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

DECREE

AMENDMENT AND SUPPLEMENT OF A NUMBER OF ARTICLES OF THE GOVERNMENT'S DECREE No. 36/2016 / ND-CP OF MAY 15, 2016 ON MANAGEMENT OF MEDICAL EQUIPMENT

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

Pursuant to the November 26, 2014 Investment Law;

At the proposal of the Minister of Health;

The Government issued a decree amending and supplementing a number of articles of the Government's Decree No. 36/2016 / ND-CP of May 15, 2016, on management of medical equipment.

Article 1. Amending and supplementing a number of articles of the Government's Decree No. 36/2016 / ND-CP of May 15, 2016, on management of medical equipment

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

"first. Medical equipment are types of implements, instruments, materials, implants, reagents and in vitro calibrators, software (software) that meet the following requirements simultaneously:

a) Used alone or in conjunction with the designation of a medical equipment owner to serve people for one or more of the following purposes:

- Diagnosis, prevention, monitoring, treatment and mitigation of diseases or compensate for injuries and injuries;

- Check, replace, adjust or support anatomy and physiological processes;

- Support or maintain life;

- Control conception;

- Disinfect medical equipment, including chemicals used in the testing process;

- Provide information for the diagnosis, monitoring and treatment through measures to check samples derived from the human body.

b) Not using pharmacological, immunological or metabolic mechanisms in or on human bodies or if using these mechanisms, it is only supportive to achieve the purpose specified at Point a of this Clause. "

2. To add Clause 6 to Article 3 as follows:

"6. Trading in medical equipment and raw materials for production of medical equipment containing narcotics and pre-substances in addition to meeting the provisions of this Decree must comply with the provisions of law on prevention, anti-drug. ”

3. Chapter II is amended as follows:

"Chapter II

CLASSIFICATION OF MEDICAL EQUIPMENT

Article 4. Types and principles of classification of medical equipment

1. Medical equipment consists of 2 groups divided into 4 categories based on the potential risks related to technical design and production of medical equipment:

a) Group 1 includes medical equipment of category A, which is a medical device with a low level of risk.

b) Group 2 includes medical equipment of category B, C and D, in which:

- Medical equipment of category B is medical equipment with low average risk level;

- Medical equipment of category C is medical equipment with a high average risk level;

- Medical equipment of category D is medical equipment with a high level of risk.

2. Principles for classification of medical equipment:

a) The classification of medical equipment must be based on the classification rules of risk level and must be done by the establishment which has declared the conditions for classification of medical equipment according to the provisions of the Decree. this intention;

b) Medical equipment that has only one purpose of use but which can be classified into two or more levels of risk, the classification according to the highest level of risk applies;

c) Medical equipment with many uses and each use purpose has different levels of risk, the classification according to the highest risk level is applied;

d) Medical equipment designed for use in conjunction with another medical equipment, each medical equipment may be classified with a specific level of risk but the classification results must be based on the highest level of risk for the ultimate use of the combined medical equipment.

3. The Minister of Health shall detail the classification of medical equipment in accordance with international treaties on classification of medical equipment of the Association of Southeast Asian Nations which Vietnam is member.

Article 5. Establishments that classify medical equipment

1. The classification of medical equipment must be carried out by establishments qualified under the provisions of Article 7 of this Decree.

2. Establishments for classification must base themselves on the definitions prescribed in Article 2 of this Decree and the principles prescribed in Article 4 of this Decree and the documents prescribed at Points e, g, h and i of the amounts. 1 Article 26 of this Decree and the classification rules issued by the Ministry of Health to carry out the classification of medical equipment.

3. Establishments that classify medical equipment must take responsibility before law for the classification results for medical equipment they have classified.

4. In case of differences in the results of classification of medical equipment among classification establishments, the Ministry of Health shall decide on the classification of medical equipment.

Article 6. Conditions, dossiers, procedures for granting and adjusting medical practice certificates for medical equipment

1. Conditions applicable to applicants for medical practice certificates (hereinafter referred to as practice certificates for short):

a) Having a university or higher degree in engineering or medical or pharmaceutical majors;

b) Having worked directly on medical equipment for 24 months or more within 48 months up to the date of filing;

c) The training course on classification of medical equipment has been completed according to the Ministry of Health's training program at medical facilities which have been granted continuous training codes.

2. Dossiers and procedures for granting new practice certificates:

a) Dossiers of application for new practice certificates:

- A written request for the grant of a new practice certificate according to Form No. 17 prescribed in Appendix I attached to this Decree;

- Original or certified copy of university degree diploma in technical or medical specialization or above. In cases where diplomas granted by foreign countries are granted, they must be recognized by the Ministry of Education and Training;

- Original or certified copy of Certificate of training in classifying medical equipment is still valid (03 years from the date of signing);

- Two 04 cm x 06 cm color photos taken on a white background for a period of no more than 6 months, up to the date of submission;

- Original or certified copy of people's identity card or citizenship or passport of the applicant;

- The original or a copy of the working time confirmation form, made according to the form prescribed in Appendix III enclosed with this Decree. In case the person performing the classification of medical equipment works at many different establishments but the working time at a facility is not enough for 24 months, he / she must provide a certification of each establishment to prove the full time. working time as stipulated in point b clause 1 of this Article.

b) Procedures for granting new practice certificates:

- Within 20 days from the date of receiving the dossier, the Ministry of Health must conduct the evaluation of the dossier;

- In case of valid dossiers: within 10 working days from the date of evaluation, the Ministry of Health shall grant practice certificates according to Form No. 10 prescribed in Appendix IV enclosed with this Decree and public on the electronic portal the following information: practice certificate of the person performing the classification and the application file for practicing certificate of the person performing the classification.

- In case of invalid records:

Within 5 working days from the date of completion of the appraisal, the Ministry of Health must issue a written notice to the applicant for the completion of the dossier. The written notice must specify the documents to be supplemented and the contents to be amended;

Upon receiving a written request for a complete dossier, the applicant for a practice certificate must amend and supplement it according to the contents stated in the document and send additional dossiers to the Ministry of Health. After receiving additional dossiers, the Ministry of Health continues to carry out the evaluation of dossiers according to the provisions of this Clause;

In case of additional valid dossiers: The Ministry of Health shall grant practice certificates according to the provisions of this Clause;

In case the supplementary dossier is still invalid: the Ministry of Health requires the applicant to continue practicing the application.

Within 60 days from the date the Ministry of Health issues amended and supplemented notices, the applicants for practice certificates must submit the amended and supplemented dossiers as required. After the above time limit, the requester does not make any amendments or supplements or after 03 months from the date of the first submission of the application but the supplementary dossier does not meet the requirements, the submitted dossier is no longer valid.

3. Dossiers and procedures for adjusting the contents of medical equipment classification practice certificates:

a) Dossiers of request for adjustment of practice certificate contents:

- A written request for adjustment of information in the practice certificate according to Form No. 18 prescribed in Appendix I attached to this Decree;

- The original or a copy of the paper evidencing the change in the case of changing administrative information: name, identity card number or identity card or passport of the person performing the classification;

- Original or certified copy of the Certificate of training in medical equipment classification for cases of changing the scope of practice or updating the Certificate of training in classifying equipment medical;

- The original or a copy of the working time confirmation form, made according to the form prescribed in Appendix III enclosed with this Decree. In case the person performing the classification of medical equipment works at many different establishments but the working time at a facility is not enough for

24 months, he / she must provide a certification of each establishment to prove the full time. working time as prescribed at Point b, Clause 1 of this Article.

b) Adjustment procedure:

- Within 10 days after receiving the dossier of request for adjustment, the Ministry of Health must conduct the evaluation of the dossier;

- In case of valid dossiers: The Ministry of Health shall grant practice certificates according to Form No. 11 prescribed in Appendix IV attached to this Decree and update the changed information on the Ministry of Health's electronic information portal. within 03 working days.

Invalid case file:

Within 05 working days from the date of appraisal minutes, the Ministry of Health must issue a written notice to the requester to complete the dossier. The written notice must specify the additional documents and contents to be amended.

Upon receiving a written request for a complete dossier, the adjustment requester must amend and supplement it according to the contents stated in the document and send additional dossiers to the Ministry of Health. After receiving additional dossiers, the Ministry of Health continues to carry out the evaluation of dossiers according to the provisions of this Clause.

In case of valid dossiers, within 03 working days from the date of appraisal minutes, the Ministry of Health shall adjust the practice certificates.

The case of additional documents is still not valid: The Ministry of Health requires the requester to continue to complete the dossier.

Within 60 days from the date the Ministry of Health issues a revised and supplemented notice, the adjustment applicant must submit the amended and supplemented dossier as required. After the above time limit, the requester does not make any amendments or supplements or after 03 months from the

date of the first submission of the application but the supplementary dossier does not meet the requirements, the submitted dossier is no longer valid.

Article 7. Conditions, dossiers and procedures for announcement of eligibility for classification of medical equipment

1. Conditions of the establishment to classify medical equipment (hereinafter referred to as classification establishments): At least 01 person has a medical equipment practice certificate.

2. Dossiers of announcement of eligibility for classification of medical equipment include:

a) Documents announcing the eligibility for classification of medical equipment according to Form No. 01 prescribed in Appendix I attached to this Decree;

b) The declaration of personnel according to the form prescribed in Appendix II issued together with this Decree, enclosed with the original or certified copy of the practicing certificate of each person performing the classification of medical equipment with name in the personnel declaration;

c) Original or certified copy of the establishment's business registration certificate or investment certificate.

