ASIAN HARMONIZATION WORKING PARTY

Ministry of Health
Sultanate of Oman

PADC
المديرية العامة للصيدلة والرقابة الدوائية
DG of Pharmaceutical Affairs & Drug Control

24th ASIAN HARMONIZATION WORKING PARTY (AHWP) ANNUAL MEETING

AHWP Capacity Building Workshop

TRACK 1: Regulatory Fundamentals

November 11, 2019

Risk Classification of Medical Devices

Wing Gang SEET

Director, RA & QA, Asia Pacific

Hillrom™


Why
Who
Risk
Classification
What
How

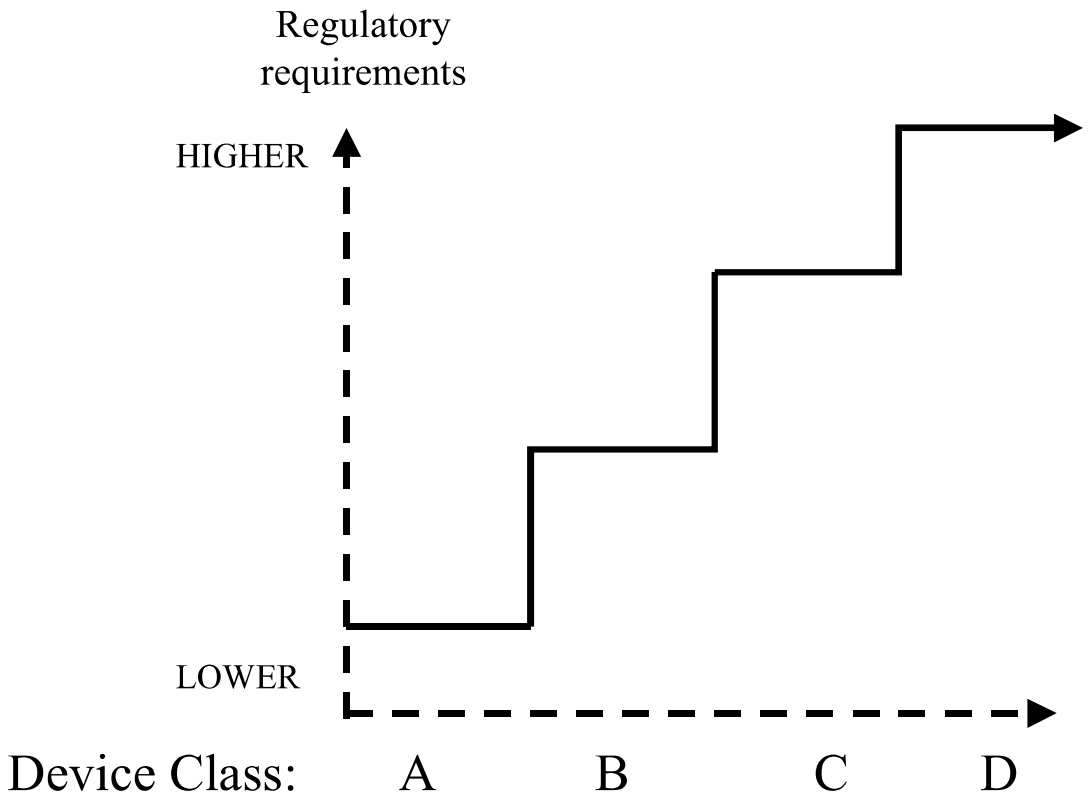
Why do we classify medical devices?

Why Classify?

- Regulatory controls should be proportional to the risk presented through using the device, to
  - The patient
  - The user
  - The environment

- The level of control should increase with increasing degree of risk

Why Classify?



Class	Risk Level
A	Low Risk
B	Low-moderate Risk
C	Moderate-high Risk
D	High Risk

Categorisation

Is the product a medical device?

vs

Classification

What level of regulatory control?

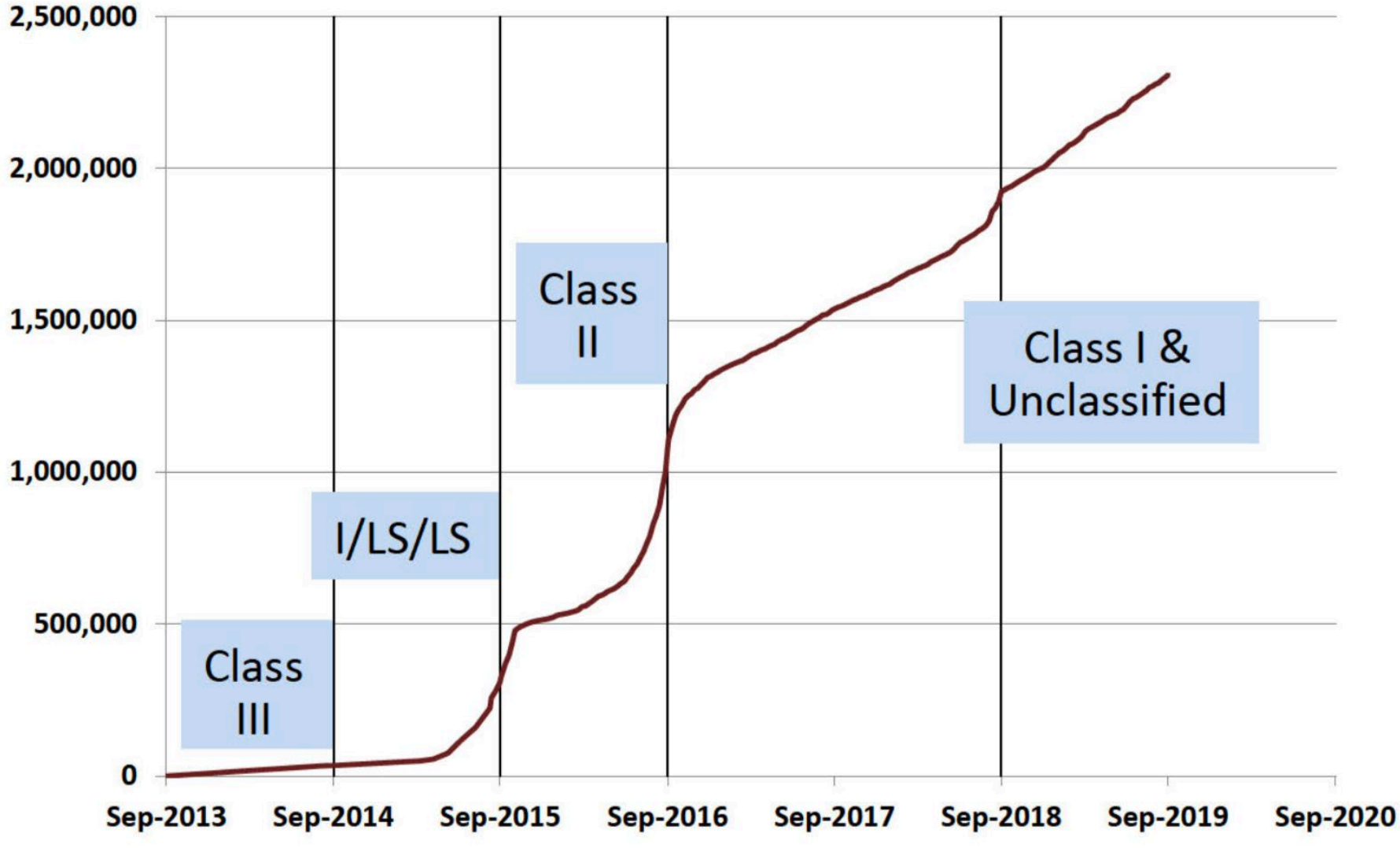
How many medical devices are there in the market?

There are more than 500,000 medical technologies registered. These fall within 16 categories of products, as determined by the Global Medical Devices Nomenclature (GMDN) Agency[3].

