# 我國醫材業者赴新南向國家參加醫療相關展覽規定彙整表

| 國家別 | 查復情形 | 備註 |
| --- | --- | --- |
| 印度 | 1.《醫療器材管理規則》規定有關醫療器材進口到印度參展，需要依據產品的風險等級向中央或州政府申請許可，該法規授權醫療器材製造或進口業者自行定義其產品之風險等級，惟須遵循「印度藥物管控聯合委員會」(Drugs Controller General of India, DCGI) 所頒佈之分類標準。<br>2. 風險等級屬A(低)、B(低中)之醫療器材，主要由州級主管機關(State Licensing Authority)管理，而風險等級屬C(中高)、D(高)之醫療器材，則主要由中央主管機關(Central Licensing Authority)監控。<br>3. 業者依據印方核發許可(效期為30至60天)，向海關提出展示用之醫材產品攜入或貨運至印度參展，並在展場備查。 | |
| 印尼 | 印尼衛生部表示，醫療器材進口參展規定如下：<br>1. 醫療器材進口參展需先向該部醫療器材司申請推薦函，為報運進口時繳交給印尼海關之必要文件，惟此要求無明文規定。<br>2. 申請推薦函時，申請者需出具申請信函並附上聲明書及貨品說明書。聲明書應載明貨品係因參展用途報運進口；申請信函、聲明書及貨品說明書等並無制式格式，且無範例可提供參考。<br>3. 倘申請文件齊全，申請者約可在 2 週內收到推薦函，但不保證一定會獲得該部推薦函。 | 印尼衛生部官員僅先以口頭答復，駐印尼經濟組將另敘函請該部正式以書面回復確認 |
| 菲律賓 | 1. 菲律賓衛生部食品藥物管理局(FDA)設備管理、輻射、健康及研究中心表示，醫材業者倘參加菲國醫材相關展覽，需提交下列文件：<br>(1) 意向書敘明參加展覽之產品，以免除設備/產品註冊程序；<br>(2) 產品型錄影本；<br>(3) 每個產品需支付 510 披索；<br>(4) 展覽邀請信；<br>(5) 營業許可證。<br>2. 擬參展醫材業者需提供 PDF 檔案並存在 USB 隨身碟，交由菲國當地展覽業者轉交FDA 註冊，註冊程序為 1 個月。 | |

| | | |
|---|---|---|
| 越南 | 1. 依據越南政府 2016 年 5 月 15 日公布第 36/2016/ND-CP 號「有關醫療器材管理」議定(Decree)第 40 條規定，醫療器材之暫時進、出口或運輸須依相關法規規定辦理。<br>2. 依據越南政府 2015 年 1 月 21 日公布第 08/2015/ND-CP 號「有關執行海關法關務程序、檢查、監督及管制程序細則及指導」議定第 53 條第 1 項規定，為供展覽或產品發表會用途之產品暫時進、出口關務程序，報關人須檢附下列文件：<br>(1) 財政部簽發之報關單(正本)；<br>(2) 運輸文件(副本)；<br>(3) 主管機關所簽發之舉辦展覽同意書(副本)；<br>(4) 進口許可證，依相關法規專業檢查結果書面通知(正本)<br>3. 至於何種醫材產品須取得進口許可證，則需參考越南衛生部 2015 年 10 月 12 日公布第 30/2015/TT-BYT 號公告(Circular)附錄 1 之產品清單(詳如 ANNEX1)，附錄 2 為申請進口許可證需填寫之相關文件表格範本(詳如ANNEX2) | |
| 柬埔寨 | 醫材展品進入柬埔寨前需事先取得其主管機關柬國衛生部核給許可證方可進口，有關醫療產品進口至柬國之許可申請程序與必要文件說明如下：<br>1. 進口藥品與醫療產品需在柬埔寨衛生部登記，以作實驗室測試。<br>2. 醫療產品依風險程度分為 A、B、C、D 等 4 級：稍低風險、低風險、稍高風險、及高風險。<br>3. 產品登記所需文件包括申請書、GMP 或 ISO 證明、自由銷售證明、授權書、產品使用手冊等。<br>4. 產品風險程度為 B、C、D 等級之醫療產品，亦須檢附出口國登記證明、製造商分析報告以及技術文件等。<br>5. 產品登記程序通常需 3-6 個月時間，然而有時可能需長達 10 個月至 1 年時間，例如當衛生部所接受之申請案件太多時。<br>6. 產品登記證明有效期限為自簽發之日起 3 年，期限前 6 個月需再申請展延。 | 駐胡志明市經濟組未提供何屬 A、B、C、D 風險等級之說明資料 |
| 泰國 | 1. 泰國食品藥物管理局(FDA)並未明文規定醫材展品需事先取得核可始能參展。<br>2. 駐泰經濟組於 2017 年 9 月 6 日考察 2017 泰國醫材展時，參展之20 多家廠商皆表示，展出產品不需事先取得許可。 | |