3. Procedures for announcement of eligibility for classification of medical equipment:

a) Before classifying medical equipment, establishments shall send dossiers of announcement of eligibility for classification of medical equipment according to regulations, Clause 2 of this Article to the Ministry of Health;

b) Upon receipt of a complete and valid dossier, the Ministry of Health shall grant to the establishment a dossier of receipt of a dossier to announce the eligibility for classification of medical equipment according to Form No. 01 prescribed in Appendix IV to the Decree. this;

c) Within 03 working days from the date of recording on the receipt of application for announcement of eligibility for classification of medical equipment, the Ministry of Health shall have to publicize on the Ministry of Health's electronic information portal. The following information is provided: name, address, telephone number and scope of the classification facility and the record of eligibility for classification of medical equipment.

4. Adjust the information in the file to announce eligibility for medical equipment classification:

a) Cases of adjustment of information in the dossier announcing eligibility for classification of medical equipment:

- Change the person performing the classification of medical equipment in case the replacement has the same scope of practice with the replaced person;

- Change administrative information: address, phone number of the classification facility; information about the legal representative of the classification agency.

b) Application file for adjustment of information in the dossier of announcement of eligibility for classification of medical equipment:

- A written request for adjustment according to Form No. 19 prescribed in Appendix I attached to this Decree, which must clearly state the changed contents (including cases of notifying persons who perform the classification without succession. continue working at the facility to conduct classification);

- In case of changing the classification: Original or certified copy of the replacement's practice certificate with the same scope of practice with the replaced person;

- In case of changing administrative information: Documents proving the change of address and phone number of the classification establishment; information about the legal representative of the classification agency.

c) Adjustment procedure:

- After receiving the application for adjustment of information in the dossier of announcement of eligibility for classification of medical equipment, the Ministry of Health grants to the establishment a receipt to adjust the dossier of announcement of classification criteria. medical equipment according to Form No. 13 prescribed in Appendix IV attached to this Decree;

- Within 03 working days from the date on the receipt of adjustment of documents to announce eligibility for classification, the Ministry of Health is responsible for updating information on the Ministry of Health's electronic information portal. . In case of refusal, there must be a written reply, clearly stating the reason.

5. Classification establishments may only classify medical equipment after they have been granted a dossier of receipt by the Health Ministry to announce the eligibility for classification of medical equipment.

6. In the course of operation, the classification establishment must re-implement the procedures for announcement of eligibility for classification of medical equipment if there is a change in the classifier whose scope of practice is not included. Records of previous eligibility classification.

Article 8. Temporary suspension of classification activities

1. Cases of suspension:

a) To classify medical equipment before the conditions for classification of medical equipment have not yet been announced;

b) Using documents does not guarantee the truthfulness and accuracy to announce the eligibility for classification of medical equipment;

c) Not satisfying the conditions prescribed in Article 7 of this Decree;

d) Issuing false classification results to reduce the level of risk of medical equipment;

dd) Issue the classification results signed by the person who is not named in the application form to announce the classification criteria or is not a legal representative;

e) Failure to remedy consequences or remedy consequences but fail to meet the requirements of management agencies;

g) Failing to publicize the classification results promulgated as prescribed at Point c, Clause 5, Article 66 and Clause 8, Article 68 of this Decree.

2. Suspension procedure:

a) During the inspection process, if it detects or suspects that the classification establishment or the person performing the classification acts in violation specified in Clause 1 of this Article, the inspection agency shall make a written record of the work according to The form prescribed in Appendix XII issued together with this Decree and propose competent agencies to request classification establishments, who perform the classification of suspension of classification of medical equipment, and at the same time send minutes of the Ministry of Health within 24 hours from the time of completion of the minutes;

b) Within 24 hours after receiving the minutes, the Ministry of Health shall notify the Department of Health, the General Department of Customs and the Customs of the border gates to suspend the settlement of the dossiers related to medical equipment using the classification results recorded in the working minutes until the official conclusion of the Ministry of Health, and the Ministry of Health sends a written request to the facility for classification. contents recorded in the working minutes;

c) Within 03 working days after receiving the explanation report of the classification establishment, the Ministry of Health is responsible for evaluating the contents of the explanatory statement of the classification establishment;

d) In case of accepting explanations of classification establishments and not requiring remedial measures, the Ministry of Health shall issue written notices on termination of suspension of fertilizer activities. species. The document on termination of suspension of classification activities shall be sent to the classification establishments, the Health Service, the General Department of Customs and the border-gate customs offices and posted publicly on the Ministry of Health's electronic information portal;

e) In case of accepting explanations of classification establishments and requiring remedial measures, the Ministry of Health shall issue written notices to classification establishments for remedial action. consequence. This document is sent to the classification facility, Department of Health, General Department of Customs and Customs of the border gates and posted publicly on the Portal of the Ministry of Health;

The classification facility suspended from classification activities must report in writing to the Ministry of Health after completing the remedial work.

Within 03 working days after receiving the corrective report of the classification establishment suspended from classification activities, the Ministry of Health shall issue a document to terminate the temporary suspension or request to continue the remedy. recovering the consequences or carrying out the withdrawal procedures prescribed in Article 9 of this Decree. This document is sent to the establishment of the classification, Department of Health, General Department of Customs and Customs of the border gates and posted publicly on the Portal of the Ministry of Health.

e) In case of refusal to explain the classification by the classification agency, the Ministry of Health shall issue a written request to the dossier-receiving agencies to announce the eligibility for classification to implement the prescribed withdrawal procedures at Article 9 and dealing with medical equipment using recalled classification results as stipulated in Article 10 of this Decree.

Article 9. Revocation of application forms for announcement of eligibility for classification of medical equipment, medical equipment practice certificates and medical equipment classification results

1. Revoke the receipt of documents to announce eligibility for medical equipment classification:

a) Cases of recall:

- Forging documents in the dossier of announcement of eligibility for classification of medical equipment;

- Failure to meet the conditions specified in Clause 1, Article 7 of this Decree;

- Issuing classification results when being suspended from operation;

- Issue the classification results of medical equipment to reduce the risk of the second medical equipment for 12 months;

- Do not carry out remedial measures or overcome consequences but fail to meet the requirements of the management agency.

b) Recovery procedure:

- Within 01 working day since the conclusion of the violation of the classification by the classification establishment in one of the cases specified at Point a of this Clause, the Ministry of Health shall have to issue a collection document. when the receipt of the application file discloses the eligibility for classification of medical equipment, it must clearly state the remedial measures (if any) and cancel the information of the classification establishment that has been revoked. receive dossiers of announcement of eligibility for classification of medical equipment on the Ministry of Health's electronic information portal.

The document of revocation of the receipt of application documents for announcement of eligibility for classification of medical equipment is sent to the classification facility, Department of Health, General Department of Customs and Customs of the border gates and posted publicly on Electronic portal of the Ministry of Health;

- After receiving the document of withdrawal of the receipt of dossier of announcement of eligibility for medical equipment classification by the Ministry of Health, the classification establishment shall immediately stop the classification of medical equipment and to take remedial measures (if any) and at the same time take responsibility for settling consequences caused by their law-breaking acts;

- In case the classification establishment fails to comply with or fails to fully comply with the contents of the document revoking the receipt of the dossier to announce the eligibility for classification of medical equipment, the Ministry of Health shall have to transfer the dossier. preliminarily go to other functional agencies to continue the settlement according to the provisions of law.

2. Revocation of medical equipment classification practice certificates:

a) Cases of recall:

- Forging documents in dossiers of application for medical equipment classification practice certificates;

- Implementing classification of medical equipment when not eligible under the provisions of this Decree;

- To classify and promulgate the results of classification of medical equipment when the training certificate has passed on the classification of medical equipment which has expired;

- Misclassification reduces the risk level of the second medical equipment for 12 months;

- To classify and promulgate classification results while being suspended from operation, including cases where the establishments carry out the classification that they are working on, which are temporarily suspended or revoked. Publication records qualify for classification.

b) Procedures for revoking practice certificates:

- Within 01 working day from the date of conclusion on whether the person performing the classification acts in violation of one of the cases specified at Point a of this Clause, the Ministry of Health shall have to issue the document. a revocation of a practicing certificate, which requires the classification establishment where the classification person is working to implement remedial measures due to the violation of the classifier. (if any) at the same time cancel the information of the person performing the classification of medical equipment, whose practice certificate has been withdrawn from the Ministry of Health's electronic information portal.

The document of revocation of the practice certificate is sent to the person who performs the classification, the basis of classification of where the person is working, the Department of Health, the General Department of Customs and the Customs of the border gates and posted publicly on Electronic portal of the Ministry of Health;

- After receiving a document revoking the practice certificate, the person performing the classification and the classification facility where he or she is working shall immediately stop the classification of medical equipment and take measures. overcome consequences (if any), and at the same time be responsible for resolving consequences caused by their law violations;

- In case the person performing the classification and the establishment of the classification of the place where the person is working does not comply with or not abide by the contents of the document revoking the practicing certificate, the Ministry of Health shall carry out the collection procedure. the receipt of the application form for the announcement of eligibility for classification and transfer of the dossier to other functional agencies for further settlement according to the provisions of law.