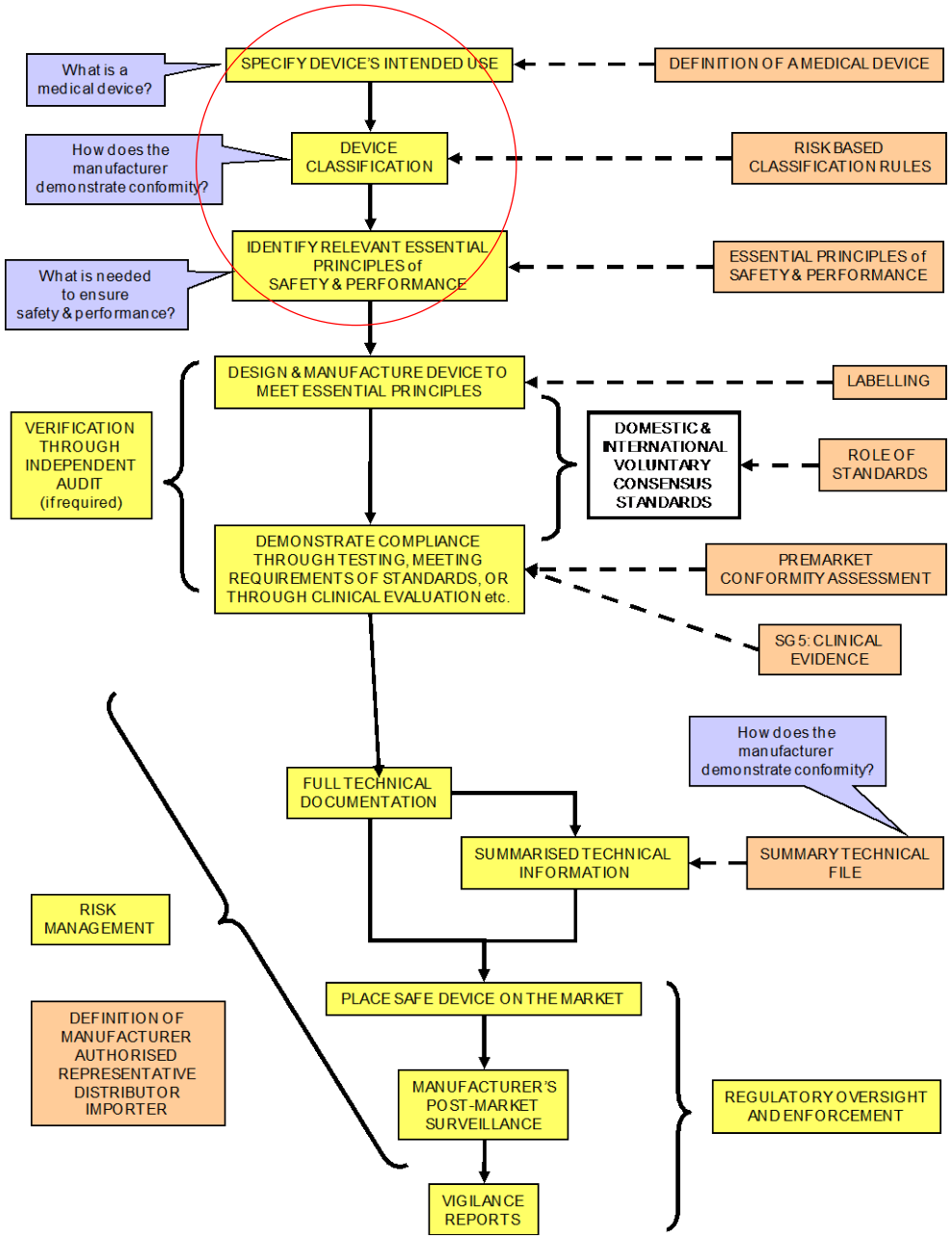
Code	Classification	Example
01	**Active implantable technology**	Cardiac pacemakers, neurostimulators
02	**Anesthetic respiratory technology**	Oxygen mask, gas delivery unit, anesthesia breathing circuit
03	**Dental Technology**	Dentistry tools, alloys, resins, floss, brushes
04	**Electromechanical medical technology**	X-ray machine, laser, scanner
05	**Hospital hardware**	Hospital bed
06	**In vitro diagnostics technology**	Pregnancy test, genetic test, glucose strip
07	**Non-active implantable technology**	Hip or knee joint replacement, cardiac stent
08	**Ophthalmic and optical technology**	Spectacles, contact lenses, intraocular lenses, ophthalmoscope
09	**Reusable instruments**	Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes
10	**Single use technology**	Syringes, needles, latex gloves, balloon catheters
11	**Technical aids for disabled**	Wheelchairs, walking frames, hearing aids
12	**Diagnostic and therapeutic radiation technology**	Radiotherapy units
13	**Complementary therapy devices**	Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups
14	**Biological-derived devices**	Biological hearth valves
15	**Healthcare facility products and adaptations**	Gas delivery systems
16	**Laboratory equipment**	Most IVD which are not reagents

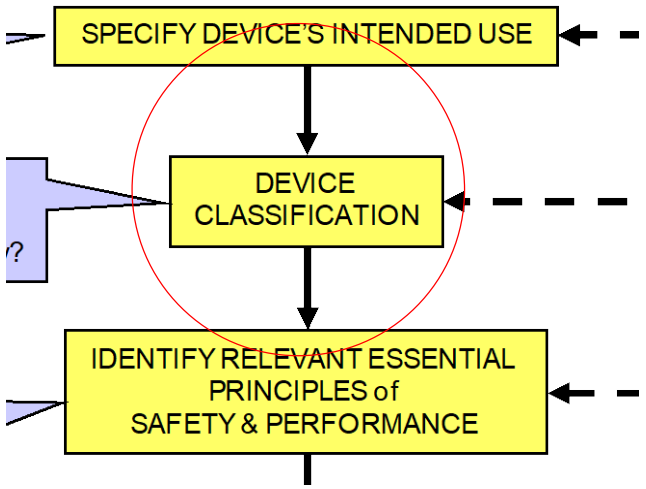
GUDID Records and Submission Compliance Dates

Data Current as of October 22, 2019

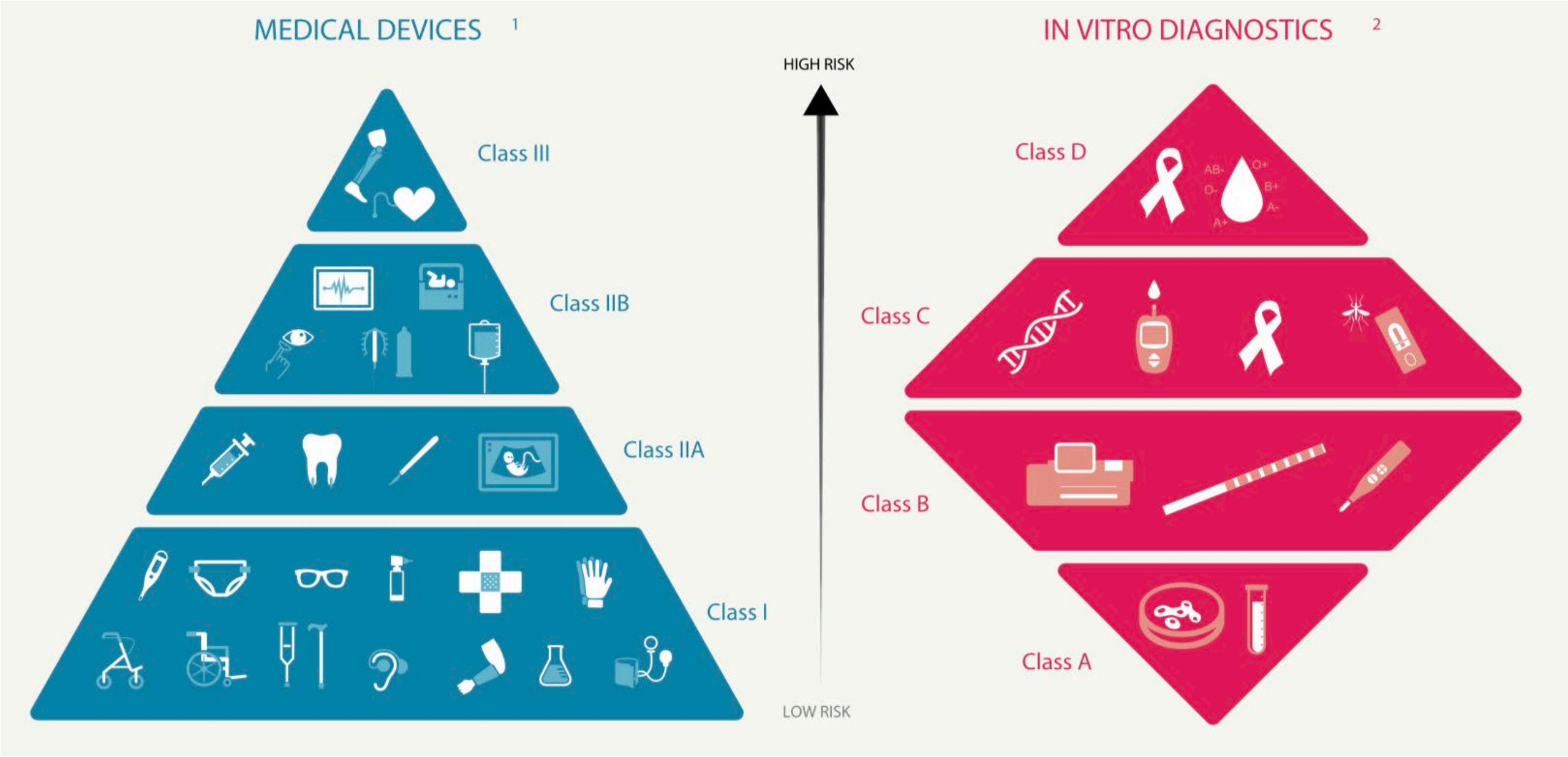


Who should classify medical devices?


What is a medical device?
SPECIFY DEVICE'S INTENDED USE
DEFINITION OF A MEDICAL DEVICE
How does the manufacturer demonstrate conformity?
DEVICE CLASSIFICATION
RISK BASED CLASSIFICATION RULES
What is needed to ensure safety & performance?
IDENTIFY RELEVANT ESSENTIAL PRINCIPLES of SAFETY & PERFORMANCE
ESSENTIAL PRINCIPLES of SAFETY & PERFORMANCE
DESIGN & MANUFACTURE DEVICE TO MEET ESSENTIAL PRINCIPLES
LABELLING
VERIFICATION THROUGH INDEPENDENT AUDIT (if required)
DOMESTIC & INTERNATIONAL VOLUNTARY CONSENSUS STANDARDS
ROLE OF STANDARDS
DEMONSTRATE COMPLIANCE THROUGH TESTING, MEETING REQUIREMENTS OF STANDARDS, OR THROUGH CLINICAL EVALUATION etc.
PREMARKET CONFORMITY ASSESSMENT
SG 5: CLINICAL EVIDENCE
How does the manufacturer demonstrate conformity?
FULL TECHNICAL DOCUMENTATION
SUMMARISED TECHNICAL INFORMATION
SUMMARY TECHNICAL FILE
RISK MANAGEMENT
PLACE SAFE DEVICE ON THE MARKET
DEFINITION OF MANUFACTURER AUTHORISED REPRESENTATIVE DISTRIBUTOR IMPORTER
MANUFACTURER'S POST-MARKET SURVEILLANCE
REGULATORY OVERSIGHT AND ENFORCEMENT
VIGILANCE REPORTS


SPECIFY DEVICE'S INTENDED USE
DEVICE CLASSIFICATION
IDENTIFY RELEVANT ESSENTIAL PRINCIPLES of SAFETY & PERFORMANCE

What is risk classification of medical devices?



