Regulatory requirements for Medical Device Clinical Trials

For SingHealth Cluster

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IMD School
International Medical Device School

ARQon

FOUNDER

MAY NG
Group CEO

ARQon Group 8 years, MedtechBOSS 3 years, IMDS Group 3 years

- 2 years as Product Manager for **IVDs, Poison & Radiation device**
- 10 years in **Singapore Health Science Authority (HSA)**, established Singapore registration, approved 1400 devices, key authoring guidances CSDT & GDPMDS
- 4 years in **Biosensors, Regulatory Director drug eluting stent** for:
  - ***Product registration*** in *Asia, Europe and global countries*
  - ***Regulatory compliance*** *from product design, manufacturing and distribution (DHF/DD/TF, Clinical trial, Customs, Labelling, Product changes, Recall)*
  - ***Technical documentation & Site compliance from regulator audit*** *(EU DEKRA, TUV SUD, KR MFDS, AU TGA, JP PMDA, BZ ANVISA, SG HSA)*

Education

- Grad Dip (Medtech Manufacturing) in A*STAR Simtech, Singapore
  MSc (Biomed. Eng) in NTU, BSc (Biochem & Microbio) in UPM Malaysia

External roles

- **SG (NHIC, A*STAR, IPI, NUS), Korea (KHIDI)** - Regulatory & quality advisor
- **ASEANMed** – Co chair
- **US-ASEAN Planning Medical device committee** - ASEANMed rep
- **China-ASEAN Medical Cooperation Committee** - Singapore Rep
- **Trainer to Authorities & International speaker:** HKMDD, TFDA, TH FDA, SFDA, etc
- **Past committees:** AHWP, ACCSQ-MDPWG, ARPA, RAPro, PMO's TEC, SMF Council

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Resource information also from:

- HSA
- IMDRF

CONTENTS

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Medical Device Definition

MEDICAL DEVICE (as set out in the HPA): means

(a) any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

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

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

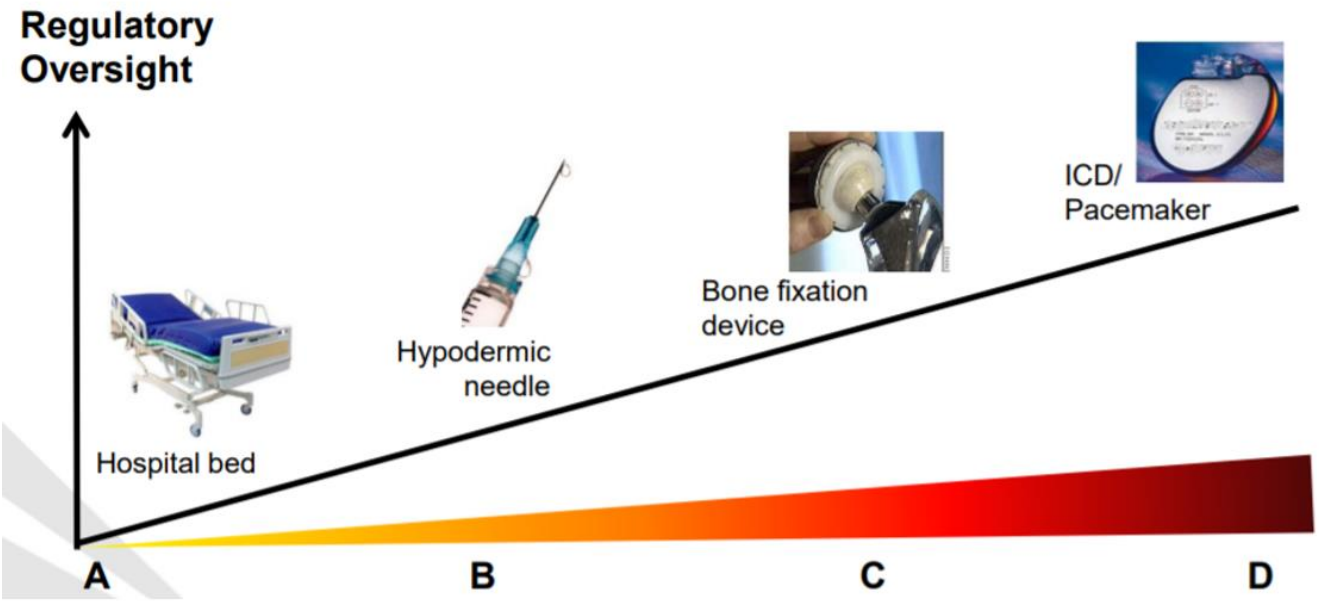
(vii) providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purposes, and

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; and

(b) the following articles: (i) any implant for the modification or fixation of any body part; (ii) any injectable dermal filler or mucous membrane filler; (iii) any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means.

Medical Device Risk Classification

Medical Devices were categorized into 4 risk classes, aligned with the international rule-based classification system



HSA Classification also according to guidelines of
International Medical Device Regulatory Forum (IMDRF)

Medical Device Risk Classification

Table A4.1 Examples of medical devices by risk class[a]

Class	Risk	Examples
A	Low	Syringes, examination gloves, patient hoists, stethoscopes, wheelchairs, IVD instruments, microbiological culture media
B	Low–moderate	Surgical gloves, infusion sets, pregnancy tests
C	Moderate–high	Condoms (unless with spermicide (class D)), infusion pumps, neonatal incubators, therapeutic and diagnostic X-ray, lung ventilators, haemodialysers, anaesthesia equipment, self-test glucose strips, IVDs for the diagnosis of Neisseria gonorrhoea
D	High	Implantable cardioverter defibrillators, pacemakers, breast implants, angioplasty balloon catheters, spinal needle, IVDs for the diagnosis of HIV, hepatitis C or hepatitis B

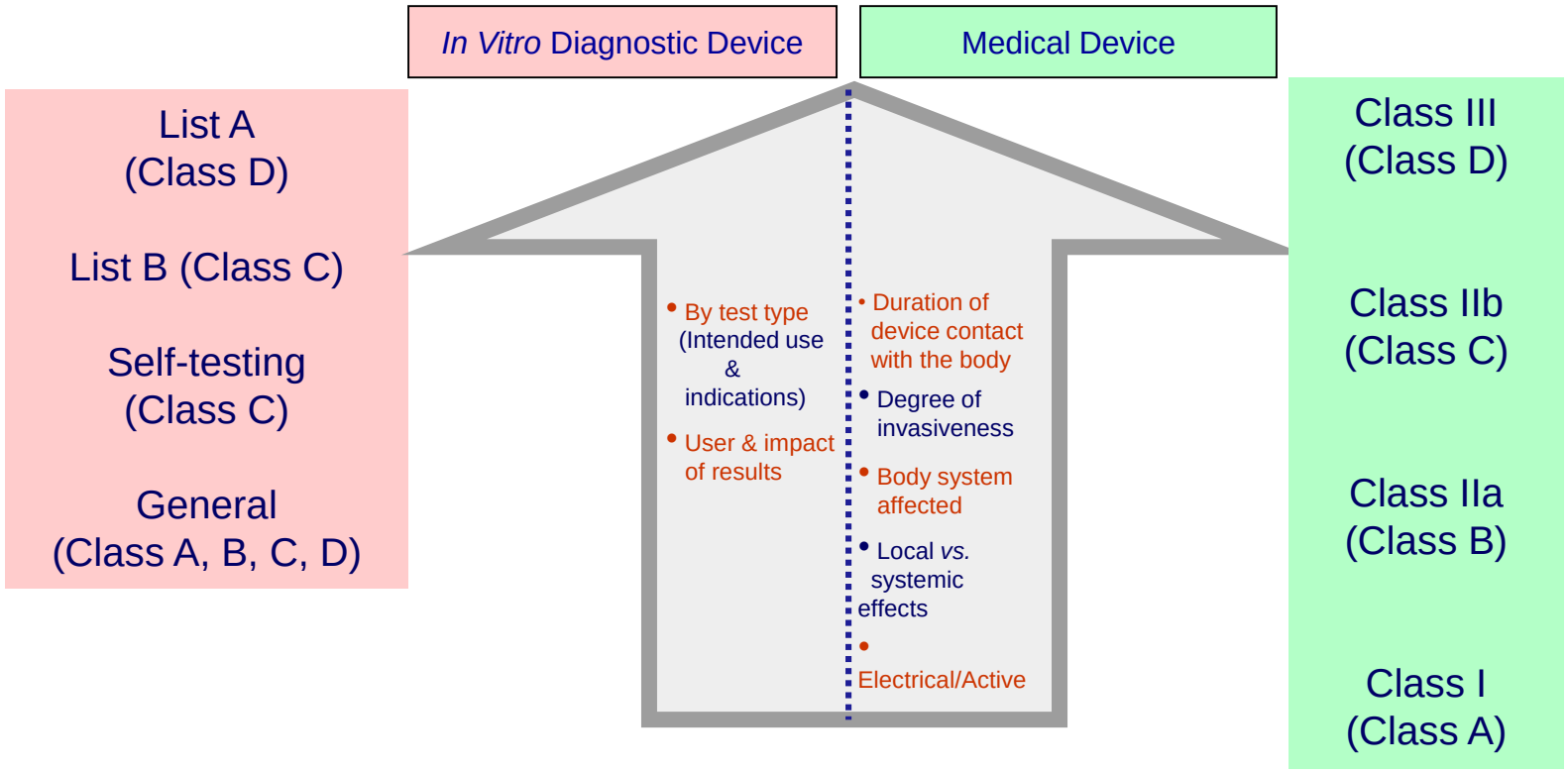
[a] The actual classification of each device depends on the claims made by the manufacturer for its intended use and the technology or technologies it utilizes. As an aid to interpreting the purpose of each rule, illustrative examples of medical devices that should conform to the rule have been provided in the table above. However, it must be emphasized that a manufacturer of such a device should not rely on it appearing as an example but should instead make an independent decision on classification taking account of its particular design and intended use.

