MEDICAL DEVICE REGISTRATION

Liew Lai Chee
RA Manager, ASEAN
GE Healthcare Pte. Ltd.
18 Feb 2014

GE imagination at work

MMDA
MALAYSIA MEDICAL DEVICE ASSOCIATION

Agenda

1. Guidance available?
2. Documentation
3. MedC@st

MMDA
MALAYSIA MEDICAL DEVICE ASSOCIATION

Guidance documents

- Good Distribution Practice for Medical Device (GDPMD)
- How to Apply for Establishment License Under Medical Device Act 2012 (Act 737)
- Guidelines on Medical Device Registration Under Act 737
- Medical Device Guidance Document - Guidance on The Product Grouping
- Guidance Documents on In Vitro Diagnostic (IVD) Medical Device

Comprehensiveness of the information required

Class	Document to be submitted
Class A	Only DoC
Class A (S)	Report/cert on the validation of sterilization process and DoC
Class A (M)	Report/cert on the validation of measuring function and DoC
Class B	CSDT and its supporting documents and DoC
Class C	*CSDT and its supporting documents and DoC
Class D *Clinical evidence is a must*	

Documentation for medical device registration

Medical Device Registration Form

- The form is divided into 8 parts
- Information & supporting documents must be provided as required in the form.
- Supporting document should be in PDF format and the size should not exceed 15MB