MedTech Europe – The European Medical Technical Industry – in figures (2016)

Are they the same?

GHTF/IMDRF	Singapore	EU	China	US
A	A	I	I	I
B	B	IIa	II	II
C	C	IIb	III	III
D	D	III		

Are they the same?

GHTF/IMDRF		Singapore		EU (MDD)		China		US
A		A		I		I		I
B	≈	B	≈	IIa	≠	II	≠	II
C		C		IIb		III		III
D		D		III				

FINAL DOCUMENT

Title: Principles of Medical Devices Classification

Authoring Group: Study Group 1

Endorsed by: The Global Harmonization Task Force

Date: June 27, 2006

Georgette Lalis, GHTF Chair

The document herein was produced by the Global Harmonization Task Force, which is comprised of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: February 9, 2007

- Rule-based system

General Medical Device	
Non-invasive Devices	1 - 4
Invasive Devices	5 - 8
Active Devices	9 -12
Additional rules	13 - 16

In Vitro Diagnostic (IVD) medical devices
6

How to do risk classification for medical devices?

Factors influencing Device Classification

General Medical Devices

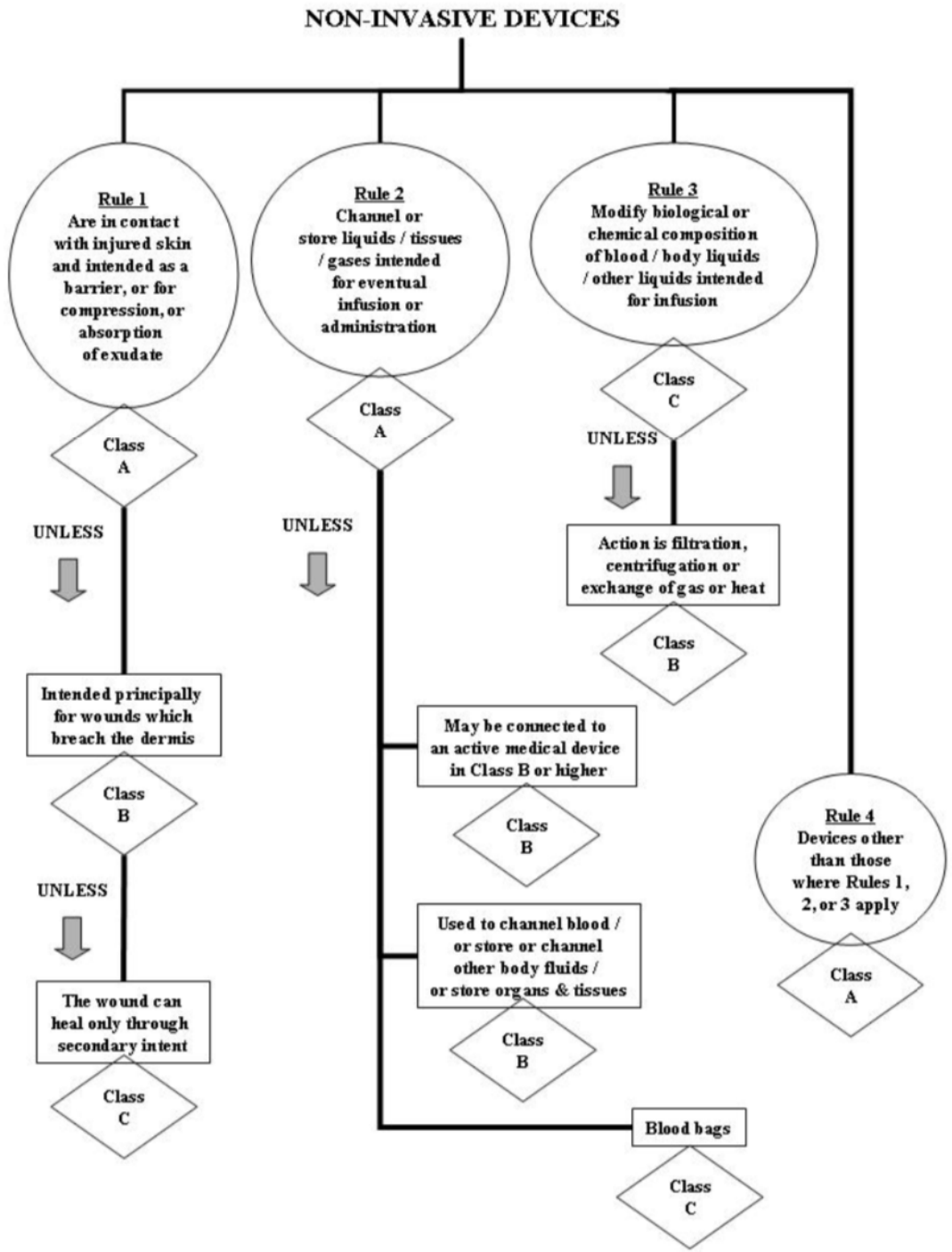
- Factors
  - duration of device contact with the body
  - the degree of invasiveness
  - whether the device delivers medicinal products or energy to the patient
  - whether they are intended to have a biological affect on the patient
  - local versus systemic effects
  - etc

Factors influencing Device Classification

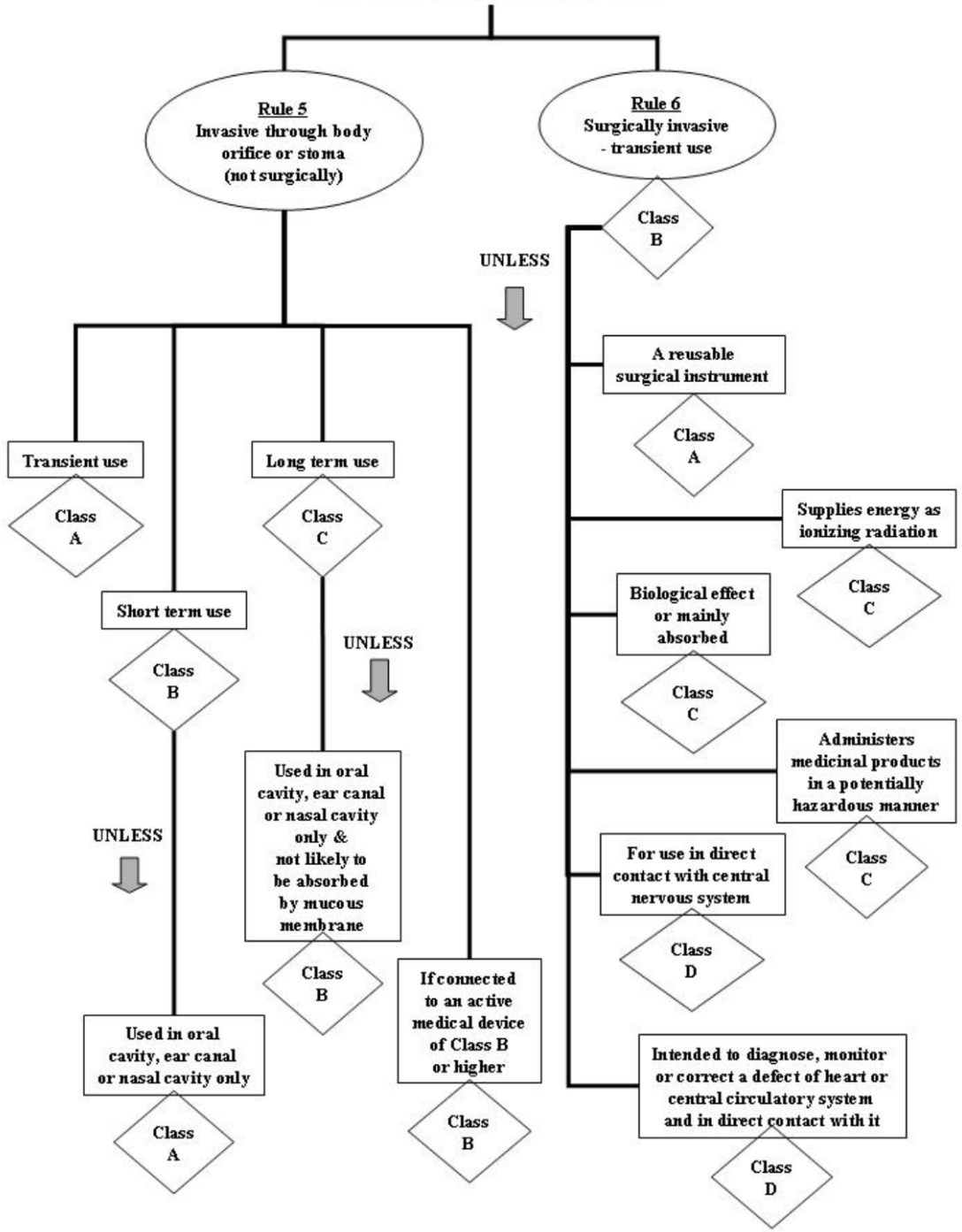
General Medical Devices

- If, based on the manufacturer's intended purpose, two or more classification rules apply to the device, the device is allocated the highest level of classification indicated.
- Where one medical device is intended to be used together with another medical device, that may or may not be from the same manufacturer, the classification rules should apply separately to each of the devices.