| | | |
|---|---|---|
| 緬甸 | 1. 緬甸商務部貿易推廣機構(Myantrade)表示，倘僅供參展用途，需依據緬甸暫准通關措施辦理，即向商務部申請 Open General License 之進口許可，並向海關填寫敘明用途之通關文件及繳交保證金，該保證金於再出口時退還。<br>2. 上述許可證係由駐地邀展單位統一向商務部申請，並於申請表上填寫展品相關資訊。<br>3. 倘展品進口係為銷售目的，則需經由緬甸食藥署(FDA)核發推薦證明並申請進口許可。應備文件為我醫材之國際標準認證、廠商分析證書及產品相關資訊等。 | 駐緬經濟組表示，左列規定，緬甸均有明文規定，惟實務上亦有許台商未依規定而自行攜入方式參展，未來恐遭遇困難。 |
| 馬來西亞 | 1. 馬來西亞衛生部醫材管理局表示，依據 Medical Device (Exemption)Order 2016，自 2016 年 4 月 18 日起，僅用於展示用途之進口醫材產品，不須向該局註冊，惟須於展示前通知該局該等產品基本資訊。<br>2. 前述通知程序為製造商或馬國代理人/代理商/進口商填妥產品資料表(如附件)，併同產品包裝標籤或載有產品資料之促銷文宣(如宣傳手冊或目錄)送交該局，亦可由展覽主辦單位統一送交該局辦理。<br>3. 倘該局審查通過後，將會核發文件給參展業者，即可於該文件核發日起算 60 日內，將展示用之醫材產品攜入馬國參展。 | |
| 新加坡 | 1. 新加坡健康科學局(HSA)規定，倘參展產品在該國屬未註冊產品，須填寫申請表格(Form 32-A)向該局申請進口許可，並依進口方式不同須提供不同資料，說明如下：<br>(1) 倘以手提行李形式攜入，申請時需附上護照影本；倘選擇以海運進入，則無須提供護照影本。<br>(2) HAS 審理時間約 10 個工作天，獲 HSA 許可後，其展品即可於展覽期間展出。<br>(3) 參展期間，醫材產品須標示「僅供展示」，若展出產品具輻射功能，同時須依該國國家環境局(NEA)規範操作，無 NEA 許可不得啟動設備。<br>(4) 參展結束後，展出產品均需銷毀或攜出新加坡。<br>2. 檢附 HSA 規定如附件。 | |

FormMJ,)—5

[See sub-rule (4) of rule20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B Medical Device.

Licence Number:.....

1. Mis (Name and full address of manufacturer with telephone, fax and e-mail) has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at _____(address of manufacturing facility where the manufacturing will be carried out).
2. Details of medical device(s) [Annexed].

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: State Licensing Authority
Date: [To be signed digitally]

Annexure:

| S.N. | Generic name | Model No. | Intended use | Class of medical device | Material of constructi ση | Dimension (if any) | Shelf life | Sterile or Non sterile | Brand Name{if registered under the Trade Marks Act, 1999) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

FormMD-7

[See sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

Application for Grant of Licence to Manufacture for Sale or for Distribution of Class C or Class D

1. Name of Applicant:
2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate/registered office/ manufacturing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
6. Fee paid on Rs receipt/challan/transaction id
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:

   i) the manufacturing site is ready for audit or shall be ready for audit on.....in accordance with the requirements of Medical Devices Rules, 2017.

   (ii) I shall comply with aII the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:
Date:

Signature
(Name and designation)
[To be signed digitally]

Annexure:

| S.N. | Generic name | Model No. | Intended use | Class of medical device | Material of constructi on | Dimension (if any) | Shelf life | Sterile or Non sterile | Brand Name(if registered under the Trade Marks Act, 1999) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

**AUGUST 2016**

# GN-32: Guidance Notes for Importation of Unregistered Medical Devices for Exhibition in Singapore

Revision 3

HSA Health Sciences Authority

## PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

# 1. INTRODUCTION

## 1.1. Purpose

This document provides guidance to an importer in seeking approval from HSA to import unregistered medical devices into Singapore for exhibition purposes via cargo or hand-carry mode, and an overview of the regulatory control of these unregistered medical devices.