General Information on Medical Device

Information on Manufacturer of Medical Device

Grouping of Medical Device

Common Submission Dossier Template (CSDT) & supporting documents

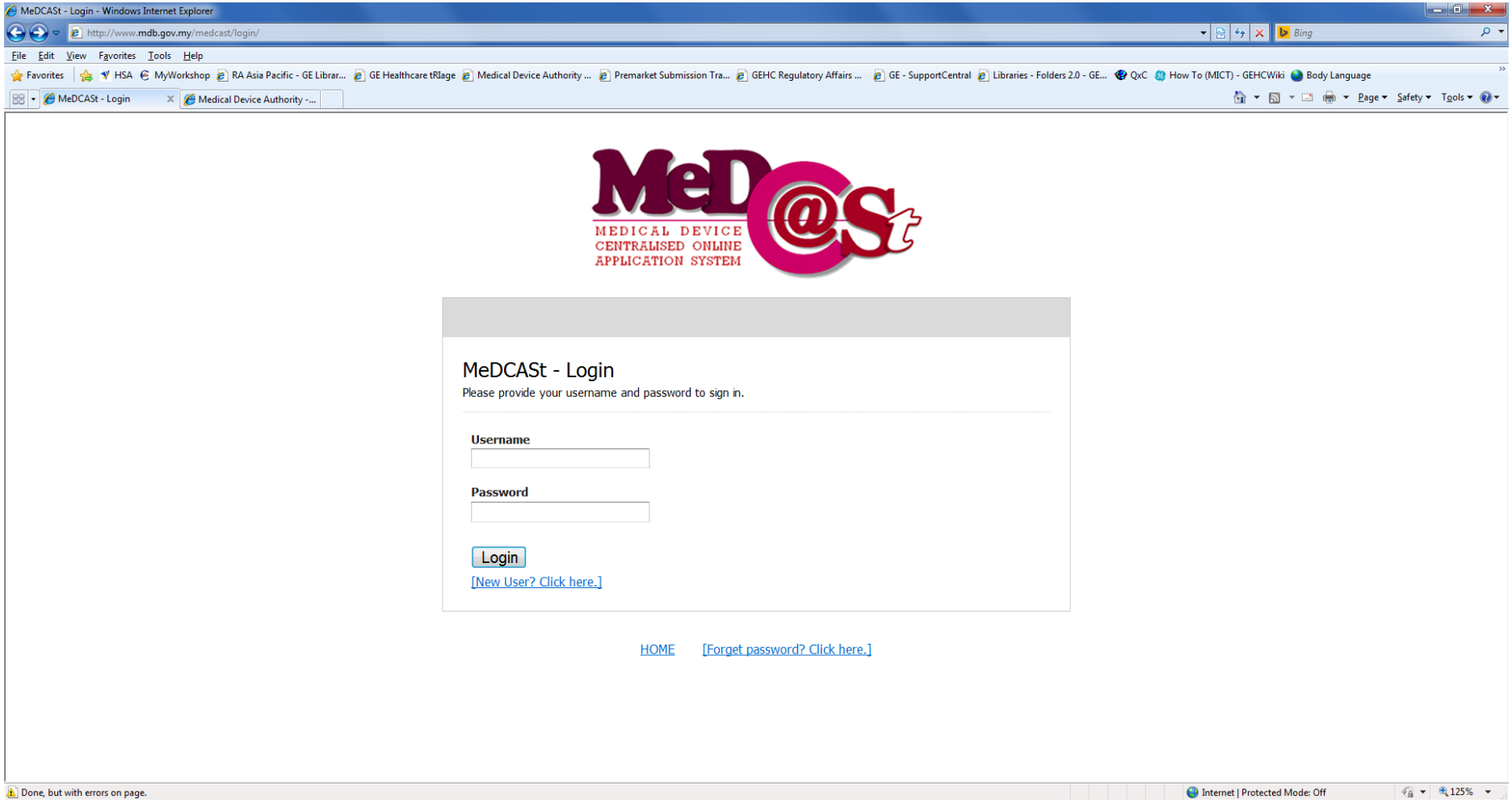
Post-Market Vigilance History

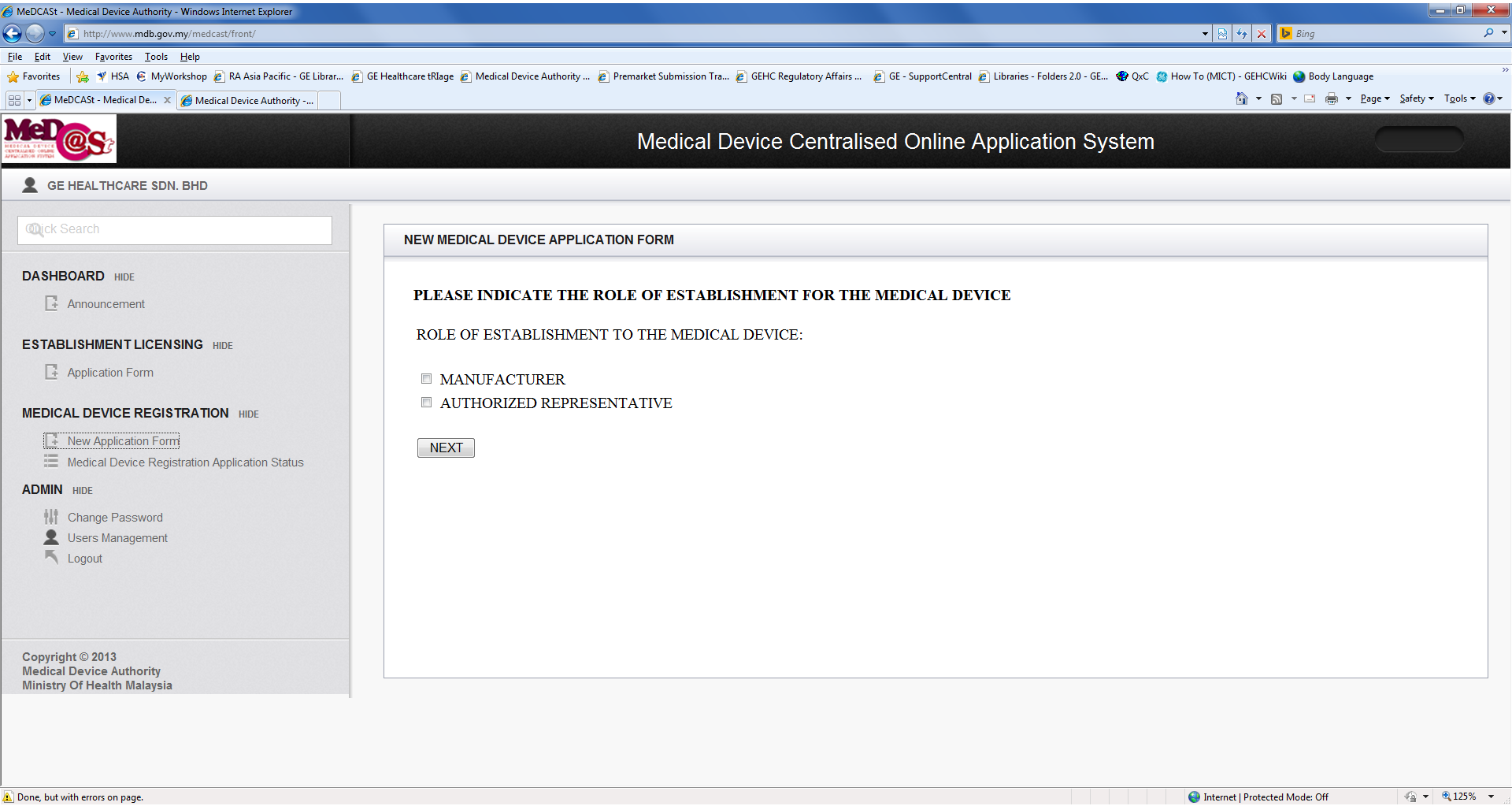
Declaration of Conformity

Attestation for Medical Device Registration

http://www.mdb.gov.my/medcast

http://www.mdb.gov.my/medcast/login/




MeDCASt - Medical Device Authority - Windows Internet Explorer
http://www.mdb.gov.my/medcast/front/
File Edit View Favorites Tools Help
MeDCASt - Medical De...
Medical Device Authority -...
Medical Device Centralised Online Application System
GE HEALTHCARE SDN. BHD
Quick Search
DASHBOARD HIDE
Announcement
ESTABLISHMENT LICENSING HIDE
Application Form
MEDICAL DEVICE REGISTRATION HIDE
New Application Form
Medical Device Registration Application Status
ADMIN HIDE
Change Password
Users Management
Logout
Copyright © 2013
Medical Device Authority
Ministry Of Health Malaysia
NEW MEDICAL DEVICE APPLICATION FORM