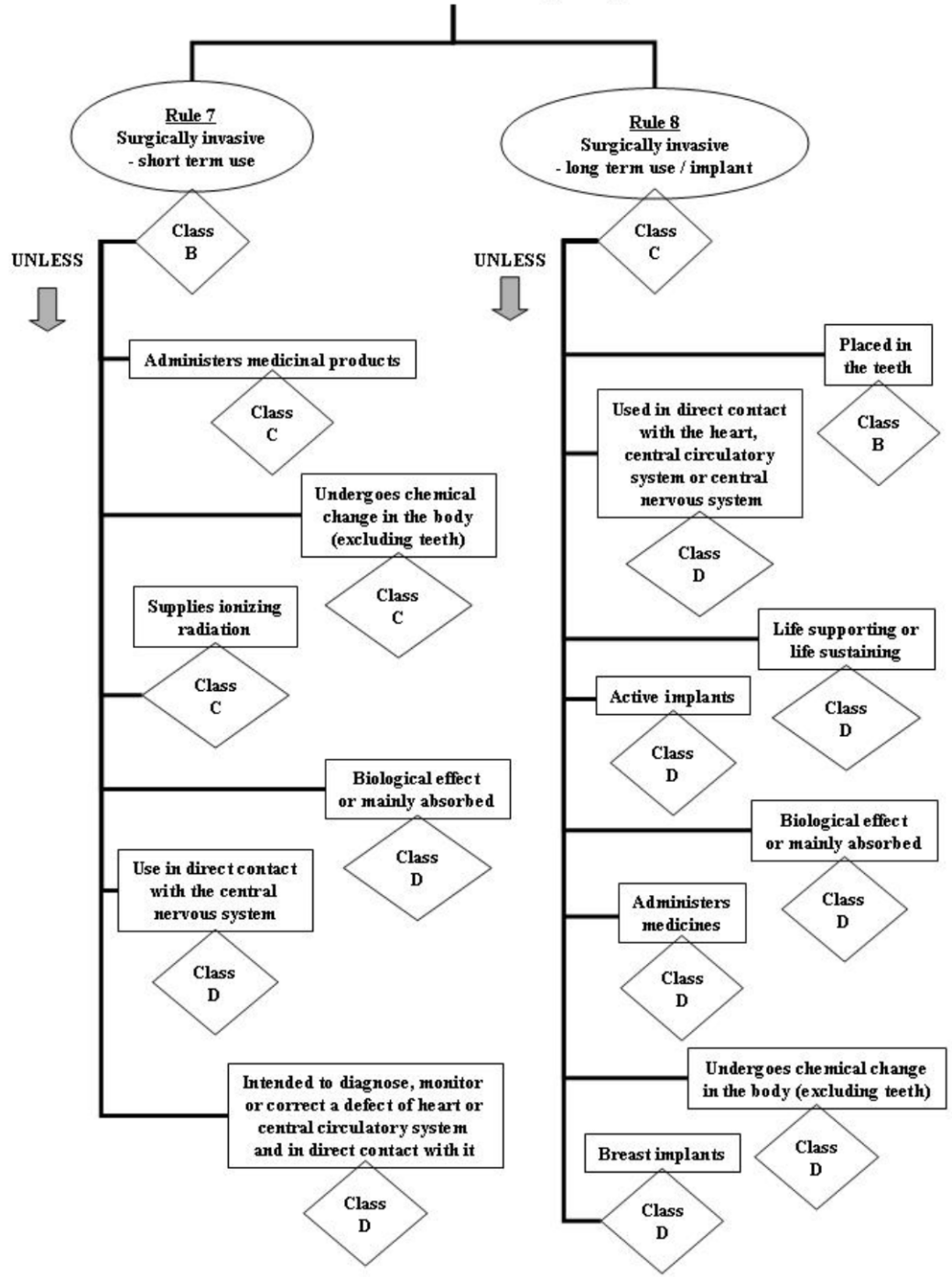
Rules for General Medical Devices


NON-INVASIVE DEVICES
Rule 1
Are in contact with injured skin and intended as a barrier, or for compression, or absorption of exudate
Class A
UNLESS
Intended principally for wounds which breach the dermis
Class B
UNLESS
The wound can heal only through secondary intent
Class C
Rule 2
Channel or store liquids / tissues / gases intended for eventual infusion or administration
Class A
UNLESS
May be connected to an active medical device in Class B or higher
Class B
Used to channel blood / or store or channel other body fluids / or store organs & tissues
Class B
Blood bags
Class C
Rule 3
Modify biological or chemical composition of blood / body liquids / other liquids intended for infusion
Class C
UNLESS
Action is filtration, centrifugation or exchange of gas or heat
Class B
Rule 4
Devices other than those where Rules 1, 2, or 3 apply
Class A

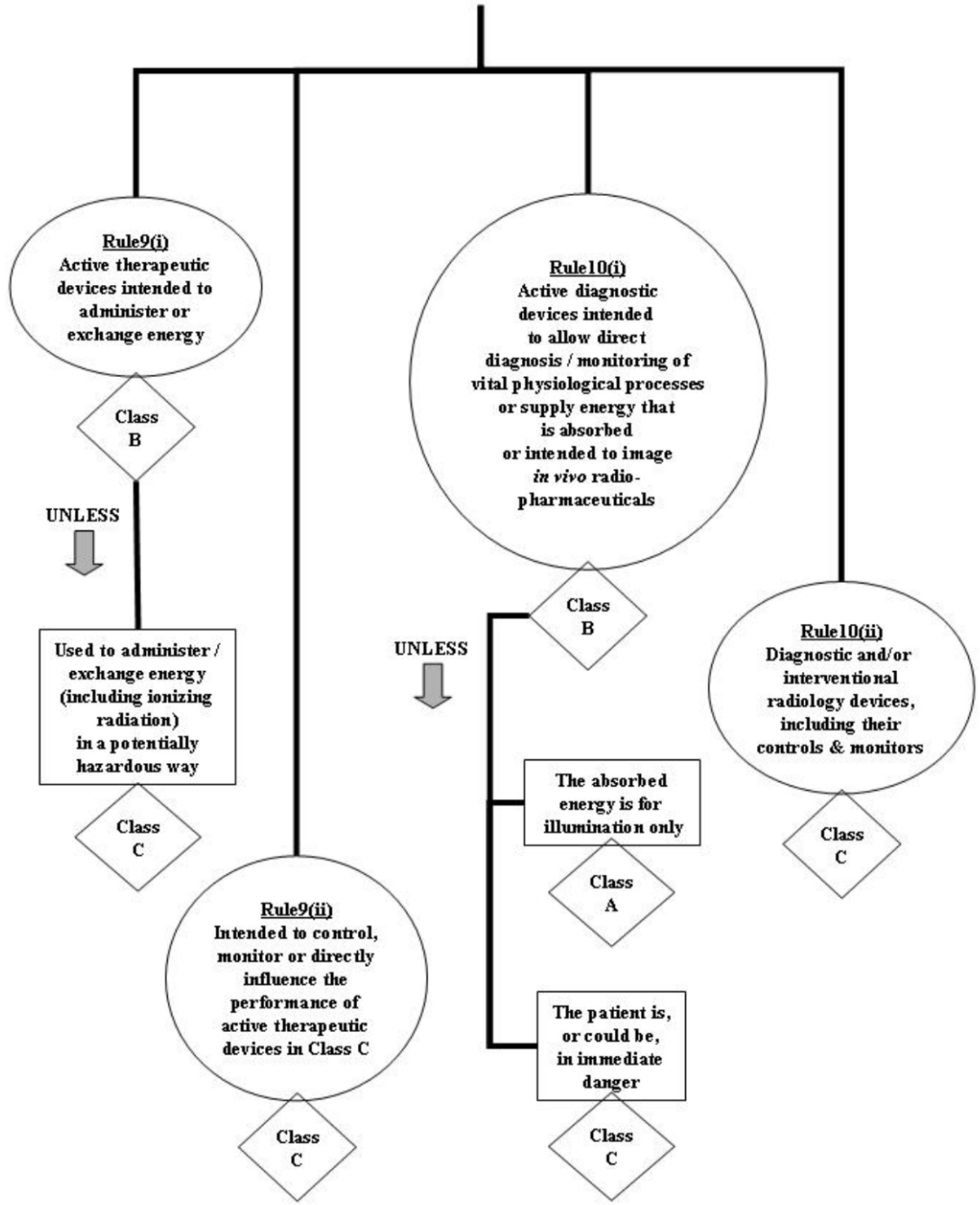
INVASIVE DEVICES (1 of 2)