Exhibitors are also reminded that any unregistered medical device which is permitted for display at the exhibition shall not be supplied for use locally, including distribution of free samples or the use of such medical devices on a human for demonstration purpose. These unregistered products shall be destroyed or exported out of Singapore within the timeframe stipulated by HSA after the exhibition.

## 1.2. Background

Under the Health Products Act, medical devices are subject to regulation in Singapore. The import and supply of all medical devices are required to be licensed by HSA before any of such activities can be legally carried out, unless otherwise exempted under the provisions of the law. The supply of an unregistered medical device is an offence under Health Products Act.

Products that are clearly indicated by their manufacturer not to be used on humans are not medical devices under the definition in the law. Such products will not be subject to medical device regulatory controls in Singapore and hence are excluded from the scope of this guidance note.

Exhibitors who require confirmation if their product is a medical device can use the Medical Devices Risk Classification Tool or submit the Health Product Enquiry Form to hsa_prod_class@hsa.gov.sg, to determine the classification of the products. The tool and form are available at the HSA website: www.hsa.gov.sg > Health Products Regulation > Medical Devices > Overview.

### 1.3. Scope

This document is applicable to all applicants who are importing unregistered medical devices of any risk classification into Singapore for exhibition purposes.

Local companies exhibiting locally-manufactured medical devices are not required to obtain any approval for displaying their products at exhibitions. However, the manufacturer is still required to display prominent labels or signage that the medical device is not allowed to be used on human nor supplied for use locally.

### 1.4 Making an application

The applicant shall submit the application form FORM 32A and required supporting documents by either fax or email. FORM 32A is published in HSA website www.hsa.gov.sg > Health Products Regulation > Medical Devices > Regulatory Guidances.

| Mode of Importation | FORM 32A | Information of event (Eg.Brochures, official website) | Passport Page with Personal Particulars of Importer |
|---|---|---|---|
| Cargo | ✓ | ✓ | **N.A** |
| Hand-carry | ✓ | ✓ | ✓ |

**Table 1. Documents to be submitted**

Please submit your application early so that the approval for the importation can be issued in time for the exhibition. A processing time of up to 10 working days may be needed upon submission of a complete application.

### 1.5. Definitions

MEDICAL DEVICE: Means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of

(a) diagnosis, prevention, monitoring, treatment or alleviation of any disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(c) investigation, replacement, modification, or support of the anatomy or of a physiological process;

(d) supporting or sustaining life;

(e) control of conception;

(f) disinfection of medical devices; or

(g) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

IMPORT: with its grammatical variations and cognate expressions, means to bring or cause to be brought into Singapore by land, sea and air.

EXPORT: with its grammatical variations and cognate expressions, means to bring or cause to be brought out Singapore by land, sea and air.

SUPPLY: (as set in the Health Products Act):

in relation to a health product, means to transfer possession of the health product by any means whether or not for reward, and includes the following:

(a) to sell the health product, whether by retail, wholesale or auction;

(b) to expose or display the health product as an invitation to treat;

(c) to transfer possession of the health product by exchange, gift, lease, loan, hire or hire-purchase;

(d) to supply the health product in connection with —

(i) a contract for the provision of any goods or the performance of any service; or

(ii) any advertising, sponsorship or promotional activity;

(e) to supply the health product by way of administration to or application in any person in the course of any diagnosis, treatment or test;

(f) to offer, agree or attempt to supply the health product in any of the ways described in paragraphs (a) to (e) or to cause or permit the health product to be so supplied; and

(g) to keep or possess the health product for the purpose of supplying it in any of the ways described in paragraphs (a) to (f);

## 2. VERIFICATION WITH OTHER CONTROLLING AGENCIES

For importation procedures into Singapore, please refer to the Singapore Customs website for more information.

For products containing X-ray, laser, ultraviolet or radiation emission characteristics, please refer to the National Environment Agency (Radiation Protection and Nuclear Science Department) website for further details.

All persons issued with an importer's licence under the Health Products Act (HPA) must comply with the HPA and their regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Licensees must also comply with all other applicable laws and their regulations.

