



PERSATUAN PERALATAN PERUBATAN MALAYSIA
(MALAYSIA MEDICAL DEVICE ASSOCIATION) (0596-05-7)
MMDA Secretariat
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For Office Use:

Membership No.

MEMBERSHIP APPLICATION FORM

COMPANY REGISTRATION NUMBER:

COMPANY INFORMATION: -

Name: _____
Address: _____

Tel. No. _____ Fax No. _____
Website _____

REPRESENTATIVE INFORMATION: -

Representative Name: _____ Email: _____
Designation: _____ Mobile No: _____
Alternate Representative: _____ Email: _____
Designation: _____ Mobile No: _____

TYPE OF MEMBERSHIP: -

Ordinary Member Associate Member
(Refer to General Information for definition)

ESTABLISHMENT TYPE: -

Manufacturer (Local) Importer Distributor
 Local Authorized Representative (LAR)

Others:

- Exporter(Manufacturer for export) Principal Representative Office Wholesaler
 CAB Govt Tendering Agent Consultant
 Traders None of the Above(please specify):

TYPE OF PRODUCTS: -

GMDN CATEGORIES	GMDN TERM	PLEASE TICK AND PROVIDE ANY OTHER INFORMATION TO SUPPORT THIS APPLICATION
01	Active implantable devices	<input type="checkbox"/>
02	Anaesthetic and respiratory devices	<input type="checkbox"/>
03	Dental devices	<input type="checkbox"/>
04	Electromechanical medical devices	<input type="checkbox"/>
05	Hospital hardware	<input type="checkbox"/>
06	In vitro diagnostic devices (IVD)	<input type="checkbox"/>
07	Non-active implantable devices	<input type="checkbox"/>
08	Ophthalmic and optical devices	<input type="checkbox"/>
09	Reusable instruments	<input type="checkbox"/>

10	Single use devices	<input type="checkbox"/>
11	Technical aids for disabled persons	<input type="checkbox"/>
12	Diagnostic and therapeutic radiation devices	<input type="checkbox"/>
13	Complementary therapy devices	<input type="checkbox"/>
14	Biologically-derived devices	<input type="checkbox"/>
15	Healthcare facility products and adaptations	<input type="checkbox"/>

PLEASE INDICATE CURRENT NUMBER OF PRODUCTS PER CLASS ACCORDING TO FOLLOWING PRODUCT CLASSIFICATION:-

Class A
 Class B
 Class C
 Class D

PLEASE ATTACH QUALITY MANAGEMENT SYSTEMS CERTIFICATE (IF APPLICABLE):-

- GDPMD
- ISO 9001
- ISO 13485
- Others (Issued by Foreign Authorities)



MEMBERSHIP IN OTHER TRADE ASSOCIATIONS:-

YES (Pls specify) _____ NO

Signature: _____

Name: _____

Date: _____

Company Stamp:



FOR OFFICE USE ONLY

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REJECT

PARTICULARS OF PROPOSER

Name of Proposer: _____ Company Name: _____
Signature _____ Date: _____

PARTICULARS OF SECONDER

Name of Proposer: _____ Company Name: _____
Signature _____ Date: _____

Approved at Committee Meeting

Checklist:-

<input type="checkbox"/>	Form 9 (Where Applicable)
<input type="checkbox"/>	Form 13 (Where Applicable)
<input type="checkbox"/>	Form 24 (Where Applicable)
<input type="checkbox"/>	Form 49 (Where Applicable)
<input type="checkbox"/>	Form 83 (Where Applicable)
<input type="checkbox"/>	Latest Annual Return Submitted to CCM
<input type="checkbox"/>	Company's Profile
<input type="checkbox"/>	Product Catalogues
<input type="checkbox"/>	Cheque

