is determined that the medical devices do not have any factor causing bad effect on users' health, within 03 working days from the day on which the meeting minutes of the council is received, the Ministry of Health shall issue the written notification to the registration number holder in Vietnam.

5. If it is determined that the medical devices have defect causing bad effect on users' health, the Ministry of Health shall follow the procedures for suspension of such devices from sale according to regulations in clauses 2, 3 and 4 Article 32 of this Decree.

Article 34. Handling of medical devices whose owner or whose registration number's holder terminates the production or is bankrupt or dissolved

1. If the medical devices has been issued with the registration number but the owner of such medical devices declares terminating the production or declares bankruptcy or dissolution, such medical devices shall be on market for not exceeding 24 more months counted from the date of such declaration, provided that the holder of the registration number in Vietnam shall undertake to provide the warranty and maintenance as well as provide materials for replacing or serving the use of medical devices for 08 years, unless the holder of the registration number is the standing representative office in Vietnam of the foreign trader who is the owner of such medical devices.

2. If the medical devices has been issued with the registration number but the registration number holder is bankrupt or dissolved, such medical devices shall be on market for not exceeding 24 months counted from the date of such bankruptcy/dissolution, provided that the distributing establishment shall undertake to provide the warranty and maintenance as well as provide materials for replacing or serving the use of medical devices for not more than 08 years.

3. The holder of the registration number or the distributing establishment shall send the dossier about its undertaking to the Ministry of Health within 60 days from the day on which the product owner or the holder of the registration number declares terminating the manufacture or declares bankruptcy or dissolution.

4. The undertaking dossier shall consist of:

a) A written undertaking to provide the warranty and maintenance and provide materials serving the use of medical devices using the form provided in Annex XI enclosed with this Decree;

b) A list of medical devices having registration number kept by such establishment whose owner or whose registration number's owner of the medical devices declared terminating the manufacture or declared bankruptcy or dissolution.

5. Within 15 working days from the day on which the undertaking prescribed in clause 4 of this Article, the Ministry of Health shall make a written response on the approval or refusal of the maintenance of registration of medical devices. In case of refusal, explanation shall be provided.

6. If the registration of medical devices specified in clauses 1 and 2 of this Article is revoked by the Ministry of Health, the registration number holder or the distributing establishment shall recall all the medical devices being on market, unless such devices has been purchased.

Section 5. REVOCATION OF REGISTRATION NUMBER OF MEDICAL DEVICES

Article 35. Cases where registration number is revoked

1. The applicant uses fraudulent documents to apply for registration.

2. The registration of 03 batches of the medical devices is revoked within the effective period of the registration number, applicable to types B, C or D medical devices, or for 05 years, applicable to Class A medical devices, unless the registration number holder voluntarily recalls the medical devices as prescribed in Article 32 of this Decree.

3. The applicant falsifies the contents of the registration number without permission.

4. The registration number holder terminates its operation or is no longer authorized by the product owner and no substitute organization has been appointed, except for cases specified in Article 34 of this Decree.

5. Quality of medical devices being sold on market is not consistent with the registration quality.

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

7. The owner of the registration number or the distributing establishment of the medical devices has not given undertakings as prescribed in clauses 1 and 2 Article 34 of this Decree.

8. The effective period of registration of the medical devices specified in clauses 1 and 2 Article 34 of this Decree has expired.

9. The medical devices were manufactured at an establishment unconformable to requirements specified in this Decree.

Article 36. Procedures for revocation of registration number

1. During the inspection, if any case specified in clauses 1, 2, 3, 4, 5, 6 and 8 Article 35 of this Decree is discovered, the agency conducting the inspection shall send an inspection record to the Ministry of Health or the Department of Health having issued the registration number (hereinafter referred to as “registration number issuer”).

2. Within 05 working days from the day on which the record specified in clause 1 of this Article is issued, the registration number issuer shall consider deciding the revocation of the registration number within its management.

3. After issuing the decision to revoke the registration number, the agency issuing the decision on revocation shall:

a) Publish on the web portal of the registration number issuer the decision on revocation of registration number and send such decision to the registration number holder, the Ministry of Health and other Departments of Health nationwide;

b) Annul information related to medical devices which has been posted on the web portal of the registration number issuer.

4. When the decision to revoke the registration number made by the registration number issuer has been received, Departments of Health shall publish it on the web portal and direct professional bodies to supervise the revocation of the medical devices.

Chapter V

MANAGEMENT OF TRADING OF MEDICAL DEVICES

Section 1. CONDITIONS FOR TRADING MEDICAL DEVICES

Article 37. Class B, C or D medical devices trading establishments

As establishment must satisfy the following conditions to trade in Class B, C or D medical devices:

1. Having technical staff with acceptable qualifications for installing or guiding the use of medical devices which such establishment trades, at least 01 of whom has the qualifications of technology or medicine/pharmacy of college or higher level or has the qualifications of medical devices technology of college or higher level and his/her profession is conformable to the medical devices which the establishment trades.

2. Having storage facilities conformable to the requirements specified in clause 3 Article 13 of this Decree and having vehicles for delivering medical devices conformable to requirements specified in clause 4 Article 13 of this Decree, unless otherwise prescribed by laws. If the establishment does not have storage facilities or vehicles, a contract with an establishment capable of storing and transporting medical devices shall be concluded.

Article 38. Procedures for declaration of eligibility to trade medical devices

1. The declaration of eligibility to trade medical devices shall consist of:

a) A declaration form of eligibility to trade medical devices using the form No. 07 specified in Annex I enclosed with this Decree;

b) A list of employees using the form specified in Annex II enclosed with this Decree;

c) Papers proving that the storage facilities and vehicles are conformable to requirements specified in clauses 3 and 4 Article 13 of this Decree. Such papers shall be certified by the establishment declaring the eligibility to trade medical devices.

2. Procedures for declaration of eligibility to trade medical devices:

a) Before trading Class B, C or D medical devices, heads of medical devices trading establishments shall send an declaration of eligibility to trade medical devices specified in clause 1 of this Article to the Department of Health of the area where the trading establishment's headquarters are located;

b) If the declaration is satisfactory, the Department of Health shall issue the establishment with the certification of declaration using the form No. 05 in Annex IV enclosed with this Decree;

c) Within 03 working days from the day on which the declaration of eligibility to trade medical devices, the Department of Health shall publish the following information on its web portal: name and address of the establishment trading medical devices and the declaration of eligibility to trade medical devices.

3. The establishment shall be allowed to trade Class B, C or D medical devices only when the procedures specified in point b clause 2 of this Article are fully conducted, except for cases specified in Article 39 of this Decree.

4. During its operation, if there is any change in employee staff, storage system or transport vehicles, the trading establishment shall re-conduct the procedures for declaration of eligibility to trade medical devices.

Article 39. Trade of Class B, C or D medical devices which is not required to satisfy conditions nor follow procedures for declaring eligibility to trade medical devices

1. Class B, C or D medical devices in the list of medical devices issued by the Minister of Health shall be traded like other normal goods.

2. The trade of medical devices specified in clause 1 of this Article is not required to satisfy conditions specified in Article 37 of this Decree and is not required to follow the procedures for declaring the eligibility to trade prescribed in Article 38 of this Decree, provided that such trading is conformable to the requirements for storage and transport prescribed by the product owner.

