MINISTRY OF HEALTH
No. 24/2011/TT-BYT

SOCIAL REPUBLIC OF VIETNAM
*Independence - Freedom - Happiness*

*Hanoi, 21 June 2011*

# CIRCULAR

## Guiding the import of medical device

Pursuant to the Commercial Law dated 14 June 2005;

Pursuant to the Law on Quality of Products and Goods dated 21 November 2007;

Pursuant to the Government's Decree No. 12/2006/ND-CP of 23 January 2006 detailing the implementation of the Commercial Law regarding activities of international goods trading and activities of goods sale and purchase agency, processing and transit with foreign countries;

Pursuant to the Government's Decree No. 89/2006/ND-CP dated 30 August 2006 on labeling of goods;

Pursuant to the Government's Decree No. 188/2007/ND-CP dated 27 December 2007 defining the functions, tasks, powers and organizational structure of Ministry of Health;

Pursuant to the Decision No. 10/2010/QD-TTg of 10 February 2010 on certificates of free sale for exports and imports;

The Ministry of Health hereby guides the import of medical device as follows:

## I. GENERAL PROVISIONS

### Article 1. Regulation Scope

This Circular shall regulate the import of 100% new medical devices for circulation in Vietnam of Vietnamese traders and the related organizations and individuals (hereinafter called the importer).

### Article 2. Interpretation of terms

Medical device is types of equipment, devices, materials, chemicals, including necessary software which are used alone or in combination, for human for purpose of:

a) Prevent, monitor, diagnose, treat, alleviate disease or compensate for an injury.

b) Investigate, replace, modify and support for surgery during the medical examination and treatment;

c) Support and sustain life;

d) Control contraception;

đ) Disinfecting medical devices (excluding chemicals, insect and bacterium killing products for family uses and health);

e) Specialized transport for health activities;

## Chapter II
## PROVISIONS ON AUTHORITY AND PROCEDURES FOR GRANTING LICENSE OF IMPORT OF MEDICAL DEVICE

### Article 3. Provisions on import of medical device

1. Legal conditions:

It requires the business registration certificate or investment certificate which will set out the scope of business of trading and importing medical device.

2. Human resource conditions:

a) The officer who are mainly responsible for technical assistance shall meet one of the following requirements:

- Having Bachelor's degree in Biomedical Electronics, Biomedical Physics; or University degree in Technology, Medicine, Pharmacy, as well as attain certification on medical device issued by legal medical technology training facilities or equivalent training certificates issued by foreign countries in accordance with equipment that the enterprise shall ask to import.

- For the officers having university degree in Technology, Medicine, Pharmacy and gaining practical working experience directly related to technical medical device or managing medical device in legal facilities in more than three years and getting approved by manager of enterprise, it shall not be required to possess certification in medical device.

b) Having technical cadres and personnel capable of guiding the installation, warranty and maintenance of medical devices related to those imported by the enterprise.

3. Conditions of facilities

- Having warehouses and other facilities to store medical device, ensuring that the equipments shall be kept in proper conditions as to protect from the effects of light, temperature extremes, excessive humidity and other conditions.

- Having fire and explosion prevention and fighting equipment and maintain a safe and hygienic environment in accordance with the provisions of law

4. Labeling of the imported medical device:

It must be implemented in accordance with the regulations of the Government's Decree No. 89/2006/ND-CP dated 30 August 2006 on labeling of goods and Circular No. 09/2007/TT-BKHCN dated 6 April 2007 of Ministry of Science and Technology guiding the implementation of a number of articles of the Government's Decree No. 89/2006/ND-CP dated 30 August 2006 on labeling of goods and several related regulations.

### Article 4. Scope of issuing import license for medical device

1. The importer shall obtain an import license of Ministry of Health for import of medical devices in the list as stipulated in Appendix 1 enclosed the promulgation of this Circular.

2. Medical devices not listed in the Appendix 1 but used for application of new diagnosis and therapeutic methods and imported into Vietnam for the first time shall require an import license from the Ministry of Health.

3. The importer shall not get the import license of medical devices which are not included in the list as stipulated in Appendix 1, except the cases regulated in Item 2, Article 4 of this Circular; however, it is required to ensure the regulations at point b and c, Item 1, Article 5 of this Circular.