3. Revoke classification results:

a) Cases of recall:

- The results of misclassification reduce the risk of medical equipment;

- The classification result signed by a person who is not named in the dossier receipt for receiving the announcement of eligibility for classification or is not the legal representative of the classification establishment;

- The results of classification are falsified;

- Classification results are issued when the classification facility is temporarily suspended or when the receipt of the application for classification is announced.

b) Recovery procedure:

- Within 01 working day from the conclusion of the classification results in one of the cases specified at Point a of this Clause, the Ministry of Health shall issue documents to withdraw classification results , in which it is required to classify establishments to implement remedial measures caused by violations (if any) and at the same time cancel information on the results of classification of medical equipment which have been withdrawn. on the electronic portal of the Ministry of Health;

Documents to withdraw classification results are sent to medical equipment classification establishments, Department of Health, General Department of Customs and Customs of border gates and posted publicly on the Ministry of Health's electronic information portal. sacrifice.

- After receiving the documents on the classification results, the classification establishment shall recover all classification results recorded in the recall documents and at the same time be responsible for resolving the consequences caused by causing law violations;

In case the classification establishment fails to abide by or fails to fully comply with the contents of the document to withdraw classification results, the Ministry Health shall carry out procedures for

revocation of the receipt of dossiers to announce the eligibility for classification and transfer dossiers to other functional agencies for further settlement according to law provisions.

- After receiving a document to withdraw the classification results, the agency receiving the dossier to announce the application of standards or proposing circulation numbers (hereinafter referred to as circulating grant dossiers) shall have to review check the circulation numbers you have issued. In case of detecting circulated medical equipment using the classification results already revoked by the Ministry of Health, the agency that has issued circulation numbers shall have to carry out the collection procedures. circulation of circulation for medical equipment.

Article 10. Handling of medical equipment using recalled classification results

1. In case medical equipment is carrying out procedures for requesting circulation circulation, using the classification results already withdrawn by the Ministry of Health:

a) Organizations and individuals that submit dossiers of application for publication of applicable standards or request for circulation numbers shall have to report in writing to agencies that receive circulation grant dossiers for stopping procedures. circulation number;

b) After receiving a written request from an organization or individual specified at Point a of this Clause or after receiving a written document on recovery of medical equipment classification, the dossier-receiving agency shall have to deny circulation.

2. In cases where medical equipment has been issued with circulation numbers, if the classification results have been issued by the Ministry of Health, but the goods clearance procedures have not yet been carried out:

a) Circulation number owners shall stop carrying out goods clearance procedures and report in writing to border-gate customs offices where goods clearance is planned to stop customs clearance procedures and agencies granting circulation numbers to recover circulation numbers;

b / After receiving a written request from a circulation serial number owner or after receiving a document on revocation of a medical equipment classification, the customs office shall have to stop the customs clearance procedures; The agency in charge of circulation has the responsibility to carry out the circulation circulation procedures.

3. In cases where medical equipment has been granted circulation numbers and the results of classification have been issued by the Ministry of Health, and goods clearance procedures have been carried out but not yet sold to people. use:

a) Circulating number owners shall:

- Stopping circulation of medical equipment and taking measures to recover medical equipment with circulating numbers that circulate the number of circulation records using the results of classification issued by the Ministry of Health recalled version;

- Report in writing to the customs office where the customs clearance of goods has been carried out, clearly stating the number of medical equipment that has cleared customs procedures and does not carry out the import procedures for subsequent goods lots;

- Report in writing to the agency where the circulation has been issued, which must clearly state the number of medical equipment cleared and the purchase and sale contracts (if any);

- Re-implement the circulation registration procedure.

b) After receiving the written request of the circulation number owner or after receiving a written revocation of the medical equipment classification:

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

- The agency where the circulation has been issued is responsible for carrying out the circulation revocation procedure.

4. Cases of medical equipment sold to medical establishments:

a) Circulating number owners shall:

- Report in writing to the agency where the number has been issued, which must clearly state the number of medical equipment sold to medical establishments;

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

b) In case the medical equipment has been granted a circulation number, the wrong result of classification is used but does not have the potential to affect the patient's health: The medical establishment continues to use it using such medical equipment and circulating digital owners shall have to complete the dossiers of circulation of medical equipment at medical establishments after having a new circulation number;

c) In case the medical equipment has been granted a circulation number, the wrong result of the classification has been used, which has the potential to affect the patient's health: The medical establishment must not continue to use it. The use of such medical equipment and circulating owners is responsible for taking remedial measures to ensure the normal operation of medical facilities. ”

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

"A) Having a technical degree from a technical college or higher, a medical device or a university degree in technical or medical specialization or more For medical equipment manufacturing establishments containing narcotics and pre-substances, professional managers must have a university degree in medical, medical, pharmaceutical, chemical or biological equipment; "

5. Article 13 is amended as follows:

"Article 13. Conditions on quality management of medical equipment manufacturing establishments.

1. Meet the quality management system standards prescribed in Clause 1, Article 68 of this Decree.

2. For establishments producing medical equipment containing narcotics and pre-substances, apart from answeringTo meet the conditions specified in Clause 1 of this Article, there must be a system to monitor and manage the process of export, import, inventory and use of raw materials being narcotics and pre-substances, the process of export, import and inventory. Medical equipment containing narcotics and pre-substances and preservation warehouses meet the provisions of Article 7 of the Government's Decree No. 80/2001 / ND-CP of November 5, 2001 guiding the control of activities Legal related to domestic drugs (hereinafter referred to as Decree 80/2001 / ND-CP). ”

6. Article 14 is amended and supplemented as follows:

a) Clause 4 is amended as follows:

"4. The certificate of quality management standards is recognized by conformity assessment organizations in accordance with the law.

Where an establishment does not conduct product quality inspection on its own or does not have a treasure or does not have a means of transport and signs a contract for quality control, preservation and transportation with another establishment, it must attach the papers. The proof of that facility is eligible for quality inspection, warehouse and transport of medical equipment that we manufacture. "

b) Supplementing clause 5 as follows:

"5. Documents proving to meet the conditions specified in Clause 2, Article 13 of this Decree. "

7. Article 16 is amended as follows:

"first. Establishments may produce medical equipment only after they have been granted a reception dossier by the Health Service to announce their production conditions as prescribed at Point b, Clause 2 of this Article.

2. Procedures for announcement of production eligibility:

a) Before producing medical equipment, medical equipment manufacturing establishments shall send dossiers of announcement of production conditions according to the provisions of Article 14 of this Decree to the Health Services of localities. factory or factory based;

b) Upon receiving complete and valid dossiers, the Health Services shall grant to the establishments a dossier of receipt of dossiers to announce the production conditions according to Form No. 02 prescribed in Appendix IV attached to this Decree. In cases where establishments announce the production of medical equipment containing narcotic substances and pre-substances, the provincial / municipal Health Services shall have to send a copy of the receipt of dossiers of announcement of eligibility for production to the Ministry of Public Security.

3. Adjusting information in the dossier of announcement of eligibility for production of medical equipment:

a) Cases of information adjustment in the dossier of announcement of eligibility for production of medical equipment:

- Changing the person in charge of the production facility;

- Change of address and contact phone number.

b) A dossier of request for adjustment of information in the dossier of announcement of eligibility for production of medical equipment:

- A written request for adjustment according to Form No. 20 prescribed in Appendix I attached to this Decree, which must clearly state the changed contents;

- In case of changing professional person: papers prescribed in Clause 3, Article 14 of this Decree;

- In case of changing address, contact phone number: Proof of change of address and phone number of the production establishment.

c) Adjustment procedure:

- After receiving the application for adjustment of information in the dossier of announcement of eligibility for production of medical equipment, the Department of Health grants the establishment a receipt to adjust the dossier of production eligibility announcement. medical equipment according to Form No. 14 prescribed in Appendix IV attached to this Decree;

- Within 03 working days from the date of recording on the receipt of adjustment of documents to announce production eligibility, the Department of Health is responsible for updating the information on the electronic information portal. In case the Department of Health does not accept, there must be a written reply and clearly state the reason.

4. In the course of operation, the production establishment must redo the procedures for announcement of production eligibility if there is one of the changes related to the previously announced dossier but does not fall into the case specified at the point. a Clause 3 of this Article.

5. If a production establishment changes its production location from one province to another, it must notify the Health Service of the locality where the production establishment has made the announcement of production eligibility within 10 working days. work, from the date of relocation.

Within 03 working days from the date of receiving the notice on the transfer of production location to another province of the production establishment, the Health Service of the place where the dossier of production announcement has been issued is responsible. terminate the posting of information related to that facility. ”

8. Points a and e, Clause 1, Article 17, are amended as follows:

"A) There have been circulation numbers or import licenses granted under this Decree, except medical gases;

e) There is information about warranty facilities, conditions and warranty period, except when medical equipment is used once according to the regulations of the owner of medical equipment or if there are documents to prove it. warranty;

9. Article 22 is amended as follows:

"Article 22. Application dossiers of application standards

Dossiers of announcement of standards applicable to medical equipment of category A include:

1. Documents announcing applicable standards of medical equipment of category A according to form No. 03 prescribed in Appendix I, issued together with this Decree.

2. Classification of medical equipment according to the form prescribed in Appendix V attached to this Decree.

3. Certificate of management standardsQuality is still valid at the time of filing. For medical equipment manufactured domestically, there must be an additional receipt for the announcement of eligibility for production of medical equipment.

4. Power of attorney of medical equipment owners for organizations whose names are published according to the form prescribed in Appendix VI issued together with this Decree is still valid at the time of filing the dossier. except for cases prescribed in Point a, Clause 1, Article 21 of this Decree.

5. Certificates of satisfaction of warranty conditions granted by owners of medical equipment according to the form prescribed in Appendix VII issued together with this Decree, except for medical equipment used once according to regulations medical equipment owner or a document proving that there is no warranty.