Section 2. EXPORT AND IMPORT OF MEDICAL DEVICES

Article 40. Rules on management of export/import of medical devices

1. Any organization or individual exporting or importing medical devices must satisfy conditions specified in laws on export and import and must assure the quality of the medical devices that they exported/imported.

2. Medical devices having got the registration number in Vietnam may be exported/imported on demand without limit on quantity and without approval by the Ministry of Health.

3. The CFS shall only be issued to medical device for exports as prescribed by the Prime Minister.

4. The temporary import, temporary export or transit of medical devices shall be carried out according to laws.

5. The import of used medical devices shall be carried out according to laws.

Article 41. Export and import of medical devices

1. The production of medical devices for export is encouraged.

2. Any organization/individual importing medical devices with the registration number must satisfy the following conditions:

a) Being the registration number holder or having the power of attorney made by the holder of the registration number. The registration number holder that authorizes an

importer to import medical devices shall send the power of attorney the Ministry of Health and the customs authority as well;

b) Having storage facilities conformable to the requirements specified in clause 3 Article 13 of this Decree and having vehicles for delivering medical devices conformable to requirements specified in clause 4 Article 13 of this Decree or having the contract with the establishment capable of storing and transporting medical devices.

3. The export and import of medical devices shall comply with laws on customs. When conducting customs procedures, the organization importing medical devices is not required to prove the conformity with conditions specified in Clause 2 of this Article.

Article 42. Import license

1. Cases in which a license to import medical devices is required:

a) Such medical devices does not have the registration number and is imported for scientific research or testing or for guiding the use of medical devices or for repairing medical devices;

b) Such medical devices do not have the registration number and is imported to be used as aids;

c) Such medical devices do not have the registration number and is imported for personal healthcare.

2. An application for the import license shall consist of:

a) A written application form for an import license using the form No. 08 provided in Annex I enclosed with this Decree;

b) Documents that give brief description of medical devices technology using the forms provided in Annex VIII enclosed with this Decree and technical documents and instructions for such medical devices;

c) The Certificate of conformity with quality control standards of the establishment producing the medical devices applying for the import license;

d) For medical devices imported for research, a certified true copy of the decision on approval for the research project and documents proving that such products have been permitted in the exporting country by the competent agency;

dd) Regarding medical devices imported to be use in training, the original copy of the training plan and documents proving that such products have been permitted in the exporting country by the competent agency;

e) For medical devices imported to be used as aids, a copy of the decision on approval for aid receipt by the competent authority and documents proving that such products have been permitted in the exporting country by the competent agency ;

g) For cases where medical devices are imported for personal healthcare, the prescription by the doctor.

3. Procedures for processing the application for the license for importing medical devices:

a) After receiving the application, the Ministry of Health shall issue the applicant with the certification of declaration using the form No. 06 provided in Annex IV enclosed with this Decree;

b) If the application is not required to be amended, the Ministry of Health shall conduct inspection serving the issuance of the license for importing medical devices within 15 working days from the date written on the certification of declaration. If the application is rejected, a written response containing explanation shall be made;

c) If the application is unsatisfactory, within 05 working days from the date written on the certification of declaration, the Ministry of Health shall send a written response to the applicant for completion. The notification shall specify the information to be supplemented and the information to be adjusted;

d) After receiving the request for modification of the application, the applicant shall modify the documents according to the written notification and re-send the application to the Ministry of Health. The date of receipt of the completed application shall be written on the certification of declaration;

If the applicant fails to fully comply with the request, the Ministry of Health shall notify the applicant for completing it;

After 60 days from the day on which the request of the Ministry of Health is received, if the applicant fails to complete the application, the procedures for applying for the import license shall be re-conducted.

dd) If the application is satisfactory, the Ministry of Health shall issue the license for importing medical devices according to regulations in point b of this clause. The import license shall be sent to the applicant and the customs authority.

Article 43. Application for CFS of domestically produced medical devices

1. An application for the Certificate of free sale of medical devices without the registration number shall include:

a) A written application form for the Certificate of free sale using the form No. 11 provided in Annex I enclosed with this Decree;

b) Documents specified in Article 22 (applicable to Class A medical devices) or Article 26 (applicable to Class B, C or D medical devices).

2. The application for the certificate of free sale of medical devices must satisfy requirements specified in Article 23 (applicable to Class A medical devices) or Article 28 (applicable to Class B, C or D medical devices).

3. The application for the Certificate of Free sale of medical devices with the registration number shall include the application form using the form No. 12 provided in Annex I enclosed with this Decree.

Article 44. Competence in and procedures for issuance, reissuance and revocation of the Certificate of free sale

1. The Minister of Health shall be responsible for the issuance, reissuance and revocation of the Certificate of free sale of medical devices.

2. Procedures for issuance, reissuance and revocation of the Certificate of free sale shall comply with regulations of the Prime Minister on the issuance of the Certificate of Free sale.

Section 3. RIGHTS AND OBLIGATIONS OF ORGANIZATIONS AND INDIVIDUALS TRADING MEDICAL DEVICES

Article 45. Rights of establishments trading medical devices

1. To request the medical devices seller provides sufficiently information and documents to be used for tracing the origin and the warranty of medical devices.

2. To request organizations/individuals importing, distributing or using products to cooperate with them in recalling and handling defective medical devices.

3. To request the holder of the registration number of the medical devices to provide warranty on the medical devices.

4. To be notified by the holder of the registration number of the defective medical devices.

5. Other rights as prescribed in laws.

Article 46. Obligations of establishments trading medical devices

1. Conduct internal supervision to maintain the quality of medical devices prescribed by the holder of the registration number.

2. Provide sufficiently and promptly information about:

a) Instruction on how to use the medical devices; conditions for ensuring the safety, storing, calibrating, inspecting and maintaining medical devices;

b) Give notification of defective medical devices.

3. Retain medical devices supervision dossier and trace the origin or recall medical devices according to regulations in this Decree.

4. Promptly notify the registration number holder and the authority of the defective medical devices.

5. Comply with laws and decisions on inspection issued by competent agencies.

6. Other obligations as prescribed in laws.

Chapter VI

MEDICAL DEVICES SERVICES

Section 1. CONSULTANCY ABOUT MEDICAL DEVICES TECHNOLOGY

Article 47. Conditions for providing consultancy services on medical devices technology

1. The provision of services for consulting about the listing and formulation of technical structure and specifications of medical devices technology shall be conducted by an individual who has been issued with the certificate of completing the training in consulting medical devices technology.

2. Requirements applicable to individuals providing consultancy services on medical devices technology:

a) Having university level qualifications specified in technique or medicine/pharmacy;

b) Having at least 5 years' experience of working in the field of medical devices technology at a medical devices-providing facility;

c) Having been tested and recognized by training institutions to be capable of consulting on medical devices technology according to the training program issued by the Ministry of Health.

3. The consultant shall provide only consultancy on medical devices technology when he/she has obtained the certification of declaration for the application for declaration of eligibility to provide consultancy about medical devices technology as prescribed in point b clause 2 Article 48 of this Decree.

Article 48. Procedures for declaration of eligibility to provide consultancy on medical devices technology

1. An application for declaration of eligibility to provide consultancy on medical devices technology shall include:

a) An application form for declaration of eligibility to provide consultancy using the form No. 09 specified in Annex I enclosed with this Decree;

b) Certified true copies of qualifications specified in points a and c clause 2 Article 47 of this Decree;

c) A certificate of working time using the form in Annex II enclosed with this Decree.