**Article 5. Dossier and procedures for import permit of medical device**

1. Dossier for import license of medical device (1 set) includes:

a) Application form for granting the import permit shall be signed and sealed by the managers who will be responsible before the law or legally authorized persons in accordance with the regulation form in Appendix 2 enclosed the promulgation of this Circular.

b) Legal Document:

Business registration certificate or investment certificate (certified true copy/ notarized)

c) Document for import of medical device

- Legitimate and valid ISO 13485 or ISO 9001 certification, the international recognized standard for quality management of the producing countries, firms to the imported medical device.
- Legitimate and valid Certificate of Free Sale (CFS) for imported medical device in the producing countries, or Certificate to Foreign Government of FDA, or CE Mark Certificate (original or certified copy in Vietnam or legalized by diplomatic representative offices or Embassy of the Socialist Republic of Vietnam in the producing countries). Minimum information in Certificate of free sale for imported medical devices shall be in accordance with Appendix 3 enclosed with the promulgation of this Circular.
- Legitimate and valid authorization letter of producing firms or legal distributors for the agencies which are allowed to import and distribute the medical devices in Vietnam (original or certified copy or legalized by diplomatic representative offices or Embassy of the Socialist Republic of Vietnam in the producing countries)
- The catalogue of imported medical device (original or copy certified by the import agencies)
- Technical description of medical devices in Vietnamese according to the Appendix 4 enclosed the promulgation of this Circular.

2. Dossier applying for the import of medical devices shall be arranged in the order as stipulated in Appendix 5 enclosed the promulgation of this Circular and must be constrained to a set of closure for each type of equipment and clearly addressed the name of importer and contact address in cover page. If a medical device is imported by different producing firms and countries, their products shall have enough documents and be arranged in the order as stipulated in the agency's request for issuance of the import license.

3. Procedures for requesting the issue of licenses for import of medical device

a) For importer whose medical device imported for the first time: They shall make the request for the issue of import license in accordance with the instruction in Item 1 and 2, Article 5 of this Circular. The document shall be sent to the Ministry of Health (Department of Medical Equipment & Construction) directly to the following address: No. 138A, Giang Vo, Ba Dinh, Hanoi

- For some medical devices not listed in the Appendix 1 but used for application of new diagnosis and therapeutic methods and imported into Vietnam for the first time: in addition to the conditions, the procedures of application for import permits specified in Item 1, Article 5 of this Circular, the equipment must be accompanied with results of clinical tests, and be appraised and permitted for import by the Scientific and Technological Council of Ministry of Health.

For some special medical device accepted by foreign organizations and recommended to use in countries, Ministry of Health shall consider the exemption of clinical trial basing on the conclusion of the Scientific and Technological Council of the Ministry of Health.

b) For importer whose medical device imported for the second time onward: (from the effective date of this Circular)

- The importer is not required to submit their legal document as stipulated at point b, Article 5 of this Circular
- If importing medical device of the same type, same producing firm and country as issued with an import license by the Ministry of Health, it is not required to submit the catalogue, the technical description of medical device as defined at point c, Item 1, Article 5 of this Circular.
- The importer shall submit the copy of the previous import license issued by the Ministry of Health.

**Article 6. Issuance of the import license for the medical device**

1. The Ministry of Health shall assess to issue the import license for the medical device listed in the Appendix 1 within 15 working days after receiving the adequate and regular document. In case the import license is not been issued, Ministry of Health (Department of Medical Equipment & Construction) will response the importing company in written including the reason.
2. Valid time of import license: The import license shall be valid for 01 ( one) year from the date of issue, promulgation.
3. Fees for issuing import license: The importer shall pay import fees in accordance with the current regulations and as stipulated in the Decision No. 44/2005/QD-BTC dated 12 July 2005 and Decision 59/2008/QD-BTC dated 21 July 2008 of the Ministry of Finance stipulating regime on collection, payment, management and use of the fees for appraising conditional business activities in the health care sector, fees for appraising standards and conditions for medical pharmaceutical practice, fees for granting export-import licenses and medical and pharmaceutical practice certificates.

## CHAPTER III
## HANDLING OF VIOLATIONS

**Article 7. Handling of violations**

1. In case the importer forges or edits the dossier, documents and legal papers of Vietnamese or foreign authorities; uses forged seal or forges a signature or seal of the importer and related ones in the dossier for importing medical device, the Ministry of Health (Department of Medical Equipment & Construction) shall send a written warning to the importer and stop receiving application and considering their import document, as following:

a) Stop receiving and assessing the importer's dossier for import of medical device within 03 months in the case of a first infraction;

b) Stop receiving and assessing the importer's dossier for import of medical device from 06 months to 12 months in the case of a second infraction within a 12 month period;

c) Depending on the level of violation, the Ministry of Health (Department of Medical Equipment & Construction) shall send the written notice to the importer and stop receiving, assessing the dossier for import of medical device.