Medical Device Risk Classification

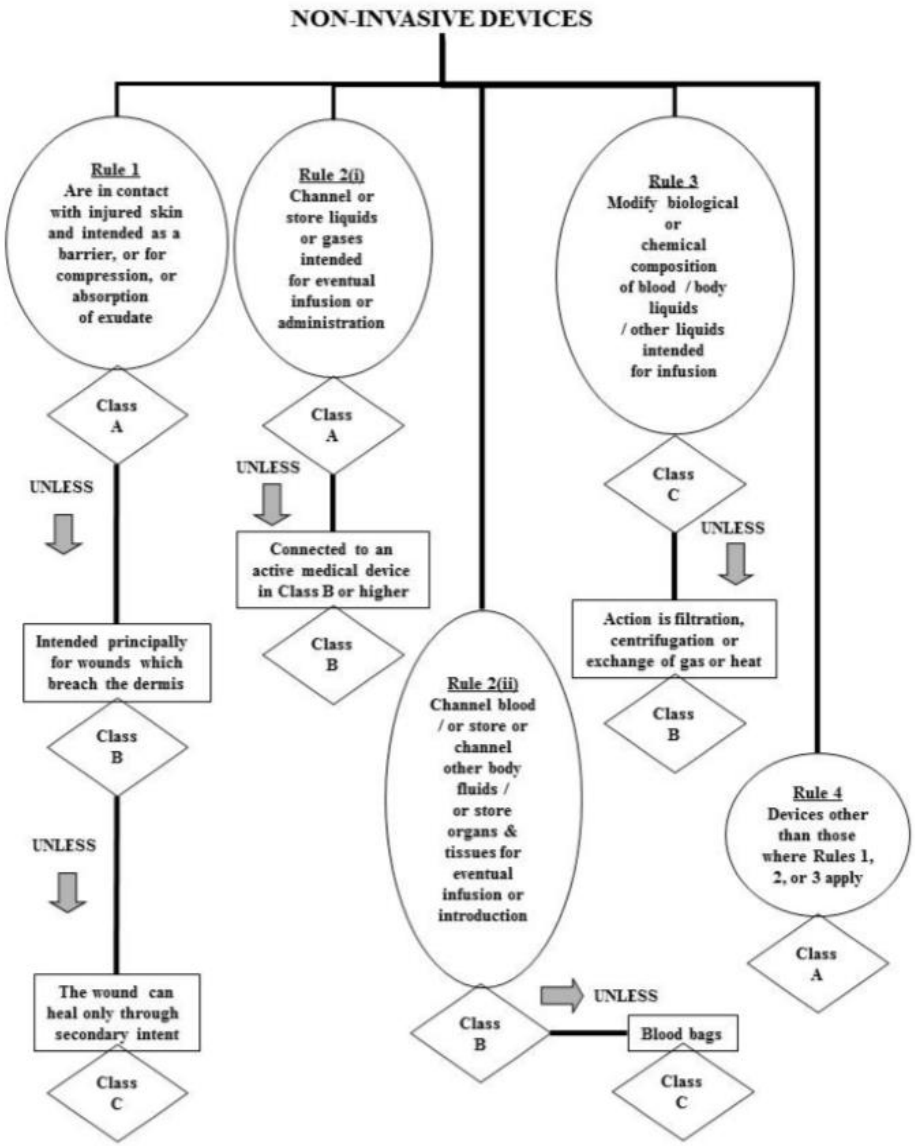
COUNTRY	United States	Europe	Canada	Australia	Singapore
Philosophy	Risk based Classification				
Reg. Framework	• Food, Drug & Cosmetics Act 1976 • Code of Federal Register (CFR)	• AIMD 90/385/EEC • MDD 93/42/EEC • IVDD 98/79/EEC • MDR & IVDR	• Food & Drugs Act • Medical Device Regulations	• Therapeutics Good Act 1989 •Therapeutics Good (MDs) Regulations 2002	•Health Products Act •Medical Device Regulations
Classification Systems	Class I (Exempt + General Controls) Class II (Gen + Special Controls) Class III (Gen + Special Controls + PMA)	Class I, IIA, IIB, III Class A, B, C, D (4 Classes)	Class I, II, III, IV (4 Classes)	Class I, IIA, IIB, III Class A, B, C, D (4 Classes)	Class A, B, C, D (4 Classes)
Conformity Assessment	• Premarket Approval (PMA) by FDA • Premarket Notification (510k) by FDA and 3rd parties accredited by FDA • Quality System • Vigilance Reporting	• Evaluation by Notified Bodies • Conformity assessment/MQMS/ Type Testing • Vigilance Reporting	• Evaluation by Health Canada • Quality System (MDSAP mandatory) • Vigilance Reporting	• Evaluation by Notified Bodies or Competent Authority for Class III, Combinations, Local manufactured • Conformity assessment/QMS/ Type Testing • Vigilance Reporting	• Full Evaluation • Abridged Evaluation (Benchmarked GHTF/IMDRF) • Quality System • Vigilance Reporting

