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

No.: 30/2015/TT-BYT	*Hanoi, 12 October 2015*

CIRCULAR

ON IMPORT OF MEDICAL EQUIPMENT

Pursuant to the Commercial Law dated 14/6/2005;

Pursuant to Decree No. 187/2013/ND-CP dated 20/11/2013 of the Government detailing the implementation of Commercial Law on trading of international goods and activities of trading and processing agents and goods transit with foreign countries;

Pursuant to Decree No. 63/2012/ND-CP dated 31/08/2012 of the Government defining functions, duties, powers and organizational structure of the Ministry of Health;

At the request of the Director of Department of Medical Equipment and Health Facilities;

The Minister of Health issues the Circular providing for the import of medical equipment.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

1. This Circular defines the authority, dossier and procedures for issue of import Permit of 100% brand new medical equipment (hereafter referred to as the import Permit) included in the List specified in Annex 1 issued with this Circular.

2. The import of medical equipment in the form of foreign aid (including medical equipment of over 80% quality), temporary import and re-export, temporary export and re-import, border transfer of goods, medical equipment as movable property, in service of personal needs with diplomatic status and personal luggage shall comply with the provisions of Decree No. 187/2013/ND-CP dated 20/11/2013 of the Government detailing the implementation of the Commercial Law on trading of international goods and activities of trading and processing agents and goods transit with foreign countries and the guidelines of the Ministry of Industry and Trade.

Article 2. Interpretation of terms

In this Circular, the terms below are construed as follows:

1. Medical equipment is the types of equipment, tool, material and in-vitro diagnosis chemical and software used separately or combined with each other as indicated by the owner to serve people for one or a lot of purposes as follows:

a) Diagnosis, prevention, monitoring, treatment and mitigation of disease or injury compensation;

b) Checking, replacement, modification or surgery support and physiological process;

c) Life support or sustainment;

d) Kiểm soát sự thụ thai Conception control;

dd) Sterilization of medical equipment (not including chemicals and insecticides and disinfectants for domestic and medical use);

e) Use for medical equipment;

g) Special transport for medical activities.

2. In-vitro diagnostic chemical includes the reagent, diagnostic chemical, cleaning solution used for medical equipment (in-vitro diagnostic biologicals excluded)

3. Manufacturer is the unit carries out the design, production, assembly, packaging and labeling the medical equipment before provided.

4. Distributor is any organization or individual in foreign countries authorized by the owner to distribute n the medical equipment.

5. Medical equipment owner (hereafter referred to as owner) is any organization or individual directly implementing or permitting other organizations or individuals to use his/her name to provide the medical equipment in his/her own name or any label, design, commercial name or other names or other codes under the ownership or control of such organizations or individuals and shall take responsibility for the design, production, assembly, label, packaging, or maintenance, repair of medical equipment or define a purpose of use for such medical equipment.

Article 3. Principles for issue of import Permit

1. The issue of medical equipment import Permit only applies to the imported medical equipment included in the List specified in Annex 1 issued with this Circular.

2. The medical equipment not included in the List specified in Annex 1 issued with this Circular shall be imported without the import Permit but must still ensure the dossier to trace their origin and quality management of medical equipment as prescribed by law.

Chapter II

AUTHORITY, DOSSIER AND PROCEDURE FOR NEW ISSUE, RENEWAL, MODIFICATION, RE-ISSUE AND REVOCATION OF MEDICAL EQUIPMENT IMPORT PERMIT

Article 4. Authority of new issue, renewal, modification, re-issue and revocation of medical equipment import Permit

The Minister of Health shall decide the new issue, renewal, modification, re-issue and revocation of medical equipment import Permit

Article 5. Forms of issue of medical equipment import Permit

1. The new issue of medical equipment import Permit is applied in case such medical equipment is requested for issue of medical equipment import Permit for the first time or the medical equipment import Permit has expired without renewal as stipulated in Clause 1, Article 13 of this Circular.

2. The renewal of medical equipment import Permit is applied in case the medical equipment has been issued with the import Permit.

3. The modification of content of import Permit is applied to the cases where the import Permit is still valid but its content has changes. The duration of import Permit must not be modified.

4. The re-issue of medical equipment import Permit is applied where the import Permit is still valid but it is lost or damaged.

Article 6. Dossier for new issue of medical equipment import Permit

1. The written request for new issue of medical equipment import Permit of the organizations or individuals is under the Form No.01 specified in Annex 2 issued with this Circular.