## 3. AVAILABLE IMPORTATION MODES

### 3.1 Import as Cargo Goods

Importation of unregistered medical devices as cargo goods should be carried out by a Singapore registered entity on behalf of the exhibitor.

An approval for importation of unregistered medical devices for exhibition purposes will be issued to the Singapore registered entity. The approval permits the import of multiple consignments of unregistered medical devices for the specified event, and is valid for the period from the date of issuance to date of expiry.

### 3.2 Import via Hand-Carry by Exhibitor

Limited quantities of unregistered medical devices to be used for exhibitions may be imported via hand-carry by an overseas exhibitor on an individual basis. It is the exhibitor's responsibility to ensure that the importation is in compliance with the relevant authorities such as the Singapore Customs regulations and any other aviation or shipping requirements.

An importer's licence for importation of unregistered medical devices for exhibition purposes will be issued to the exhibitor.

## 4. HANDLING OF UNREGISTERED MEDICAL DEVICES DURING THE EXHIBITION

Exhibitors of unregistered medical devices are required to ensure that the medical devices exhibited cannot be supplied in Singapore. The exhibitor's display booth and unregistered medical devices shall be prominently indicated with labels or signage "SOLELY FOR DISPLAY PURPOSES ONLY. NOT INTENDED FOR SUPPLY".

Unregistered medical devices imported for exhibition purposes shall not be used for clinical purposes or demonstration on humans. There is no restriction for activating the devices at exhibitions provided it does not pose any safety issues to the public. However, the National Environment Agency (NEA) has prohibited the energizing or switching on of medical devices which can emit radiation such as X-ray equipment and lasers in the public, unless the appropriate radiation licences have been obtained from NEA. Please check with NEA for further details.

Anyone found to be supplying unregistered medical devices may be prosecuted under the Health Products Act, and shall be liable to be punished with a fine of up to $50,000 or imprisonment term not exceeding 2 years, or both. Please refer to Section 1.5 of this guidance notes for the meaning of "supply",

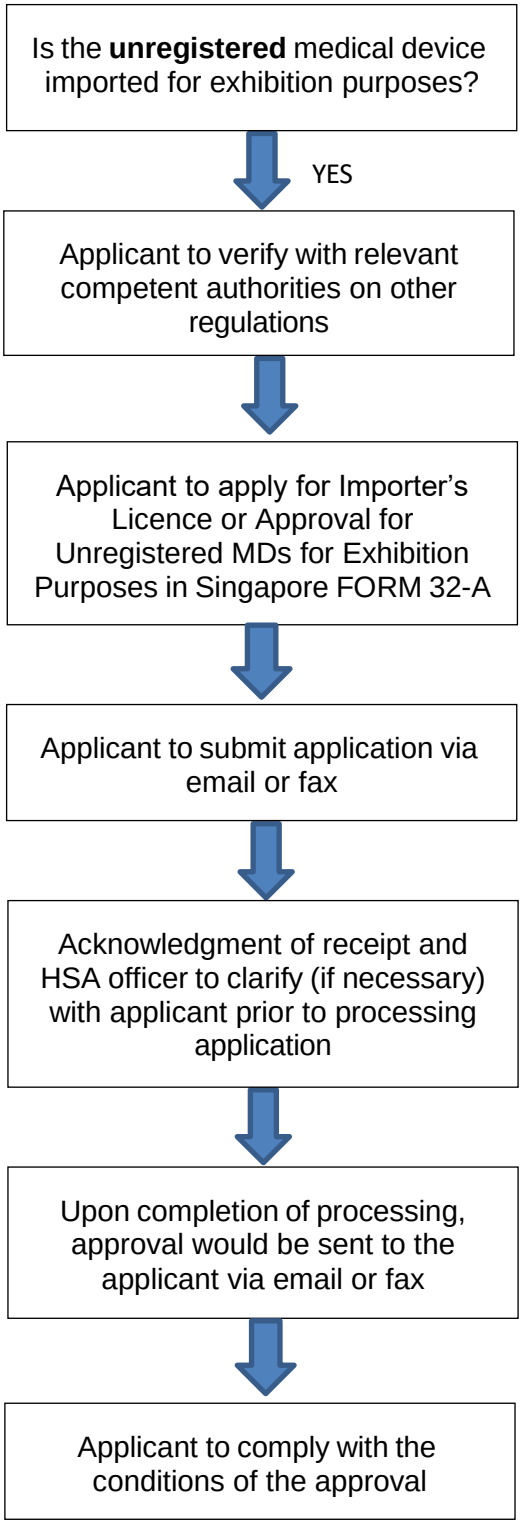
## 5. POST EXHIBITION HANDLING OF UNREGISTERED MEDICAL DEVICES

After the exhibition, all importers must ensure that these unregistered medical devices are destroyed or exported out of Singapore according to the stipulated licensing conditions in the importer's licence.