2. Procedures for declaration of eligibility to provide consultancy on medical devices technology:

a) Before providing consultancy on medical devices technology, the applicant shall send the documents specified in clause 1 of this Article to the Ministry of Health;

b) If the application is satisfactory, the Ministry of Health shall issue the certification of declaration using the form No. 07 provided in Annex IV enclosed with this Decree;

c) Within 03 working days from the date written on the certification of declaration, the Ministry of Health shall publish the following information on its web portal: name, address, phone number of the consultant; scope of consultancy on medical devices technology and the declaration of eligibility to provide consultancy on medical devices technology.

3. During its operation, if there is any change related to the accepted declaration, the consultant shall re-conduct the procedures for declaration of eligibility to provide consultancy on medical devices technology.

Section 2. INSPECTION AND CALIBRATION OF MEDICAL DEVICES

Article 49. Rules for inspection and calibration of medical devices

1. Medical devices shall be inspected according to laws on product quality and shall be calibrated according to regulations by the manufacturer, except for cases specified in clause 2 of this Article.

2. The inspection and calibration of medical devices being measurement instruments or radiological equipment shall comply with regulations on measuring and atomic energy.

3. The inspection of medical devices shall be conducted by establishments which have declared the eligibility to provide services on inspection and calibration for medical devices.

4. The calibration of medical devices shall be conducted by an establishment which has declared the eligibility to provide services on inspection and calibration for medical devices or by the warranty provider of the holder of the registration number of the medical devices.

Article 50. Requirements for establishments conducting inspection and calibration of medical devices

1. Employees:

There shall be at least 2 technical employees (civil servants or employees working under contracts which are valid for 12 months or more or employees working under indefinite contracts) who satisfy the following conditions:

a) Having qualifications of college or higher level specified in technique or medicine/pharmacy;

b) Having professions suitable for the medical devices he/she is assigned to inspected/calibrated.

2. Facilities and equipment:

There shall be laboratories. The laboratory shall obtain the certificate of conformity with the national standard on competence of testing and calibration laboratories TCVN ISO/IEC 17025 or the international standard ISO/IEC 17025 (hereinafter referred to as the certificate of conformity with testing and calibration standards).

3. The establishment shall carry out the inspection/calibration of medical devices only when it has obtained the certification of declaration of eligibility to conduct the inspection/calibration of medical devices as prescribed in clause 2 of this Decree.

Article 51. Declaration of eligibility to conduct inspection/calibration

1. A declaration of eligibility to conduct the inspection/calibration shall consist of:

a) An application form for declaration using the form No. 10 specified in Annex I enclosed with this Decree;

b) A list of employees using the form specified in Annex II enclosed with this Decree;

c) The certificate of conformity with testing and calibration standards which is valid at the time of declaration.

2. Requirements for the declaration of eligibility to conduct the inspection/calibration:

a) Documents serving the declaration of eligibility to conduct the inspection/calibration shall be compiled into 01 dossier, readable and arranged in order specified in clause 1 of this Article; there shall be separators between different parts, there shall be cover pages and the table of contents;

b) Regarding the Certificate of conformity with testing and calibration standards: an original copy or a certified true copy or a copy certified by the applicant shall be included;

If the copy certified by the organization declaring the eligibility to conduct the inspection/calibration is used, at the time of submission of the declaration, the original copy shall be presented for comparison or data sources shall be provided so that the receiving body can check the validity of such documents.

Any Certificate of conformity with inspection/calibration standards which is not made in English or Vietnamese shall be translated into Vietnamese. The translation must be authenticated according to laws.

Article 52. Procedures for declaring the eligibility to conduct the inspection/calibration

1. Before conducting the inspection/calibration of medical devices, heads of the inspection/calibration establishment shall send the application specified in clause 1 Article 51 of this Decree to the Ministry of Health.

2. If the declaration is satisfactory, the Ministry of Health shall issue the establishment with the certification of declaration using the form No. 08 in Annex IV enclosed with this Decree.

3. Within 03 working days from the date written on the slip of receiving, the Ministry of Health shall publish the following information on its web portal: name, address, phone number of the establishment conducting the inspection/calibration of medical devices; scope of the inspection/calibration and the declaration of eligibility to conduct the inspection/calibration.

4. During its operation, if there is any change related to the accepted declaration, the inspection/calibration establishment shall re-conduct the procedures for declaring the eligibility to conduct the inspection/calibration of medical devices.

Chapter VII

INFORMATION AND LABEL OF MEDICAL DEVICES

Article 53. Information about medical devices

1. Information about medical devices is meant to serve healthcare practitioners and users with guidelines on the reasonable and safe use of medical devices.

2. Information about medical devices must be sufficient, objective, accurate, honest, understandable and must not cause misunderstanding.

3. Responsibility for communicating information about medical devices:

a) The registration number holder and the trading establishment of the medical devices shall publish the information about the level of risks and information related to the use of medical devices;

b) Medical facility shall communicate information about medical devices within their establishment;

c) Health workers shall communicate information about the level of risks of the use of Class C or D medical devices on the patients;

d) Medical devices management agencies shall publish the information on medical devices.

4. Any organization and individual communicating information about medical devices must be responsible for the information it/he/she has provided.

5. The Minister of Health shall develop medical devices information system.

Article 54. Labels of medical devices

1. The labeling of medical devices shall comply with regulations in Decree No. 89/2006/ ND-CP dated August 30, 2006 by the Government on labeling of goods and the label must contain:

a) Name of the medical devices;

b) The registration number of the medical devices;

c) Name and address of the holder of the registration number of the medical devices;

d) The origin of the medical devices;

dd) Date of production or expiry date. The date of production and the expiry date must be written in the format [dd/mm/yyyy] or [mm/yyyy].

e) Number of batch or the serial number of the medical devices;

g) Guidance for seeking information about the warranty provider, guidelines for using the medical devices, technical documents serving the repair and maintenance according to regulations in clause 2 Article 17 of this Decree.

2. Medical devices imported into Vietnam whose label does not contain sufficiently the information specified in clause 1 of this Article must be enclosed with a supplementary label containing such information written in Vietnamese and the original label of the devices shall be retained.

Chapter VIII

MANAGEMENT AND USE OF MEDICAL DEVICES AT MEDICAL FACILITIES

Article 55. Rules on management and use of medical devices

1. The management and use of medical devices must be conformable with the purposes, utilities, policies and economical and effective.

2. The inspection, maintenance, repair, verification and calibration must comply with regulations of the producer, unless otherwise prescribed by laws.

Regarding medical devices with strict labour hygiene and safety requirements, apart from the regulations on inspection, maintenance, repair, verification and calibration specified in this Decree, laws on labour hygiene and safety shall be complied with as well.

3. Documents on medical devices shall be compiled, managed and retained sufficiently; the settlement of medical devices in kind or in cash shall be conducted according to current laws on accounting and statistics and other relevant law provisions; funding for the conduct of tasks specified in Clause 2 of this Article shall be secured.

4. Medical facilities shall submit to the inspection and supervision of competent regulatory bodies specified in medical devices management.