2. Valid Certificate of free sale of types of imported medical equipment at the time of submission of dossier.

3. The valid ISO 13485 or ISO 9001 quality systems certification (hereafter referred to as ISO Certification) of the manufacturer at the time of dossier submission.

4. The valid Letter of authorization from medical equipment owner to organizations or individuals importing the medical equipment under the Form specified in Annex III issued with this Circular (hereafter referred to as Letter of authorization) at the time of dossier submission.

5. The technical material describing the types of medical equipment in Vietnamese language under the Form No. IV issued with this Circular.

6. Catalogue describing the functions and technical parameters of types of imported medical equipment.

7. The clinical assessment material and manual of owner or manufacturer for the medical equipment specified in section 49 of Annex I issued with this Circular.

8. Report on result of import of medical equipment by the time of dossier submission for new issue of medical equipment import Permit in case where the import Permit has expired without renewal as stipulated in Clause 2, Article 5 of this Circular. The report on result of import of medical equipment is under the Form specified in Annex 6 issued with this Circular.

Article 7. Dossier for renewal of medical equipment import Permit

1. The written request for renewal of medical equipment import Permit from the organizations or individuals is under the Form 02 specified in Annex 2 issued with this Circular.

2. The valid Certificate of free sale of types of imported medical equipment at the time of dossier submission.

3. The valid ISO certification of the medical equipment manufacturer at the time of dossier submission.

4. The valid letter of authorization at the time of dossier submission.

5. The report on result of import of medical equipment by the time of dossier submission for renewal of medical equipment import Permit is under the Form specified in Annex 6 issued with this Circular.

Article 8. Dossier for modification of medical equipment import Permit

1. The dossier for modification from the manufacturing firm or country of medical equipment:

a) The written request for modification of import Permit from organizations or individuals importing the medical equipment is under the Form 03 specified in Annex II issued with this Circular;

b) The valid Certificate of free sale for types of medical equipment with the added contents for modification from the manufacturing firm or country of medical equipment at the time of dossier submission;

c) The valid ISO Certification from manufacturing firm or country of medical equipment.

2. The dossier for modification of name of importing organizations or individuals or name of imported medical equipment.

a) The written request for modification of import Permit from the organizations or individuals importing the medical equipment is under the Form 03 specified in Annex 2 issued with this Circular.

b) The technical materials describing the type of imported medical equipment in Vietnamese is under the Form specified in Annex 4 issued with this Circular and the Catalogue describing the functions and technical parameters of the type of imported medical equipment in case of modification of name of medical equipment.

Article 9. Dossier for re-issue of medical equipment import Permit

The dossier for re-issue of medical equipment import Permit in case of loss or damage: The written request for re-issue of import Permit from the organizations or individuals importing the medical equipment is under the Form No. 04 specified in Annex 02 issued with this Circular.

Article 10. Requirements for papers in dossier for new issue, re-issue, renewal and modification of medical equipment import Permit

1. The dossier for new issue, re-issue, renewal and modification of import Permit (hereafter referred to as the import dossier) is made into 01 set as follows:

a) The documents in the import dossier is clearly printed and arranged in the order specified in Articles 6, 7, 8 and 9 of this Circular with separation between documents, cover page and list of documents.

b) The import dossier including various types must have all technical materials describing the types and catalogue of each type of imported medical equipment.

2. Requirements for Certificate of free sale in the import dossier:

a) Submission of original or certified copy or copy with seal of the organization requesting the import or copy with signature of individual requesting the import. In case of submission of copy of Certificate of free sale with the seal of organization requesting the import or signature of individual requesting the import, there must be an original presented for comparison.

b) Where the Certificate of free sale is issued by the foreign body, before submission as stipulated under Point a of this Clause, the following requirements must be met:

- If the language used in the Certificate of free sale is not English or Vietnamese, it must be translated into Vietnamese;

- Consularly legalized under the provisions of Decree No. 111/2011/ND-CP dated 02/12/2011 of the Government on consular certification and consular legalization (hereafter referred to as

Decree No. 111/2011/ND-CP) except that the Certificate of free sale is issued by the competent body of the countries signing the Agreement on mutual legal assistance with Vietnam.

c) Where the Certificate of free sale of the types of imported medical equipment has no indication of time limit for expiration, it must be the original issued within 24 months from the date of issue.