Besides, the Ministry of Health (Department of Medical Equipment & Construction) shall declare the violation of the importer on the official website of the Ministry of Health; inform the inspection agency, customs agency and authorized agencies for consideration and handling in accordance with the law.

2. Depending on the level of violation, organizations and individuals shall be sanctioned administratively or be prosecuted for criminal responsibilities; shall compensate according to the law in case causing material damage.

## CHAPTER IV
## IMPLEMENTATION PROVISIONS

**Article 8. Execution responsibilities**

1. Department of Medical Equipment & Construction is a standing body of the Ministry of Health, taking responsibilities for receiving, and submitting to Advisory Council for Import License in medical device –Ministry of Health for assessment.

2. The inspectors of the Ministry of Health shall be responsible for cooperating with related departments and bureaus under the management of the Ministry of Health to implement the inspection of business activities and import of medical device nationwide.

3. The health department of provinces and cities under directly Central Government shall be responsible for implementing the inspection of business activities and import of medical device in the locality.

4. The importing companies shall be responsible for seriously implementing the regulations of the law and for type, quantity and quality of imported goods and for conducting notification, recall, and warning activities for unsafe, unfavorable products to the users and communities.

5. The importer shall periodically report once a year (before 30 January of each year) to the Ministry of Health (Department of Medical Equipment & Construction) on the import of medical device (name of devices, quantities, types, producing firms and countries,

units using the equipment, import value) in accordance with the regulations in Appendix 6 enclosed the promulgation of this Circular.

After the annual report time, the Advisory Council – Ministry of Health shall to assess and issue the medical device import license based on the report of the importing company for the next time.

In case of change of name, transaction address of the importer, leaders, technical managers, import managers…., the enterprises shall send a written report to the Ministry of Health (Department of Medical Equipment & Construction) after the time of change.

**Article 9. Validity**

This Circular shall be valid after 15 August 2011.

Repealing regulations concerning the import of medical device as stipulated in Circular No. 08/2006/TT-BYT dated 13 June 2006 of the Ministry of Health guiding the import of vaccines, medical biological products; chemicals, insecticides, sterilizers used in household and health fields and health equipment facilities and Circular No.09/2006/TT-BYT dated 11 July 2006 of the Ministry of Health on instructing the modification, addition of section IV, appendix 9 of the Circular No.08/2006/TT-BYT dated 13 June 2006 of the Ministry of Health on instructing the import of vaccines, health products, chemicals, insecticides, sterilizers used in household and health fields and health equipment facilities.

In the course of implementation, if any difficulties and problem arise, please promptly report to the Ministry of Health (Department of Medical Equipment & Construction) for consideration and handling./.

***To:***
- Office of the Government (Department of Science and Education, Gazette, Web Portal)
- Ministry of Justice (Legal Affairs Bureau);
- Ministries, Ministerial-level agency, Government agency;
- Ministry of Finance (Customs head office);
- Ministry of Industry and Trade (Export – Import Department);
- Minister of Health (for reporting);
- Vice-ministers of Health;
- Vietnam Medical Equipment Association;
- Vietnam medical equipment joint stock company;
- The health department of provinces and cities under directly Central Government;
- Units under the management of Health Ministry;
- Medical equipment importing enterprises;
- The web portal of Health Ministry;
- Archives: VT, TB-CT (03), PC (02)

**On behalf the Minister of Health**
**Vice-Minister**
**(signed)**

**Nguyen Thi Kim Tien**

**Appendix 1: List of medical devices (100% new) which is imported by import license of Ministry of Health**

*(issued together with Circular No.24/2011/TT-BYT dated 21/6/2011of Ministry of Health)*