Article 56. Management and use of medical devices at State medical facilities

Apart from complying with regulations in Article 55 of this Decree regarding the management and use of medical devices, state medical facilities shall conform to the following regulations:

1. Medical devices in state medical facilities shall be managed and used according to laws on the management and use of State-owned property.

2. Policies on management and use of medical devices shall be published.

3. The investment in or the conduct of the purchase of medical devices shall conform to the following rules:

a) The investment as well as the purchase of medical devices shall be conformable to the functions, tasks and demand of the unit and current laws on bidding;

b) State medical facilities are encouraged to use domestically produced medical devices. Regarding domestically produced medical devices which are declared by the Ministry of Health to be conformable to the requirements on quality and supply, the bidding documents and the invitations for bid shall contain provisions that forbid the bidders from offering imported medical devices.

Article 57. Powers and responsibilities of medical facilities in the management and use of medical devices

1. A medical facility shall have the following powers:

a) To request the registration number holder to carry out the periodic maintenance during the warranty period;

b) To request the seller to supply technical documents about medical devices;

c) To receive medical devices that is used for scientific research or for guiding the use of medical devices.

2. Medical facility shall have the following responsibilities:

a) Use and operate medical devices according to the guidance by its owner;

b) Periodically maintain, inspect and calibrate medical devices according to the guidance by its owner or according to laws;

c) Conduct testing and assessment of quality of medical devices;

d) Report cases of defective medical devices and other information at the request of competent agencies.

Chapter IX

ONLINE DECLARATION AND REGISTRATION

Article 58. Cases subject to online declaration, registration or licensing

1. Declaration of eligibility for medical device classification.

2. Declaration of eligibility to produce medical devices.

3. Declaration of applied standards for medical devices.

4. Registration of medical devices.

5. Declaration of eligibility to trade medical devices.

6. Declaration of eligibility to provide consultancy on medical devices technology.

7. Declaration of eligibility to conduct the inspection/calibration of medical devices.

8. Application for the license to import medical devices.

9. Application for the CFS for domestically-produced medical devices.

Article 59. Online application for declaration, registration or licensing

A valid online declaration, online application for registration or the license or the CFS (hereinafter referred to as the online registration application) shall satisfy the following requirements:

1. It contains sufficient documents according to regulations applicable to written application which are transformed into electronic documents. Such electronic documents shall be named according to the name of the form in the written application.

2. Information about the declaration, the application for registration or license shall be declared sufficiently and accurately according to information provided in the electronic documents.

Article 60. Procedures for online declaration

1. The legal representative shall make declaration, download electronic documents, confirm with public digital signatures and pay charges according to the procedures specified on the web portal of the Ministry of Health or the Department of Health.

2. When the online application has been submitted, the representatives at law shall receive a receipt note.

3. The online application receiving body shall carry out administrative procedures for the application according to regulations in this Decree.

4. The result of the online administrative procedures is an electronic document with the digital signature of the receiving body and shall have legal effect like the one of the normal administrative procedures.

Article 61. Retention of online applications

1. In case of online application, the applicant shall retain the written documents of the application.

2. If any document of the registration dossier specified in clause 1 of this Article is lost or damaged, the registering establishment shall send a written notification to the receiving body, recomplete the dossier; when the application has been recompleted, the applicant shall notify the receiving body in writing and update the information after being approved by the receiving body.

3. Within 35 days from the day on which the notification of the loss of the application is received, if the applicant fails to issue a written notification of the recompletion of the application, the receiving body shall:

a) Annul information posted on the web portal that is related to the establishment conducting the classification of the medical devices, the establishment producing the medical devices, the establishment trading the medical devices, the person/establishment providing the consultancy about the medical devices technology, the establishment inspecting/calibrating the medical devices, the registration number of the medical devices;

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

4. The registering establishment shall not continue its operation and the medical devices shall not be placed on the market from the time the receiving body annuls the information as prescribed in clause 3 of this Article.

Chapter X

ORGANIZATION OF IMPLEMENTATION

Article 62. The Ministry of Health

The Ministry of Health shall be answerable to the Government for the management of medical devices and shall have the following tasks and powers:

1. Request the Government or the Prime Minister to promulgate or promulgate by itself within their competence legislative documents, National technical regulation, strategies, policies and plans regarding medical devices.

2. Direct and conduct the implementation of legislative documents, strategies, policies and plans regarding medical devices.

3. Conduct the communication of information about medical devices.

4. Provide training for human resources whose work involves medical devices.

5. Publish on the web portal of the Ministry of Health information about:

a) The winning price of the bidding for medical devices of medical facilities nationwide;

b) The list of medical devices whose registration number has been revoked.

6. Conduct inspection, resolve complaints/denunciations and impose penalties for violations against laws pertaining to medical devices.

7. Promote the international cooperation in medical devices.

Article 63. The Ministry of Science and Technology

1. Issue the list of medical devices and measurement instruments subject to obtaining model approval, inspection and/or calibration after receiving the opinion of the Ministry of Health.

2. Preside over or cooperate with the Ministry of Health in formulating national standards on medical devices; conduct inspection of the quality of medical devices being measurement instruments or radiological equipment.

Article 64. The Ministry of Finance

1. Guide the management of state property being medical devices of state medical facilities after receiving the opinion of the Ministry of Health.

2. Provide detailed regulations on the management and use of charges and fees pertaining to medical devices according to laws on charges and fees.

Article 65. People's Committees of provinces and central-affiliated cities

1. Manage activities related to the trade and use of medical devices in local areas.

2. Conduct the communication of information about medical devices in local areas.

3. Provide training for human resources whose work involves medical devices in local areas.

4. Publish on the web portals of People's Committees of provinces or central-affiliated cities and send the Ministry of Health information about:

a) The winning prices of the bidding for medical devices of medical facilities in local areas;

b) The list of medical devices whose registration number has been revoked within local areas.

5. Conduct inspection, resolve complaints/denunciations and impose penalties for violations against laws pertaining to medical devices in local areas.

Article 66. Organizations and individuals trading medical devices

1. Organizations and individuals trading medical devices shall be responsible for the safety and quality of medical devices they trade.

2. Holders of the registration numbers shall:

a) Publish the applied standards or conduct the registration of medical devices according to regulations of this Decree;

b) Establish and maintain the medical devices warranty providers or conclude contracts with medical devices warranty providers;

c) Formulate and retain medical devices supervision dossiers and trace the origin of medical devices according to regulations in this Decree, except for disposable medical devices as prescribed by the owners of the medical devices;

d) Print sufficiently and accurately information about the products on their labels or their enclosed documents according to laws on labeling and provisions of this Decree;

dd) Promptly give sufficient and accurate warning about the risks of causing bad effect on users' health and on the environment ; guide the sellers and the consumers to prevent; provide information about requirements applicable to the transport, storage and use of medical devices;

e) Promptly terminate the free sale of the medical devices, notify relevant parties and take measures to handle or eliminate the issues or recall the defective equipment as provided for in this Decree. In cases where medical devices have to be destroyed, such destruction must comply with laws on environmental protection and relevant law provisions. The owners of the registration numbers shall pay fully the cost of such destruction activity;

g) Comply with laws and decisions on inspection issued by competent agencies;

h) Provide compensation according to laws in case of defection of the medical devices;

i) Take responsibility for ensuring that the following papers are kept valid during the validity of the registration numbers:

- The Certificate of conformity with quality control standards of the establishment producing the medical devices;

- The Certificate of free sale, applicable to Class B, C or D imported medical devices;

- The power of attorney, except for cases specified in point a clause 1 Article 21 of this Decree;

- The Certificate of eligibility to provide warranty.

k) Other obligations as prescribed by laws.