3. Requirements for ISO certification in the import dossier:

Submission of original or certified copy or copy with seal of the organization requesting the import or copy with signature of individual requesting the import. In case of submission of copy with the seal of organization requesting the import or the copy with signature of individual requesting the import, provide the additional information related to the ISO Certificate of the organization issuing the ISO Certificate for comparison.

4. Requirements for letter of authorization:

a) Submission of original or certified copy or copy with seal of the organization requesting the import or the copy with signature of individual requesting the import. In case of submission of copy letter of authorization with the seal of organization requesting the import or signature of individual requesting the import, there must be the original presented for comparison.

b) Where the letter of authorization issued by the foreign body, before submission as stipulated under Point a of this Clause, the following requirements must be met:

- If the language used in the letter of authorization is not English or Vietnamese, it must be translated into Vietnamese;

- Consularly legalized under the provisions of Decree No. 111/2011/ND-CP except that the Certificate of free sale is issued by the competent body of the countries signing the Agreement on mutual legal assistance with Vietnam.

5. For the Catalogue describing the functions and technical parameters of types of imported medical equipment:

Submission of original or certified copy or copy with seal of the organization requesting the import or the copy with signature of individual requesting the import. In case of submission of copy with the seal of organization requesting the import or signature of individual requesting the import, there must be the original presented for comparison.

Article 11. Receipt of dossier for new issue, renewal or re-issue of import Certificate

1. The organizations or individuals requesting the new issue, renewal or re-issue of import Certificate (hereafter referred to as the importing unit) shall submit their dossier at the Ministry of Health (Department of Medical Equipment and Health Facilities).

2. After receiving the dossier, the Ministry of Health shall issue the importing unit the Receipt of dossier. The time to receive the dossier for issue of medical equipment import Permit is from the date indicated on the seal of receipt of incoming official letters of the Ministry of Health.

Article 12. Procedure for new issue of import Certificate

1. Within 05 working days from the date indicated in the Receipt, the Ministry of Health shall review the completeness and validity of dossier for new issue of import Permit.

2. In case the dossier is complete and valid, the Ministry of Health shall hold a meeting of its consultation Council for issue of medical equipment import Permit (hereafter referred to as the consultation Council) for review and opinions to the dossier for new issue of import Permit within 10 working days from the date indicated in the Receipt.

a) Where the consultation Council has no requirement for modification or addition of import dossier and agrees to issue the import Permit, the Ministry of Health shall issue the new import Permit within 10 working days from the date of minutes of meeting of consultation Council. The date of minutes is the date of meeting of Council.

Based on the such minutes, the Minister of Health shall consider and decide the issue of medical equipment import Permit and reply in writing in case of disapproval for issue.

b) Where the consultation Council requires modification or addition of dossier:

- Within 05 working days from the date of minutes of consultation Council, the Ministry of Health must give a written notice to the importing unit for modification or addition of importing dossier. The written notice should specify which document needs addition or modified contents. The notice of dossier completion is done only one time except for the case of contents which the Ministry of Health has given the notice of completion but the unit requesting import has failed to complete them or improperly as required by the Ministry of Health.

- When receiving the written requirement for modification or addition of import dossier, the importing unit must modify or add it in accordance with the contents specified in the written requirement and send such dossier to the Ministry of Health. The date of receipt of modified or added dossier is specified on the seal of receipt of incoming official letters of the Ministry of Health and shall be processed as stipulated in Clause 1 and Point a, Clause 2 of this Article.

- Where the importing unit has modified or added the import dossier but improperly with the requirement, the Ministry of Health shall notify the importing unit for further completion of importing dossier as stipulated in Clause 1 and 2 of this Article.

- In case of requirement for modification or addition of import dossier but after sixty (60) days after the Ministry of Health gives a written notice of modification or addition of import dossier but the importing unit fails to comply with such requirement, the Ministry of Health shall refuse to further review such dossier.