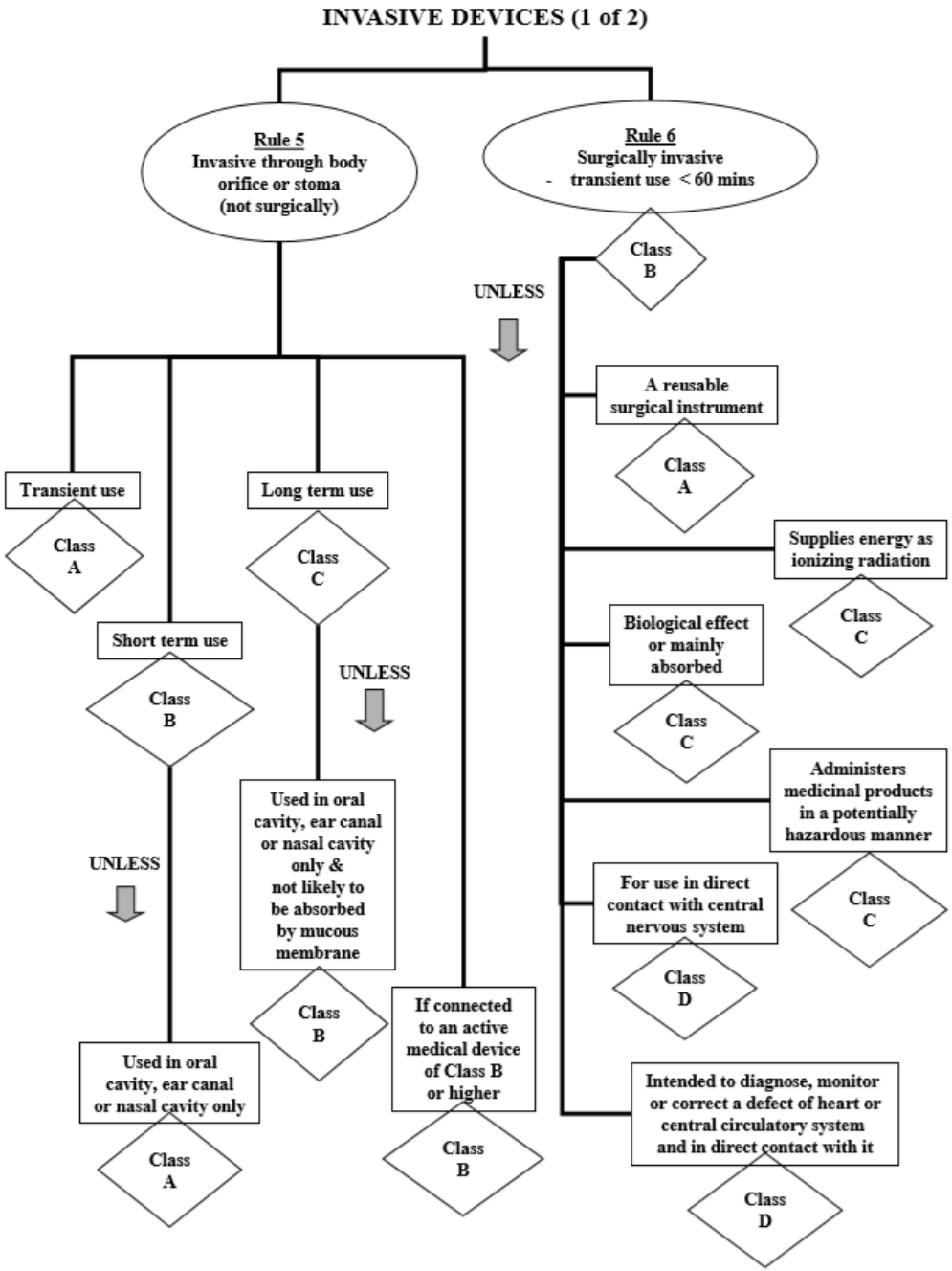
Medical Device Risk Classification

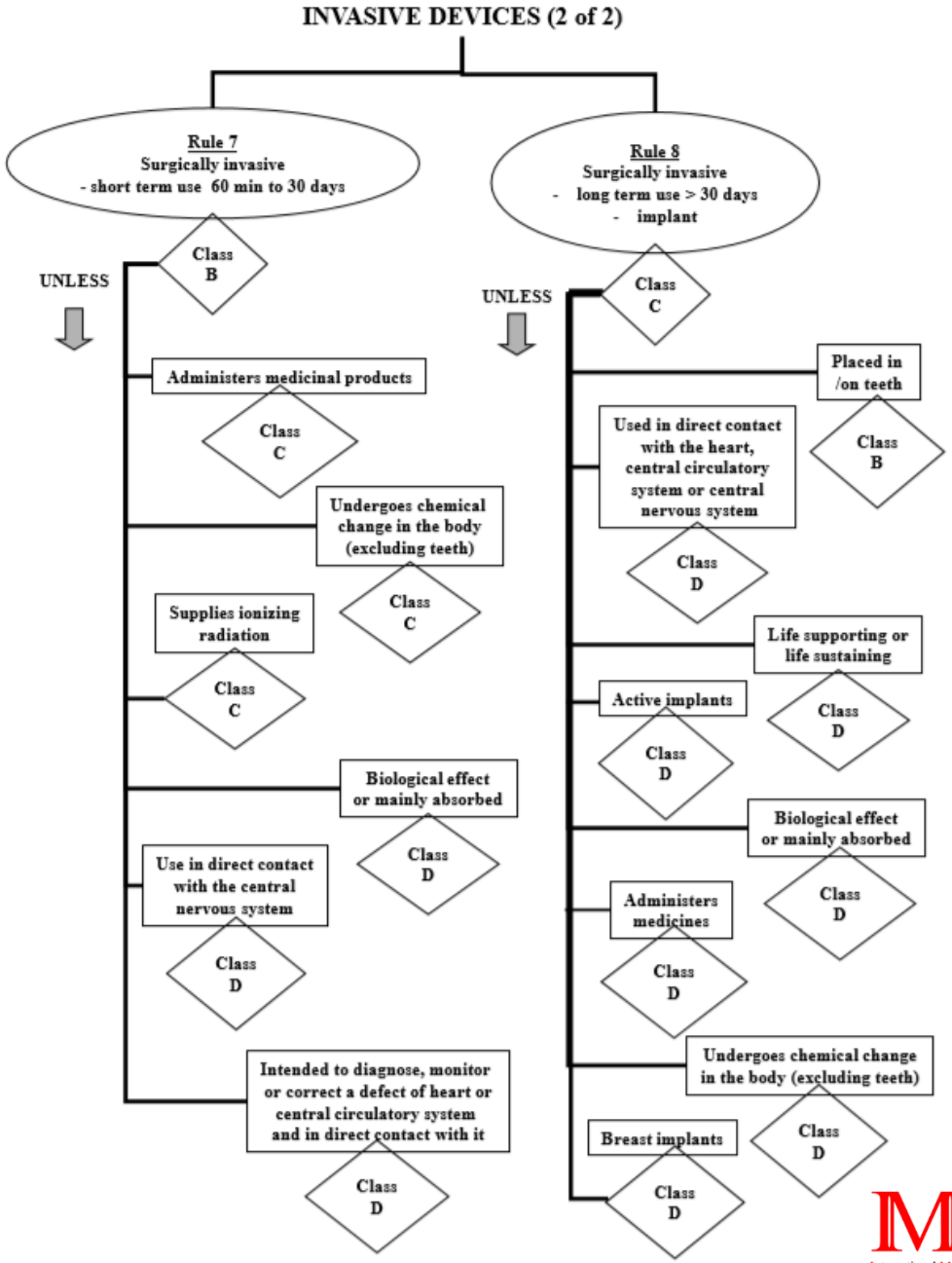
Product risk classification IVD and MD

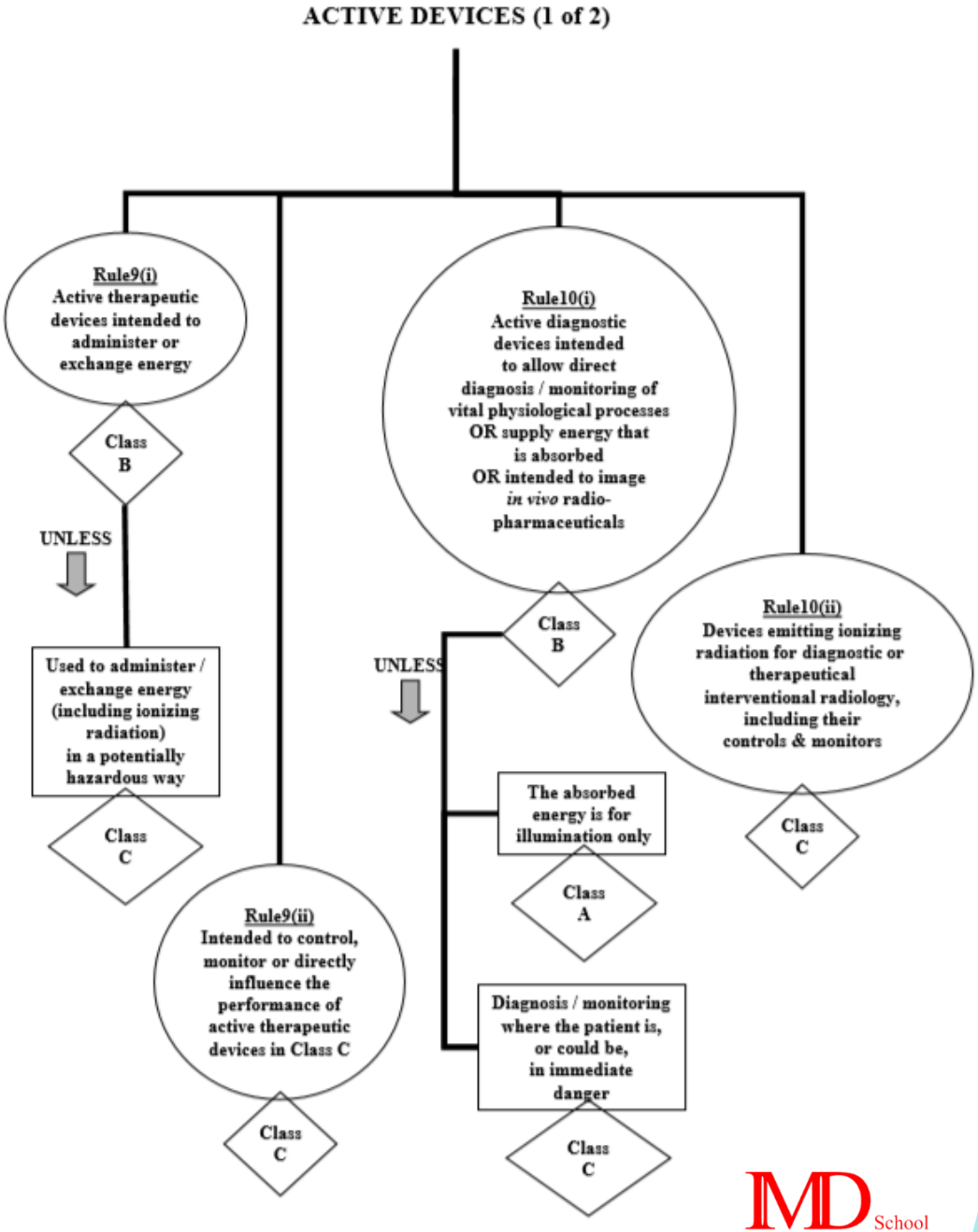


Medical Device Risk Classification

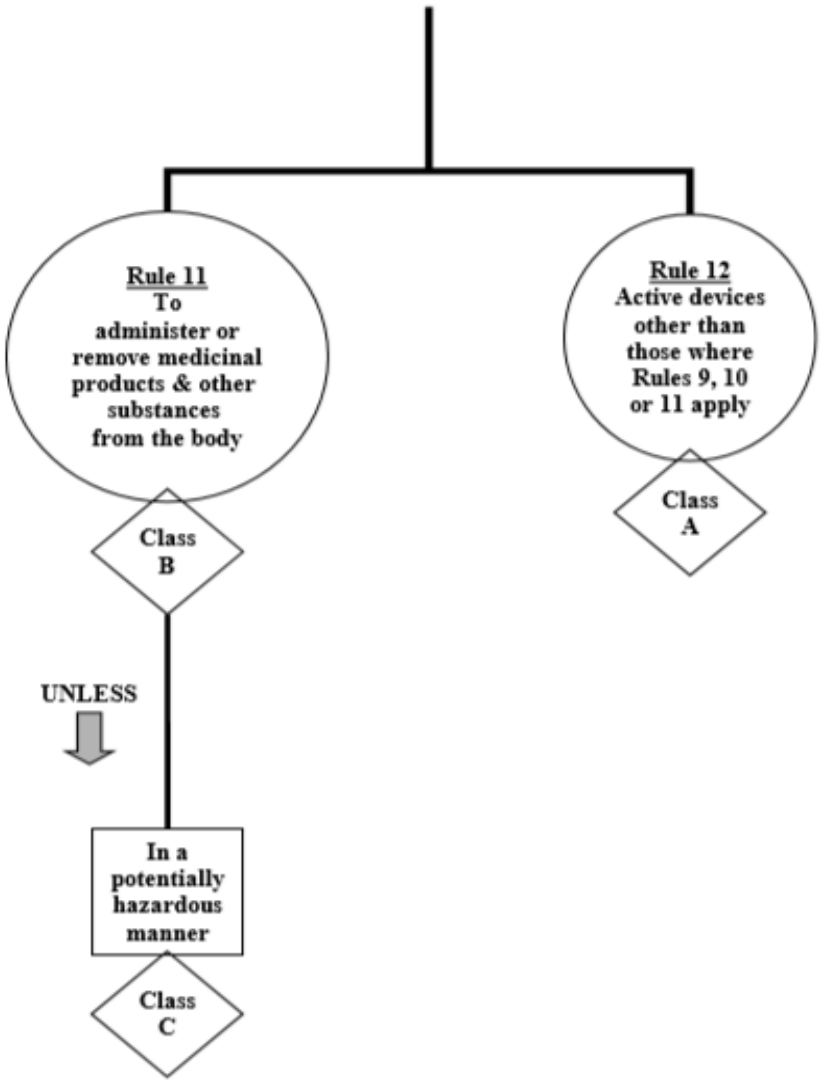


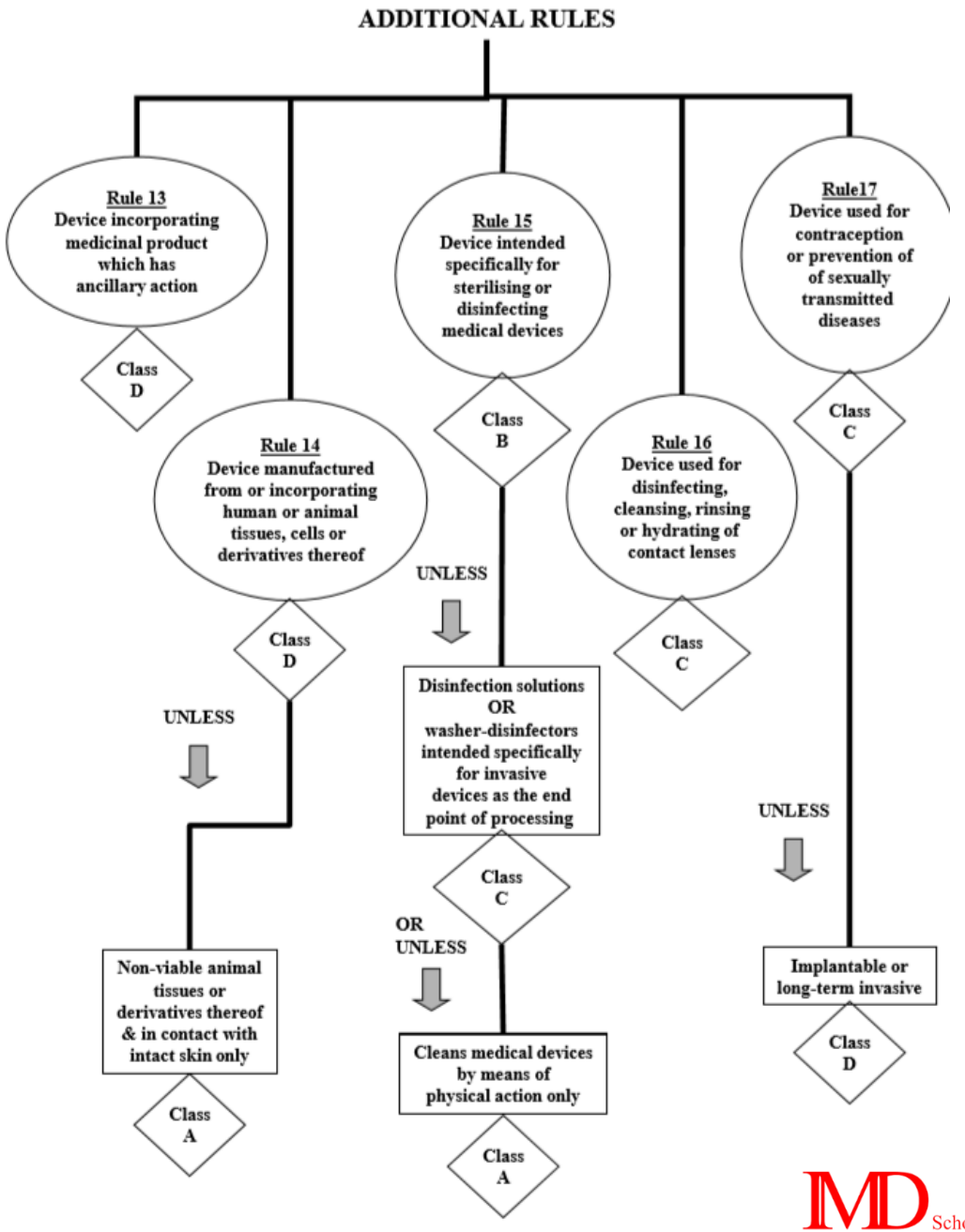




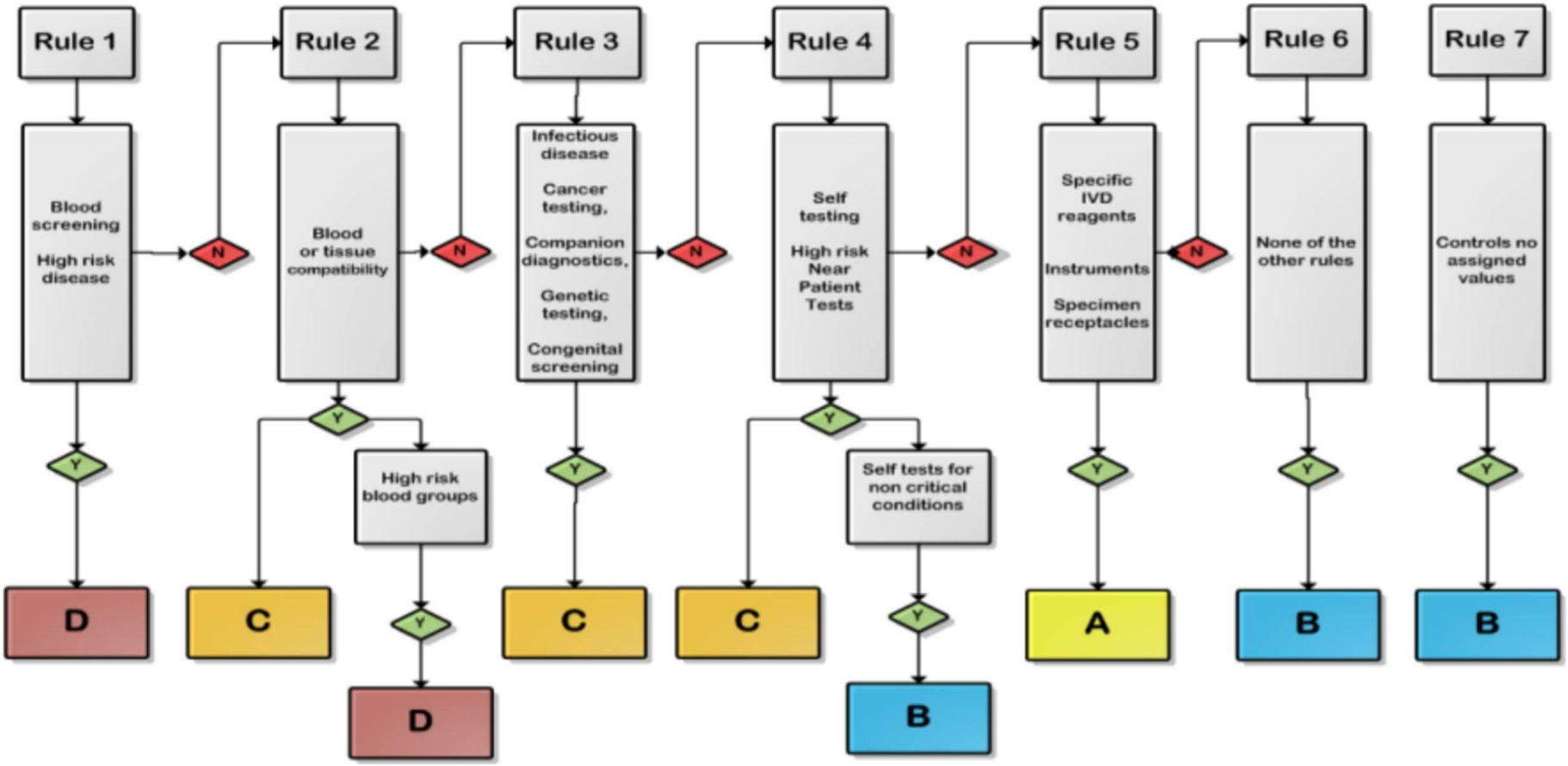


ACTIVE DEVICES (2 of 2)





Risk Classification for IVD



Risk Classification for Software

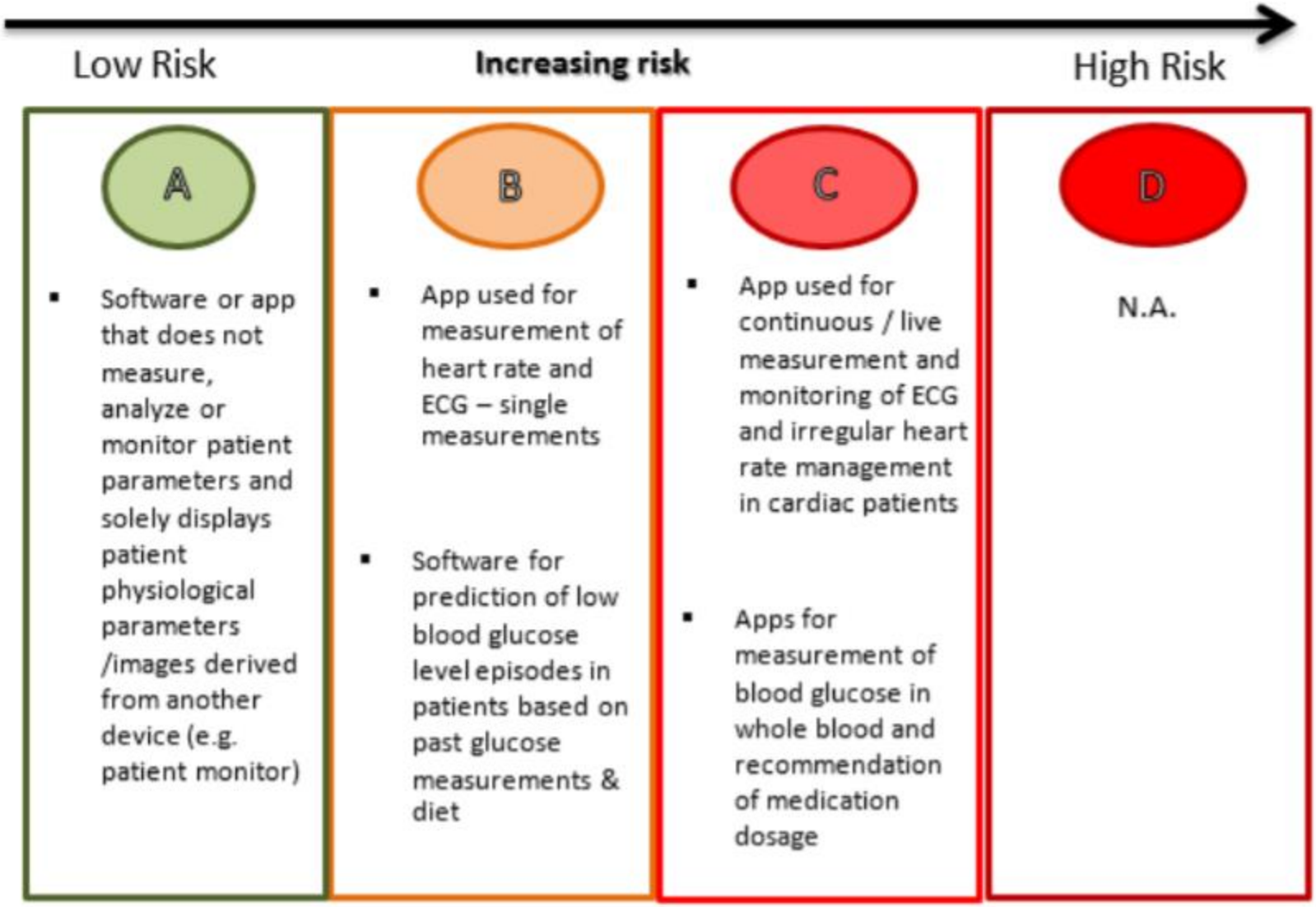


***Table 1**: Examples of Telehealth Medical Devices of various risk classes.*

Singapore MOH Artificial Intelligence in Healthcare Guidelines (AIHGle)

Artificial Intelligence (AI) is increasingly being used throughout the healthcare continuum – from administration, to clinical