PLEASE INDICATE THE ROLE OF ESTABLISHMENT FOR THE MEDICAL DEVICE
ROLE OF ESTABLISHMENT TO THE MEDICAL DEVICE:
MANUFACTURER
AUTHORIZED REPRESENTATIVE
NEXT
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MEDICAL DEVICE APPLICATION FORM (FORM ID: D127-20130828-1982)

Note: * is compulsory field

GENERAL INFORMATION		SUPPORTING DOCUMENTS
IS THE MEDICAL DEVICE FOR EXPORT ONLY ?* ?	○ YES ◉ NO	
IS THE MEDICAL DEVICE CONTAINS ANY ACTIVE INGREDIENT, POISON OR DRUG ?* ?	○ YES ◉ NO	
TYPE OF DEVICE* ?	◉ GENERAL DEVICE ○ IN-VITRO DIAGNOSTIC DEVICE (IVD)	
CLASS OF DEVICE* ?	○ CLASS A ○ CLASS B ◉ CLASS C ○ CLASS D	
CLASSIFICATION RULES* ?		
MEDICAL DEVICE CATEGORY* ?	[Select]	
MEDICAL DEVICE NAME* ?		
	BRAND:	
DESCRIPTION OF MEDICAL DEVICE* ?		
INTENDED USE OF MEDICAL DEVICE* ?		
HS CODE ?		
GMDN CODE ?		

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CLASSIFICATION RULES* ?		
MEDICAL DEVICE CATEGORY* ?	[Select]	
MEDICAL DEVICE NAME* ?		
	BRAND:	
DESCRIPTION OF MEDICAL DEVICE* ?		
INTENDED USE OF MEDICAL DEVICE* ?		
HS CODE ?		
GMDN CODE ?		