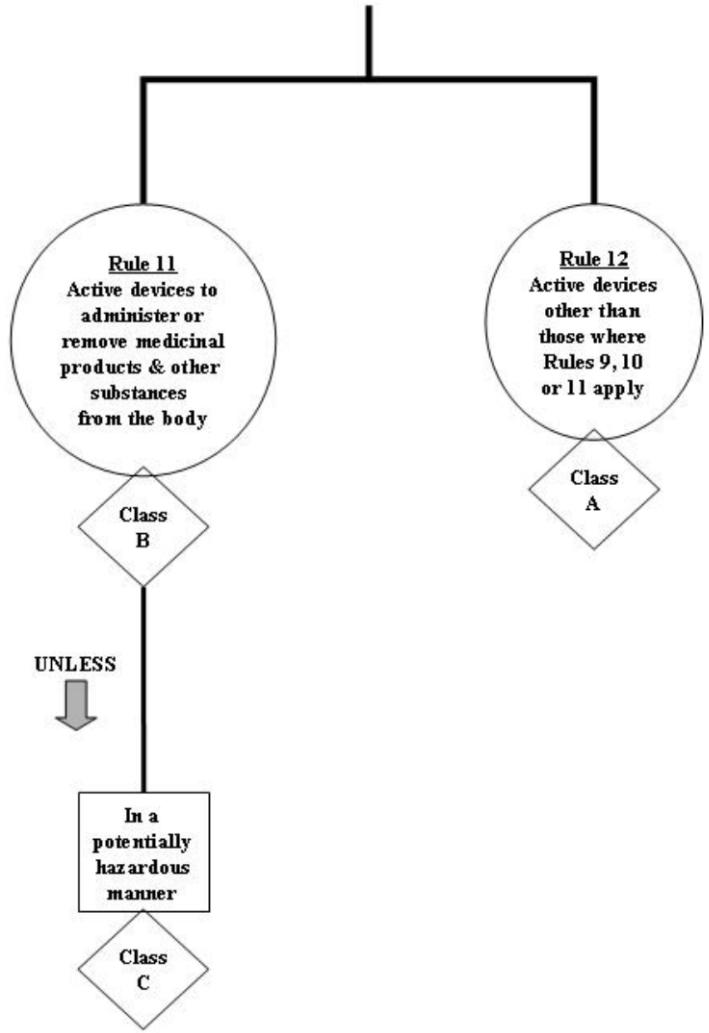
INVASIVE DEVICES (2 of 2)

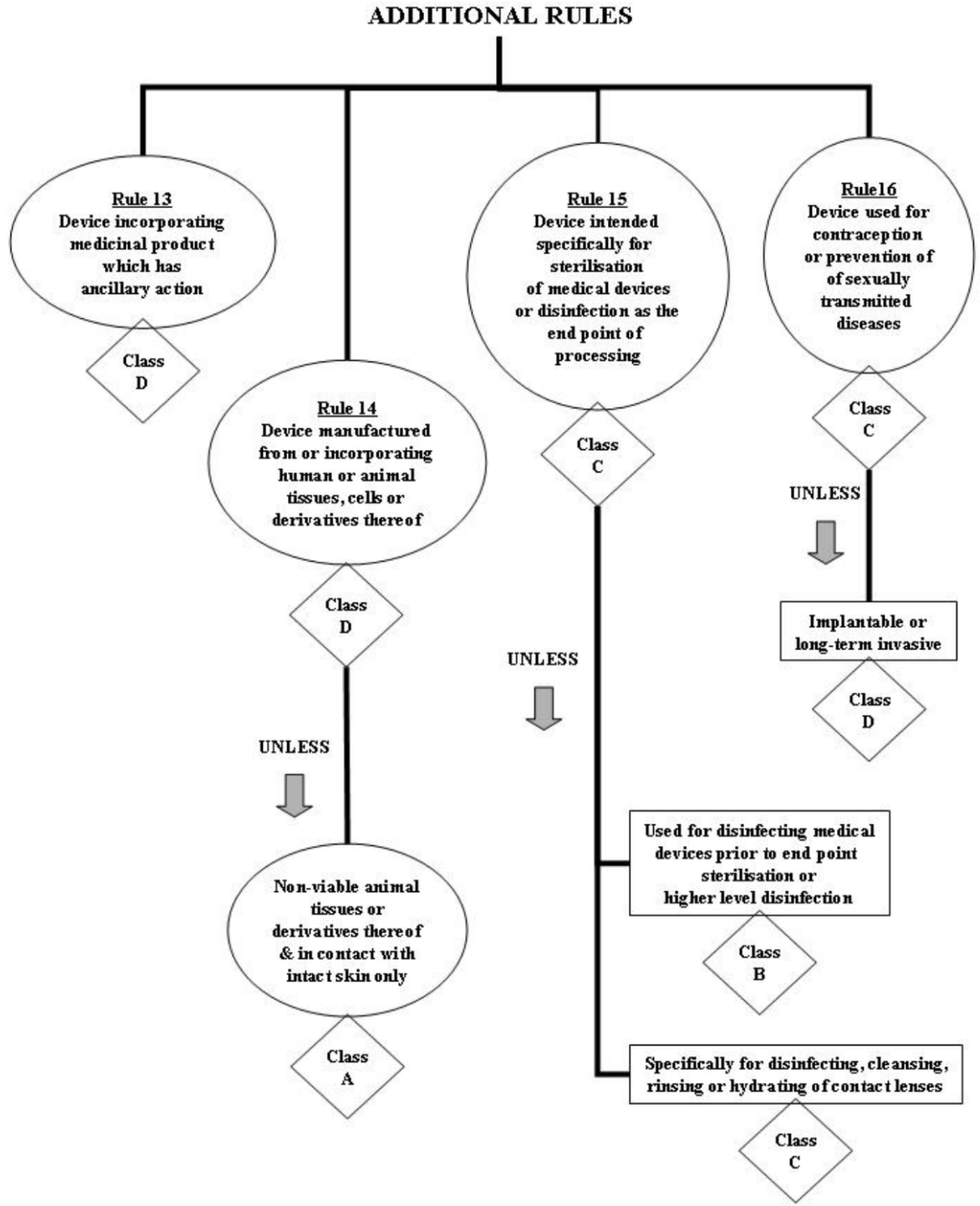


ACTIVE DEVICES (1 of 2)



ACTIVE DEVICES (2 of 2)




ADDITIONAL RULES
Rule 13
Device incorporating medicinal product which has ancillary action
Class D
Rule 14
Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof
Class D
UNLESS
Non-viable animal tissues or derivatives thereof & in contact with intact skin only
Class A
Rule 15
Device intended specifically for sterilisation of medical devices or disinfection as the end point of processing
Class C
UNLESS
Used for disinfecting medical devices prior to end point sterilisation or higher level disinfection
Class B
Specifically for disinfecting, cleansing, rinsing or hydrating of contact lenses
Class C
Rule16
Device used for contraception or prevention of of sexually transmitted diseases
Class C
UNLESS
Implantable or long-term invasive
Class D

Determination of Medical Device Risk Class

The Manufacturer should

Decide if the product concerned is a medical device

Document the intended use of the medical device

Establish the proper classification for the device using the rules

- where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated
- special national rules that apply within a particular jurisdiction

Non-Invasive Devices	Applicable
Rule 1. All non-invasive devices which come into contact with injured skin: - 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;	
- are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	
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.	
Rule 2. All non-invasive devices intended for channelling or storing • body liquids or tissues, • liquids or • gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	
unless they are intended for use of • channeling blood, or • storing or channeling other body liquids, or • for storing organs, parts of organs or body tissues, in which case they are Class B.	
unless they are blood bags, in which case they are Class C.	
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of • blood, • other body liquids, or • other liquids intended for infusion into the body are in Class C,	
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	
Rule 4. All other non-invasive devices are in Class A.	

Invasive Devices	Applicable
Rule 5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: • are not intended for connection to an active medical device, or • are intended for connection to a Class A medical device only.	
- are in Class A if they are intended for transient use;	
- are in Class B if they are intended for short-term use;	
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	
- are in Class C if they are intended for long-term use;	
unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear- drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.	
Rule 6. All surgically invasive devices intended for transient use are in Class B,	
unless they are reusable surgical instruments, in which case they are in Class A; or	
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	
unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or	
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	
unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	

Invasive Devices	Applicable
Rule 7. All surgically invasive devices intended for short-term use are in Class B,	
unless they are intended to administer medicinal products, in which case they are in Class C; or	
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	
unless they are intended to supply energy in the form or ionizing radiation, in which case they are in Class C; or	
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;	
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	
Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class C,	
unless they are intended to be placed into the teeth, in which case they are in Class B; or	
unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
unless they are intended to be active implantable medical devices, in which case they are Class D; or	
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	
unless they are intended to administer medicinal products, in which case they are in Class D; or	
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	
unless they are breast implants, in which case they are in Class D.	

Active Devices	Applicable
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	
unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	
Rule 10(i). Active devices intended for diagnosis are in Class B:	
- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	
- if they are intended to image *in vivo* distribution of radiopharmaceuticals, or	
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	
unless they are specifically intended for: a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	
Rule 10(ii). Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	
unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	
Rule 12. All other active devices are in Class A.	

Additional Rules	Applicable
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,	
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class A.	
Rule 15. All devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in Class C.	
unless they are intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection, in which case they are in Class B; or	
unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class C.	
Rule 16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	
unless they are implantable or long-term invasive devices, in which case they are in Class D.	

Case 1

150ml Syringes, Large Plastic Garden Syringe for Scientific Labs, Watering, Refilling

- 150ml Syringes: Each syringe is individually sealed, clean, safe and sterile. Great for refilling and measuring essential oil, inks, lubricants, sealants, glues, adhesives, solvents, light oil etc
- The gradations marks are clear and well-printed, hold up to multiple washings after different uses. The plunger works smoothly, and the rubber tip on the plunger makes a tight seal
- Polypropylene Barrel, for measuring and dispensing fluids/chemicals, lab use & experiments, succulents garden watering
- The plunger can pull right out of the back and the rubber seal can be taken off for cleaning as well
- Not work with quick-setting super glue because of work time. Make sure whatever glue you are trying to use has enough time for you to load it in and dispense

Case 2

60 ml Disposable Syringe, Sterile Single Pack, 50 ml to 60 ml Medical Grade Catheter Tip

- 60 ml (2 oz.) Syringe, (50 ml to 60 ml) Single Disposable Syringe Individually Packed
- Leakproof. Will hold fluid without leaking.
- Sterile. Latex Free. Non-pyrogenic. Non-Toxic.
- Disposable. One time use. Medical Grade. Catheter Tip.
- FDA & ISO Registered. Syringe is contained in sterilized plastic bag.