decision support to increase system efficiency and improve patient outcomes. However, alongside the benefits are also risks and ethical concerns if AI is not safely designed and implemented.

To support patient safety and improve trust in the use of AI in healthcare, the Ministry of Health (MOH), the Health Sciences Authority (HSA), and the Integrated Health Information Systems (IHiS) co-developed the MOH Artificial Intelligence in Healthcare Guidelines (AIHGle) (read as 'agile').

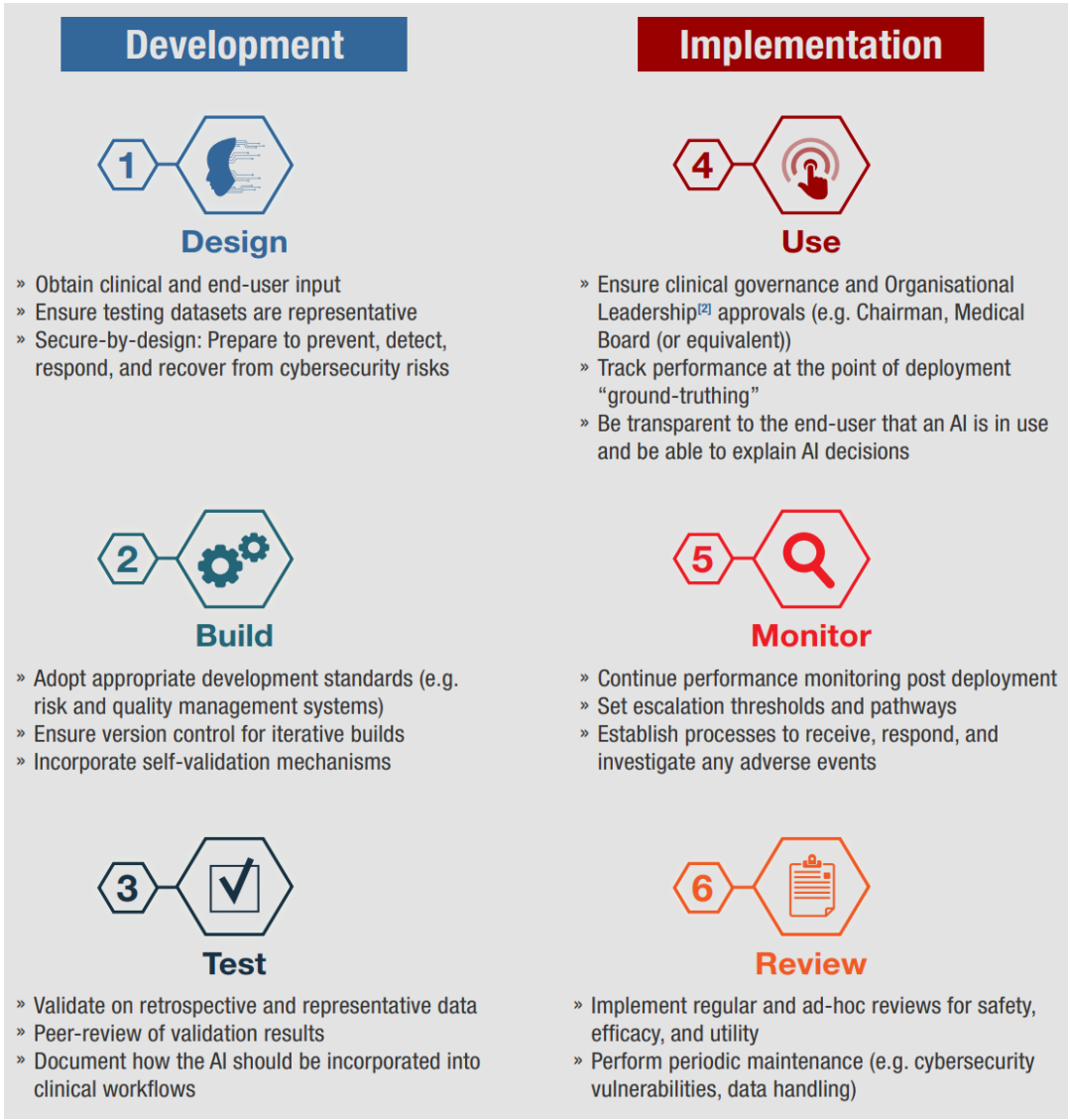
The Guidelines:

a) **Share good practices with AI developers** (e.g. manufacturers or companies) and **AI implementers** (e.g. healthcare institutions – hospitals, clinics, laboratories); and
b) **Complement HSA's regulations of AI-Medical Devices** (AI-MDs).