3. In case of incompletion or invalidity:

a) Within 10 working days from the date recorded on the Receipt, the Ministry of Health shall give a written notice to the importing unit for modification or addition of import dossier. The written notice must specify which document or content needs modification. The notice of dossier completion is done only one time except for the case of contents which the Ministry of Health has given the notice of completion but the unit requesting import has failed to complete them or improperly as required by the Ministry of Health.

b) When receiving the written requirement for modification or addition of importing dossier, the importing unit must carry out the modification or addition in accordance with the contents specified in the written requirement and send the modified or added dossier to the Ministry of Health. The date of receipt of modified or added dossier is specified on the seal of receipt of incoming official letters of the Ministry of Health

c) Where the importing unit has modified or added the import dossier but improperly with the requirement, the Ministry of Health shall inform the importing unit to further complete the import dossier in accordance with the provisions under Point a of this Clause;

d) If there is no more requirement for modification or addition of import dossier, the Ministry of Health shall issue the new import Permit in accordance with the provisions under Point a, Clause 2 of this Article.

4. In case of requirement for modification or addition of import dossier but after sixty (60) days after the Ministry of Health gives a written notice of modification or addition of import dossier but the importing unit fails to comply with such requirement, the Ministry of Health shall refuse to further review such dossier.

Article 13. Procedures for renewal or modification of import Permit

1. The time limit for submission of dossier for renewal or modification of import Permit:

a) The dossier for renewal and modification of import Permit must be submitted to the Ministry of Health at least 15 working days before its expiration. The time to submit the dossier is from the date of submission recorded on the Receipt;

b) After the time limit specified under Point a of this Clause, if wishing to be issued with the import Permit, the importing unit must request the issue of new import Permit.

2. Within 05 working days from the date recorded on the Receipt, the Ministry of Health shall review the completion or validity of dossier for renewal or modification of import Permit.

3. Where the dossier is complete and valid, the Ministry of Health shall renew or modify the import Permit within 10 working days from the date recorded on the Receipt.

4. Where the dossier is not complete and valid: Comply with the provisions in Clause 3, Article 11 of this Circular.

5. In case of requirement for modification or addition of import dossier but after sixty (60) days after the Ministry of Health gives a written notice of modification or addition of import dossier but the importing unit fails to comply with such requirement, the Ministry of Health shall refuse to further review such dossier.

Article 14. Procedure for re-issue of import Permit

Within 05 working days from the date recorded on the Receipt, the Ministry of Health shall re-issue the import Permit.

Article 15. Consultation Council for issue of medical equipment import Permit

1. The consultation Council for issue of medical equipment import Permit is established under the decision of the Ministry of Health is responsible for:

a) Giving advice to the Minister of Health of the technical professional issues related to the imported medical equipment;

b) Reviewing and giving opinions about the dossier for issue of medical equipment import Permit before submission to the Minister of Health for decision.

2. Providing assistance to the consultation Council is the secretary Group including the specialists of Department of Medical Equipment and Health Facilities.

Article 16. Validity of medical equipment import Permit

The validity of medical equipment import Permit is until the validity of the letter of authorization and up to 01 year from the date of signature and issue.

Article 17. Fees for new issue, renewal, modification and re-issue of medical equipment import Permit

The unit importing the medical equipment shall pay the fees for new issue, renewal, modification and re-issue of import Permit at the Ministry of Health as prescribed by law on fees and charges.

Article 18. Revocation of medical equipment import Permit

1. The cases of revocation of medical equipment import Permit:

a) The importing unit forges the dossier for issue of medical equipment import Permit;

b) Organizations or individuals modifies or erases for change of content of medical equipment import Permit;

c) The importing unit has terminated its operation or no longer authorized by the owner or medical equipment manufacturer without transfer of import right to the replacing organization;

d) The medical equipment circulated in the market has defects causing adverse effect to the health of users with impossible remedy.

dd) The medical equipment import Permit has been issued beyond the authority or with improper dossier or procedure as prescribed by this Circular.

e) The medical equipment whose circulation duration is over according to the notice of the manufacturer or owner of medical equipment or competent authorities.

2. The procedures for revocation of medical equipment import Permit

a) During the examination or inspection, if detecting any breach specified in Clause 1 of this Article, the unit performing the examination or inspection shall make a record and send it to the Ministry of Health;

b) Within 05 working days after receiving the record specified under Point a of this Clause, the Ministry shall review and decide the revocation of medical equipment import Permit. The revocation Decision is posted on the website of the Ministry of Health and sent to the customs authorities and organizations or individuals responsible for import.

3. After having the revocation Decision of medical equipment import Permit, the importing unit shall revoke the imported medical equipment specified in the revocation Decision and stop the import of such equipment.