3. The representative offices of the holders of the registration numbers shall fully implement the obligations specified in clause 2 of this Article.

Chapter XI

IMPLEMENTARY CLAUSE

Article 67. Effect

1. This Decree comes into effect from July 01, 2016.

2. Clause 10 Article 12 of Decree No. 89/2006/ND-CP dated August 30, 2006 by the Government shall be annulled by the effect of this Decree.

Article 68. Transitional clause

1. A producer of medical devices which has operated before the effective date of this Decree may continue its operation, provided that the declaration of eligibility to produce medical devices is made before July 01, 2017. Particularly regarding regulations on the quality control system: the producers of medical devices shall complete the application of the ISO 9001 quality control system before January 01, 2018 and the ISO 13485 the quality control system before January 01, 2020.

2. Trading establishments which has operated before the effective date of this Decree may continue their operation, provided that the declaration of eligibility to trade medical devices has been made according to regulations in this Decree before January 01, 2017.

3. Providers of medical devices services that have operated before the effective date of this Decree may continue their service provision, provided that they have submitted the application for declaration of eligibility to provide consultancy about medical devices technology or of the eligibility to conduct the inspection/calibration of medical devices before July 01, 2017.

4. Medical devices produced in Vietnam or imported into Vietnam before the effective date of this Decree are allowed to be sold freely until it is disposed as prescribed in clause 1 Article 22 of the Law on the management and use of State-owned property or until the expiry date written on the certificate of registration.

5. The issuance of the license for importing medical devices or the issuance of the registration number of medical devices which is domestically produced or in vitro diagnostic reagents shall comply with current law provisions until the expiration of the period specified in clause 6 of this Article. Validity periods:

a) An import license shall be effective until June 30, 2017, for Class A medical devices, or December 31, 2017, for Class B, C and D medical devices, except for cases specified in clause 1 Article 42 of this Decree;

b) The registration number of domestically produced medical devices or in vitro diagnostic reagents shall be effective until the expiry date written on the Certificate of registration.

6. Declarations of applied standards for Class A medical devices shall be received since January 01, 2017 and the corresponding certifications of declaration shall be effective since July 01, 2017; the application for registration of Class B, C or D medical devices shall be received since July 01, 2017 and the registration numbers of medical devices shall be effective from January 01, 2018.

7. The labels of the medical devices produced in Vietnam or imported into Vietnam before the date specified in clause 5 of this Article are accepted until the expiry date of the medical devices or until the medical devices are disposed as prescribed in clause 1 Article 22 of the Law on the management and use of State-owned property or until the expiry date written on the certificate of registration.

Article 69. Responsibility for guiding and implementing

1. The Minister of Health shall be responsible for guiding and monitoring the implementation of this Decree.

2. Ministers, Heads of ministerial-level agencies, Heads of Governmental agencies, Presidents of People's Committees of all levels and relevant agencies, organizations and individuals shall be responsible for implementing this Decree./

ON BEHALF OF THE GOVERNMENT

THE PRIME MINISTER

Nguyen Xuan Phuc

ANNEX I

FORMS OF DECLARATIONS, APPLICATIONS FOR LICENSING, APPLICATIONS FOR ISSUANCE OF THE CERTIFICATE OF REGISTRATION

(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government on eligibility for

medical device classification. Decision of National Board

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Form No. 01

Name of establishment **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

DECLARATION OF ELIGIBILITY FOR MEDICAL DEVICE CLASSIFICATION

To: The Ministry of Health (the Department of Medical devices and Works)

1. Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: [2].....

Phone number: ..... Fax: .....

Email: ……. Website (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Classifying technician(s)[3]:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Professional ability: .....

Experience of working in field of medical devices: .....month(s).

Hereby declare the eligibility to classify medical devices

Attachments:

List of employees' CE

certificate of experience (working time) Qualifiers

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We - the establishment declaring eligibility to classify medical devices - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. The classification of medical devices is conducted according to laws. We will take wholly the responsibility for the results of classification we conducted.

3. Any change related to the information in the declaration will be notified to the Ministry of Health (the Department of Medical devices and Works).

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location
2. The address written on the enterprise registration certificate is required
3. All the technicians shall be specified

Form No. 02

Name of establishment **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

DECLARATION OF ELIGIBILITY TO PRODUCE MEDICAL DEVICES

To: .....[2].....

1. Name of establishment: .....

Tax codes: .....

Address: .....
[3] .....

Address of establishment: .....[4].....

Phone number: ..... Fax: .....

Email: ……. Website (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Professional:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Professional ability: .....

Experience of working in field of medical devices: .....month(s).

4. Medical devices produced by establishment:

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Hereby declare the eligibility to produce medical devices

Attachments:

List of employees. Document

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We - the establishment declaring eligibility to produce medical devices - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Declared conditions are ensured and maintained during our operation.

3. Any change related to the information in the declaration will be notified to the Department of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered

3. The address written on the Certificate of Business registration is required

4. If such address is the same as the one written on the Certificate of Business registration, write “tại trụ sở” (at the headquarter)

5. If such document is unavailable, documents specified in rows 6, 7, 8, 9 and 10 are required

Form No. 03

Name of establishment **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

DECLARATION OF APPLIED STANDARDS FOR TYPE A MEDICAL DEVICES

To: .....[2].....

1. Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: ..... [3] .....

Phone number (landline): ..... Fax: .....

Email:.....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Class A medical devices:

Name of the medical devices: .....

Model/code of product:.....

Packaging specifications (if any): .....

Name of establishment: .....

Address of establishment: .....

Applied standards: .....

4. Information about the product owner:

Name: .....

Address: .....

5. Information about warranty establishment:

Name: .....

Address: .....

Phone number (landline): ..... Phone number (mobile): .....

Hereby declare the applied standards for Class A medical devices

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We - the establishment declaring the applied standards for Class A medical devices - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical devices receive quality assurance and are sold according to the declared information.

3. Any change related to the information in the declaration will be notified to the Department of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

3. The address written on the Certificate of Business registration is required

Form No. 04

Name of establishment **-------** No.:	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------** .....[1]....., ...*[Date]*.....

APPLICATION FOR ISSUANCE OF REGISTRATION NUMBER OF MEDICAL DEVICES

To: The Ministry of Health (Department of Medical devices and Works).

1. Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: ……[2].....

Phone number: ..... Fax: .....

Email:.....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Medical devices to be registered:

Name of the medical devices: .....

Model: .....

Packaging specifications (if any): .....

Type of medical devices: .....

Name of manufacturer: .....

Address of manufacturer: .....

4. Information about the product owner:

Name: .....

Address: .....

5. Information about warranty establishment:

Name: .....

Address: .....

Phone number (landline): ..... Phone number (mobile): .....

Attachments:

Classification table of medical devices, Certificate

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Mẫu Đề nghị phê duyệt

We - the establishment applying for the registration number of medical devices - undertake that:

1. The provided information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical devices receive quality assurance and are sold according to the registration dossier.