Community Acquired Pneumonia and COVID-19 Artificial Intelligence (AI) Predictive Engine (CAPE)

The Singapore Eye LEsioN Analyzer, or SELENA

Singapore MOH Artificial Intelligence in Healthcare Guidelines (AIHGle)



References

HSA Guidelines:

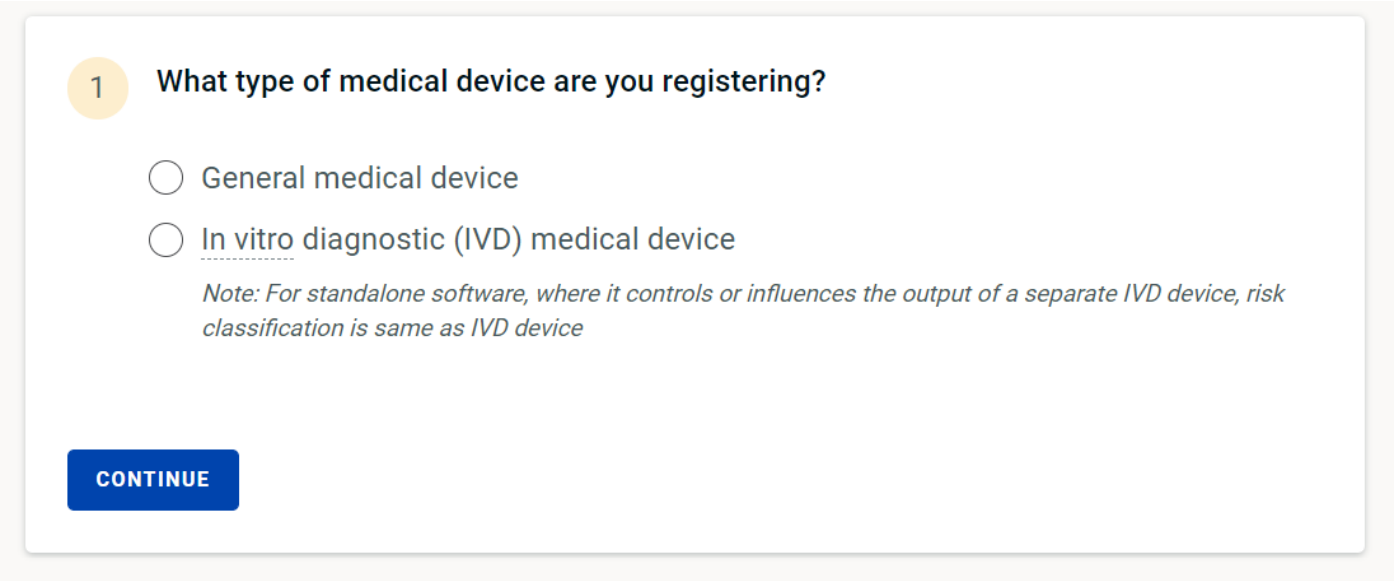
- HSA GN-13: Guidance on the Risk Classification of General Medical Devices
- HSA GN-15: Guidance on Medical Device Product Registration
- HSA Regulatory Guidelines for Telehealth Products
- HSA Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach
- HSA GN-14: Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices

In collaboration with HSA:

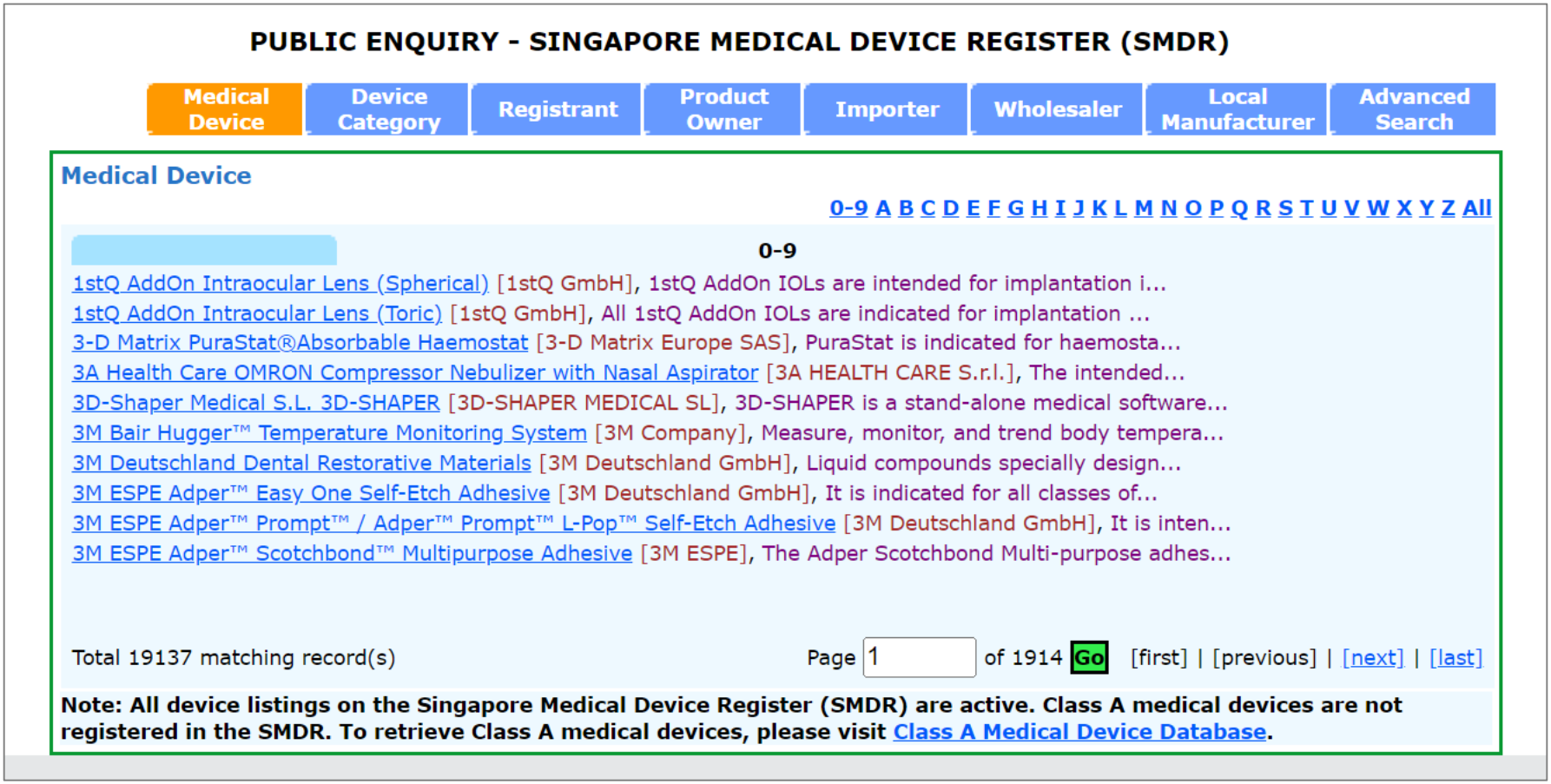
- SSC TR 67:2018 Connected Medical Device Security
- MOH Artificial Intelligence in Healthcare Guidelines (AIHGle)

HSA Risk classification tool

https://www.hsa.gov.sg/medical-devices/registration/risk-classification



HSA SMDR



PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Medical Device | Device Category | Registrant | Product Owner | Importer | Wholesaler | Local Manufacturer | Advanced Search

Medical Device

0-9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z All

0-9

1stQ AddOn Intraocular Lens (Spherical) [1stQ GmbH], 1stQ AddOn IOLs are intended for implantation i...
1stQ AddOn Intraocular Lens (Toric) [1stQ GmbH], All 1stQ AddOn IOLs are indicated for implantation ...
3-D Matrix PuraStat®Absorbable Haemostat [3-D Matrix Europe SAS], PuraStat is indicated for haemosta...
3A Health Care OMRON Compressor Nebulizer with Nasal Aspirator [3A HEALTH CARE S.r.l.], The intended...
3D-Shaper Medical S.L. 3D-SHAPER [3D-SHAPER MEDICAL SL], 3D-SHAPER is a stand-alone medical software...
3M Bair Hugger™ Temperature Monitoring System [3M Company], Measure, monitor, and trend body tempera...
3M Deutschland Dental Restorative Materials [3M Deutschland GmbH], Liquid compounds specially design...
3M ESPE Adper™ Easy One Self-Etch Adhesive [3M Deutschland GmbH], It is indicated for all classes of...
3M ESPE Adper™ Prompt™ / Adper™ Prompt™ L-Pop™ Self-Etch Adhesive [3M Deutschland GmbH], It is inten...
3M ESPE Adper™ Scotchbond™ Multipurpose Adhesive [3M ESPE], The Adper Scotchbond Multi-purpose adhes...

Total 19137 matching record(s) Page 1 of 1914 Go [first] | [previous] | [next] | [last]

Note: All device listings on the Singapore Medical Device Register (SMDR) are active. Class A medical devices are not registered in the SMDR. To retrieve Class A medical devices, please visit Class A Medical Device Database.