Chapter III

IMPLEMENTATION PROVISION

Article 19. Effect

1. This Circular takes effect from 30/11/2015.

2. The Circular No. 24/2011/TT-BYT dated 21/06/2011 of the Minister of Health guiding the import of medical equipment shall be invalidated from the effective date of this Circular.

Article 20. Transitional provision

1. In case the documents referred to in this Circular are modified, added or superseded or annulled, such documents shall apply.

2. The medical equipment import Permits issued under the Circular No. 24/2011/TT-BYT dated 21/06/2011 of the Minister of Health guiding the import of medical equipment are still used until the end of validity recorded in the Permit.

3. For the medical equipment not included in the List specified in Annex 01 issued with this Circular have been issued with the import Permit, it shall be imported without the import Permit from the effective date of this Circular.

Article 21. Implementation responsibility

Director of Department of Medical Equipment and Health Facilities, Chief of ministerial Office, Chief of ministerial Inspector, Director General of Departments or General Departments under the Ministry of Health; Director of Departments of Health and other relevant organizations or individuals are liable to execute this Circular.

Any problem arising during the implementation of this Circular should be reported to the Ministry of Health (Department of Medical Equipment and Health Facilities) for review and settlement./.

FOR THE MINISTER
DEPUTY MINISTER

Nguyen Viet Tien

ANNEX 1

LIST OF MEDICAL EQUIPMENT WITH REQUIRED IMPORT PERMIT
(Issued with Circular No. 30/2015/TT-BYT dated 12/10/2015 of the Minister of Health Issued with Circular No. 30/2015/TT-BYT dated 12/10/2015 of the Minister of Health)

No.	Product description	Code
Diagnostic equipment		
1.	X-ray imaging diagnostic equipment	9022.12.00 9022.13.00 9022.14.00
2.	Magnetic resonance system	9018.13.00
3.	Ultrasonic diagnostic scanner	9018.12.00
4.	Endoscopic diagnostic system	9018.19.00
5.	Cyclotron System	9022.90.90

6.	Diagnostic equipment with radioactive isotopes (PET, PET / CT, SPECT, SPECT / CT system, iodine concentration equipment I^{130}, I^{131})	9022.12.00
7.	Automatic refractometer	9018.50.00
8.	Electrophysiology machine (EEG machine, ECG machine, electro-mechanical machine)	9018.11.00 9018.19.00
9.	Retinal power meter	9018.50.00
10.	Oosteoporosis meter	9018.12.00 9022.14.00
11.	Retinal scanners / fundus fluorescence scanner	9018.50.00
12.	Ultrasonic fetal heart detector	9018.12.00
13.	Respiratory function meter/analyzer	9018.19.00
14.	Biochemical analyzer	9027.80.30
15.	Electrolyte and blood gas analyzer	9027.80.30
16.	Hematology analyzer	9027.80.30
17.	Coagulation meter	9027.80.30
18.	Erythrocyte sedimentation rate meter	9027.80.30
19.	Elisa Elisa test system	9027.80.30
20.	Blood group analyzer	9027.80.30
21.	Cell extraction unit	9027.80.30
22.	Platelet aggregation and functional analysis meter	9027.80.30
23.	Bacteria and virus identifier	9027.80.30
24.	Immunological analyzer	9027.80.30
25.	Reagents, diagnostic chemicals, cleaning solution used for medical equipment	3006.20.00 3822.00.10 3822.00.20 3822.00.90
Treatment equipment		
26.	X-ray treatment equipment	9022.14.00
27.	Endoscopic surgery system	9018.90.90
28.	Radiotherapy equipment (Cobalt machine for cancer treatment cobalt, linear accelerators for cancer treatment, gamma scalpel of various kinds, brachytherapy equipment of various kinds	9022.21.00
29.	Patient monitor	9018.19.00
30.	Infusion pump, electric injection pump	9018.31.90
31.	Scalpel (high-frequency, laser, ultrasound)	9018.90.30
32.	Surgical microscopes	9011.80.00
33.	Equipment system for prostate surgery	9018.90.30
34.	Cardiopulmonary bypass machine	9018.90.30