RULE 1
RULE 2
RULE 3
RULE 4
RULE 5
RULE 6
RULE 7
RULE 8
RULE 9(i)
RULE 9(ii)
TUKE 10(i)
RULE 10(ii)
RULE 11
RULE 12
RULE 13
RULE 14
RULE 15
RULE 16

Annex 1 MD Regulations

Classification Rules

APPENDIX 1

Classification rules to classify medical device, excluding *in vitro* diagnostic medical device

(1) NON-INVASIVE MEDICAL DEVICE

Rule	Explanation
Rule 1:	
All non-invasive medical devices which come into contact with injured skin—	Medical devices covered by this rule are extremely claim sensitive.
(a) are in **Class A** if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;	EXAMPLE: simple wound dressings, cotton wool
(b) are in **Class B** if they are intended to be used principally with wounds which have breached the dermis, including medical devices principally intended to manage the microenvironment of a wound;	EXAMPLE: non-medicated impregnated gauze dressings
unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in **Class C**.	Medical devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. EXAMPLE: dressings for chronic ulcerated wounds, dressings for severe burns

MEDICAL DEVICE APPLICATION

Note: * is compulsory field

GENERAL INFORMATION

SUPPORTING DOCUMENT

IS THE MEDICAL DEVICE FOR EXP

IS THE MEDICAL DEVICE CONTAIN

TYPE OF DEVICE* ? GENER

CLASS OF DEVICE* ? CLASS

CLASSIFICATION RULES* ?

MEDICAL DEVICE CATEGORY* ? [Select]

MEDICAL DEVICE NAME* ?

BRAND:

DESCRIPTION OF MEDICAL DEVICE* ?

INTENDED USE OF MEDICAL DEVICE* ?

HS CODE ?

GMDN CODE ?

- [Select]
- MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICA
- MD 0101 - Non-active devices for anaesthesia, emergency and inten
- MD 0102 - Non-active devices for injection, infusion, transfusion and
- MD 0103 - Non-active orthopaedic and rehabilitation devices
- MD 0104 - Non-active medical devices with measuring function
- MD 0105 - Non-active ophthalmologic devices
- MD 0106 - Non-active instruments
- MD 0107 - Contraceptive medical devices
- MD 0108 - Non-active medical devices for disinfecting, cleaning, rins
- MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assi...
- MD 0200 - NON-ACTIVE IMPLANTS
- MD 0201 - Non-active cardiovascular implants
- MD 0202 - Non-active orthopaedic implants
- MD 0203 - Non-active functional implants
- MD 0204 - Non-active soft tissue implants
- MD 0300 - DEVICES FOR WOUND CARE
- MD 0301 - Bandages and wound dressings
- MD 0302 - Suture material and clamps
- MD 0303 - Other medical devices for wound care
- MD 0400 - NON-ACTIVE DENTAL DEVICES AND ACCESSORIES
- MD 0401 - Non-active dental equipment and instruments
- MD 0402 - Dental materials
- MD 0403 - Dental implants
- MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
- MD 1101 - Devices for extra-corporal circulation, infusion and haemo
- MD 1102 - Respiratory devices, including hyperbaric chambers for ox
- MD 1103 - Devices for stimulation or inhibition
- MD 1104 - Active surgical devices
- MD 1105 - Active ophthalmologic devices

MEDICAL DEVICE APPLICATION FORM (FORM ID: D127-20130828-1982)

Note: * is compulsory field

GENERAL INFORMATION

IS THE MEDICAL DEVICE FOR EXPORT ONLY ?* ? ○ YES

IS THE MEDICAL DEVICE CONTAINS ANY ACTIVE INGREDIEI

TYPE OF DEVICE* ? ◉ GENERAL DEVICE ○ IN-VITR

CLASS OF DEVICE* ? ○ CLASS A ○ CLASS B ◉

CLASSIFICATION RULES* ?

MEDICAL DEVICE CATEGORY* ? [Select]

MEDICAL DEVICE NAME* ?

BRAND:

DESCRIPTION OF MEDICAL DEVICE* ?