Case 2

60 ml Disposable Syringe, Sterile Single Pack, 50 ml to 60 ml Medical Grade Catheter Tip

Applicable rule

Rule 2. All non-invasive devices intended for channelling or storing

- body liquids or tissues,
- liquids or
- gases

for the purpose of eventual infusion, administration or introduction into the body are in Class A,

Case 3

2.5ml/cc Disposable Sterile Syringe with 23Ga Needle, Single Aseptic and Separate Packaging (20Pack)

- Suitable for animal epidemic prevention
- Veterinary disposable syringe, this product has undergone sterile operation ，individually blister packed.
- Industrial sterile syringes are suitable for: poultry, pigs, cows, chickens, ducks, geese or dogs, cats.

Case 4

2.5ml/cc Disposable Sterile Syringe with 23Ga Needle, Single Aseptic and Separate Packaging (20Pack)

Syringe is design for medical purposes to inject fluids into or withdraw fluids from the body. The syringe has a graduated barrel, a plunger, a hub and a needle.

Case 4

2.5ml/cc Disposable Sterile Syringe with 23Ga Needle, Single Aseptic and Separate Packaging (20Pack)

Applicable rule

Rule 2. All non-invasive devices intended for channelling or storing

- body liquids or tissues,
- liquids or
- gases

for the purpose of eventual infusion, administration or introduction into the body are in Class A,

Rule 6. All surgically invasive devices intended for transient use are in Class B,

What about IVD medical devices?

Risk Class for IVD medical devices

Risk Class	Risk Level
A	Low Individual Risk and Low Public Health Risk
B	Moderate Individual Risk and/or Low Public Health Risk
C	High Individual Risk and/or Moderate Public Health Risk
D	High Individual Risk and High Public Health Risk

Rules for General Medical Devices

Rule 1: IVD Medical Devices intended for the following purposes are classified as Class D:

- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or
- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening often incurable disease with a high risk of propagation

Rule 2: IVD Medical Devices intended to be used for blood grouping , or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as Class C, except for ABO, rhesus (C,c,D,E, e) and anti-Kell determination which are classified as Class D.

Rule 3: IVD Medical Devices are classified as Class C if they are intended for use:

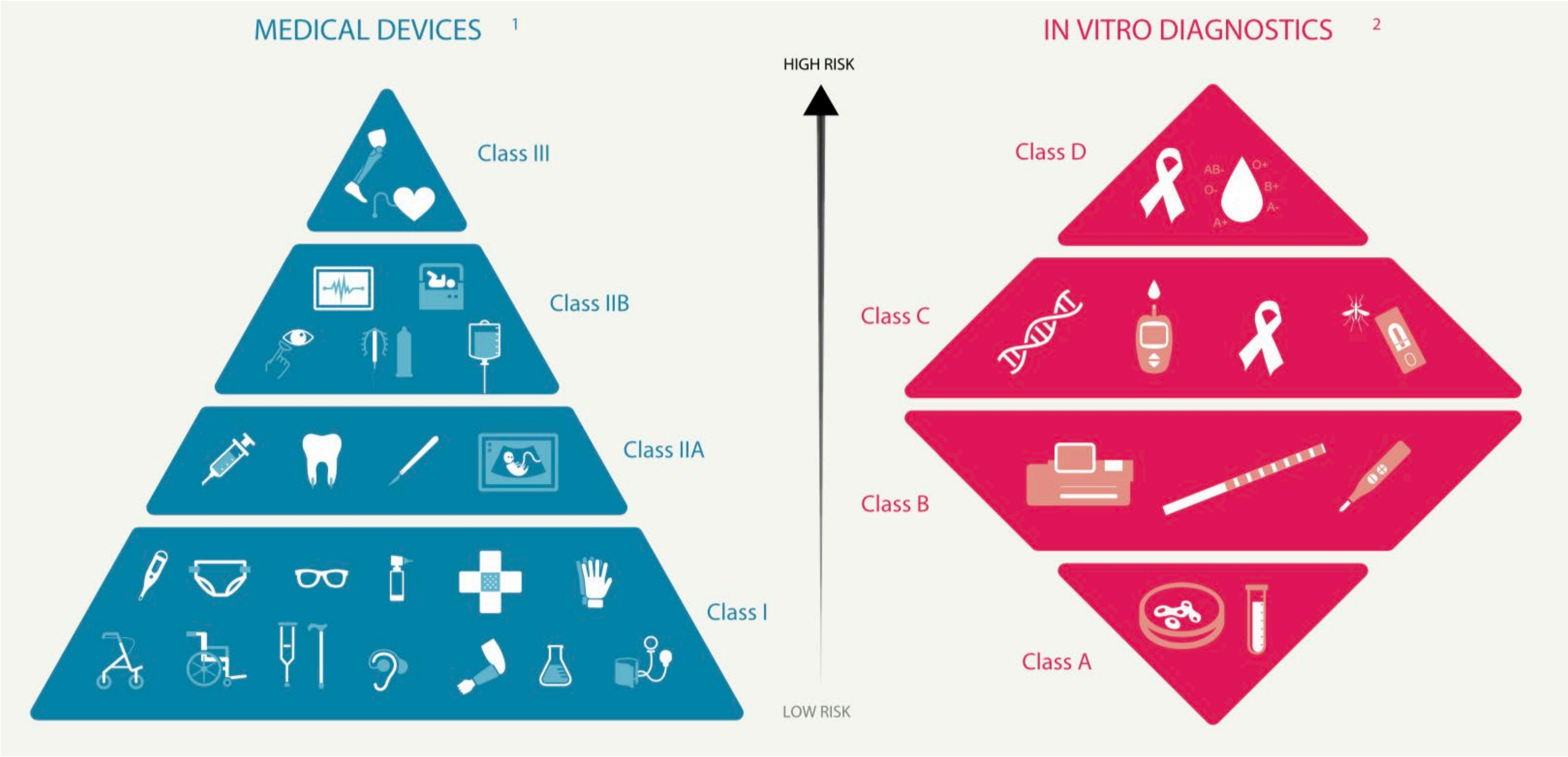
- in detecting the presence of, or exposure to, a serious sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*.
- in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: *Neisseria meningitidis* or *Cryptococcus neoformans*.
- in detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested. Examples: CMV, *Chlamydia pneumoniae*.
- in screening pre-natal women in order to determine their immune status towards transmissible agents. Examples: Rubella or *Toxoplasma gondii.*
- in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life- threatening situation for the patient. Example: *Legionella pneumophila*.
- in screening for selection of patients for selective therapy, or in the diagnosis of, cancer, NOTE: those IVD Medical Devices where the therapy decision would usually be made only after further investigation and those used for monitoring and cancer staging would fall into class B under rule 6.
- in predictive genetic screening, when the outcome of the test would ordinarily result in a substantial impact on the life of the individual. Examples: Guthrie test for phenylketonuria, Huntington's Disease, Cystic Fibrosis.
- to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient. Example: Cardiac markers, Cyclosporin, Prothrombin time testing .
- In the management of patients suffering from a life-threatening infectious disease. Example : HIV Viral Load

Rule 4: IVD Medical Devices intended for near-patient testing and self-testing are classified as Class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

Rule 5: The following IVD Medical Devices are classified as Class A:

- Reagents which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.
- Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures
- Specimen receptacles

Rule 6: IVD Medical Devices not covered in Rules 1 through 5 are classified as Class B.



MedTech Europe – The European Medical Technical Industry – in figures (2016)

Determination of Medical Device Risk Class

The Manufacturer should

Decide if the product concerned is an IVD medical device

Document the intended use of the medical device

Establish the proper classification for the device using the rules

- Where an IVD Medical Device has multiple intended uses as specified by the manufacturer, which places the device into more than one class, it will be classified in the higher class.
- special national rules that apply within a particular jurisdiction

End of Risk Classification

ASIAN HARMONIZATION WORKING PARTY

Ministry of Health
Sultanate of Oman

PADC
المديرية العامة للصيدلة والرقابة الدوائية
DG of Pharmaceutical Affairs & Drug Control