35.	Positioning equipment in surgery	9018.90.30
36.	Cryosurgery equipment	9018.90.30
37.	Infant incubator, infant heater	9018.90.30
38.	Anesthesia machine/with ventilator	9018.90.30
39.	Ventilator	9019.20.00
40.	Cardiac defibrillators, pacemaker	9018.90.30
41.	High-pressure oxygen chamber	9019.20.00
42.	Extracorporeal lithotripsy system/endoscopic lithotripsy	9018.90.30
43.	High-intensity ultrasound equipment system for tumour treatment	9018.12.00
44.	Dialysis equipment	9018.90.30
45.	Ophthalmologic surgery system (Excimer Laser, Femtosecond Laser, Phaco, vitreous cutter, corneal flap microkeratome)	9018.50.00
46.	Eyeglasses, contact lenses (near-sighted, far-sighted, astigmatism) and preservative solution of contact lenses	9004.90.10
47.	Laser treatment machine used in ophthalmology	9018.50.00
48.	Types of permanent implant equipment and material (over 30 days) in the body	90.21 3006.40 3006.10
49.	Types of interventional equipment and material in the body of cardiological and cranial nerve specialty	90.21

In case of dispute related to the application of HS code in the list, the Ministry of Health and Ministry of Finance (General Department of Customs) shall consider and agree on the code.

***Note**: Annually, the Ministry of Health (Department of Medical Equipment and Health Facilities) shall review, modify, add and update the List of Annex 01 to create favorable conditions for the importing units and in accordance with the reality in management of import of medical equipment.*

ANNEX II

FORM OF APPLICATION FOR ISSUE OF MEDICAL EQUIPMENT IMPORT PERMIT
(Issued with Circular No. 30/2015/TT-BYT dated 12/10/2015 of the Minister of Health)

Form No.01 – Application for new issue of medical equipment import Permit

Form No.02 – Application for renewal of medical equipment import Permit

Form No.03 – Application for modification of medical equipment import Permit

Form No.04 – Application for re-issue of medical equipment import Permit

Form No.01 – Application for new issue of medical equipment import permit

Name of importing unit

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: ……./…….(*) *(**)……., date ..... month.... year.....*

Application for new issue of medical equipment import Permit

To: the Ministry of Health (Department of Medical Equipment and Health Facilities)

Importing unit Importing unit:

Address:

Tax code:

Tel: Fax:

Legitimate representative Legitimate representative:

Contact Tel: Mobile phone:

Officer in charge of importing activities:

Contact Tel: Mobile phone:

Request the issue of medical equipment import Permit according to the following list:

No.	**Name of medical equipment**	**Model**	**Firm/country of manufacture**	**Firm/country of owner**	**Distributing firm/country** *(if any)*	**Year of manufacture**

1. Import purpose:

2. Duration of Certificate of free sale:

3. ISO Duration of ISO Certificate:

4. Duration of Letter of authorization:

5. Commitment of the importing unit:

- Takes responsibility to guarantee the quality, type and amount of imported medical equipment in accordance with the contents of application. The medical equipment is 100% brand new.

- Takes responsibility to warrant the medical equipment and provide chemicals, materials and replacement components during utilization.

- Meets the requirements and conditions about the contingent of officials responsible for techniques and ensures the efficiency and safety of medical equipment for the users and environment, ensures the conditions about facilities and means of transport without effect on quality of imported equipment; ensures the requirements for label of goods and equipment in accordance with regulations.

- Ensures the use of imported medical equipment in accordance with the contents of application and accept the inspection and examination of competent authorities

We shall take full responsibility before law for breach of above commitment.

Importing unit
(Signature, full name and seal)

(*)Abbreviated symbol of the importing unit

(**)Name of province/city where the importing unit's head office is located.

Form No.02 – Application for renewal of medical equipment import Permit

Name of importing unit **-------**	**SOCIALIST REPUBLIC OF VIETNAM** **Independence - Freedom - Happiness** **----------**
No.: ……./…….(*)	*(**)……., date ..... month.... year.....*

Application for renewal of medical equipment import Permit

To: Ministry of Health (Department of Medical Equipment and Health Facilities)

Importing unit:

Address:

Tax code:

Tel: Fax:

Legitimate representative Legitimate representative:

Contact Tel: Mobile phone:

Officer in charge of importing activities Officer in charge of importing activities:

Contact Tel: Mobile phone:

Request the renewal of medical equipment import Permit according to the following list:

No.	**Name of medical equipment**	**Model**	**Firm/country of manufacture**	**Firm/country of owner**	**Distributing firm/country** *(if any)*	**Year of manufacture**

1. Issued import Permit No……dated……..

2. Duration of Certificate of free sale:

3. Duration of ISO Certificate:

4. Duration of Letter of Authorization:

5. Reasons for renewal:

6. Attached documents:.....

We undertake to fully and properly comply with regulations of law of the State and the Ministry of Health on import of medical equipment and shall take full responsibility before law for any breach.