| No. | Medical equipment name |
|---|---|
| **Diagnostics equipments** | |
| 1 | Assorted X-ray diagnosis system |
| 2 | Magnetic resonance imaging system of various kinds |
| 3 | ultrasonic diagnosis system |
| 4 | Endoscopic diagnosis system |
| 5 | Cyclotron system, |
| 6 | Radioisotope diagnostic equipment ( PET, PET/CT, SPECT, SPECT/CT system, thyroid uptake system) |
| 7 | Auto refracto-meter, keratometer |
| 8 | electro physiological measurement system(Electro-encephalographic, Electro-cardiographic apparatus, Electro-mechanical) |
| 9 | Electro-retompgraph |
| 10 | bone mineral density (BMD) measurement system |
| 11 | Optical Coherence Tomography OCT/ Fluorescent Fundus Camera |
| 12 | Ultrasound fetal doppler |
| 13 | Respiratory function metering and analyzing system |
| 14 | Biochemical testing apparatus |
| 15 | Electrolyte, Blood gas analyzer |
| 16 | Hematologic testing apparatus |
| 17 | Coagulation timer |
| 18 | erythrocyte sedimentation rate (ESR) meter |
| 19 | Elisa test system |
| 20 | Blood group analyzer |
| 21 | Cell separator |
| 22 | platelet aggregation & function analyzer |
| 23 | Bacteria and virus-identifying apparatus |
| 24 | Immune testing apparatus |
| **Treatment equipments** | |
| 25 | X-ray treatment system |
| 26 | Endoscope system |
| 27 | Radio-therapeutic apparatus (Cancer treatment Cobalt machine, Linear accelerator for cancer treatment with different energy intensity, Gammar operation knives, Close radio-therapeutic apparatus) |
| 28 | Patient monitors of various kinds |

| | |
|---|---|
| 29 | Infusion pump,<br>electronic syringe |
| 30 | Electronic scalpels, Laser scalpels, Ultrasonic scalpels |
| 31 | Surgical microscope |
| 32 | Assorted prostate treatment apparatus |
| 33 | Artifical heart-lung apparatus |
| 34 | Surgical navigation systems |
| 35 | Cryosurgical system |
| 36 | Infant warmer, hospital incubator |
| 37 | Marcotizers, Marcotizers-respirators |
| 38 | Breathing support apparatus |
| 39 | Cardiac fibrillation breakers and pacemakers |
| 40 | Hyperbaric oxygen Chamber |
| 41 | Lithotrity apparatus |
| 42 | High intensity focused ultrasound system in cancer treatment |
| 43 | Hemofiltration apparatus |
| 44 | Ophthalmic surgical system (laser excimer, Phemtosecond Laser, Phaco, Vitreoretinal surgery system) |
| 45 | Medical contact lense (myopia, hypermetropia, astigmatism) and its solution |
| 46 | Laser optic-treatment system |
| 47 | Implantable device (> 30 days) |
| 48 | Invasive device, instrument used in high intensity department: cardiovascular, neural, skull-brain |
| **Other equipments** | |
| 49 | medical gas system |
| 50 | assorted ambulances; specialized ambulance vehicles |

*Noted: This list in Appendix 1 is subject to be revised, added yearly by Ministry of Health (Department of Medical Equipment and Construction) in order to meet the practical status and suitable to the regulatory control on medical device importation.*

**Appendix 2: Application form for import permission of medical device**

*(issued together with Circular No. 24/2011/TT-BYT dated 21/6/2011 of Ministry of Health)*

Importer's name

Socialist Republic of Vietnam
Independence - Freedom - Happiness

No: .....

*..... ,date.....month.....year.....*

**Application form for import permission of medical device**

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

Name of enterprise that requests import:
Address:
Phone: Fax:
Director :
Phone: Mobile:
Officer in charge of import
Phone: Mobile:

Please allow us to import Medical device mentioned in the list below:

| No | Medical device 's name | Model | Manufacturer | Country of manufacturer | Year of production | Address to send the product to Vietnam |
|---|---|---|---|---|---|---|
| | | | | | | |

1. Purpose of importing:
2. Importer undertakes:

- Responsibilities for ensuring the quality, type and quantity of medical device imported in accordance with the application, medical device is 100% new.
- To meet the requirements, conditions in terms of the staff responsible for technical, efficiency and safety of medical device to users and the environment, ensure the condition of facilities and means of transport so as not to affect the quality of imported equipment. Ensure the requirements of trademarks of goods and equipment as prescribed.
- To ensure the use of imported medical device according to the application, to be subject to inspection and supervision of related authorities.

If we offense the above committed, we shall bear full responsibility before law.