## 6. FLOWCHART

The process on the application for approval from HSA is summarized in Annex 1.

## Annex 1: General workflow for application to import unregistered medical devices for exhibition purposes in Singapore




**END OF DOCUMENT**

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

**Contact Information:**

Ms. Lim Na/ Ms. Catherine Koh
Audit & Licensing Division
Health Products Regulation Group
Health Sciences Authority

150 Cantonment Road,
Cantonment Centre, Block A #01-02
Singapore 089762
www.hsa.gov.sg

**E**: HSA_LCB_MDEx@hsa.gov.sg
**T**: +65 6866 1072, +65 6304 5453
**F**: +65 6478 9068

HSA Health Sciences Authority

# FORM 32-A
# APPLICATION FOR IMPORTATION OF UNREGISTERED MEDICAL DEVICES FOR EXHIBITION

**AUDIT & LICENSING DIVISION**
**Health Products Regulation Group**
150 Cantonment Road
Cantonment Centre, Blk A, #01-02
Singapore 089762
Tel: 65 68663522 Fax: 65 64789068
Website: www.hsa.gov.sg

## SECTION A: DETAILS OF EXHIBITION

**Name :** _____

**Period :** _____

## SECTION B: MODE OF IMPORTATION (tick one only)

☐ Via Cargo

☐ Via Hand-carry

## SECTION C: SUPPORTING DOCUMENTS (to be submitted with this application)

☐ Information of Event (E.g. Brochures, official website)

☐ Passport Page with Personal Particulars of Importer (For hand-carry only)

## SECTION D: DETAILS OF IMPORTER

| | |
|---|---|
| **Name of Company** | |
| **Address of Company** | |
| **Unique Entity Number (For Singapore registered entity only)** | |
| **Name of Applicant**<br>**NRIC or Passport Number** | |
| **Preferred Contact Details (Contact Number & Email)** | **Contact No:** |
| | **Email:** |
| **Does the company already hold medical device importer's licence with HSA?** | **Yes / No** *(delete as appropriate)*<br>**Importer's licence number : ES**_____ |

**FORM 32-A**
**APPLICATION FOR IMPORTATION OF UNREGISTERED MEDICAL DEVICES FOR EXHIBITION**

**SECTION E: DECLARATION BY APPLICANT**

With reference to the information listed in Sections A, B, C and D of this form:

(i) I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

(ii) I am aware of my duties and obligations under Part VIII of the Health Products Act and shall ensure that they are performed.

(iii) I shall comply fully with the conditions imposed on the importer's licence upon its issuance.

(iv) I am aware that supply of the unregistered medical devices imported for exhibition purposes is prohibited and constitutes an offence under Section 15 of the Health Products Act.

All applicants under the Health Products Act (HPA) must comply with the HPA and its regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

Name & Signature of Applicant

Date (dd/mmm/yyyy)

Company Stamp

**PIHAK BERKUASA PERANTI PERUBATAN**
***Medical Device Authority***
**KEMENTERIAN KESIHATAN MALAYSIA**
***Ministry of Health Malaysia***
Portal: www.mdb.gov.my
Email: mdb@mdb.gov.my

# NOTIFICATION OF MEDICAL DEVICE FOR DEMONSTRATION OR EDUCATION PURPOSE

(In accordance with Medical Device (Exemption) Order 2016)

Please complete all information requested on this form. *(All fields are mandatory unless stated otherwise)*

## 1. GENERAL INFORMATION

Period of Demonstration//training (education):

## 2. DETAILS OF APPLICANT AND COMPANY

Name of Person Responsible:

NRIC/Passport Number:

Designation:

Organization/Company Name:

Organization/Company Address:

| City: | State: |
|---|---|
| Telephone No.: | Email Address: |

Please skip this question if your organization/company is not an "establishment" according to the definition under Section 2 of Act 737.