Importing unit
(Signature, full name and seal)

(*) Abbreviated symbol of the importing unit

(**) Name of province/city where the importing unit's head office is located

Form No.03 – Application for modification of medical equipment import Permit

Name of importing unit

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: ……./…….(*)

(**)……., date ..... month.... year.....

Application for modification of medical equipment import Permit

To: Ministry of Health (Department of Medical Equipment and Health Facilities)

Importing unit:

Address:

Tax code:

Tel: Fax:

Legitimate representative:

Contact Tel: Mobile phone:

Officer in charge of importing activities:

Contact Tel: Mobile phone:

Request the modification of medical equipment import Permit according to the following list:

No.	**Name of medical equipment**	**Model**	**Firm/country of manufacture**	**Firm/country of owner**	**Distributing firm/country** *(if any)*	**Year of manufacture**

1. Issued import Permit No……dated……..
2. Duration of Certificate of free sale:
3. Duration of ISO Certificate:
4. Duration of Letter of Authorization:
5. Reasons for modification:
6. Attached document:.....

I/we undertake to fully and properly comply with regulations of law of the State and the Ministry of Health on import of medical equipment and shall take full responsibility before law for any breach.

Importing unit
(Signature, full name and seal)

(*) Abbreviated symbol of the importing unit

(**) Name of province/city where the importing unit's head office is located

Form No.04 – Application for re-issue of medical equipment import Permit

Name of importing unit

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: ……./…….(*)

(**)……., date ..... month.... year.....

Application for re-issue of medical equipment import Permit

To: Ministry of Health (Department of Medical Equipment and Health Facilities)

Importing unit:

Address:

Tax code:

Tel: Fax:

Legitimate representative:

Contact Tel: Mobile phone:

Officer in charge of importing activities:

Contact Tel: Mobile phone:

Request the re-issue of medical equipment import Permit according to the following list:

No.	**Name of medical equipment**	**Model**	**Firm/country of manufacture**	**Firm/country of owner**	**Distributing firm/country** *(if any)*	**Year of manufacture**

1. Issued import Permit: No……dated....

2. Reasons for re-issue of Permit: .....

3. Attached document: .....

I/we undertake to fully and properly comply with regulations of law of the State and the Ministry of Health on import of medical equipment and shall take full responsibility before law for any breach.

Importing unit
(Signature, full name and seal)

(*) Abbreviated symbol of the importing unit

(**) Name of province/city where the importing unit's head office is located

ANNEX III

FORM OF LETTER OF AUTHORIZATION
(Issued with Circular No. 30/2015/TT-BYT dated 12/10/2015 of the Minister of Health)

To be printed on company letterhead of the product owner (name, address)

Date…….

LETTER OF AUTHORISATION

To: Ministry of Health (Department of Medical Equipment and Health Facilities)

We, *(Name and address of product owner)*, as the legal manufacturer *(product owner)* do hereby authorize *(Name and address of the importer)* to import the following medical equipment:

(Products list: name of medical equipment)

We commit to provide and support all information concerning product information, product quality upon request from the Vietnam Ministry of Health (Department of Medical Equipment and Health Facilities) for the medical equipment mentioned above.

This authorization letter is valid until: …… date (dd/mm/yy)

Legitimate representative of legal manufacturer (product owner)

Signature

(Full name and title)

ANNEX IV

FORM OF TECHNICAL MATERIAL DESCRIBING TYPE OF IMPOTED MEDICAL EQUIPMENT
(Issued with Circular No. 30/2015/TT-BYT dated 12/10/2015 of the Minister of Health)

Name of importing unit	**SOCIALIST REPUBLIC OF VIETNAM**
-------	**Independence - Freedom - Happiness**