**Director of the importer**

*(Sign, Sealed by)*

**Appendix 3: Minimum requirements for certificate of free sale (CFS) of imported medical device**

Certificate of free sale (CFS) for products of medical device are made on white paper, A4-sized, in English and include the following minimum information:

a)Name of organization issues CFS

b) Reference number of CFS

c)Issued date of CFS

d) Name of products or goods which is granted CFS

e)Kind/ catergory of products or goods which is granted in CFS

f) Name and address of manufacturer

g) Stating on the CFS that the products and goods manufactured and sold freely in the market of producing country.

h) Full name, signature and title of the person who granted CFS and seal of the issuing organization.

**Appendix 4: Technical description of the imported medical device**

*(issued together with Circular No. 24/2011/TT-BYT dated 21/6/2011 of the Ministry of Health)*

| No | Item | Brief description |
|---|---|---|
| 1 | **Description of the medical device** | |
| 1.1 | Description of medical device | Brief description of the principles of operation and features, specifications of medical device; indicate if the equipment uses new technologies, e.g : nano technology, then provide a description of the new technologies |
| 1.2 | The list of components and accessories (inc luding chemicals en closed) | List of components and accessories of the medical device; for facilities that use chemicals and reagents, list those chemicals, reagents. |
| 1.3 | Intended uses / Indications a s labeled | *Indicate intended purpose of using/* indications on label of imported medical device. |
| 1.4 | User Guide | Brief instructions to use the device according to written manuals or written information of imported medical device. |
| 1.5 | Contraindications | Information on contraindications - means the cases not to use the device because of safety for patients, for example, medical history, physical characteristics of the patient, etc ...; follow strictly the content approved in the producing country and on the label of imported medical device |
| 1.6 | Warning and caution | The warning information and caution in using medical device, including preventive measures to protect patients avoid the risks of using the medical device, which may be the warning information on the adverse effects or misuse and measures to prevent |
| 1.7 | Adverse effects may occur | Information about adverse effects related to the usage of medical device are recorded through clinical test and post-trade monitoring was done earlier for imported medical device |
| 2 | **Circulated information of product in countries** (if any) Provides information about the countries that approved for marketing of products, the first country to grant registration / permitting the circulation of medical device | |
| 3 | **Registered indications in other countries** (if any) List registered countries together with its approved indications for use in | |

| | |
|---|---|
| | those countries; date of issuance of registration |
| 4 | **Important safety / performance related information**<br>- Provide information about the reportable adverse events related to the use of medical device; recall/Field safety corrective actions conducted as per requirement of regulatory authorities in countries<br>- If medical device containing one of the following, a description of the following must be provided:<br>• Animal or human cells, tissues or derivatives thereof, rendered non-viable – e.g. porcine heart valves, catgut sutures, etc.<br>• Cells, tissues and/or derivatives of microbial or recombinant origin – for example dermal fillers based on hyaluronic acid derived from bacterial fermentation processes; irritating ingredients, ionizing - e.g.: X-rays, or non-ionizing - for example laser, ultrasound, etc |

**Appendix 5:**

**The order of filing dossier to applying permission for medical device import**

*(issued together with Circular No. 24/2011/TT-BYT dated 21/6 /2011 of Ministry of Health)*

1. An application for import licenses of medical device according to the form in Appendix 2 of the Circular.
2. Certificate of business registration or certificate of investment.
3. Dossier of imported medical device (in order for each category, companies, producing countries in the application of import licensing unit)
    a) Certificate of standards of international quality management ISO 13485 or ISO 9001 of producers, producing country of imported medical device
    b) Certificate of free sale for the imported medical device ;
    c) Letter of Authorization from manufacturers or legitimate distributors for the importer.
    d) The description of the product (Catalogue) of every type of imported medical device.
    đ) Technical description of the imported medical device in Vietnamese following form in Annex 4 of the Circular.
    e) The copy of Import license is granted by the Ministry of Health (if any).

**Appendix 6: The annual report sample for imported medical device**

*(issued together with Circular No. 24/2011/TT-BYT dated 21/ 6/2011 of the Ministry of Health)*

Importer's name

Socialist Republic of Vietnam
Independence - Freedom - Happiness

No: .....

*... ... .....,date.....month.....year.....*

**Annual Report for Imported Medical device**

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

Name of importer:

Address:

Phone: Fax:

Import unit... reported the importing of medical device in year of... as following:

| No | Medical device 's name | Model | Manufacturers/ producing country | Year of production | Date/month of import | Organization using the equipment | Imported Quantity | Value in VND | Import Licensing of the Ministry of Health |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | |
| 2 | | | | | | | | | |
| ... | ... | | | | | | | | |

**Director of the importer**

*(Sign, Sealed by)*