If your organization/company is an "establishment" according to the definition under Section 2 of Act 737, please state—

a) the type of your "establishment" according to the type of establishment in Section 2 Act 737

| | Manufacturer | | Authorized Representative | | Distributor | | Importer |
|---|---|---|---|---|---|---|---|

b) status of your establishment license under Act 737

| | | | |
|---|---|---|---|
| | Already submitted license application<br>Please provide application form identification (Form ID) no<br>…… | | Already obtained establishment license<br>Please provide license no<br>…… |

## 3. MEDICAL DEVICE INFORMATION

- Please provide details of the medical device according to **Appendix A**
- Please provide supporting document for medical device: Sample of the medical device packaging label/promotional material (such as brochure, pamphlet or catalogue) that contain information

**PIHAK BERKUASA PERANTI PERUBATAN**
***Medical Device Authority***
**KEMENTERIAN KESIHATAN MALAYSIA**
***Ministry of Health Malaysia***
Portal: www.mdb.gov.my
Email: mdb@mdb.gov.my

about the intended use/ general description/mode of action of the medical device.

## 4. ATTESTATIONS & DECLARATION

**I, the undersigned hereby declare that:**

a. The product(s) indicated on this application:

(i) Is/are a medical device(s) according to the definition of "medical device" set out in Section 2, Medical Device Act 2012 (Act 737);

(ii) Has/have been classified according to Rules of Classification of Medical Device, as set out in the First Schedule of the Medical device Regulations 2012 (MDR 2012); and

(iii) Has/have met all the labelling requirements set out in the Sixth Schedule of the MDR 2012.

b. I shall be responsible for the establishment and implementation of a system to monitor safety and performance of this/these medical device(s) and take the necessary actions should there be any occurrence of adverse incident during the period of the demonstration, exhibition or training involving the medical device;

c. I am aware that the permission is restricted to the importation and/or supply for the unregistered medical device(s) for the purpose of demonstration, exhibition or training *only*. Therefore, I shall undertake that the medical device(s)—

(i) **Shall be removed from** the demonstration, exhibition or training site soonest possible after the demonstration, exhibition or training has ended;

(ii) **Shall not be placed** in the Malaysian market;

(iii) **Shall not be used** on a human or a patient.

**I, the undersigned, hereby attest that** the information and attachment provided on this notification is/are accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall be liable to a fine not exceeding **RM 500,000.00** or to imprisonment for a term not exceeding **3 years** or to both. (S.76 Act 737 refers).

| | |
|---|---|
| Signature: | |
| Name: | Designation: |
| Date: | |
| Company stamp: | |

**PIHAK BERKUASA PERANTI PERUBATAN**
***Medical Device Authority***
**KEMENTERIAN KESIHATAN MALAYSIA**
***Ministry of Health Malaysia***
Portal: www.mdb.gov.my
Email: mdb@mdb.gov.my

**APPENDIX A**

**MEDICAL DEVICE DETAILS (Repeat as needed)**

| No. | Medical Device name | Brand/ model | Manufacturer's name *(as it appears on the label)* | Description of Medical device | Intended use of Medical device | Class & classification rule *(according to First Schedule on Rules of Classification of Medical Device, MDR 2012):* | Site(s) details (name, address) | Quantity to be imported/ supplied | Marketing Approval Status in other country(-ies) *[Please state the name (s) of country (ies) ]* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Registered/ licensed/ approved | Exempted/ notified/self-declared | *Others (please specify)* |
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# 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<br>9022.13.00<br>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. | Electrophysiologymachine (EEG machine, ECG machine, electro-mechanical machine) | 9018.11.00<br>9018.19.00 |
| 9. | Retinal power meter | 9018.50.00 |
| 10. | Oosteoporosis meter | 9018.12.00<br>9022.14.00 |
| 11. | Retinal scanners / fundus fluorescence scanner | 9018.50.00 |
| 12. | Ultrasonic fetalheart 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. | ElisaElisa 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<br>3822.00.10<br>3822.00.20<br>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. | Cardiopulmonarybypassmachine | 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 ultrasoundequipment system for tumour treatment | 9018.12.00 |
| 44. | Dialysisequipment | 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<br>3006.40<br>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 ofimportingunit
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SOCIALISTREPUBLICOF VIETNAM
Independence - Freedom - Happiness
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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 ofimportingunit
---

SOCIALISTREPUBLICOF VIETNAM
Independence - Freedom - Happiness
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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 ofimportingunit
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SOCIALISTREPUBLICOF VIETNAM
Independence - Freedom - Happiness

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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 ofimportingunit
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SOCIALISTREPUBLICOF VIETNAM
Independence - Freedom - Happiness

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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*