Singapore Medical Device Register (SMDR)

Class A

Class B/C/D

Local Authorities & Industry with IMDS – Supporting Innovation ie Digital Medical Device

Regulator

TECH
ENABLING REGULATORY COMPLIANCE
An Initiative by HSA

SUPPORTING INNOVATION AND FASTER ACCESS TO SAFE MEDICAL DEVICES

Industry

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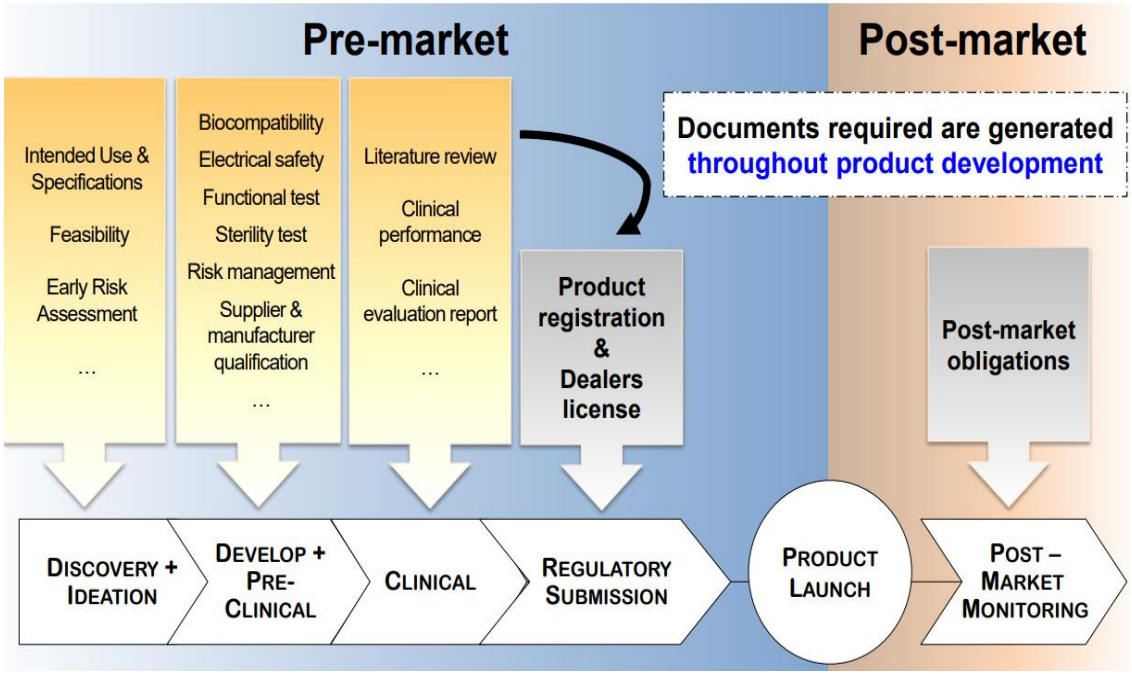
Program overview of medical devices lifecycle, from R&D to commercialization for MEDTECH PROFESSIONALS.



MEDTECH START-UP REGULATORY ROADMAP

HELP YOUR PRODUCT DEVELOPMENT TEAM TO SET UP MDF AND QMS

Step 1: Local/Global Regulatory Strategy

Global Regulatory Strategy
eg Countries, Class, Clinical, QMS **(consultation)**

Step 2: Quality Management System

Quality Management System
(**set up medical device design & development procedures**)

QMS (application) to Certification body (if required eg ISO13485, EU MDR/IVDR, USQSR)

QMS (Audit) by certification body or relevant body

QMS (Obtaining Certification)

Step 3: Medical Device File

Medical Device File (**set-up medical device documentations**)

Step 4: Local/Global Product Registration

SG HSA: Product Registration (**Dossier preparation**)

SG HSA: Product registration **(Dossier submission)**

CE Notified Body: Product Registration **(Dossier preparation)**

CE Notified Body: Product registration **(Dossier Submission)**

Product Registration in ASEAN Countries

Global/Asia Registration

Class I	Class IIa / II	Class IIb / II	Class III
Class A	Class B	Class C	Class D
General IVD	General IVD	List B IVD	List A IVD

01 Risk classification, exemption/registration, documents & lead time

02 Preparation of Technical Documents

03 Appoint In-Country Representative for Product License holding (ARQon)

04 Product Registration by Local Authorised Rep.

05 Product Approval

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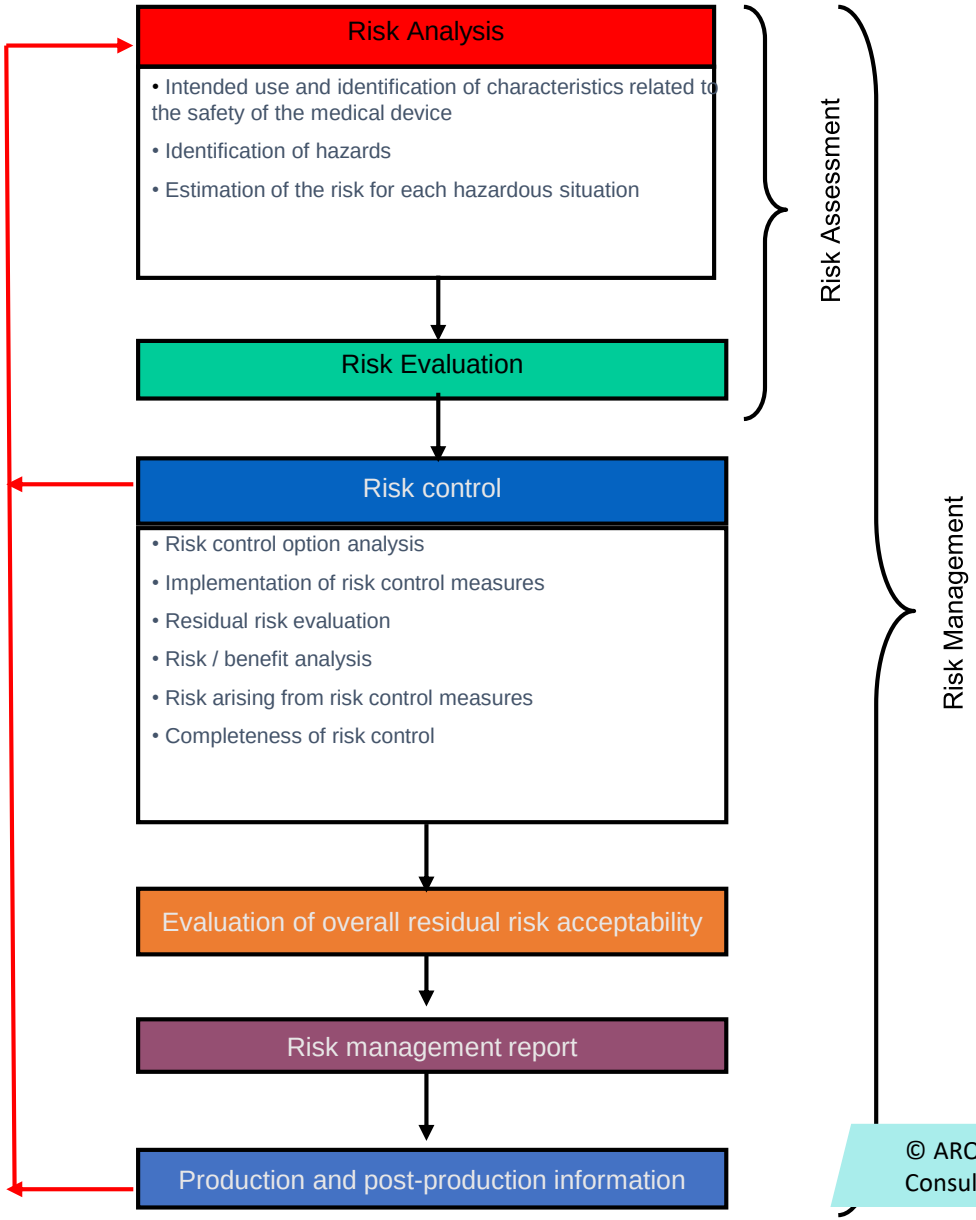
Risk Management based on ISO14971



Design Failure Mode and Effects Analysis (DFMEA)

No.	Item and Item Function	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Cause(s)/ Mechanisms of Failure	Likelihood	Risk Index (H / M / L)

List the component/ module /system to be analyzed & its intended function

Identify the failure mode associated with Item Function being delivered

Identify the impact of the failure to the end user:

- Injury
- Performance Issue

Identify the root cause of the failure

Assign the severity & likelihood

Calculate the Risk Index based on the severity and likelihood ratings.

CONTENTS

- Medical Device Definition & Classification
- Clinical Research Requirements
- Adverse Event Reporting
- Q&A

Clinical Trial & CRM Regulations

Clinical Trial regulations are intended:

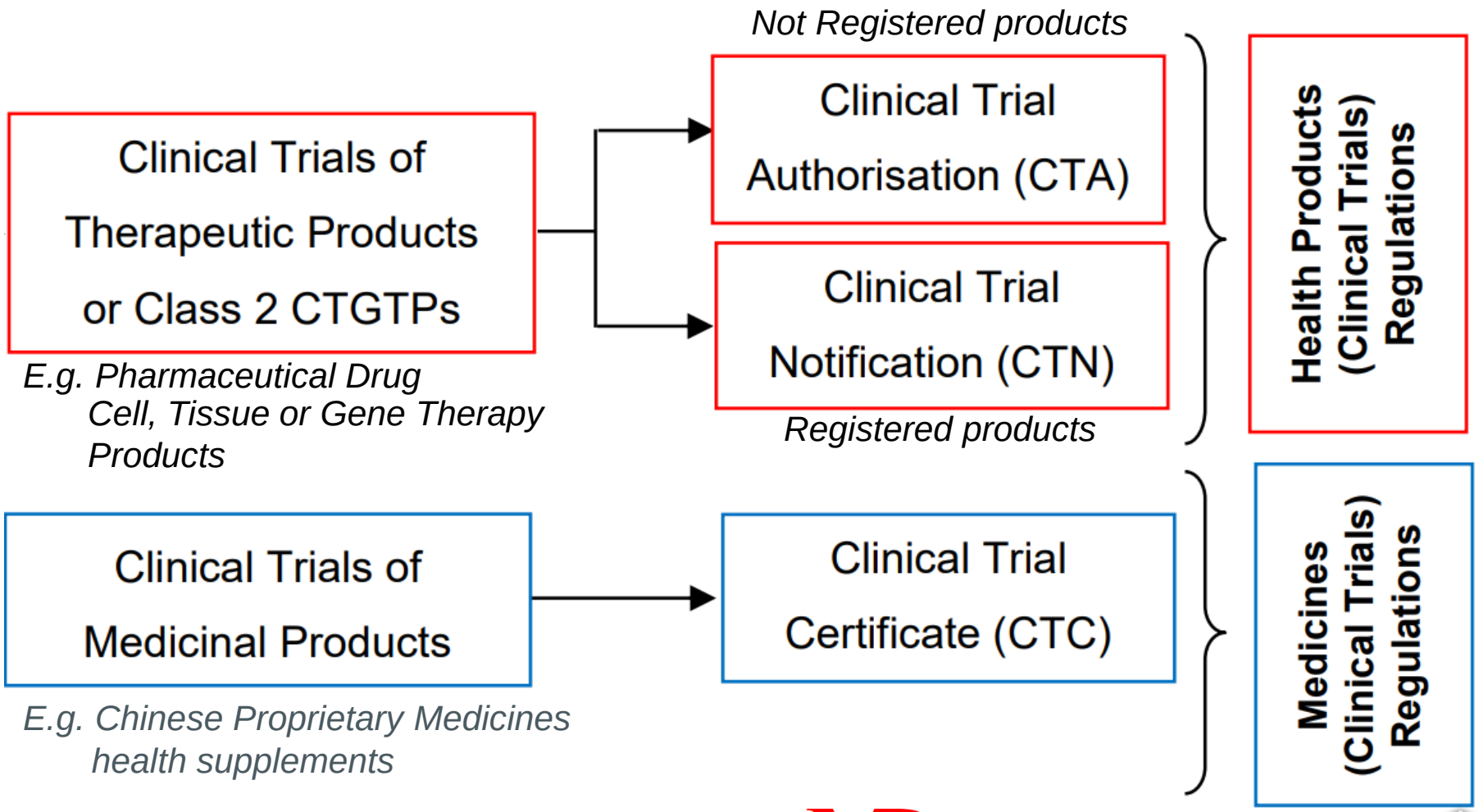
to regulate **the conduct** of regulated clinical trials, including the parties (e.g., sponsor, investigator) critical to ensuring that clinical trials are conducted in accordance with Good Clinical Practice.