6. Brief description of medical equipment techniques in Vietnamese according to Form No. 01 prescribed in Appendix VIII issued together with this Decree, enclosed with technical documents describing functions and technical parameters of medical equipment issued by medical equipment owners.

Particularly for in vitro reagents, calibration agents and materials: Technical documents in Vietnamese according to Form No. 02 prescribed in Appendix VIII issued with this Decree together with materials on materials, on product safety, production processes, clinical and pre-clinical research reports including stability reporting.

7. Standard conformity certificates according to regulations or product standards published by medical equipment owners, together with results of assessment of chemical, physical and microbiological parameters and other parameters of establishments meet the conditions prescribed by the law on the assessment of conformity to the domestic medical equipment. Evaluation results must conform to standards announced by the owner.

8. Instructions for use of medical equipment.

9. Sample of labels will be used when circulating in Vietnam of medical equipment.

10. Free circulation certificates remain valid at the time of submission of dossiers for imported medical equipment. ”

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

a) Point b, Clause 2 is amended as follows:

"B) For Certificate of quality management standard: Submit the original or certified copy or a copy certified by the organization that proclaims the applicable standard;

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

b) Supplementing point g clause 2 as follows:

"G) For a certificate of free circulation: Submit a consular legalized copy or a certified copy of the consular legalization.

In case the certificate of free circulation is not in English or not in Vietnamese, it must be translated into Vietnamese. Translations must be authenticated according to the provisions of law.

In case the certificate of free circulation does not specify the expiry date, the expiry date of the certificate of free circulation is calculated as 36 months from the date of issue. "

11. To supplement Clause 4 of Article 24 as follows:

"4. In the process of circulation of medical equipment, the circulation number owner is responsible for notifying the circulation-issuing agency within 10 working days from the date of the following changes:

a) Change of address of medical equipment owner or owner of medical device circulation number;

b) Change of the name of the circulation number owner. The circulation number owner shall send a notice of change, enclosed with proofs and labels according to the provisions of Article 54 of this Decree;

c) Change one of the information on the name and address of the medical equipment manufacturing establishment. The owner of circulation numbers is responsible for attaching a written notice of changes in the following documents: Free circulation certificate and a valid certificate of quality management standards at the time of submission. ;

d) Change of packaging specifications for in vitro diagnostic medical equipment. Owners of circulating numbers shall have to send a written notice of change of documents according to the provisions of Clauses 6 and 9, Article 22 of this Decree;

d) Change of warranty facility. Owners of circulation numbers shall have to send a written notice of change of documents according to the provisions of Clause 5, Article 22 of this Decree;

e) Change the label, change the manual but do not change the instruction. The owner of circulation numbers is responsible for attaching a notice of change of documents corresponding to the changed contents. "

12. Article 25 is amended and supplemented as follows:

"Article 25. Forms of circulation registration

1. Newly issued circulation numbers applicable to medical equipment in the following cases:

a) Medical equipment for the first time for circulation circulation;

b) Medical equipment which has been granted circulation but has one of the following changes: Types of medical equipment; production materials affect the function of in vitro diagnostic medical equipment and disposable medical equipment;

c) Medical equipment has been granted circulation but nohe made registration for extension of circulation number within the time limit prescribed in Clause 3, Article 27 of this Decree.

2. Quickly issue new circulation numbers for medical equipment in the following cases:

a) Medical equipment has been circulated in at least 02 countries in the following countries: Japan, Canada, Australia, America, EU member countries;

b) Has been circulated in Vietnam before December 31, 2018 and meets the following conditions:

- Having circulated for at least 03 years within 5 years to the date of filing;

- There is no warning information regarding the quality and safety of such medical equipment.

3. Extension of circulation numbers applicable to cases where the circulation circulation numbers expire according to the provisions of Clause 3, Article 27 of this Decree. "

13. Article 26 is amended and supplemented as follows:

a) Modify clause 1 as follows:

"first. A dossier of application for new circulation of medical equipment without corresponding national technical regulations:

a) A written request for issuance of new circulation numbers, made according to Form No. 04, prescribed in Appendix I attached to this Decree;

b) Classification of medical equipment according to the form prescribed in Appendix V issued together with this Decree;

c) Validation of quality management standards at the time of filing;

d) Power of attorney of the medical equipment owner for the establishment to register for circulation in the form prescribed in Appendix VI issued together with this Decree is still valid at the time of filing, except cases prescribed at Point a, Clause 1, Article 21 of this Decree;

e) A certificate of satisfaction of warranty conditions issued by the owner of medical equipment according to the form prescribed in Appendix VII issued together with this Decree, except for medical equipment used once according to regulations. of medical equipment owners or having documents proving no warranty;

e) The certificate of free circulation is still valid at the time of submission of dossiers for imported medical equipment;

g) A brief description of the technical equipment of medical equipment in Vietnamese according to Form No. 01 prescribed in Appendix VIII issued together with this Decree, enclosed with technical documents describing functions and technical parameters of medical equipment promulgated by medical equipment owners;

Particularly for in vitro reagents, calibration agents and materials: Technical documents in Vietnamese according to Form No. 02 prescribed in Appendix VIII issued with this Decree together with materials on materials, on product safety, production processes, clinical and pre-clinical research reports including stability reporting;

h) The general technical dossier follows the guidelines of the ASEAN Agreement on medical equipment;

i) Guidelines for use of medical equipment;

j) For medical equipment of category C and D with human body intrusion: Summary of clinical test data according to the form prescribed in Appendix IX enclosed with this Decree together with research results clinical trials, except in the following cases:

- Medical equipment has been circulated and granted a certificate of free circulation by one of the following countries: EU, Japan, Canada, Australia (TGA) member states, the US (FDA);

- Medical equipment has been issued before this Decree takes effect;

- Other cases as prescribed by the Minister of Health.

l) For in vitro diagnostic medical equipment of category C and D, there must be an inspection certificate prescribed by the Minister of Health, except for the following cases:

- Medical equipment has been granted a certificate of free circulation by one of the following countries: EU, Japan, Canada, Australia (TGA) member states, the US (FDA);

- Medical equipment has been issued before this Decree takes effect;

m) Sample of labels will be used when circulating in Vietnam of medical equipment;

n) Receipt of application file for publication of sufficient production conditions in accordance with products for issuance of circulation registration numbers for domestically produced medical equipment;

o) Report on business results within the time limit for issuance of circulation numbers according to Form No. 01 prescribed in Appendix X enclosed with this Decree, for medical equipment already granted circulation before the Decree This decision is valid for exemption from submitting a summary of clinical trial data or accreditation certificates. "

b) Modify point c clause 2 as follows:

"C) Documents as stipulated in points b, c, d, e, e, g, h, i, m, n and o clause 1 of this Article."

c) Modify point c clause 3 as follows:

"C) Documents as stipulated in points b, c, d, e, e, g, h, i, m, n and o clause 1 of this Article."

d) Supplementing clause 5 as follows:

"5. Application file for quick issue of circulation number:

a) For cases specified at Point a, Clause 2, Article 25:

The documents specified in Clause 1 of this Article and at least 01 free circulation certificate of the competent authority of one of the following countries: EU, Japan, Canada and Australia member countries (TGA), USA (FDA) valid at the time of filing;

b) For the case specified at Point b, Clause 2, Article 25:

The papers specified in Clause 1 of this Article and have the following papers:

- There are at least 03 contracts to provide such medical equipmentwith medical facilities in Vietnam;

- The medical establishment's written certification of such medical equipment has no warning information regarding the quality and safety of such medical equipment during use. "

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

a) Modify point c clause 2 as follows:

"C) Certificate of validity of quality management standards at the time of filing;"

b) Supplementing point g clause 2 as follows:

"G) The general technical dossier shall comply with the guidance in the ASEAN Agreement on medical equipment in cases where it has been granted circulation but at the time of circulation of the law, it is not prescribed in the dossier. The circulation grant proposal must have a common ASEAN technical dossier. "

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

a) Point a, Clause 2 is amended as follows:

"A) For Certificate of quality management standard: Submit the original or certified copy or a copy certified by the establishment applying for circulation.

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

b) Point e, Clause 2 is amended as follows:

"E) For inspection certificate: Submit the original or certified copy or a certified copy of the establishment applying for circulation."

16. Article 29 is amended and supplemented as follows:

a) Supplementing Point d, Clause 3 as follows:

"D) Organizing the appraisal to grant new circulation numbers within 30 days from the date stated in the dossier receipt slip for cases specified in Clause 2, Article 25 of this Decree."

b) Modify clause 5 as follows:

"5. Upon receiving a written request for supplementation or amendment of circulation circulation dossiers, establishments requesting circulation circulation must supplement and amend them according to the contents already written in documents and send them to the Ministry. Medical;

In case the establishment requests circulation numbers for supplementing or modifying the dossier but not in accordance with the requirements, the Ministry of Health shall notify the establishment to continue to complete the dossier as prescribed in Clause 4 of this Article;

After 90 days from the date the Ministry of Health requests in writing that the establishment does not supplement or modify the dossier or if after 5 times of amendment and supplementation of the file from the date the Ministry of Health requests amendment, For the first time, if the dossier still fails to meet the requirements, it must re-apply from the beginning of the procedure for circulation circulation;

In the process of modifying and supplementing dossiers if the papers prescribed at Points c, d and e, Clause 1, Article 26 expire, the organizations and individuals applying for the circulation registration

numbers must submit additional papers. The replacement sheet is still valid. These papers must meet the requirements specified in Article 28 of this Decree. "

c) Modify point c clause 8 as follows:

"C) Change one of the information on the name and address of the medical equipment manufacturing establishment. Owners of circulation numbers are responsible for attaching a written notice of changes in the following documents: Free circulation certificates and certificates of quality management standards still valid at the time of submission. ; "

d) Modify point d clause 8 as follows:

"D) Change of packaging specifications for in vitro diagnostic medical equipment. The circulation number owner is responsible for attaching a notice of change of documents corresponding to the changed contents; "

d) To supplement Point e, Clause 8 as follows:

"E) Change of label, change of instruction manual but not change of designation: Circulating owner owner is responsible for attaching a notice to change documents corresponding to changed contents."