INTENDED USE OF MEDICAL DEVICE* ?

HS CODE ?

GMDN CODE ?

- MD 1104 - Active surgical devices
- MD 1105 - Active ophthalmologic devices
- MD 1106 - Active dental devices
- MD 1107 - Active devices for disinfection and sterilisation
- MD 1108 - Active rehabilitation devices and active prostheses
- MD 1109 - Active devices for patient positioning and transport
- MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted...
- MD 1111 - Software
- MD 1200 - DEVICES FOR IMAGING
- MD 1201 - Imaging devices utilising ionizing radiation
- MD 1202 - Imaging devices utilising non-ionizing radiation
- MD 1300 - MONITORING DEVICES
- MD 1301 - Monitoring devices of non-vital physiological parameters
- MD 1302 - Monitoring devices of vital physiological parameters
- MD 1400 - DEVICES FOR RADIATION THERAPY AND THERMO TI
- MD 1401 - Devices utilising ionizing radiation
- MD 1402 - Devices utilising non-ionizing radiation
- MD 1403 - Devices for hyperthermia / hypothermia
- MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy
- AIMD 0100 - GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICE
- AIMD 0101 - Active implantable medical devices for stimulation / inhil
- AIMD 0102 - Active implantable medical devices delivering drugs or
- AIMD 0103 - Active implantable medical devices substituting or repla
- IVD 0100 - LIST A REAGENTS AND REAGENT PRODUCTS, INCLU
- IVD 0101 - AB0 system P.U. (A) 500 230 Code Scope expression
- IVD 0102 - Rhesus (C, c, D, E, e)
- IVD 0103 - Anti-Kell
- IVD 0200 - LIST A REAGENTS AND REAGENT PRODUCTS, INCLU
- IVD 0201 - HIV infection (HIV 1 and 2)
- IVD 0202 - HTLV I and II

[Select]

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CLASSIFICATION RULES* ?		
MEDICAL DEVICE CATEGORY* ?	[Select]	
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DESCRIPTION OF MEDICAL DEVICE* ?		
INTENDED USE OF MEDICAL DEVICE* ?		
HS CODE ?		
GMDN CODE ?		

GMDN

Global Medical Device Nomenclature (GMDN) is a system of internationally agreed generic descriptors used to identify all medical device products.

The 12 categories in the GMDN (Global Medical Device Nomenclature) Code table are:
Code Term
01 Active implantable devices
02 Anaesthetic and respiratory devices
03 Dental devices
04 Electro-mechanical devices
05 Hospital hardware
06 In vitro diagnostic devices
07 Non-active implantable devices
08 Ophthalmic and optical devices
09 Reusable instruments
10 Single use devices
11 Technical aids for disabled persons
12 Diagnostic and therapeutic radiation devices

GMDN

- The **Global Medical Device Nomenclature** (GMDN) is an international nomenclature system used by regional or national regulatory bodies to consistently describe medical devices. GMDN codes are used to assist in the:

✓ consistent assessment of devices before they are approved for supply

✓ ongoing monitoring of devices once they are available for supply.

UMDNS CODE	UMDNS TERM English
11578	Endoscopic Power Supplies, Line-Operated
11581	Enema Bags
11582	Enema Kits
11583	Enema Tips
11585	Ear/Nose/Throat Treatment Units
11587	Enucleators
11588	Alarms, Enuresis
11589	Epilators
11592	Ergometers
11597	Bougies, Esophageal
11599	Esophageal Coolers
11600	Esophageal Motility Analyzers
11601	Stethoscopes, Esophageal
11603	Esophagoscopes
11604	Esthesiometers
11606	Droppers, Ether
11608	Ethylene Oxide Analyzers
11614	Evoked-Potential Units
11617	Excavators, Endaural
11618	Exchange Transfusion Kits
11620	Exercise Stairs
11621	Stools, Exercise
11623	Exercisers
11625	Exercisers, Arm
11627	Exercisers, Chest
11628	Exercisers, Finger
11629	Exercisers, Hand
11630	Exercisers, Leg and Ankle
11631	Exercisers, Continuous Passive Motion
11633	Quadriceps Boards
11634	Exercisers, Respiratory
11636	Exercisers, Shoulder
11638	Exercisers, Trapeze
11652	Charts, Eye
11653	Cups, Eye
11654	Droppers, Eye
11655	Irrigation Kits, Eye