3. Any change related to the information in the application will be notified to the Ministry of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location

2. The address written on the Certificate of Business registration is required

Form No. 05

Name of establishment **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

APPLICATION FOR REISSUANCE OF REGISTRATION NUMBER OF MEDICAL DEVICES

To: The Ministry of Health (Department of Medical devices and Works).

Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: ……[2].....

Hereby apply for reissuance of the registration number of medical devices:

Number of the obtained certificate of registration for sale:.....

Date of issue: ..... Effective duration: .....

Reasons for applying for reissuance of the registration number of medical devices: .....

We undertake that this information above is truthful. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

---

1. Location
2. The address written on the Certificate of Business registration is required

Form No. 06

Name of establishment **-------** No.:	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------** .....[1]....., ...*[Date]*.....

APPLICATION FOR EXTENSION OF THE REGISTRATION NUMBER OF MEDICAL DEVICES

To: The Ministry of Health (Department of Medical devices and Works).

Name of establishment: .....

Tax codes or Number of the representative office establishment license: .....

Address: ……[2].....

Hereby apply for extension of the registration number of medical devices:

The obtained registration number: .....

Date of issue: ..... Effective duration: .....

Date of 1st extension: ..... Effective duration: .....

Date of 2nd extension: ..... Effective duration: .....

Attachments:

The obtained certificate of registration

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We - the establishment applying for the registration number of medical devices - undertake that:

1. The provided information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical devices receive quality assurance and are sold according to the registration dossier.

3. Any change related to the information in the application will be notified to the Ministry of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location

2. The address written on the Certificate of Business registration is required

Form No. 07

Name of establishment **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

DECLARATION OF ELIGIBILITY TO TRADE MEDICAL DEVICES

To: .....[2].....

1. Name of establishment: .....

Tax codes: .....

Address: ……[3].....

Transaction office (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Technicians of the trading establishment[4]:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Professional ability: .....

4. List of medical devices traded by the establishment:

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Hereby declare the eligibility to trade medical devices

Attachments:

List of employees Document on storage facilities

Certificates for medical devices

We - the establishment declaring eligibility to trade medical devices - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Medical devices receive quality assurance and are sold according to the laws.

3. Any change related to the information in the declaration will be notified to the Department of Health of .....[5].....

Legal representative of establishment

(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location

2. The name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

3. The address written on the Certificate of Business registration is required

4. All the technicians shall be specified

5. The province/central-affiliated city where the establishment is headquartered

Form No. 08

Name of importing organization/individual	**SOCIALIST REPUBLIC OF VIETNAM**
--------	**Independence - Freedom - Happiness**

No.:	.....[1]....., ...*[Date]*.....

APPLICATION FOR THE PERMIT TO IMPORT MEDICAL DEVICES

To: The Ministry of Health (Department of Medical devices and Works).

Name of importing organization/individual: .....

Tax codes or National ID number/ Passport number: .....

Lawful representative: .....

Contact number: .....

Hereby apply for the permit to import the following medical devices:

1. Importing purpose: .....

2. User: …….....

3. I/We - the importing organization/individual - hereby undertake to:

- Take responsibility for ensuring the quality, model, quantity of imported medical devices.

- Ensure the proper use of imported medical devices.

I/We will take all legal responsibility for any violation I/we commit.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location

Form No. 09

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....[Date].....

DECLARATION OF ELIGIBILITY TO PROVIDE CONSULTANCY ON MEDICAL DEVICES TECHNOLOGY

To: The Ministry of Health (Department of Medical devices and Works).

1. Provider of consultancy about medical devices technology:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Address: .....

Phone number: ..... Email: .....

Professional ability: .....

2. Scope of consultancy:

medical devices technology serving the consultant

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Hereby declare the eligibility to provide consultancy on medical devices technology

Attachments:

Qualification of the consul

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I undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, I will take wholly the responsibility and will incur penalties according to laws.

2. Any change in the declaration of eligibility to provide consultancy about medical devices technology will be reported to the Ministry of Health.

The consultancy provider
(Signature and full name)

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1. Location

Form No. 10

Name of establishment **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

DECLARATION OF ELIGIBILITY TO CONDUCT THE INSPECTION/CALIBRATION OF MEDICAL DEVICES

To: The Ministry of Health (Department of Medical devices and Works).

1. Name of establishment: .....

Tax codes: .....

Address: ……[2].....

Transaction office (if any): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Technicians of the trading establishment[3]:

Full name: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

Professional ability: .....

4. Scope of inspection: List of medical devices subject to inspection by the eligible establishment

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5. Scope of calibration:

…….[4].....

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Hereby declare the eligibility to conduct the inspection/calibration of medical devices

Attachments:

List of employees Certificate of conn

formity with testing and calibration standards

We - the establishment declaring the eligibility to conduct the inspection/calibration of medical devices - undertake that:

1. The declared information is accurate, lawful and conformable. In any case where the information is forged or falsified, we will take wholly the responsibility and will incur penalties according to laws.

2. Declared conditions are ensured and maintained during our operation.

3. Any change in the declaration of eligibility to conduct inspection/calibration of medical devices will be reported to the Ministry of Health.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location

2. The address written on the Certificate of Business registration is required

3. All the technicians shall be specified

4. The list of medical devices subject to inspection by the eligible establishment is required

Form No. 11

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]....., ...[Date].....

APPLICATION FOR THE CERTIFICATE OF FREE SALE FOR MEDICAL DEVICES WITHOUT REGISTRATION NUMBER

To: The Ministry of Health (Department of Medical devices and Works)

1. Name of establishment: .....

Tax codes: .....

Address (according to the business registration): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Manufacturer:

Name of establishment: .....

Address of the headquarter (according to the business registration): .....

Address of manufacture place: .....

Phone number: ..... Fax: .....

To fulfill the requirements of the importing country, we hereby apply for the Certificate of Free Sale (CFS) for the following medical devices:

Member of Certifying

Direction to authority issuing

We commit ourselves to taking legal responsibility for the information declared above.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location

Form No. 12

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....[Date].....

APPLICATION FOR THE CERTIFICATE OF FREE SALE FOR MEDICAL DEVICES WITH REGISTRATION NUMBER

To: The Ministry of Health (Department of Medical devices and Works)

1. Name of establishment: .....

Tax codes: .....

Address (according to the business registration): .....

2. Lawful representative:

Full name: .....

National ID number/ Passport number: ....., Date of issue: ....., Place of issue: .....

Phone number (landline): ..... Phone number (mobile): .....

3. Manufacturer:

Name of establishment: .....

Address of the headquarter (according to the business registration): .....

Address of manufacture place: .....

Contact number: ..... Fax: .....

To fulfill the requirements of the importing country, we hereby apply for the Certificate of Free Sale (CFS) for the following medical devices:

[illegible]

We commit ourselves to taking legal responsibility for the information declared above.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location

ANNEX II

LIST OF EMPLOYEES
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....[Date].....

LIST OF EMPLOYEES

Name of establishment: .....

Address: .....

| | | |

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Location

ANNEX III

CERTIFICATE OF WORKING TIME
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]..... .....*[Date]*.....

CERTIFICATE OF WORKING TIME

To: .....[2].....

My name is: .....

Date of birth: .....

National ID number/ Passport number: ....., Date of issue: .....,
Place of issue: .....