17. Article 30 is amended as follows:

“Article 30. Requirements for management of medical equipment after sales

Circulating owners must establish, organize and manage the traceability of medical equipment in the market and fully store equipment management records, including at least:

1. Dossiers of registration for circulation of medical equipment, in which the paper copies are required for the following papers:

a) Power of attorney from the owner of medical equipment for the establishment to conduct circulation registration, except for the case specified at Point a, Clause 1, Article 21 of this Decree;

b) A certificate of satisfaction of warranty conditions granted by the owner of the medical equipment, except for medical equipment used once according to the regulations of the owner of medical equipment or with documents. I don't have a warranty;

c) Certificate of free circulation.

2. Distribution dossiers (in cases where the circulation number owners are representative offices, they must not be archived but must request the establishments to which they authorize import to perform this responsibility).

3. Records of monitoring of incidents, complaints and remedial measures; which identifies the name, type, quantity and number of medical equipment lots; especially for medical equipment with errors or risks of causing unsafe for users.

4. The dossier of quality management of medical equipment, including:

a) The Certificate of Origin shall comply with the Government's Decree No. 31/2018 / ND-CP of March 8, 2018 detailing the Law on Foreign Trade Management regarding goods origin;

b) Quality certification of each lot by the owner of a medical device or a manufacturerexport named in the dossier of registration for circulation of medical equipment;

c) Medical equipment inspection results for medical equipment fall into the cases specified in Clause 1, Article 49 of this Decree. "

18. Article 31 is amended as follows:

"Article 31. Handling of medical equipment with warnings about potential risks seriously threatening public health or may lead to death for users

1. In cases where medical equipment has warnings of competent Vietnamese or international authorities about potential risks seriously threatening public health or may result in death for users, Circulating owners are responsible for notifying health facilities that are using the medical equipment about the risk of being warned and conducting an investigation, determined within 30 days from the date of receipt. be warned. In cases where the investigation and determination must take more than 30 days, there must be a written report to the Ministry of Health, clearly stating the reasons and proposing solutions to ensure safety for users.

2. Where medical equipment in Clause 1 of this Article is determined to be a medical device with an error affecting the health of the user, the circulation number owner shall:

a) Temporary suspension of circulation of such medical equipment lots;

b) There must be a written notice to the Ministry of Health and organizations and individuals that are implementing the distribution and use of such medical equipment. The notice must specify the production lot, the error factor which adversely affects the health of the user as well as the possibility or failure to remedy such factor;

c) Make a plan to handle or recover the batch of medical equipment with errors;

d) Reporting to the Ministry of Health after completing the recovery or withdrawal of medical equipment.

3. In cases where medical equipment can overcome errors affecting the health of users:

a) Within 03 working days from the date of receiving the notice of the owner of medical device circulation number, the Ministry of Health shall issue a decision on suspension of circulation for equipment lots. medical;

The content of the decision to suspend circulation includes:

- Name of medical equipment suspended;

- Number of batches of medical equipment suspended;

- Circulation number of medical equipment is suspended.

h) After having a decision to suspend circulation of medical equipment lots, the circulation number owner shall have to remedy the error factors affecting the users' health;

c) After completing the correction of the error factor affecting the health of the user, the circulation number owner shall have to send a written report to the Ministry of Health together with the inspection results for the case. Medical equipment specified in Clause 1, Article 49 of this Decree or subject to commitments on ensuring the quality of medical equipment after having remedied errors in reporting documents for other medical equipment;

d) Within 20 days from the date of receiving the report on correcting error factors affecting the health of users of medical equipment lots circulated by the owner of the number, the Ministry of Health shall have to to issue decisions to terminate suspension of circulation of medical equipment lots. If the Ministry of Health does not agree to terminate the suspension of circulation, there must be a written reply, clearly stating the reason for the refusal.

4. In case medical equipment cannot remedy the error factor, thus adversely affecting the health of users:

a) The Ministry of Health is responsible for issuing decisions to recover all medical equipment lots with errors.

The content of the recall decision includes:

- Name of medical equipment recovered;

- Number of batches of medical equipment recovered;

- Circulation numbers of medical equipment are withdrawn.

b) The circulation number owner shall recover all medical equipment lots with errors within the time limit decided by competent state agencies and bear all expenses for the recovery of medical equipment lots. I have an error.

c) In case the time limit for revocation is decided by a competent state agency, if the circulating owner does not recover the faulty medical equipment lot, he / she shall be forced to withdraw it according to regulations. of the law on handling administrative violations. "

19. Article 32 is amended as follows:

"Article 32. Handling of cases where medical equipment has incidents which affect users' health

1. In cases where medical equipment has occurred, which seriously threatens the public health or causes death to users, the circulation number owner shall:

a) Notice on the website of the circulation number owner (if any) and at the same time issue a written notice of the incident to the establishments purchasing, selling and using medical equipment lots and the Ministry of Health. ;

b) Suspending the circulation of medical equipment lots related to incidents;

c) Conduct investigation and verification of the cause of the incident;

d) Reporting to the Ministry of Health after the investigation and verification results are obtained. In case of an incident that is caused by a medical device's fault, it is necessary to state the error factor as well as whether or not it is possible to remedy that factor. Perform recovery or recovery of lots of medical equipment with holesi, report to the Ministry of Health after completing the recovery or withdrawal of medical equipment batches.

2. In case medical equipment has not caused a fatal incident but seriously affects the health of the user, the circulation number owner shall:

a) Notify in writing to the Ministry of Health about incidents;

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

c) Reporting to the Ministry of Health after the investigation and verification results are obtained. In the case of an incident that is caused by a medical device error, it is necessary to specify the error factor as well as whether or not it is possible to remedy that factor. Implementing the recovery or revocation of defective medical equipment lots and reporting to the Ministry of Health after completing the recovery or withdrawal of medical equipment lots.

3. The handling of medical equipment with errors affecting the health of users shall comply with the provisions of Clauses 3 and 4, Article 31 of this Decree. "

20. Article 33 is amended as follows:

"Article 33. Forms of handling, overcoming and recovering medical equipment with errors

1. Forms of handling medical equipment with errors include:

a) Instructions on remedial measures;

b) Fix errors of medical equipment;

c) Replacement of medical equipment with errors with corresponding medical equipment;

d) Recovery for re-export or disposal.

2. Medical equipment with recalled errors in the following forms:

a) Voluntary recall is carried out by the circulation number owner;

b) Compulsory withdrawal of cases prescribed in Article 35 of this Decree. "

21. Article 35 is amended and supplemented as follows:

a) Modify clause 2 as follows:

"2. Medical equipment with 03 lots were revoked during the period of validity of the circulation registration, unless the circulation number owner voluntarily withdraws. "

b) Add clause 10, 11 and 12 as follows:

"ten. The owner of circulation numbers shall not comply with the provisions of Point i, Clause 2, Article 66 of this Decree, except for the case specified in Article 34 of this Decree.

11. Dossiers of publication of circulation serial owners do not comply with the provisions of Articles 22 and 23 of this Decree or the use of forged papers in publication dossiers.

12. Medical equipment is classified not according to regulations on classification of medical equipment after the Ministry of Health's conclusion. "

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

"A) Posting the decision of revocation of numbers circulated on the electronic portal of the circulating agency, and at the same time sending a decision to withdraw circulation to the circulation number owner, the Ministry of Health and the Department of Health the provinces, cities directly under the central government and customs offices; "

23. Article 37 is amended as follows:

"Article 37. Conditions of establishments purchasing and selling medical equipment of types B, C and D

1. Having at least 01 technical staff with a college degree in engineering or a medical, pharmaceutical or college technical degree of medical equipment or more or having a college degree or higher but a specialization is dug created in accordance with the type of medical equipment purchased and sold by the establishment;

2. Having storage and transport facilities meeting the following minimum conditions:

a) Storage warehouse:

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

- Ensure airy, dry, clean, not near pollution sources;

- Meet other storage requirements of medical equipment according to the user manual.

b) Means of transporting medical equipment from sale and purchase establishments to delivery places in conformity with types of medical equipment purchased and sold by establishments;

In case there is no storage facility or means to preserve medical equipment, there must be a contract with a facility capable of preserving and transporting medical equipment.