UMDNS CODE	UMDNS TERM English
11727	Fittings/Adapters, Pneumatic, DISS
11729	Fittings/Adapters, Luer
11731	Fittings/Adapters, Pneumatic, Quick-Connect
11736	Flicker-Fusion Units
11740	Floor Mats, Antibacterial
11744	Flow Timers
11745	Flow Totalizers
11746	Flowmeters
11748	Flowmeters, Gas
11751	Dressings, Fluff
11757	Radiographic/Fluoroscopic Units, General-Purpose
11758	Radiographic/Fluoroscopic Units, Mobile
11761	Fluxmeters
11769	Foot Boards
11771	Footstools
11772	Footstools, Conductive
11773	Footstools, Nonconductive
11774	Forceps
11775	Forceps, Biopsy
11777	Forceps, Dressing
11779	Forceps, Laparoscopic
11780	Forceps, Epilation
11781	Forceps, Fixation
11782	Forceps, Gallbladder
11784	Forceps, Hemostatic
11785	Forceps, Intestinal
11787	Forceps, Lung
11788	Forceps, Obstetrical
11790	Forceps, Specimen
11791	Forceps, Sponge
11792	Forceps, Sterilizer Transfer
11793	Forceps, Stone Manipulation
11794	Forceps, Suction
11797	Forceps, Tissue
11798	Forceps, Utility
11799	Jars, Forceps

HS Code

- The Harmonized Commodity Description and Coding System or the **Harmonized System** (HS) is an international nomenclature (at 6 digit level) developed by the World Customs Organisation (WCO) for the classification of goods
- HS is a multipurpose product nomenclature with uses that range from tariff collection and trade statistics compilation to trade negotiations, determination of origin of goods and monitoring of controlled goods.

HS Code	HS Description
90183200	TUBULAR METAL NEEDLES & NEEDLES FOR SUTURES
90183910	CATHETERS
90183990	OTHER SYRINGES, NEEDLES, CATHETERS, CANNULAE AND THE LIKE NES
90184100	DENTAL DRILL ENGINES WITH OR WITHOUT OTHER DENTAL EQUIPMENT
90185000	OTHER OPHTHALMIC INSTRUMENTS & APPLIANCES
90189020	INTRAVENOUS ADMINSTRATION SETS

GMDN CODE ?		
ROLE OF ESTABLISHMENT	**AUTHORIZED REPRESENTATIVE**	
PRE-MARKET CLEARANCE/APPROVAL BY THE AUTHORITY BELOW ?		
(PLEASE TICK THE RELEVANT BOX BELOW AND ATTACH COPY/COPIES OF SUPPORTING DOCUMENTS)		
☐ US FDA		UPLOAD
☐ NOTIFIED BODY (Based on EU Medical Device Directive) Notified Body Name : Notified Body Number :		UPLOAD
☐ AUSTRALIA TGA		UPLOAD
☐ CANADA TPD		UPLOAD
☐ JAPAN MHLW		UPLOAD
☐ NONE OF ABOVE (Please specify:)		UPLOAD
CONFORMITY ASSESSMENT DONE BY CAB* ?	◉ YES ○ NO CAB REGISTRATION NO. : NAME OF CAB :	UPLOAD

INFORMATION OF MANUFACTURER ?		**SUPPORTING DOCUMENT**
NAME OF MANUFACTURER*		
ADDRESS OF MANUFACTURER*		
POSTCODE/ZIPCODE*		
COUNTRY*	[Select]	

GROUPING OF MEDICAL DEVICE*

Grouping of medical device

Information on grouping of medical device to be registered;

The grouping should be done in accordance to the Rule of Grouping as stipulated in 2nd Schedule of the Regulation;

- Single
- System
- Family
- Set

PART II

MEDICAL DEVICE GROUPING

General principles of grouping

3. (1) An application to register medical devices may be made according to their grouping.