24th ASIAN HARMONIZATION WORKING PARTY (AHWP) ANNUAL MEETING

AHWP Capacity Building Workshop

TRACK 1: Regulatory Fundamentals

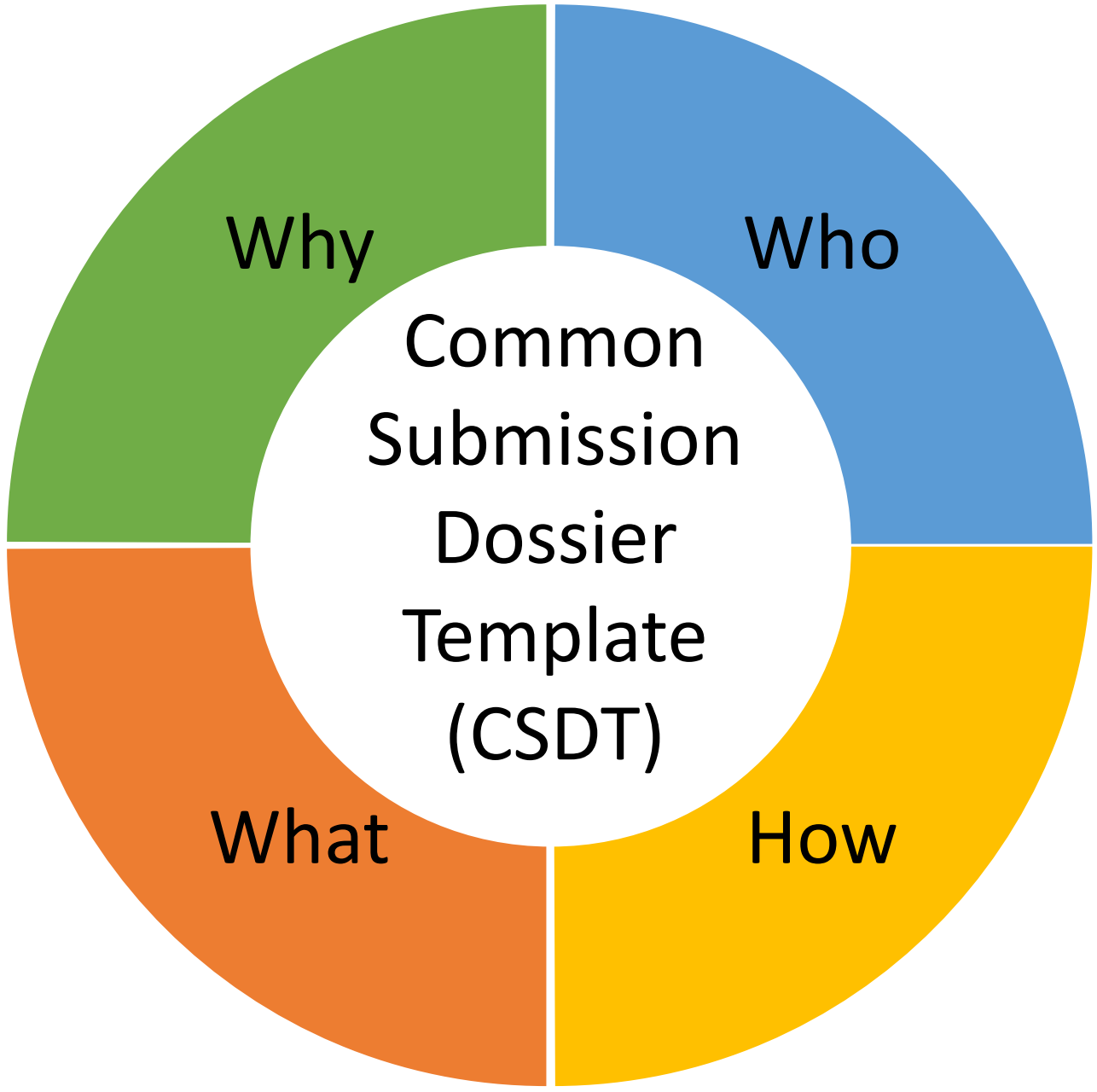
November 11, 2019

Common Submission Dossier Template (CSDT)

Wing Gang SEET

Director, RA & QA, Asia Pacific

Hillrom™


Why
Who
Common Submission Dossier Template (CSDT)
What
How

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Guidance for Preparation of a Common Submission Dossier Template Dossier for General Medical Device Product Submission

Authoring Group: Working Group 1, Pre-Market: General MD

Date: 30 October 2015

Mr. Essam Mohammed Al Mohandis
Chair, Working Group 1

Product Registration

- Submission
  - Administrative: Country Specific
  - Technical: common?

1. INTRODUCTION

1.1. Purpose

The document is intended to provide guidance for submission of device information to the regulatory authorities; structured in the format of one common template acceptable by all AHWP member economies regulators. It is envisaged that a Common Submission Dossier Template (CSDT) will harmonize the differences in documentation formats that presently exist in different AHWP member economies jurisdictions. The adoption of this guidance document in AHWP member economies will eliminate the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different regulatory authorities.

Who had implemented CSDT?

ASEAN MEDICAL DEVICE DIRECTIVE

one vision
one identity
one community

ANNEX 4
ASEAN Common Submission Dossier Template

1. INTRODUCTION

The Common Submission Dossier Template (CSDT) should reduce the differences in documentation formats that presently exist in different ASEAN jurisdictions. The adoption of the CSDT in ASEAN should minimise the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different Regulatory Authorities.

2. SCOPE

This CSDT is intended to apply to all medical devices. For IVD medical devices, the Regulatory Authority of the Member State may choose to adopt this CSDT or prescribe another format for regulatory submissions to that Member States. The depth and detail of the information contained in the CSDT will depend on:

- the classification of the subject medical device;
- the complexity of the subject medical device.

The format of the CSDT recommended herein is based upon the goal of both regulators and product owners to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading. Requirements for post-market vigilance or adverse event reporting are outside the scope of this document.

3. EXECUTIVE SUMMARY

An executive summary shall be provided with the common submission dossier template, which shall include the following information:

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ASEAN Common Submission Dossier Template

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What is CSDT?

Structure of CSDT

3. Executive Summary

4. ELEMENTS OF THE COMMON SUBMISSION DOSSIER TEMPLATE

4.1. Relevant Essential Principles and Methods Used to Demonstrate Conformity

- 4.1.1 Essential Principles and Evidence of Conformity

4.2 Device Description

- 4.2.1 Device description and features
- 4.2.2. Intended use
- 4.2.3. Indications
- 4.2.4. Instructions of use
- 4.2.5. Contraindications
- 4.2.6. Warnings
- 4.2.7. Precautions
- 4.2.8. Potential adverse effects
- 4.2.9. Alternative therapy
- 4.2.10. Materials
- 4.2.11. Other Relevant Specifications
- 4.2.12. Other Descriptive Information

4.3 Summary of Design Verification and Validation Documents

- 4.3.1. Pre-clinical Studies
  - 4.3.1.1. Software Verification and Validation Studies
  - 4.3.1.2. Devices Containing Biological Material
- 4.3.2. Clinical Evidence
  - 4.3.2.1. Use of Existing Bibliography

4.4. Device Labelling

- 4.4.1. Samples of Labels on the Device and its Packaging
- 4.4.2. Instructions for Use

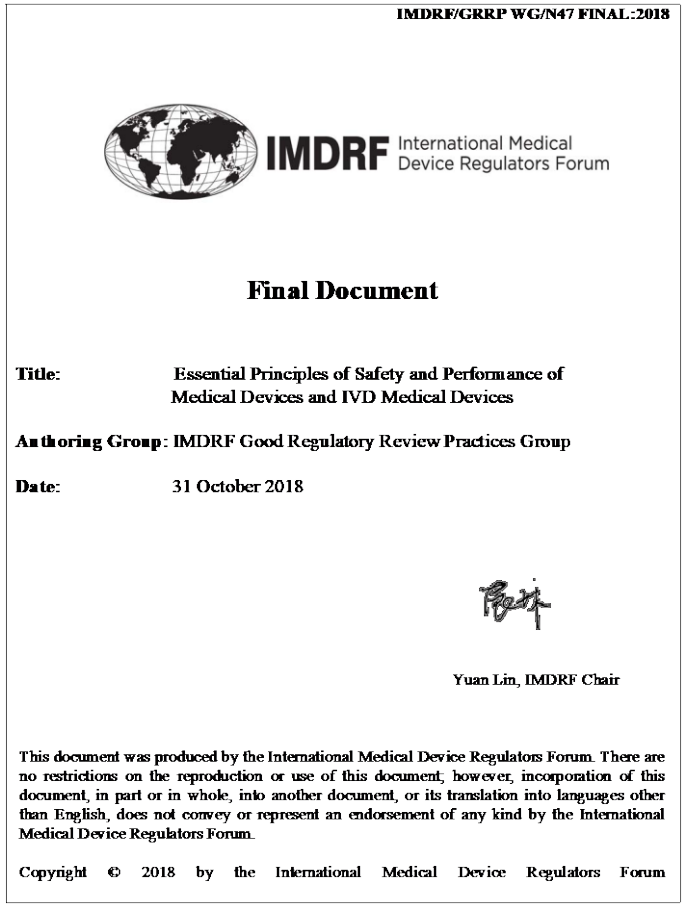
4.5. Risk Analysis

- 4.5.1 Results of Risk Analysis

4.6. Manufacturer Information

- 4.6.1 Manufacturing Process

Essential Principles of Safety and Performance



IMDRF/GRRP WG/N47 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices Group

Date: 31 October 2018

Yuan Lin, IMDRF Chair

- IMDRF
  - Essential Principles
- Australia TGA
  - Essential Principles
- Japan PMDA
  - Essential Principles
- EU Medical Device Directive (MDD)
  - Essential Requirements
- EU Medical Device Regulations (MDR)
  - General Safety and Performance Requirements