I hereby apply for your verification of the following information:

I am working/worked for: .....

From .....[date].....to.....[date].....

Position: .....

Main task: .....

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I look forward to your support.

Best regards!

....., ...*[Date]*.....	
VERIFIED BY	**APPLICANT**
(Signature, full name, verification of the unit)	*(Signature and full name)*

_____

1. Location
2. Name of the unit where the applicant works is required

ANNEX IV

MODELS OF NOTES OF RECEIPT OF AN APPLICATION, CERTIFICATE OF REGISTRATION FOR SALE

(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

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Certificate of registration for sale

Form No. 01

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

No.: .....

Hanoi, [date]

CERTIFICATION OF DECLARATION OF ELIGIBILITY FOR MEDICAL DEVICE CLASSIFICATION

1. Name of the establishment: .....

2. Address: .....

3. Phone: ..... Fax: .....

4. Number of the application of the establishment: .....
Date: .....

5. Components of the application:

1.	Declaration of eligibility for medical device classification	☐
2.	List of employees	☐
3.	Certificate of working time	☐
4.	Qualifications of each classifying technician	☐

RECEIVING OFFICER
(Signature, position and full name)

Form No. 02

DEPARTMENT OF HEALTH OF ....[1].....

No.: .....

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

.....[1]....., ...*[Date]*.....

CERTIFICATE OF DECLARATION OF ELIGIBILITY TO PRODUCE MEDICAL DEVICES

1. Name of manufacturer: .....

2. Address: .....

3. Phone: ..... Fax: .....

4. Number of the application of the establishment: ..... Date: .....

5. Name of the medical devices to be produced by the establishment:

.....

6. Components of the application:

1.	Declaration of eligibility to produce medical devices	☐
2.	List of employees	☐
3.	Documents on assignment and appointment of professionals of the establishment	☐
4.	Certificate of working time	☐
5.	Qualifications pertaining to medical devices technique or medical devices management of the professionals	☐
6.	Certificate of conformity with quality control standards	☐
7.	Documents proving that conditions of location, area and factory are in conformity with the requirements of medical devices that the establishment produces	☐
8.	Documents about medical devices and manufacturing and quality inspection procedures suitable for the medical devices that the establishment produces.	☐
9.	Contracts with eligible establishments for conducting quality inspection of medical devices that the establishment produces	☐
10.	Documents on storage facilities for medical devices	☐
11.	Documents on transport vehicles for medical devices	☐

RECEIVING OFFICER
(Signature, position and full name)

---

1. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

2. Location

Form No. 03

DEPARTMENT OF HEALTH OF ....[1].....	**SOCIALIST REPUBLIC OF VIETNAM**
----------	**Independence - Freedom - Happiness**

No.:	.....[2]....., ...*[Date]*.....

CERTIFICATE OF DECLARATION OF APPLIED STANDARDS FOR TYPE A MEDICAL DEVICES

1. Name of the establishment: .....

2. Address: .....

3. Number of the application of the establishment: ..... Date: .....

4. Class A medical devices:

Name of the medical devices: .....

Model/code of product:.....

Name of manufacturer: .....

Address of manufacturer: .....

Applied standards: .....

5. Information about the product owner:

Name: .....

Address: .....

6. Information about warranty establishment:

Name of establishment: .....

Address: .....

Phone number (landline): ..... Phone number (mobile): .....

7. Components of the application:

1	Application for declaration of applied standards of Class A medical devices	☐
2	Classification table of medical devices	☐
3	Note of receipt of the declaration of eligibility to produce medical devices	☐
4	Certificate of conformity with quality control standards	☐
5	LETTER OF AUTHORIZATION by the product owner	☐
6	Certificate of eligibility to provide warranty	☐
7	Documents containing technical summary of the medical devices	☐
8	The standard which the product owner declares to apply	☐
9	Certificate of conformity	☐
10	Written instruction for the medical devices	☐
11	Sample of the label of the medical devices	☐

RECEIVING OFFICER
(Signature, position and full name)

---

1. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

2. Location

Form No. 04

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

No.:	*Hanoi, [date]*

RECEIPT NOTE FOR THE APPLICATION FOR REGISTRATION NUMBER OF MEDICAL DEVICES

1. Name of establishment: .....

2. Address: .....

3. Number of the application of the establishment: ..... Date: .....

4. Application for registration for sale of medical devices in different cases:

1.	Application for issuance of the registration number	☐
2.	Application for extension of the registration number	☐
3.	Application for reissuance of the registration number	☐

5. Components of the application:

1.	Application for the registration number	☐
2.	Classification table of medical devices	☐
3.	Certificate of conformity with quality control standards	☐
4.	LETTER OF AUTHORIZATION by the product owner	☐
5.	Certificate of eligibility to provide warranty	☐
6.	Certificate of registration for imported medical devices	☐
7.	Documents containing technical summary of the medical devices	☐
8.	Documents containing description of technical features of the medical devices	☐
9.	Written instruction for the medical devices	☐
10.	Summary of data on clinical test of types C and D medical devices used by putting into human bodies	☐
11.	Certificate of inspection, applicable to medical devices used for types C and D in-vitro diagnosis	☐
12.	Sample of the label of the medical devices	☐
13.	Certificate of conformity	☐
14.	Decision to approve the model	☐

RECEIVING OFFICER
(Signature, position and full name)

Form No. 05

DEPARTMENT OF HEALTH OF ....[1].....	**SOCIALIST REPUBLIC OF VIETNAM**
----------	**Independence - Freedom - Happiness**

No.:	.....[2]....., ...*[Date]*.....

CERTIFICATE OF DECLARATION OF ELIGIBILITY TO TRADE MEDICAL DEVICES

1. Name of the trading establishment: .....

2. Address: .....

4. Number of the application of the establishment: ..... Date: .....

4. Components of the application:

1.	Declaration of eligibility to trade medical devices	☐
2.	List of employees	☐
3.	Certificate of working time	☐
4.	Qualifications pertaining to medical devices technology or medical devices management of the professionals	☐
5.	Documents on storage facilities for medical devices	☐
6.	Documents on transport vehicles for medical devices	☐

RECEIVING OFFICER
(Signature, position and full name)

_____

1. Name of the Department of Health of the province/central-affiliated city where the establishment is headquartered is required

2. Location

Form No. 06

THE MINISTRY OF HEALTH **----------** No.: ...../NKTTBYT	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------** *Hanoi, [date]*

RECEIPT NOTE FOR THE APPLICATION FOR THE PERMIT TO IMPORT MEDICAL DEVICES

1. Name of importing organization/individual: .....

2. Tax codes or National ID number/ Passport number: .....

3. Number of the application of the organization/individual: ..... Date: .....

4. Medical devices to be imported: .....

No.	Name of medical devices
1.	
2.	

RECEIVING OFFICER
(Signature, position and full name)

Form No. 07

THE MINISTRY OF HEALTH **----------** No.:	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------** *Hanoi, [date]*

CERTIFICATE OF DECLARATION OF ELIGIBILITY TO PROVIDE CONSULTANCY ON MEDICAL DEVICES TECHNOLOGY

1. Provider of consultancy about medical devices technology:

Full name: .....

Address: .....

Phone: .....