(2) Medical devices may be grouped into one of the following categories:

(a) single;

(b) family;

(c) system;

(d) set;

(e) *in vitro* test kit; and

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GROUPING OF MEDICAL DEVICE*

MEDICAL DEVICE GROUPING : ? [Select]

SAME MANUFACTURER* ? YES NO

LIST OF MEDICAL DEVICE*

Medical Device	Name of Manufacturer	
		CLASS A
		CLASS A
		CLASS A

If the device has a large number of medical device, please list out the medical device in an excel spread sheet template and UPLOAD. The template can be downloaded [here].

UPLOAD

CSDT and its supporting documents

- Executive summary
- Relevant essential principles and rule used to demonstrate conformity
- Description of medical device
- Summary of design verification and validation documents
- Pre-clinical studies
- Software validation studies
- Medical device containing biological material
- Clinical Evidence
- Use of existing bibliography
- Medical device labelling
- Risk analysis
- Manufacturer information

Essentially the CSDT contains the elements of the GHTF STED

COMMON SUBMISSION DOSSIER TEMPLATE (CSDT) ?	DOCUMENT UPLOAD
PLEASE UPLOAD YOUR CSDT HERE*	UPLOAD

SUPPORTING DOCUMENTS FOR COMMON SUBMISSION DOSSIER TEMPLATE (CSDT) ?	DOCUMENT UPLOAD
1. RELEVANT ESSENTIAL PRINCIPLES AND METHOD USED TO DEMONSTRATE CONFORMITY*	
Essential Principles and Evidence of Conformity	UPLOAD

Essential Principles Conformity Checklist

Medical Device Control Office
Department of Health
Medical Device Administrative Control System

Make: _____

Model: _____

Clause	Essential Principle	Applicable	Method of Conformity	Identity of Specific Documents
General Requirements				
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			
2.	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risks associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:			

Other Descriptive Information	◉	○	○

3. SUMMARY OF DESIGN VERIFICATION AND VALIDATION DOCUMENTS*

UPLOAD

Please check the box(es) below to indicate that the element(s) has been addressed in the content of supporting document attached

	YES	NO	N/A	
Pre-clinical Studies	○	○	◉	
Software Validation Studies	○	○	◉	
Devices Containing Biological Material	○	○	◉	
Clinical Evidence	○	○	◉	
Use of Existing Bibliography	○	○	◉	
Sterilization Validation	○	○	◉	
Validation For Measuring Function	○	○	◉	

4. DEVICE LABELLING*

Samples of Labels on the Device and its Packaging	UPLOAD
Instructions for Use, Training Materials & Instructions for Installation and Maintenance	UPLOAD

5. RISK ANALYSIS*

Results of Risk Analysis	UPLOAD

6. MANUFACTURER INFORMATION*

Manufacturing Process	UPLOAD

POST-MARKET VIGILANCE HISTORY (WITHIN THE LAST 5 YEARS) ?

History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies (Please check the appropriate box)

Post-market vigilance history

Information on the history of post-market vigilance;

- Recalls status
- Reportable adverse incidents
- Banning or restriction of the medical device in other countries
- Pro-active post-market surveillance study conducted

Post-Market : Surveillance & Vigilance

- The **pro-active collection** of information on the quality, safety and performance after the Medical Device is placed on the market.

Post-Market Surveillance Information is used for:

- injury prevention
- product improvement
- development of standards
- regulatory refinement

Why is it important?

Limitations in premarket assessment

↳ understanding the risks & hazards associated with the device.

⇨ timely intervention by the Authorities to safeguard public health.

= an effective form of regulatory oversight

Adverse Events

Death

Hospitalisation due to serious injury

Life-threatening

Disability/ incapacity

Reportable Adverse Event / Criteria

1. an event has occurred
2. the device is associated with the event
3. the event led to death, or serious injury of a patient, user or others.
4. or no death or serious injury but if AE recurs, it may cause death or serious injury.