CRM regulations are intended:

to regulate **the product and dealers** (manufacturers, importers, suppliers) and to **safeguard the supply chain** relating to health products/medicinal products that are imported, locally manufactured or supplied for use in clinical research.

A) Clinical Trial submission to HSA - REQUIRED

Regulated Clinical Trial



A) Clinical Trial submission to HSA – NOT REQUIRED

Not Regulated Clinical Trial

(i) observational clinical trials of therapeutic products, Class 2 CTGTPs or medicinal products;

(ii) clinical studies in which therapeutic products or medicinal products are used for a known effect, and are not the subject of investigation for potential efficacy, safety, pharmacokinetics etc.;

(iii) medical device clinical trials; or

(iv) food and nutrition studies involving the use of medical devices

Class 1 CTGTP means a CTGTP that —

(a) is the result of only minimal manipulation of human cell or tissue;

(b) is intended for homologous use;

(c) is not combined or used with a therapeutic product or a medical device; and

(d) is assigned by HSA as a Class 1 CTGTP due to a lower health risk to a user of the product.

NB: Clinical trials of Class 1 CTGTP will be regulated under the Human Biomedical Research Act.

B) Clinical Research Material submission to HSA - REQUIRED

Clinical Research Material Notification

Clinical research means any research involving **human subjects.**

CRM means any registered or unregistered TP, MP, MD, applicable CTGTP, or placebo, that is manufactured, imported or supplied for the purpose of being used in clinical research, by way of administration to a trial participant in accordance with the research protocol or for a clinical purpose.

CRM may be imported, locally manufactured or procured from local commercial sources.

B) Clinical Research Material submission to HSA - REQUIRED

Clinical Research Material Notification

Product type	Key regulations for CRM
Therapeutic products	Health Products (Clinical Research Materials) Regulations
* Class 2 CTGTPs * Class 1 CTGTPs for which a manufacturer/ importer/ wholesaler notification has not been made to HSA	
Medicinal products	Medicines (Medicinal Products as Clinical Research Materials) Regulations
Medical devices	Health Products (Medical Devices) Regulations

B) Clinical Research Material submission – NOT REQUIRED

Not Required CRM notification

- Locally registered CRM obtained from local commercial sources
- Import of locally registered CRM for local clinical research use if the importer already has a valid importer's licence for the import of CRM
- Supply of a locally registered CRM by its local manufacturer for local clinical research use if the manufacturer has a valid manufacturer's licence
- Supply of CRM by a local manufacturer if the manufacture of the CRM being supplied comprises solely of the packaging or labelling of the CRM
- Import of a minimally manipulated CTGTP CRM for local clinical research use by a known importer
- Supply of a minimally manipulated CTGTP CRM by its known manufacturer for local clinical research use

For products imported solely for export to overseas trial sites, CRM notification is not applicable. You would need to apply for an approval to import these products accordingly:

- **Therapeutic products:** Importer's licence for therapeutic products
- **Medical devices:** Import for re-export approval for medical device
- **CTGTP:** Import for re-export for CTGTP

B) Clinical Research Material submission to HSA – NOT REQUIRED

Category	Examples	Comments / additional notes
Research material that is not a TP, CTGTP, MP or MD	• Human tissue biopsy samples donated for use in laboratory research and not intended for clinical use • Stationery, plastic bags for general use, tablet computers	Since the research material is not a TP, CTGTP, MP or MD, and therefore not a CRM, the requirements of the Health Products Act, Medicines Act and CRM regulations are not applicable. As such, the importer will not require an *Importer's Licence* from HSA in order to import the research material. HSA also need not be notified of the import in accordance with the CRM regulations. If you are unsure as to whether the research material / product to be used is a TP, CTGTP, MP or MD, please submit a Health Products Classification Enquiry via HSA website.
Products excluded from the CRM regulations E.g., MP specified in the First Schedule of the Medicines (MP as CRM) Regulations 2016, Class 1 CTGTPs that are manufactured / imported / supplied by known manufacturers / importers / wholesalers	• Homeopathic medicine • Medicated oil and balm • Quasi-medicinal products • Traditional medicine • Herbal remedy • Raw materials used as ingredients in the preparation or manufacture of any medicinal product, e.g., active pharmaceutical ingredients, intermediates, excipients	The First Schedule of the Medicines (Medicinal Products as Clinical Research Materials) Regulations contains a list of medicinal products excluded from the CRM regulations. This list is aligned to the list of medicinal products exempted from product licence and dealers' licensing requirements. As such, an *Importer's Licence* will not be required under the Medicines Act. HSA also need not be notified of the import in accordance with the CRM regulations. However, if the active pharmaceutical ingredient contains, or is a substance that is listed as a poison under the Poisons Act, a *Form A Poisons licence* will be required.

B) Clinical Research Material notification to HSA – NOT REQUIRED

TP, CTGTP, MP or MD that is intended for **non-clinical** purposes only (e.g., used in laboratory or animal research only and not administered or applied to humans).	• A TP that is imported or locally manufactured for toxicology tests in rats • A drug-coated coronary stent (MD) that is imported or locally manufactured for proof-of-concept studies in monkeys • Clinical trial kits containing TP that are imported for disposal or destruction in Singapore	As the TP, CTGTP, MP or MD is not administered to humans or not intended for a clinical purpose, they are not considered to be CRM. However, the import and supply of the product will be subject to applicable requirements of the Health Products Act, Medicines Act and/or related subsidiary legislation. For TP, companies not holding a valid *Importer's Licence* and are only importing TP for non-clinical purposes will require an *Importer's Licence for Restricted Activity(ies)*. For MD, please refer to *Special Access Routes* for medical devices on HSA website.
TP, MP or MD that is not intended for **local** clinical research use	• TP imported solely for export for use in regional clinical research (not including Singapore as a trial site) • TP that is locally manufactured for export only	Products that are imported solely for export or manufactured solely for export are not CRM. Therefore, the exceptions and requirements of the CRM regulations are not applicable. For TP, the import-for-export will be governed by the Health Products Act and the Health Products (Therapeutic Products) Regulations. Companies not holding a valid *Importer's Licence* and are only importing TP solely for export will require an *Importer's Licence for Restricted Activity(ies)*. For MD, please refer to *Special Access Routes* for medical devices on HSA website.
TP, MP that is used by participants in the clinical research, but not as an investigational or auxiliary CRM*	Registered TP/MP used as • pre-medication • rescue medication • treatment for trial-related adverse events • concomitant medication for co-morbidities	TP/MP that are not regulated as CRM (i.e., not investigational or auxiliary CRM) will be subject to controls under the Health Products Act, Health Products (Therapeutic Products) Regulations or Medicines Act instead.

OTHER ADDITIONAL (IF ANY)

Substances	Additional requirements
Controlled drugs and psychotropic substances	Licences for controlled drugs and psychotropic substances **Note:** CTA/CTN/CTC and/or CRM notification acknowledgement (as applicable) should be provided in the application for the above licences. Upon trial completion, any leftover CRM must be destroyed, and the procedure witnessed by a HSA inspector. If the CRM is to be exported, a corresponding export licence should be applied and issued before the export is made.
Poisons	Form A Poisons Licence **Note:** CRMs which are therapeutic products are excluded from this requirement.
Radiopharmaceuticals	The import, export, possession, use, transport and disposal of radioactive material is regulated under the Radiation Protection Act by the National Environment Agency .
Radiofrequency	Infocomm Media Development Authority (IMDA)

HSA DEALER LICENSE – NOT REQUIRED

Activity	Licence	CRM Notification
Manufacture of CRM	Manufacturer's Licence Not required	**CRM Notification** required prior to supply of CRM by local manufacturer
Import of CRM	Importer's Licence Not required	**CRM Notification** required prior to import of CRM
Wholesale of CRM	Wholesaler's Licence Not required	-
Supply of CRM	Product Registration Not required	-

CRM Notification – Process Flow

	Clinical research not regulated by HSA	Regulated clinical trial
Drafter of CRM notification form	Importer or local manufacturer	Sponsor (on behalf of importer or local manufacturer)
Notification Form (PRISM)	CRM Notification form	Part of CTA/CTN/CTC application form
Endorsement Workflow	Importer/Local manufacturer –> Sponsor	Sponsor -> Importer/Local Manufacturer (endorsement)
Submitter	Importer or local manufacturer	Sponsor (on behalf of importer or local manufacturer)
Acknowledgment notification	Importer, local manufacturer, sponsor	Importer, local manufacturer, sponsor
Validity period of notification	1 year from the date of notification	Duration of the clinical trial

CRM Notification – Form

PT0101 CLINICAL RESEARCH MATERIAL NOTIFICATION

Fill in the application form Guideline Help

1. **Particulars of Importer / Local Manufacturer**
2. Particulars of Clinical Research
3. Particulars of Clinical Research Materials (CRM)
4. Supporting Documents
5. Declaration & Confirmation

Special Symbol | Attach | Save

Next

Fields marked with an asterisk * are mandatory.

1. Introduction

1.1 Please select *	○ Importer of CRM ○ Supply of CRM by Local Manufacturer
1.2 Please select the type of CRM to be imported or supplied *	☐ Therapeutic Product ☐ Medical Device ☐ Medicinal Product (e.g. Cell- and Tissue-based Product, Complementary Health Products)

4. Supporting Documents

To add an attachment, type in the path or hit the browse button. Then **hit the Attach Files button to save the attachment** to the list below.

Please click here for guideline on document attachment.

Documents		
4.1	IRB Approval Letter :	Browse...
4.2	Listing of Components in a Medical Device System :	Browse...
4.3	Packing list for Study-Visits Specific Kits :	Browse...
4.4	GMP certificate :	Browse...
4.5	Other Supporting Documents :	Browse...

CRM Notification – Form

PZO901 ENQUIRE@PRISM

Important Notes:
For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices.

Search Criteria

Licence/Permit/Certificate/Listing/ Notification/Registration Type *	Clinical Research Material Notification
Status *	Active
Licence/Permit/Certificate/Listing/ Notification/Registration No	CRM1600118
Product Name	
Start Date (dd/mm/yyyy)	To
Expiry Date (dd/mm/yyyy)	To

Search Reset

Please do not access the record using the new window via right mouse click.