3. For establishments purchasing and selling medical equipment containing narcotics and pre-substances:

a) Professional curators must have a university degree in medical, medical, pharmaceutical, pharmaceutical or biological equipment;

b) Having a preservation warehouse meeting the requirements of Article 7 of Decree No. 80/2001 / ND-CP;

c) Having a system to monitor and manage the process of export, import and inventory of medical equipment containing narcotics and pre-substances. "

24. Article 38 is amended and supplemented as follows:

"Article 38. Dossiers and procedures for announcement of eligibility for sale and purchase of medical equipment

1. Dossiers of announcement of eligibility for purchase and sale of medical equipment are made in 01 set, including the following papers:

a) Written announcement of eligibility for purchase and sale of medical equipment according to Form No. 07 prescribed in Appendix I issued together with this Decree;

b) The declaration of personnel according to the form prescribed in Appendix II enclosed with this Decree;

c) Documents proving preservation warehouses and means of transporting medical equipment meet the requirements prescribed in Clause 2, Article 37 of this Decree. These documents must be verified by the establishment announcing eligibility for purchase and sale;

d) Documents proving the preservation warehouse, the system of monitoring and managing the process of export, import and inventory of medical equipment containing narcotics and pre-substances meeting the requirements prescribed in Clause 3 of Article 37 This Decree. These documents must be verified by the establishment declaring eligibility for the sale of medical equipment containing narcotics and precursors.

2. Procedures for announcement of eligibility for purchase and sale:

a) Before implementationbuying and selling medical equipment of categories B, C, and D, heads of medical equipment purchase and sale establishments shall send dossiers of announcement of eligibility for purchase and sale under the provisions of Clause 1 of this Article to the Departments. Health where the buying and selling facility is located;

b) Upon receiving the dossier, the Health Service shall grant the dossier of receipt of the dossier to announce the eligibility for purchase and sale according to Form No. 05 prescribed in Appendix IV attached to this Decree;

c) Within 03 working days from the date of receipt of the dossier of announcement of eligibility for purchase and sale, the Department of Health is responsible for publicizing on the electronic portal the following information: name and address of the body medical equipment purchase and sale department; Records of announcement of eligibility for purchase and sale of medical equipment.

3. Establishments may only purchase and sell medical equipment of categories B, C and D after carrying out procedures for announcement of eligibility for purchase and sale under the provisions of Clause 2 of this Article, except for cases prescribed in Article 39 of this Decree.

4. Adjusting information in dossiers of announcement of eligibility for purchase and sale of medical equipment:

a) Cases of information adjustment in the dossier of announcement of eligibility for purchase and sale of medical equipment:

- Change of technical staff of buying and selling establishments;

- Change administrative information about address, contact phone number.

b) Application file for adjustment of information in the dossier of announcement of eligibility for purchase and sale of medical equipment:

- A written request for adjustment with the seal of the sale and purchase establishment according to Form No. 21 prescribed in Appendix I attached to this Decree, which must clearly state the changed contents;

- In case of changing technical staff: The declaration of personnel shall be made according to the form prescribed in Appendix II, enclosed with this Decree, clearly stating the changed contents;

- In case of changing administrative information: Documents proving the change of address and phone number of the purchasing establishment.

c) Adjustment procedure:

- After receiving the application for adjustment of information in the dossier of announcement of eligibility for purchase and sale of medical equipment, the Department of Health grants the establishment a receipt to adjust the dossier of announcement of eligibility for purchase and sale. medical equipment according to Form No. 15 prescribed in Appendix IV issued together with this Decree;

- Within 03 working days from the date on the receipt of adjustment of documents to announce eligibility for purchase and sale of medical equipment, the Department of Health is responsible for updating the information on the electricity portal. death. In case of refusal, there must be a written reply, clearly stating the reason.

5. In the course of operation, the purchasing and selling establishment must re-implement the procedures for announcement of purchase and sale conditions if there is one of the changes related to the previously published dossier but not in the case specified at the point. a paragraph 4 of this Article. "

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

"2. Medical equipment with a circulation number in Vietnam may be exported and imported on demand, without any quantity restrictions and not approved by the Ministry of Health, except for medical equipment containing narcotics and precursors."

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

"2. Organizations and individuals that import medical equipment with circulation numbers must meet the following conditions:

a) Being the owner of the digital circulation or with the authorization letter of the circulation number owner. The serial number owner, when authorizing an import establishment to import medical equipment, must at the same time send such authorization document to the circulation number agency and the customs office;

b) Having warehouses and means of transport meeting the requirements prescribed in Clause 2, Article 37 of this Decree or having contracts with establishments capable of preserving and transporting medical equipment;

c) Having a preservation store, a system to monitor and manage the process of export, import and inventory of medical equipment containing narcotics and pre-substances meeting the requirements prescribed in Clause 3, Article 37 of this Decree. . "

27. Article 42 is amended as follows:

"Article 42. Export and import permits

1. Cases where import permits are required:

a) Medical equipment without circulation numbers for scientific research or inspection or training to guide the use and guidance on repair of medical equipment;

b) Medical equipment has not yet had circulation numbers for the purpose of humanitarian aid and aid;

c) Medical equipment has not yet had the circulation circulation number in service of humanitarian medical examination and treatment activities;

d) Medical equipment without circulation numbers for personal use, including medical equipment manufactured according to specific use for individuals or according to diagnostic needs special of health facilities;

d) Medical equipment containing narcotics and pre-substances with circulation registration numbers and raw materials for production of medical equipment are narcotics and pre-substances;

e) Medical equipment containing imported drugs and precursors for scientific research or inspection; h) Raw materials for production of medical equipment are drugs and pre-substances imported for research or inspection purposes.

2. Cases where export permits are required:

a) Medical equipment containing narcotics and pre-substances;

b) Raw materials for production of medical equipment are narcotics and pre-substances.

3. Dossiers for granting import licenses include:

a) A written request for the grant of an import permit, made according to form No. 08, prescribed in Appendix I, issued together with this Decree;

b) A brief description of medical equipment techniques in Vietnamese according to Form No. 01 prescribed in Appendix VIII issued together with this Decree;

c) The certificate of satisfaction of quality management standards of the medical equipment manufacturing establishment, certified by the organization or individual applying for the import license;

d) In case of import for research purposes, there must be an authenticated copy of the decision approving the research project and documents proving that the medical equipment proposed for import has been approved by a competent agency. allow circulation with certification of organizations and individuals applying for import licenses;

d) In case of import for training, there must be an additional original of the training program and documents proving that the medical equipment proposed for import has been permitted by the competent agency for certification. officials and individuals requesting import permits;

e) In case of import for use for verification purposes: The unit's written certification of the inspection, clearly stating the quantity;

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

h) In case of import in service of humanitarian medical examination and treatment activities: documents proving that the medical equipment requested to be imported have been permitted by the competent agency for certification. officials and individuals requesting import permits;

i) In case of import for special diagnostic needs of medical establishments, there must be additional documents proving that the medical equipment requested to be imported has been certified for circulation by competent agencies. of organizations and individuals applying for import permits;

k) In case of import for use for personal healing purposes, there must be a copy of the doctor's written appointment suitable to the disease of the individual requesting the import.

4. Dossiers of application for import of medical equipment containing narcotics and pre-substances:

a) Dossiers of request for import of medical equipment containing narcotics and pre-substances with circulation registration numbers:

- A written request for import according to Form No. 13 prescribed in Appendix I attached to this Decree, which must clearly explain the reason if the number of medical equipment contains narcotics and pre-substances import proposals exceed 150% of the previous import volume;

- Report on business results of medical equipment containing narcotics and pre-substances according to Form No. 02 prescribed in Appendix X enclosed with this Decree;

b) A dossier of request for import of medical equipment containing narcotic substances and pre-substances for scientific research or inspection:

- A written request for import according to Form No. 13 prescribed in Appendix I attached to this Decree;

- Documents specified at Points b, c, d and e, Clause 3, Article 42 of this Decree.

5. Dossiers of application for importing raw materials for production of medical equipment containing narcotics and pre-substances for production:

a) A written request for import according to Form No. 14 prescribed in Appendix I attached to this Decree;

b) Copies of quality standards and methods of quality control of narcotic substances and pre-substances of production establishments affixed with stamps of importing establishments;

c) A certified copy of the production license of the raw material production establishment, granted by a competent management agency of the exporting country. Production licenses must be consularly

legalized in accordance with the law on consular legalization, except for cases of exemption under the provisions of law;

If the documents specified in points b and c of this clause are not presented in Vietnamese or English, the notarized translations of such documents must be submitted in Vietnamese or English.

d) To report on the use of raw materials for production of medical equipment with narcotic substances and pre-substances according to Form No. 03 prescribed in Appendix X enclosed with this Decree;

e) Report on business results of raw materials for production of medical equipment containing narcotics and pre-substances Form No. 02 prescribed in Appendix X issued together with this Decree;

e) Production and use plans for raw materials proposed for import and expected business plans for finished products manufactured from raw materials proposed for import.

6. Dossiers of application for import of raw materials for production of medical equipment containing narcotics and pre-substances for research and verification:

a) A written request for import of raw materials for production of medical equipment containing narcotics and pre-substances according to Form No. 14 prescribed inAppendix I issued together with this Decree;

b) In case of importation for research and production of medical equipment, there must be documents certified by the production establishment requesting the granting of an import permit to prove the research on the use of production materials. medical equipment containing narcotics and precursors;

c) In case of importation for use for inspection purposes, there must be additional written certification of the unit conducting the inspection, clearly stating the amount to be used for inspection.

7. Dossiers of request for export of medical equipment containing narcotic substances and pre-substances, raw materials for production of medical equipment with narcotic substances and pre-substances:

a) A written request made according to Form No. 15 or Form No. 16 prescribed in Appendix I issued together with this Decree;

b) To report on the quantity and origin of medical equipment and raw materials for production of medical equipment containing narcotics and pre-substances according to Form No. 04 prescribed in Appendix X enclosed with this Decree;

c) Written permission for the import of medical equipment and raw materials for production of medical equipment, which still contain a valid narcotic substance and pre-substances, shall be granted by competent management agencies of the importing countries. In case the import permit is not expressed in Vietnamese or English, the notarized translation of the license must be submitted in Vietnamese or English. Import permission documents must be consular legalized in accordance with the law on consular legalization, except for cases of exemption under the provisions of law.