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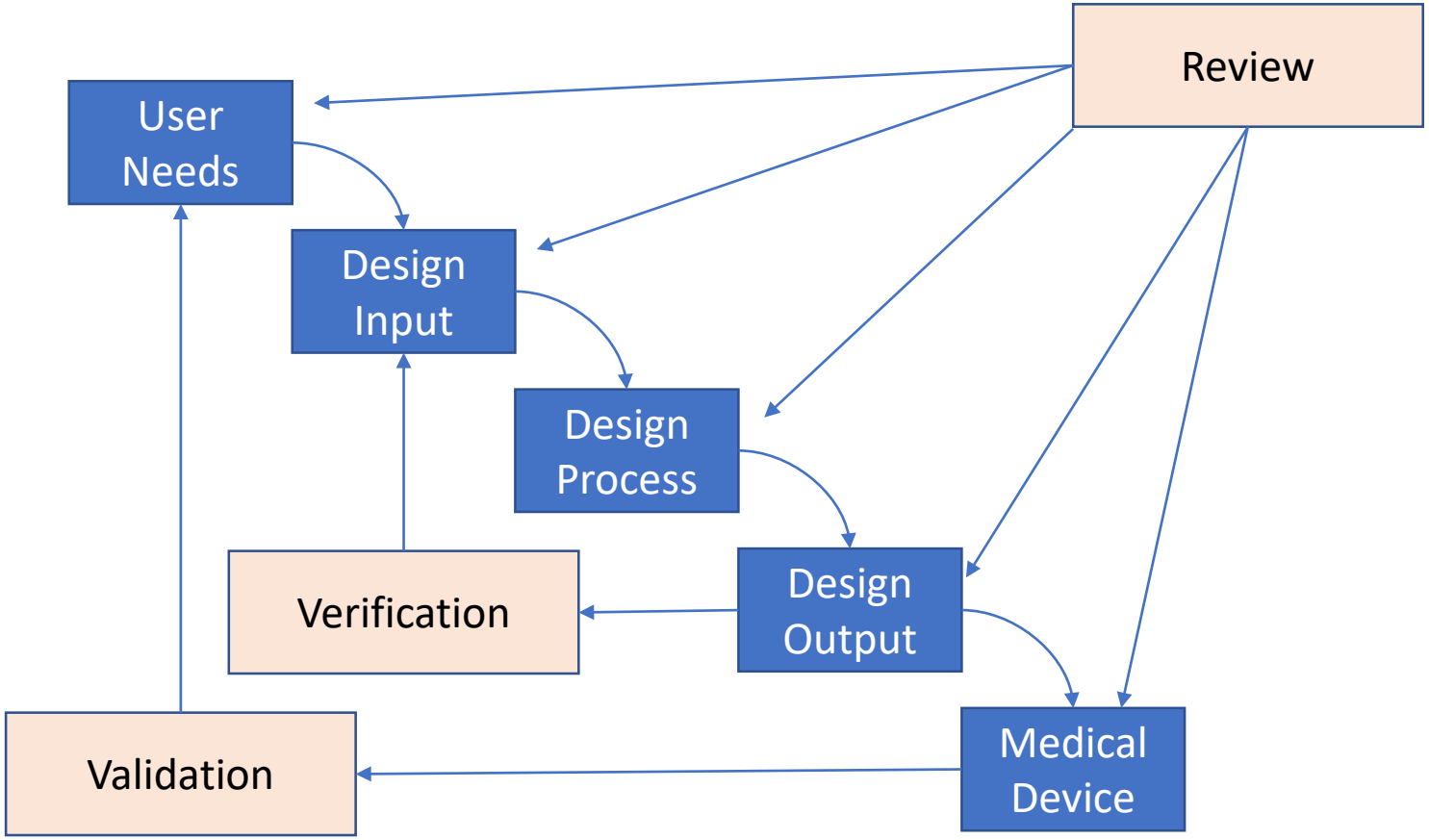
Design Verification and Validation



PART 820 -- QUALITY SYSTEM REGULATION

Subpart C--Design Controls

Sec. 820.30 Design controls.

(a) General.

(b) Design and development planning.

(c) Design input.

(d) Design output.

(e) Design review.

(f) Design verification.

(g) Design validation.

(h) Design transfer.

(i) Design changes.

(j) Design history file.

Documentation

(j) ***Design history file.*** Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

What about ISO 13485?

ISO 13485

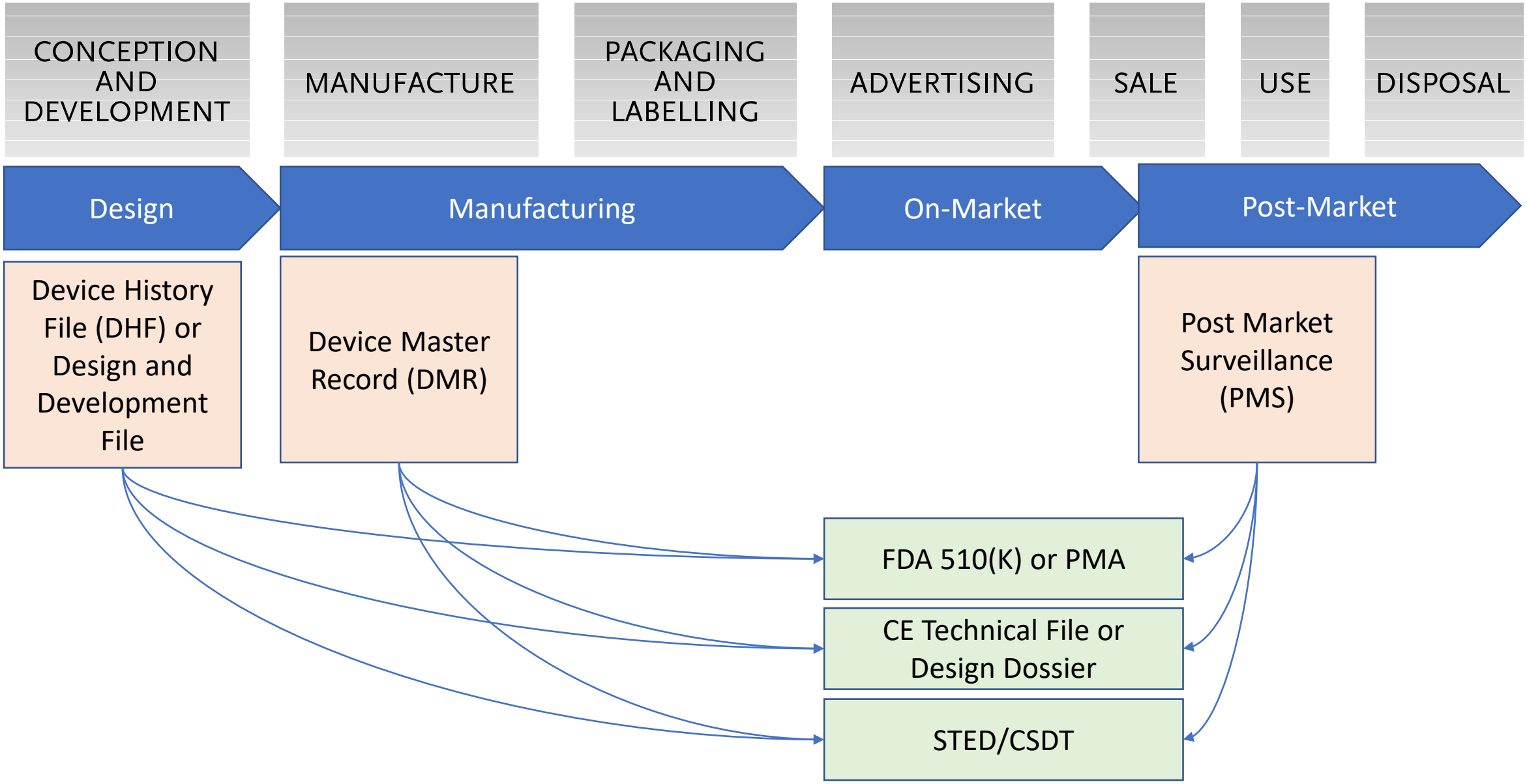
7.3 Design and development
7.3.1 General
7.3.2 Design and development planning
7.3.3 Design and development inputs
7.3.4 Design and development outputs
7.3.5 Design and development review
7.3.6 Design and development verification
7.3.7 Design and development validation
7.3.8 Design and development transfer
7.3.9 Control of design and development changes
7.3.10 Design and development files

Documentation

7.3.10 Design and development files

The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

Figure 1. Major phases in the life span of a medical device



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Challenges in preparing CSDT

Challenges

Complexity of medical device

- Variation
  - Sterile vs non-sterile
  - Sterilized by manufacturer or sterilized by user prior to use
  - Measuring function? Yes/no
  - Invasive vs non-invasive
  - Active vs non-active
  - Long term vs short term vs transient
  - ……
- Technology
  - Existing
  - Novel

Challenges

2. PREPARATION OF A PRODUCT REGISTRATION SUBMISSION BASED ON THE CSDT

The authorized representative shall take note of the following pointers when preparing a CSDT dossier for submission to local regulatory Authorities. The preparation of CSDT must be made in accordance with the requirements specified in local regulation:

- The prepared CSDT dossier shall contain all sections, i.e. sections 3.0 to 4.6.1. Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading.
- Countries or jurisdictions may set the requirement for having the label of a medical device in their national languages.
- copies of labelling, certificates and reports that are referenced within the CSDT submission shall be submitted as annexes to the CSDT;
- all reports submitted as part of the CSDT should be signed-off and dated by the person issuing the report. This person should be authorised to issue such documents;
- where supporting documents such as reports or certificates are provided, every document must be submitted in full, i.e. all the pages of a document must be submitted;
- all copies of labelling, certificates, reports and other documents submitted must be legible;
- all certificates submitted must be within its validity period.

The level of detail of information to be provided under each CSDT section may depend on the classification of the device and other requirements as defined by the country or jurisdiction in the local regulation.

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Challenges

“country” specific challenges

- Grouping of medical devices for submission
- Difference in Risk Classification
- ”Abridged” vs “Full”
- Detail report vs Summary

End of CSDT