No.: ……./…….(*)	*(**)……., date ..... month.... year.....*

TECHNICAL MATERIAL DESCRIBING TYPE OF IMPOTED MEDICAL EQUIPMENT

No.	Item	Brief description
1	**Describing type of impoted medical equipment**	
1.1	Description of medical equipment	Brief description of operating principles and features, technical parameters of the equipment; indicate if the equipment has the new technologies, eg nanotechnology, provide a description of such new technologies
1.2	List of components and accessories (including the accompanying chemical)	List all components and accessories; for equipment using chemicals, special-use reagents, list the name of such special-use chemicals and reagents
1.3	Purpose/use indication as specified on the group	Indicate the estimated purpose/use indication specified on the label of imported equipment
1.4	Use instructions	Brief instructions on usage of equipment as indicated in the Manual or information sheet of imported equipment.
1.5	Contraindication	Information about contraindication – that means the cases of prohibited use of equipment for reason of patient's safety, ex: medical history, patient's physiological characteristics, etc; in accordance with the contents approved in the country of manufacture and specified on label of imported equipment.
1.6	Warning and caution	The warning information and the points of caution upon use of equipment, including the preventive measures to protect patients to avoid risks from use of such equipment. It may be the warning information about adverse effect or wrong use and preventive measures.
1.7	Impossible adverse effect	Information about adverse effect related to the use of medical equipment is recorded through clinical test and post-sale follow-up done before for the imported medical equipment.
2	**Information about products circulated in the countries (if any)** Provide information about the countries approving and permitting the product circulation, the first country issuing the registration/permission for circulation of medical equipment.	
3	**Indication registered in other countries (if any)** List the countries issuing the circulation registration with the indication of use approved in such countries; date of issue of registration.	
4	**Information about the notable safety/operation of medical equipment products** - *(Provide information about the number of report on adverse effect related to the use of equipment; measures to recall/modify after sale done as required by the management bodies of countries).* *(If the equipment contains one of the following components, provide information about:* ● *Cell, animal or human tissue or their derivatives used as not alive - for example artificial heart valve from pig, catgut…;*	

	● *Cells, tissues and or derivatives from micro-organisms or recombinant - eg skin inflation products based on hyaluronic acid obtained from bacterial fermentation process ...; There are irritant or ionized ingredients - eg X-ray; or non-ionizing - ag laser, ultrasound ...*

Importing unit
(Signature, full name and seal)

(*) Abbreviated symbol of the importing unit

(**) Name of province/city where the importing unit's head office is located

ANNEX V

FORM OF MEDICAL EQUIPMENT PERMIT
(Issued with Circular No. 30/2015/TT-BYT dated 12/10/2015 of the Minister of Health)

MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: /BYT-TB-CT
Subject: Issue of medical equipment import Permit

Hanoi, date .. month .. year 201…

To: Importing unit……

Based on Circular No…...../2015/TT-BYT dated…….of the Ministry of Health stipulating the import of medical equipment.

Considering the contents requested in the Official Letter…..dated……from the importing unit on import of medical equipment, the Ministry of Health held a meeting for verification of import dossier and approval for issue of import Permit of medical equipment (100% brand new) based the following list:

No.	**Name of medical equipment**	**Model**	**Country of manufacture**	**Firm/country of owner**	**Distributing firm/country** *(if any)*

The importing unit…….is required to comply with the current regulations on import of medical equipment and goods labeling and must take responsibility for the amount, price and quality of imported medical equipment as prescribed by law.

This import Permit is valid until date…month….year….

POSITION OF SIGNER
Signature, full name and seal)

ANNEX VI

FORM OF REPORT ON IMPORT OF MEDICAL EQUIPMENT

(Issued with Circular No. 30/2015/TT-BYT dated 12/10/2015 of the Minister of Health)

Name of importing unit

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No.: ……./…….(*)

(**)……., date ..... month.... year.....

REPORT ON IMPORT OF MEDICAL EQUIPMENT

To: Ministry of Health (Department of Medical Equipment and Health Facilities)

Importing unit:

Address:

Tax code:

Tel: Fax:

Legitimate representative:

Contact Tel: Mobile phone:

Officer in charge of importing activities:

Contact Tel: Mobile phone:

Importing unit..... makes report on importing activities of medical equipment as follows:

No.	Name of medical equipment	Model	Amount	Firm/country of manufacture	Firm/country of owner	Distributing firm/country *(if any)*	Year of manufacture	Official letter of issuing import Permit of the Ministry of Health
1								
2								
…	…							

Importing unit
(Signature, full name and seal)

(*) Abbreviated symbol of the importing unit

(**) Name of province/city where the importing unit's head office is located