- ✓ maintain record of import and supply (**GDP**)
- ✓ maintain records of complaints (**GDP**)
- ✓ report AE to Health Authority (HA)
- ✓ notify HA on FSCAs and product recalls.

POST-MARKET VIGILANCE HISTORY (WITHIN THE LAST 5 YEARS) ?

History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies (Please check the appropriate box)

(•) YES ( ) NO

- [ ] Recall is completed
- [ ] Recall is in progress
- [ ] Reportable adverse incidents bearing implications due to the device
- [ ] The medical device is previously banned in other countries
- [ ] Field safety corrective action

Has the application/registration been rejected/suspended in other countries? * ?

(•) NO ( ) YES, Why ?

DECLARATION OF CONFORMITY*

Please upload the complete, signed and certified Declaration of Conformity. ?	UPLOAD
The declaration of conformity shall be prepared in accordance with the requirements specified in the Appendix 3 of Third Schedule of Medical Device Registration 2012 Download	

ATTESTATION FOR MEDICAL DEVICE REGISTRATION APPLICATION ?	SUPPORTING DOCUMENTS
Step 1: Click the 'Download' button to download the Attestation for Medical Device Registration form Download	
Step 2: Fill in, stamp and sign the form	
Step 3: Upload the completed form	UPLOAD

Has the company applied for Establishment License?* ( ) YES ( ) NO

NOTE:

POST-MARKET VIGILANCE HISTORY (WITHIN THE LAST 5 YEARS) ?

History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies (Please check the appropriate box)

(•) YES ( ) NO

- [ ] Recall is completed
- [ ] Recall is in progress
- [ ] Reportable adverse incidents bearing implications due to the device
- [ ] The medical device is previously banned in other countries
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Has the company applied for Establishment License?* ( ) YES ( ) NO

NOTE:

NOTE:

i. If the establishment is not licensed yet or is pending approval, the approval of the relevant medical device registration is strictly conditional to the due license of the establishment.

ii. The conditional relevant medical device registration is only valid during the transition period for the establishment license.

APPLICATION SUBMISSION

PREVIEW APPLICATION FORM

SUBMIT FORM

Declaration of conformity

- An attestation of conformity to the EPSP and compliance to the requirements to the Act and its regulation.
- Pre-requisite for medical device registration.
- The preparation of DoC should be in accordance to Appendix 3 of Schedule 3 in Medical Device Regulation
- The DoC need to be signed and uploaded in the system

Malaysia DoC

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from ..... (Day) ..... (Month) ..... (Year).

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

_____ _____

Name/Position Date

False declaration

76. (1) Any person who makes, orally or in writing, signs or furnishes any declaration, return, certificate or other document or information required under this Act which is untrue, inaccurate or misleading in any particular commits an offence and shall, on conviction, be liable to a fine not exceeding one hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

Attestation for MD Registration

ATTESTATION BY APPLICANT FOR MEDICAL DEVICE REGISTRATION

[To be printed on Company Letterhead of Applicant]

Medical Device Authority

Date:

Dear Sir,

Attestation for Medical Device Registration

I , identity card / passport number hereby attest that the information provided on this application and in any attached documents, certificates which had been duly certified true copy are accurate, correct and complete and current to this date.

I hereby attest that I have objective evidence to establish that the above medical device meets the Essential Requirements for Safety and Performance.

I hereby attest that there are no misleading claims made relating to the quality, safety and performance of the medical device.

I understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Yours Sincerely,

Signature : _____

Name : _____

Official Stamp : _____

Date : : _____

- Upon approval by the Authority and the payment of fee, the medical device will be registered in the Medical Device Register for the period of 5 years *(Section 8 of Act 737 and Reg. 6(2) of Medical Device Regulation 2012)*
- The registration number will be assigned and the certificate of registration will be issued *(Section 7(1) of Act 737)*
- The conditions of medical device registration will be imposed *(Section 8 of Act 737)*

Registration of medical device

Thank you for your attention

QUESTIONS?