DEFINITION OF GMDN DEVICE CATEGORIES

<p>Code 01</p> <p>Term: Active implantable device</p>	<p>This category includes devices relying on a source of power other than that directly generated by the human body or by gravity and intended to be totally or partially introduced, surgically or medically into the human body, or by medical intervention into a natural orifice, and which is intended to remain there after the procedure. Note: Examples of devices in this category are pacemakers, implantable infusion pumps, cochlear implants and their accessories.</p> <p>Note: See Active implantable medical device directive.</p>
<p>Code 02</p> <p>Term: Anaesthetic and respiratory devices</p>	<p>This category includes devices and accessories for supplying, conditioning, monitoring, dispensing and delivering respiratory, medical and anaesthetic gases and vapours for providing and/or controlling respiration and/or anaesthesia. Note: Examples of devices in this category are anaesthetic work stations, respiratory circuits, ventilators and their accessories.</p>
<p>Code03</p> <p>Term: Dental devices</p>	<p>This category includes devices for use in diagnosis, prevention, monitoring, treatment or alleviation of oral, maxillofacial and dental disease. Note: Examples of devices in this category are dental hand instruments, impression materials, dental amalgam, dental tools and their accessories.</p>
<p>Code 04</p> <p>Term: Electro mechanical medical device</p>	<p>This category includes devices where the operation depends upon a source of electrical energy (electro medical) or source of energy other than that directly generated by the patient's body or gravity and which uses this energy to produce its effect or action (mechanical). Note: Examples of devices in this category are EEG, infusion pumps, monitors for haemodialysis, monitors for ECG, spring driven and elastomeric pumps.</p>
<p>Code 05</p> <p>Term: Hospital hardware</p>	<p>This category includes devices which are not directly used in diagnosis or examination, nor have direct influence on the clinical evaluation of the patient's condition, test results or further treatment. Note: Examples of devices in this category are sterilizers, patient transfer equipment, as well as disinfectants.</p>
<p>Code 06</p> <p>Term: In vitro diagnostic devices</p>	<p>This category includes devices which are used for in vitro examination of samples from the human body for the purpose of determining physiological or pathological conditions. Note: Examples of devices in this category are blood glucose monitors, bilirubino meters, microbial sensitivity systems and their accessories.</p>
<p>Code 07</p> <p>Term: Non-active implantable devices</p>	<p>This category includes devices other than active implantable devices, which are implanted for longer than thirty days. Note: Examples of devices in this category are inter uterine devices, heart valves, bone prosthesis and their accessories.</p>
<p>Code 08</p> <p>Term: Ophthalmic and optical devices</p>	<p>This category includes devices for use in diagnosis, prevention, monitoring, treatment, correction or alleviation of eye diseases and optical malfunctions. Note: Examples of devices in this category are tonometers, intraocular lenses, slit lamps and their accessories.</p>
<p>Code 09</p> <p>Term: Reusable instruments</p>	<p>This category includes devices which are used in surgery or elsewhere and are intended to be cleaned and sterilized for reuse. Note: Examples of devices in this category are retractors, haemostats, drills, saws and their accessories.</p>

<p>Code 10</p> <p>Term: Single use devices</p>	<p>This category includes devices which are intended to be used only once. Note: Examples of devices in this category are intravenous infusion sets, condoms and laparotomy sponges.</p>
<p>Code 11</p> <p>Term: Technical aids for disabled persons</p>	<p>This category includes devices specially produced or generally available which compensate for, relieve, prevent or neutralize an impairment, disability or handicap. Note: Examples of devices in this category are crutches, artificial limbs, hearing aids, wheelchairs and their accessories.</p>
<p>Code 12</p> <p>Term: Diagnostic and therapeutic radiation devices</p>	<p>This category includes devices which are diagnostic and/or therapeutic and use such modalities as x-rays, magnetic resonance imaging, ultrasound imaging, computed tomography scanners and their accessories. Note: Examples of devices in this category are x-ray equipment, computed tomography scanners and their accessories.</p>
<p>Code 13</p> <p>Term: Complementary therapy devices</p>	<p>Devices that use traditional or alternative methods to diagnose or treat illness. These devices may be used alone or to complement allopathic medicine. Commonly their use is related to the body's innate energy system. Note: Examples of devices in this category include acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups.</p>
<p>Code 14</p> <p>Term: Biologically-derived devices</p>	<p>Devices incorporating human and/or animal tissues or cells, or tissue-derived products (excluding in vitro diagnostic products). Note: Examples of devices in this category include tissue heart valves, biological products for tissue regeneration, and natural grafts.</p>
<p>Code 15</p> <p>Term: Healthcare facility products and adaptations</p>	<p>Building-related products and furnishings for the function and utilization of healthcare facilities, or for home healthcare, which are not involved in patient diagnosis or disease-related treatment. Note: Examples of products in this category include electrical outlets, safety systems (e.g., electrical fail-safe systems, personnel assistance warning systems), fixed generators, sanitation products (e.g., special toilets and baths for routine hygiene), permanent floor/wall coverings, goods transportation systems, adapted and standard furniture, and their accessories</p>



GENERAL INFORMATION

APPLICATION FEES:

Ordinary Member Joining Fee:	RM600.00
Annual Subscription:	RM600.00
Total fees payable	RM1200.00

(Definition of Ordinary Member: Shall consist of organization engaged in the following categories: Distributor, Importers, Manufacture and/or LAR in Malaysia)

Associate Member Joining Fee:	RM1000.00
Annual Subscription:	RM 500.00
Total fees payable	RM1500.00

(Definition of Associate Members: Those who are not eligible for ordinary membership. The Associate member shall have rights and duties of an ordinary member save that it shall not be entitled to vote at General Meeting of the Association nor be appointed or elected as Committee.)

Cheque is to be issued in favour of PERSATUAN PERALATAN PERUBATAN MALAYSIA

SUPPORTING DOCUMENTS REQUIRED:

- | | |
|--|--------------------------------|
| (1) Form 9 (Where Applicable) | (2) Form 24 (Where Applicable) |
| (3) Form 49 (Where Applicable) | (4) Form 83 (Where Applicable) |
| (5) Annual Return-latest submission to CCM | (6) Company Profile |
| (7) Product Catalogues | |