2. Scope of consultancy: .....

3. Components of the application:

1.	Application for certificate of eligibility to provide consultancy	☐
2.	Qualifications of the consultancy provider	☐
3.	Certificate of working time	☐

RECEIVING OFFICER
(Signature, position and full name)

Form No. 08

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

No.:	*Hanoi, [date]*

CERTIFICATE OF DECLARATION OF ELIGIBILITY TO CONDUCT THE INSPECTION/CALIBRATION OF MEDICAL DEVICES

1. Name of the establishment conducting the inspection/calibration: .....

2. Address: .....

3. Phone: .....

4. Scope of inspection: .....

5. Scope of calibration: .....

6. Components of the application:

1	Application for certificate of eligibility to conduct inspection/calibration	☐
2	List of employees	☐
3	Certificate of conformity with testing and calibration standards	☐

RECEIVING OFFICER
(Signature, position and full name)

Form No. 09

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

No.:	*Hanoi, [date]*

CERTIFICATE OF REGISTRATION FOR SALE OF MEDICAL DEVICES

Pursuant to Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government on management of medical devices.

The Ministry of Health issues the certificate of registration for sale of new medical devices as follows:

1. Name of medical devices:

2. Model/code of product:

3. Packaging specifications (if any):

4. Type:

5. Name and address of the manufacturer:

6. Name and address of the product owner:

7. Name and address of the holder of the registration number:

8. Name and address of the warranty establishment:

The registration number is effective from:.....to.....

	[POSITION OF THE SIGNER]
Receiver:	[Full name, title]
.....	(Verified with seal or digital signature)

ANNEX V

CLASSIFICATION OF MEDICAL DEVICES
(*Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)*

[Name].....[1].....	**SOCIALIST REPUBLIC OF VIETNAM**
--------	**Independence - Freedom - Happiness**

No.: ....[2]..../....[3].....	.....[4]....., ...*[Date]*.....

CLASSIFICATION OF MEDICAL DEVICES

To: .....[5].....

Pursuant to Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government on management of medical devices;

Rules for classification: .....[6].....

We hereby classify medical devices as follows:

Manufacturer Mandatory Information

	Legal representative of establishment
Receiver:	*(Signature) [full name, title]*
.....	*(Verified with seal or digital signature)*

_____

1. Name of the establishment which has declared the eligibility to classify medical devices is required

2. Symbol of the document containing the classification result which is under the management of the eligible establishment

3. Code of the establishment eligible to classify is the number of the certificate of declaration of eligibility for medical device classification issued by the Ministry of Health

4. Location

5. Name of the establishment applying for classification of medical devices

6. The rules used for classifying medical devices as guided by the Ministry of Health shall be specified

ANNEX VI

LETTER OF AUTHORIZATION
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name and address of the product owner

.....[Date].....

LETTER OF AUTHORIZATION

To: .....

We, *(name and address of the owner)*, as the product owner, hereby authorize *(name and address of the establishment declaring the applied standards or applying for registration number)* to sell in Vietnam's market the following medical devices:

.....(the medical devices shall be listed[1]).....

We hereby undertake to provide and assist the fulfillment of requirements related to the information and quality and ensure the requirements pertaining to warranty and maintenance and supply of materials and substitutes for such medical devices. This LETTER OF AUTHORIZATION is effect until: ..... [date]

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. The list of medical devices under authorization may be performed as an annex enclosed with the LETTER OF AUTHORIZATION

ANNEX VII

CERTIFICATE OF ELIGIBILITY TO PROVIDE WARRANTY
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name and address of the product owner: .....

.....[Date].....

CERTIFICATE OF ELIGIBILITY TO PROVIDE WARRANTY

Name: .....

Address: .....

as the product owner, hereby verify that the following establishments are eligible to provide warranty for medical devices of .....[1].....:

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Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

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1. Full name and address of the product owner are required

ANNEX VIII

TECHNICAL DOCUMENTS OF MEDICAL DEVICES
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

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Form No. 01

DOCUMENTS CONTAINING TECHNICAL SUMMARY OF THE MEDICAL DEVICES

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.....[Date].....

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We - the applicant for registration - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

Form No. 02

TECHNICAL DOCUMENTS FOR REAGENTS, CALIBRATION SOLUTIONS, IN-VITRO CONTROL MATERIALS

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Paraphrasing tools are a boon for students and academic writers, offering efficiency and technical accuracy.

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Michael Obadias Kanda

Handbook on Research Ethics

Clinical Research

Reference

We - the applicant for registration - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

ANNEX IX

TABLE OF DATA ON CLINICAL TEST OF MEDICAL DEVICES
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name and address of the establishment applying for registration of sale of medical devices: .....[1].....

.....[Date].....

DATA ON CLINICAL TEST OF MEDICAL DEVICES

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We - the applicant for registration - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

---

1. Name and address of the establishment

ANNEX X

REPORT ON SALE OF MEDICAL DEVICES
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Holder of the registration number **-------** No.:	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------** .....[1]....., ...*[Date]*.....

REPORT ON SALE OF MEDICAL DEVICES

To: The Ministry of Health (Department of Medical devices and Works).

Name of the holder of the registration number: .....

Tax codes or Number of the representative office establishment license: .....

Address: .....

Phone number: ..... Fax: .....

Name of the lawful representative of the
establishment: .....

Phone number: ..... Phone number (mobile): .....

.... I - the holder of the registration number..... - hereby present the sale of medical devices during the effect of the registration number as follows:

Regulation of the Ministry of Health on the Medical Devices

Manufacturer

Other contents:

1. Errors occurring during the sale of the medical devices:

2. Changes during the sale:

We - the establishment selling medical devices - undertake that the information provided is truthful and we will take legal responsibility for such information.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

[1.] Location

ANNEX XI

COMMITMENT TO PROVIDING THE WARRANTY AND MAINTENANCE AND PROVIDING MATERIALS SERVING THE USE OF MEDICAL DEVICES
(Enclosed with Decree No. 36/2016/NĐ-CP dated May 15, 2016 by the Government)

Name of establishment **--------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.:	.....[1]....., ...*[Date]*.....

COMMITMENT

To: The Ministry of Health (Department of Medical devices and Works)

Name: .....

Tax codes: .....

Address: .....

Lawful representative: .....

Contact number: ..... :

We - .....[2]..... - are distributing the following medical devices:

Name of the medical devices: .....

Registration number: ..... Date of issue: .....

.....[3]..... cannot continue operating but we are still capable of quality assurance of such medical devices, we, therefore, hereby commit to:

- Taking responsibility for ensuring the quality, model, quantity of imported medical devices issued with the registration number.

- Selling medical devices for not exceeding 24 months.

- Taking responsibility for providing warranty and maintenance of medical devices.

- Providing materials and substitute fittings for 8 years during the use of the devices.

- Fulfilling requirements for technicians and ensuring the effectiveness and the safety of medical devices towards the operators and the environment, ensuring the unchanging of quality of the imported devices in conditions pertaining to facilities, transport vehicles. Ensuring the fulfillment of requirements for labels of medical devices.

- Ensuring the proper use of medical devices. Facilitating the inspection of competent authorities.

We will take all legal responsibility for any violation we commit against these above provisions.

Legal representative of establishment
(Signature) [full name, title]
(Verified with seal or digital signature)

_____

1. Location
2. Name of the distributing establishment
3. Nam of the product owner

----
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