8. The order to consider the application for licensing for import and export of medical equipment and raw materials for production of medical equipment containing narcotics and pre-substances:

a) After receiving dossiers of application for licensing for import and export of medical equipment, raw materials for production of medical equipment containing narcotics and pre-substances, the Ministry of Health shall send them to organizations and individuals. Such a person shall receive a receipt according to Form No. 06 prescribed in Appendix IV attached to this Decree;

b) In case there is no request to amend or supplement the dossier of application for licensing for import of medical equipment, raw materials for production of medical equipment containing narcotics and precursors, the Ministry of Health must proceed conduct appraisal for import licensing within 15 working days from the date on the receipt. In case of refusal, there must be a written reply, clearly stating the reason.

For the licensing of export of medical equipment containing narcotics or precursors, materials containing narcotics or precursors, the Ministry of Health must conduct the evaluation to grant export permits within 15 days. working from the date of the export notice of the Ministry of Public Security. In case of refusal, there must be a written reply, clearly stating the reason;

Export and import licenses are sent to organizations and individuals requesting export, import and customs offices. In cases where medical equipment and materials containing narcotics or pre-substances, export and import permits are sent to the Ministry of Public Security and the Ministry of Finance;

Licenses for export and import of medical equipment containing narcotics and pre-substances and raw materials for production of medical equipment are drugs and pre-substances that are granted for each export and import and have value within the time limit stated in the license.

c) In case the dossiers of application for licensing for export or import of medical equipment and raw materials for production of medical equipment contain illegal drugs and pre-substances, within 5 working days, from the date of writing on the application receipt, the Ministry of Health must issue a written notice to the organization or individual applying for the export or import of medical equipment to supplement or amend the dossier. The written notice must specify what additional documents and contents should be amended.

d) Upon receiving a written request for supplementation or amendment of import or export dossiers, organizations and individuals applying for import or export permits must supplement and amend the contents already in accordance with the contents. write in the document and send it to the Ministry of Health;

If an organization or individual requests an import or export license that has supplemented or modified the dossier but does not comply with the request, the Ministry of Health will notify such organization or individual to continue completing the lake. profile.

d) After 60 days from the date the Ministry of Health issues a written request that the organization or individual applying for import or export permit does not supplement or modify the dossier, it must re-implement it from the beginning.

e) If there are no additional or amended requirements, the Ministry of Health shall have to grant import and export permits according to the provisions of Point b of this Clause. Import and export licenses are sent to organizations and individuals requesting import, export and customs authorities. "

28. Article 43 is amended as follows:

"Article 43. Dossiers of application for certificates of free circulation for home-made medical equipment

The Ministry of Health only grants certificates of free circulation for medical equipment items which have been granted circulation registration numbers.

1. Dossiers of application for certificates of free circulation of medical equipment:

a) A written request for a certificate of free circulation according to Form No. 12 prescribed in Appendix I attached to this Decree;

b) Submit a certified copy of the certificateg Receiving the quality standards recognized by the conformity assessment organization in accordance with the law in force at the time of filing;

c) Submitting originals or copies of circulation numbers for a definite time;

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

3. The certificate of free circulation shall be issued according to Form No. 12 prescribed in Appendix IV attached to this Decree. "

29. Section 2 Chapter VI is amended as follows:

“Section 2. VERIFICATION, PERFORMANCE OF MEDICAL EQUIPMENT

Article 49. Principles for inspection and calibration of medical equipment

1. Medical equipment on the list announced by the Minister of Health must be tested for safety and technical features before being put into use (except for the case specified in Article 51 of this Decree), and period, after major repairs. The inspection of medical equipment is a means of measurement and radiation equipment shall comply with the provisions of Clause 2 of this Article.

2. Medical equipment being measuring devices or radiation equipment must carry out inspection and calibration according to the provisions of the law on atomic energy and measurement.

Article 50. Conditions for providing medical equipment inspection services

Conditions on facilities and personnel; dossiers of application for certificates; Process of submitting paperwork; The new order of granting, supplementing, re-granting and revoking the certificate of registration of medical equipment inspection is carried out in accordance with the current law on the conditions of providing services of conformity assessment service. well suited;

In particular, the satisfaction of professional requirements in the field of medical equipment inspection is prescribed as follows: each inspection process which an inspection organization registers for implementation must have at least 02 inspectors. certified training on that inspection process.

Article 51. Exemption of first-time inspection before being put into use for medical equipment

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

1. Medical equipment has a certificate of conformity;

2. Medical equipment has not yet had the circulation circulation numbers for the purpose of scientific research or training for use, maintenance and repair of medical equipment;

3. Medical equipment has not yet been imported for use for medical purposes of importers or for the purpose of humanitarian or medical examination or special diagnosis needs;

4. Medical equipment has not yet had the circulation circulation number in service of trade fair, exhibition, display and introduction activities.

Article 52. Handling medical equipment that fails to meet the inspection requirements

1. In case medical equipment has inspection results before being put into use:

a) Medical establishments must not receive and use medical equipment;

b) The inspection organization sends a written notice of the inspection result not reaching the Ministry of Health;

c) In case there are 03 medical equipment in the same lot which have the result of inspection failing to meet safety and features, the Ministry of Health shall issue a written request to the owners of circulation registration numbers to report the quantity. medical equipment is circulating on the market and being used at medical facilities;

Based on the owners' reports and unsatisfactory inspection results, the Ministry of Health shall decide on re-inspection and the number of samples subject to re-inspection or suspension of use of medical equipment;

Based on the re-inspection results, the Ministry of Health shall decide to continue the re-verification and supplement of the number of samples to be re-inspected or request the circulation registration owners to recover the entire page medical equipment in that lot;

In case there are 03 lots of medical equipment recovered within the effective term of circulation, the circulation registration number shall be withdrawn for such medical equipment. Medical equipment that has been used at medical facilities before the issuance of circulation revocation decisions continues to be used if the inspection results are satisfactory.

2. In case medical equipment has the results of periodic inspection, after the major repair is not achieved:

a) Medical establishments must not continue to use medical equipment;

b) Remove the signs of old inspection status;

c) Coordinate with the circulation owner in conducting remedies and re-testing.

d) Only use equipment when there are satisfactory inspection results. ”

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

"first. The labeling of medical equipment shall comply with the current law provisions on goods labeling.
"

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

"2. Medical equipment must be preserved, maintained, maintained, used and complied with other technical guidelines in accordance with the manufacturer's regulations and must be tested in accordance with this Decree to ensure quality. quantity.

For medical equipment with strict requirements on occupational safety and health, in addition to complying with regulations on quality assurance prescribed in this Decree, they must comply with the provisions of law. on occupational safety and health. ”

32. Article 56c modify the following:

"Article 56. Management and use of medical equipment in state health facilities

The State medical establishments, in addition to the management and use of medical equipment according to the provisions of Article 55 of this Decree, must manage medical equipment according to the following regulations:

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

2. Encouraging the use of domestically produced medical equipment. "

33. To supplement Point d, Clause 2, Article 57 as follows:

"D) Medical establishments must check quality management dossiers when receiving medical equipment; keep and update test results of all medical gas lots. ”

34. Article 58 is amended and supplemented as follows:

a) Clause 7 is amended as follows:

"7. Request for a certificate of registration of medical equipment inspection. "

b) Supplementing Clause 10 as follows:

"ten. Granting medical practice certificates for medical equipment. "

35. Supplementing clause 5 Article 60 as follows:

"5. In the course of operation, the circulation number owner may keep the number of previously received dossier-receiving votes in cases of change in Clause 4, Article 24 of this Decree; "

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

"first. In case of online registration, registration establishments must archive registration dossiers according to the provisions of Clause 1, Article 30 of this Decree. "

37. Add Items 8, 9 and 10 Article 62 as follows:

"8. Detailed provisions for the classification of medical equipment ensure compliance with international treaties on medical equipment classification of the Association of Southeast Asian Nations, which Vietnam is a member; issued training programs to classify medical equipment.

9. To promulgate a list of medical equipment which must be tested and the inspection process for each type of medical equipment in the list.