1 Matching Record(s)

Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Active Clinical Research Material Notification

S/No	HSA Appl No	CRM No	Date of Notification/Approval	Valid Until / Date of Expiry	CTC/CTA/CTN No	Research Reference / Protocol No
1	1601182X	CRM1600118	10/10/2016	09/10/2017		

CRM Notification – Form

1. Clinical Research Material Notification	
Notification Number	CRM1600118
Notification Date	10/10/2016
Valid Until	09/10/2017

2 Particulars of Importer/Manufacturer			
2.1 Unique Entity No.(UEN)	196400192M		
2.2 Company Name	PFIZER PTE LTD		
2.3 Address			
2.3.1 Address Type:	Local		
2.3.2 Postal Code: *	189721		
2.3.3 Block / House No:	152	2.3.4 Level - Unit: *	# - 00
2.3.5 Street Name:	BEACH RD		
2.3.6 Building Name:	GATEWAY EAST		
2.3.7 Country:	SINGAPORE		
2.4 Company Representative	Paris		
2.5 Designation:	RP		
2.6 Tel.No. :	12341	2.7 Fax.No. :	
2.8 Email:	paris@pfizer.co		

3. Particulars of Clinical Trial/Research	
3.1 Name of Trial/Research Sponsor:	Sponsor Name
Particulars of Clinical Research (1)	
3.2 Title of Clinical Trial/Research:	Title
3.3 Protocol/Research Reference Number:	Ref No

3.4 List of Principal Investigator(s) & Clinical Trial/Research Site(s)

Principal Investigator(s)	Clinical Trial / Research Site
Ash Chua	National Cancer Centre

4 Particulars of Clinical Research Material (CRM)

4.2 Medical Device for Investigational Purpose

No.	Device Name	Type of Medical Device	Identifier	Estimated Total Quantity	Remarks
1	MD	General Medical Device	MD01	1000	

CONTENTS

- Medical Device Definition & Classification
- Clinical Research Requirements
- Adverse Event Reporting
- Q&A

Adverse Event Reporting

Adverse event reporting

Submit the Mandatory Medical Device Adverse Event Reporting Form for Medical Device Dealers 183 KB through e-mail. Keep the email size under 2MB.

Refer to our guides if you are reporting an adverse event:

- As a healthcare professional.
- In a clinical trial.

HSA Medical Device Branch
https://www.hsa.gov.sg/medical-devices/adverse-events
- AE Report form for registered MD
- Voluntary AE Report form

HSA Clinical Trial Branch
https://www.hsa.gov.sg/clinical-trials/adverse-events
- AE Report form for MD Clinical Research
- Non-compliance CRM form.

When to report

It is mandatory for medical device companies, including product registrants, manufacturers, importers and suppliers, to report any AEs related to the medical devices they deal in.

The following medical device-associated AEs must be reported to us:

Adverse events	Report within
Serious threat to public health	48 hours
Death	10 days
Serious deterioration in state of health	10 days
Possible death or serious injury if the adverse event were to recur	30 days

CONTENTS

- Medical Device Definition & Classification
- Clinical Research Requirements
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- Q&A

Q&A – Ref. HSA and ARQon

What are the CRM records to be in place?

If the records relate to an unregistered MD CRM that is supplied for use in a regulated clinical trial, records of receipt and supply must be kept until the following time-point, whichever is latest:

- when there is no more pending or planned application for registration of the TP or MP that was tested in the clinical trial or research
- 2 years after the last of such registrations has been granted
- 2 years after HSA was informed of the termination of a clinical trial
- 6 years after the completion of a clinical trial (i.e., 6 years after "Last-Patient-Last-Visit), or
- any other period as directed by HSA

If the MD CRM (whether registered or unregistered) is supplied for use in clinical research that is not regulated by HSA, or if the MD CRM is a registered MD, records of receipt and supply must be kept for either

- the projected useful life of the medical device, or
- 2 years after the date on which the medical device was supplied, whichever is the longer period

Q&A – Ref. HSA and ARQon

Who is local sponsor

Local sponsor refers to the local company or local institution which takes responsibility for the initiation, management or financing of the clinical trial.

IRB application requirements for Medical Devices?

Key documents (and other information depends on the IRB)

- Clinical Trial Protocol
- Principal Investigator brochure
- Patient Consent form
- Product information

Is it ok to do a limited trial (eg. 10-25 people) using a device sponsored by a pharmaceutical company?

Yes, CRM notification submission required if it is medical device clinical research. Purpose of the trial to be determined

Clinical Laboratory with Lab Developed Tests (LDTs) (under RHMC/HSCA)

DISTRIBUTE OUTSIDE IN-HOUSE USE ONLY?

When distributed outside Laboratory A, it is not LDT.

Not LDT will be regulated as IVD by HSA.

OFF LABEL USE?

When it is Off-label use IVD, it is not LDT.

Licensed laboratory is responsible for the safety and efficacy of the test.

Q&A – Ref. HSA and ARQon

HSA Health Sciences Authority

FAQ

Question	Answer
Are the SAR updates applicable to applications submitted before 1 April 2022?	The updates to the Special Access Routes (SAR) for unregistered medical devices are only applicable to SAR applications submitted from 1 April 2022.
For SAR applications that include Class D medical devices that require MOH review as well as other devices that do not require MOH review, will the TAT for the entire application be longer or will those that do not require MOH review be approved first?	Yes, the TAT may be extended for the submitted application as long as it includes Class D medical devices that fall under the specific categories of Class D devices that require review by MOH. As such, please plan accordingly prior to submission.
Who is responsible for submitting the Clinical Justification Review Form to MOH for their review and approval?	All SAR supporting documents, including the Clinical Justification Review Form shall be submitted to HSA via MEDICS. HSA will liaise with MOH directly and MOH will contact applicant directly for any clarifications related to the form. HSA will inform the applicant via MEDICS on the outcome of the SAR application.
After expiry of the GN27 application, is a new GN27 application required if the healthcare facility wishes to continue using the device?	For single-use medical devices and implants, these devices shall not be used by the healthcare facility after expiry of the SAR licence. A new GN27 will be required for continued usage by the HCP. As such, companies are recommended to manage their inventories accordingly and only supply the quantity of device that is required by the healthcare facility. For equipment and reusable devices, users can continue to use these devices after expiry of the SAR licence. A new SAR application will not be required.

JOIN US

Focus group or Interest on

https://www.imdsgroup.com/contact

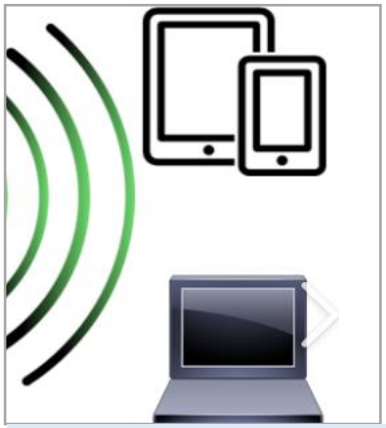
1. ***LDT Public consultation. In-house MD?***
2. ***B2B International Medical Digital Platform***
   - Forum Connection for *medtech professionals*
   - E-Commerce for *medtech companies*

IMD School
International Medical Device School

ARQon

Medical Device Approval

Drug/Cosmetic Approval



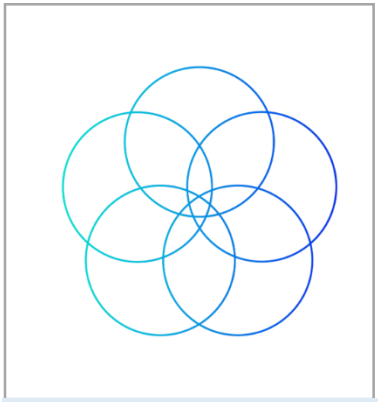
Radiation/Telcom Approval

Technical File/ISO

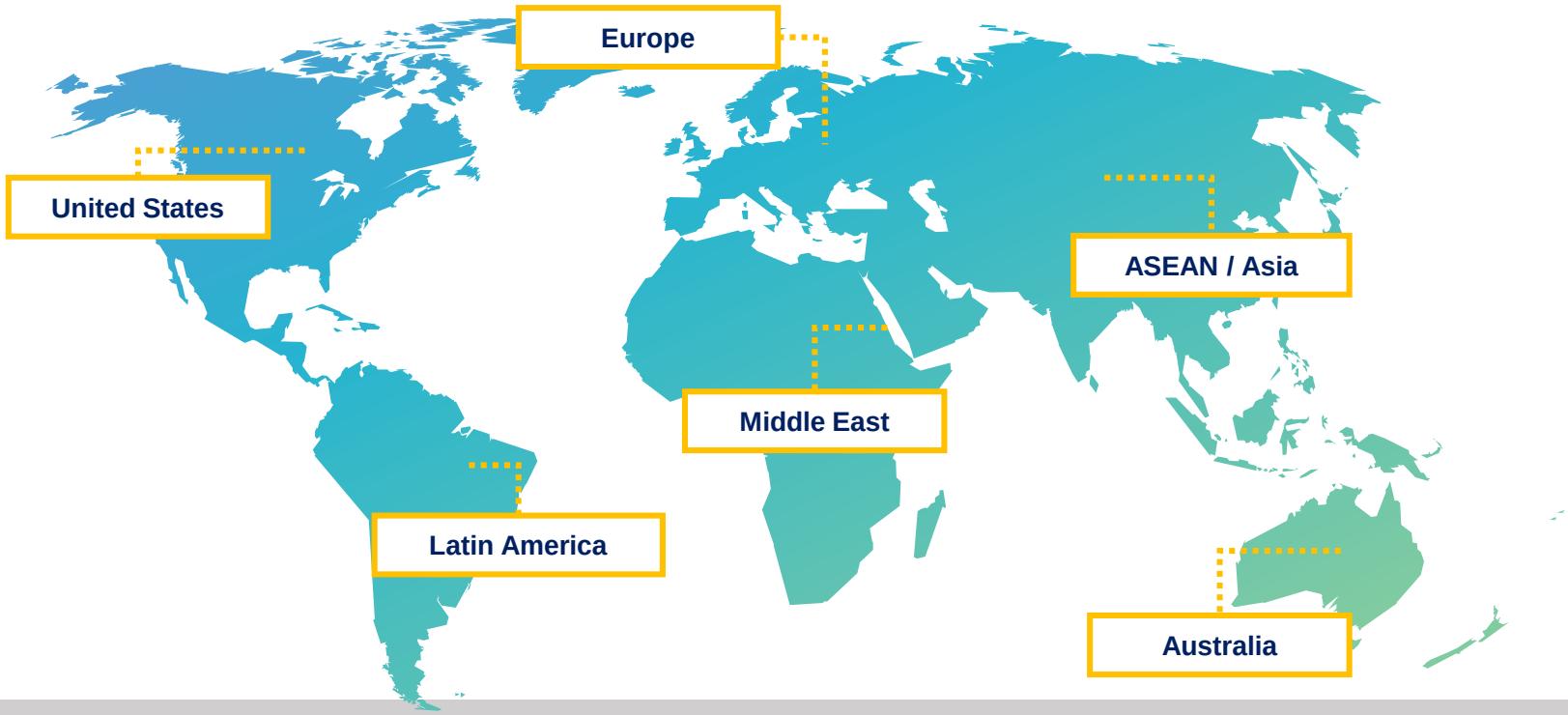
Mfr/Importer/REP

Training

Business Matching



B2B Platform



Contact us …. HQ -Singapore, ASEAN/ASIA, AU, EUROPE, US, LAMER, MIDDLE EAST, GLOBAL

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