10. Specific guidance on the ASEAN common technical dossier. ”

38. Article 66 is amended and supplemented as follows:

a) Clause 2 is amended as follows:

"2. The owner of circulation numbers is responsible for:

a) Implementing standards for application or registration for circulation of medical equipment in accordance with this Decree;

b) Establishing and maintaining medical equipment warranty facilities or signing contracts with medical equipment warranty establishments;

c) Prepare and maintain records to monitor medical equipment and perform traceability of medical equipment according to the provisions of this Decree, except for medical equipment used once according to regulations. of medical equipment owners; report to the Department of Health and the Police Department when detecting a mistake, loss of medical equipment containing narcotics and pre-substances, raw materials for production of medical equipment containing narcotics and pre-substances;

d) Fully and accurately information on products on labels and documents attached to medical equipment according to law provisions on goods labels and this Decree;

d) Warning in a timely, complete and accurate manner the risks of causing adverse impacts on users' health and environment; prevention methods for sellers and consumers; provide information on requirements for the transportation, storage, preservation and use of medical equipment;

e) Promptly stop circulation, notify related parties and take measures to handle, remedy or recover medical equipment with errors in accordance with this Decree. In case of dealing with destruction, the destruction of medical equipment must comply with the provisions of the law on environmental protection, relevant provisions of law and must bear all expenses for that destruction;

g) Complying with legal regulations, decisions on inspection and examination of competent state agencies;

h) To compensate for damage according to the provisions of law when medical equipment is at fault;

i) Be responsible for ensuring that the following documents remain valid during the period of valid circulation:

- Certificate of free circulation for imported medical equipment;

- Power of attorney except for the case specified at Point a, Clause 1, Article 21 of this Decree;

- Certificate of warranty eligibility or documents proving no warranty if not applicable.

k) To be responsible for ensuring that medical equipment is only produced during the validity of a certificate of quality management standards of production establishments;

l) Be responsible before the law for the legality and accuracy of the documents posted when implementing the procedures in this Decree;

m) To provide medical establishments where purchasing medical equipment 01 set of quality management dossiers specified in Clause 4, Article 30 of this Decree of such medical equipment;

n) Other obligations as prescribed by law. ”

b) Supplementing clause 4 as follows:

"4. Establishments that buy, sell, export, import or transfer medical equipment containing narcotics and pre-substances and raw materials for production of medical equipment containing narcotics and pre-substances are responsible for:

a) Reports on purchase, sale, export, import and transfer of medical equipment containing narcotics and pre-substances and raw materials for production of medical equipment are narcotics and money. sent according to Forms 05 and 06 prescribed in Appendix X attached to this Decree and sent to the Ministry of Health and sent to the Ministry of Public Security for the export and import of medical equipment containing narcotics and pre-substances , raw materials for production of medical equipment are narcotics and pre-substances within 10 days from the date of purchase, export, import or transfer of medical equipment or raw materials for production of medical equipment. It contains drugs and precursors;

b) 06-month reports and corresponding annual reports on the export, import, inventory, use of medical equipment containing narcotics and pre-substances, raw materials containing narcotics and precursors according to Form 03 provisions in Appendix X issued together with this Decree and sent to the Ministry of Health before July 15 and before January 15 every year;

c) Report to the Department of Health in accordance with Form No. 07 stipulated in Annex X issued with this Decree within 48 hours after detecting the mistake, loss of medical equipment containing narcotics and precursors, materials are narcotics and precursors. ”

c) Add Clause 5 as follows:

"5. Organization of classification of medical equipment:

a) In the course of operation, the organization performing the classification of medical equipment must have the responsibility to fully satisfy the conditions specified in Article 7 of this Decree;

b) To be responsible for and take remedial measures for cases of issuing false classification results on the level of risk of medical equipment or issuing wrong classification results on prescribed competence. in this Decree;

c) Announcing the classification results on the electronic portal of the Ministry of Health within 05 working days from the date of issuance.

d) To add Clause 6 as follows:

"6. Medical equipment manufacturing establishments are allowed to import active ingredients with pharmacological effects to produce medical equipment. The establishment is only allowed to use the active ingredients imported to produce medical equipment, not to use for other purposes, except for sale to other medical equipment production facilities to produce the same product. . Documents and procedures for importing active ingredients with pharmacological effects to produce medical equipment shall comply with the legislation on pharmacy. "

39. Article 68 is amended as follows:

a) Clause 5 is amended as follows:

"A) Import licenses for medical equipment of categories B, C, and D issued in 2018 expire on December 31, 2018 and import licenses issued in 2019 are valid. until the end of December 31, 2019, except for the case specified in Clause 1, Article 42 and Point d of this Clause;

For licenses to import in vitro diagnostic biologicals issued in 2018, 2019: Valid until the end of December 31, 2019 and there is no restriction on the number of imports. Customs authorities do not control the quantity of imports in this case;

Organizations and individuals dealing in medical equipment shall be responsible for ensuring that the documents specified at Point i, Clause 2, Article 66 of this Decree are valid during the validity of import permits. In case of failing to continue maintaining the validity of the above papers, organizations and

individuals dealing in medical equipment shall have to notify the Ministry of Health to withdraw the import licenses. issued as prescribed.

b) For medical equipment of category A, there is a receipt for application of standard announcement documents issued by the Department of Health, which is imported according to demand, without quantity restriction without a confirmation document. medical equipment of the Ministry of Health when implementing customs clearance procedures;

For medical equipment not included in the list of goods that must be granted import licenses and classified as medical equipment of category B, C, and D, classified by the Ministry of Health. The electronic portal will continue to be imported until December 31, 2019 on demand, without any quantity restriction without a written certification of the Ministry of Health's medical equipment when carrying out the clearance procedures. mandarin

c) Medical equipment that are in vitro diagnostic biological products have been granted circulation registration certificates in accordance with the Law on Pharmacy in 2005 and documents guiding the implementation of this Law, the use value of circulated numbers has granted valid until the end of the time stated on the circulation registration paper. Particularly for registration numbers of in vitro diagnostic biological products expired after January 1, 2019 and before December 31, 2019 shall continue to be used until the end of December 31, 2019;

Medical equipment, which are in vitro diagnostic biological products, have submitted dossiers of registration for circulation in accordance with the Law on Pharmacy 2005 before January 1, 2019, resolved under the provisions of the Pharmaceutical Law 2005;

Medical equipment are imported in vitro diagnostic biologicals for submission in the period from January 1, 2019 to the end of December 31, 2019, which are granted import permits according to the provisions of the Pharmaceutical Law 2005 and valid until December 31, 2019;

Begin receiving dossiers and issue circulation registration numbers for in vitro diagnostic medical equipment produced domestically from January 1, 2019. d) Insecticidal and germicidal chemicals and preparations for domestic and medical use have only one purpose to disinfect medical equipment which

have been granted circulation certificates if they expire after the first day. July 2016 and before January 1, 2019 continue to use that circulation certificate until December 31, 2019;

Beginning receiving dossiers and issuing circulation registration numbers for insecticidal and germicidal chemicals and preparations for domestic and medical use, only one purpose is to disinfect medical equipment from the date of January 1, 2019.

d) The domestic manufactured medical equipment which has been granted the circulation registration certificate, the use value of the granted circulation number shall be valid until the end of the time stated in the circulation registration paper. Particularly for circulation registration certificates which expire after the effective date of this Decree and before December 31, 2019, they shall continue to be used until December 31, 2019. ”

b) Clause 6 is amended as follows:

"6. Beginning to receive the application file for publication of standard of medical equipment of category A from January 1, 2017 and the application form for application of standard announcement documents shall take effect from July 1, 2017. 2017; began to receive applications for circulation of medical equipment of category B, C, and D from July 1, 2017 and the circulation of medical equipment is effective from January 1, 2017 2020, except for the cases specified at Points c and d, Clause 5 of this Article. "

c) Supplementing clause 8 as follows:

"8. Organization of the classification of medical equipment is responsible for completing the publicity of the results of classification of medical equipment issued before December 31, 2018 on the electronic portal of the Ministry of Health first. April 1, 2019.

Documents proving the classification results in the form of acknowledgment of submission of dossiers to management agencies before December 31, 2018 shall continue to be used for registration of medical equipment circulation for such dossiers. . "

d) Supplementing clause 9 as follows:

"9. All certified certificates of medical equipment classification issued before December 31, 2018 are valid for only 3 years from the date of signing. "

d) Supplementing Clause 10 as follows:

"ten. The owner of circulating numbers must review the results of classification of medical equipment according to the provisions of Clause 2, Article 4 of this Decree and report it to the Ministry of Health before July 1, 2019.

If the review results have a change in the level of risk, the circulation number owner is responsible for re-implementing the circulation registration procedure according to the new level of risk. Imported medical equipment that has been cleared and domestically produced medical equipment shipped out before December 31, 2020 under the circumstances specified in this Clause shall be circulated until the expiry date of the product. Products."

e) Add Clause 11 as follows:

"11. ASEAN General Technical Document (CSDT) is implemented from July 1, 2020. From July 1, 2020, establishments applying for circulation are not required to provide required documents. at points g, i and m, Clause 1, Article 26 of this Decree. "

g) Supplementing clause 12 as follows:

"twelfth. Medical gas production facilities must complete the application of ISO 9001 or equivalent quality management system from January 1, 2020. The Minister of Health shall specify the management of medical gas quality. sacrifice. ”

h) Supplementing clause 13 as follows:

"13. Materials, software (medical software), accessories and medical gases are not required to be registered for circulation and import licensing under this Decree. "

Article 2. Effect

1. This Decree takes effect from the date of its signing.

2. To annul the following provisions of Decree No. 36/2016 / ND-CP from the effective date of this Decree:

a) Clause 2 Article 12;

b) Point b, Clause 2, Article 15;

c) Form No. 10 Annex I;

d) Form No. 11 Annex I;

e) Form No. 08 Annex IV.

Article 3. Responsibility to organize implementation

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

2. Ministers, heads of ministerial-level agencies, heads of Government-attached agencies and presidents of provincial / municipal People's Committees and concerned agencies, organizations and individuals shall take responsibility implement this Decree.

Recipients:

- Party Central Committee Secretariat;
- Prime Minister and Deputy Prime Ministers;
- Ministries, ministerial-level agencies and Government-attached agencies;
- People's Council, People's Committee of provinces and cities directly under the Central Government;
- Central Office and Party Committees;
- Office of the General Secretary;
- Office of the President;
- National Council and Committees of the National Assembly;
- Congress office;
- Supreme People's Court;
- People's Procuratorate of the Supreme;
- State Audit;
- National Financial Supervisory Committee;
- Social Policy Bank;