First Edition(Jan/2021)

TECHNICAL GUIDELINE FOR ONLINE SUBMISSION OF MEDICAL DEVICES

Department of Food and Drug Administration
Ministry of Health and Sports
Myanmar

Contents

1. Definition of Medical device

It means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article: (i) intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; (c) investigation, replacement, modification, or support of the anatomy or of a physiological process; (d) supporting or sustaining life; (e) control of conception; (f) disinfection of medical devices; and (g) providing information for medical or diagnostic purposes by means of in–vitro examination of specimens derived from the human body; (ii) 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.

In Vitro Diagnostic (IVD) Medical Device means any reagent, reagent product, calibrator, control material kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used in vitro for examination of any specimen, including any blood or tissue donation, derived from the human body,solely or principally for the purpose of providing information: (a) concerning a physiological or pathological state or a congenital abnormality; (b) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or (c) to monitor therapeutic measures and includes a specimens receptacle.

2. Classification of Medical devices

Medical devices shall be classified into the following four classes, in accordance with risk classification rules:

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

Risk Classification for General Medical Devices

(Other than In–Vitro Diagnostic Medical Devices)

RULES

NON–INVASIVE MEDICAL DEVICES

Rule 1. All non–invasive medical 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; Examples: compression bandages
- 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. Example: dressings for chronic ulcerated wounds.

Rule 2. All non–invasive medical devices intended for channeling 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, Example: dressings sets for gravity infusion

- **Unless** they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;Example: Syringe
- **Unless** they are intended for use of channeling blood, orstoring or channeling other body liquids, or for storing organs, parts of organs or body tissues, in which case they are Class B. Example: tubes used for blood transfusion
- **Unless** they are blood bags, in which case they are Class C. Example: Blood bag

Rule 3. All non–invasive medical devices intended for modifying the biological or chemical composition of blood, other body liquids, orother liquids intended for infusion into the body are in Class C, Example: Hemodialysis solution

- **Unless** the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B. Example: Particulate filter in an extracorporeal circulation system.

Rule 4. All other non–invasive medical devices are in Class A. Example: urine collection bottles.

INVASIVE MEDICAL DEVICES

Rule 5. All invasive medical 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; Example: Examination gloves, enema devices
- **Unless** they are intended by its product owner for use on the external surface of any eyeball; or it is liable to be absorbed by the mucous membrane, in which case they are in Class B. Example: wetting or lubricating eye drops.
- are in Class B if they are intended for short–term use; Example: Urinary catheter, tracheal tubes.
- **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, Example: dressing for nose bleeds.
- are in Class C if they are intended for long–term use; Example: Urethral stent.
- **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. Example: Orthodontic wire, fixed dental prosthesis
- All invasive medical 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. Example: tracheal tubes

Rule 6. All surgically invasive medical devices intended for transient use are in Class B, Example: Surgical gloves, Needles

- **Unless** they are reusable surgical instruments, in which case they are in Class A; or Example: Drill bits and saws.

- **Unless** intended to supply energy in the form of ionising radiation, in which case they are in Class C; orExample: Catheter containing sealed radioisotopes.

- **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 Example: Insulin pen.
- **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. Example: Angiographic balloon catheter.

Rule 7. All surgically invasive medical devices intended for shortterm use are in Class B, Example: Infusion cannula.

- **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 medical devices are placed in the teeth), in which case they are in Class C;or Example: Surgical adhesive.
- **Unless** they are intended to supply energy in the form or ionising radiation, in which case they are in Class C; or Brachytherapy device.
- **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 Example: Absorbable suture, biological adhesive.

- **Unless** they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; Example: Neurological catheter.
- **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. Example: Cardiovascular catheter.

Rule 8. All implantable medical devices, and long–term surgically invasive medical devices, are in Class C, Example: Bone implants.

- **Unless** they are intended to be placed into the teeth, in which case they are in Class B; or Example: Dental filling materials.
- **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 Example: Prosthetic heart valve.
- **Unless** they are intended to be life supporting or life sustaining, in which case they are in Class D; or Example:
- **Unless** they are intended to be active implantable medical devices, in which case they are Class D; or Example: Pacemaker
- **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 Example: Bioactive implants.
- **Unless** they are intended to administer medicinal products, in which case they are in Class D; or Example: rechargeable non–active drug delivery system.

- **Unless** they are intended to undergo chemical change in the body (except if the medical 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 MEDICAL DEVICES

Rule 9 (i). All active therapeutic medical devices intended to administer or exchange energy are in Class B, Example: Muscle stimulator.

- **Unless** their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionising radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C. Example: Ventilator.

Rule 9 (ii). All active medical devices intended to control or monitor the performance of active therapeutic medical devices in Class C, or intended directly to influence the performance of such medical devices, are in Class C.Example: Active therapeutic device

Rule 10 (i). Active medical 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 medical 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 Example: Ultrasound system.
- if they are intended to image in vivo distribution of radiopharmaceuticals, or Example: Magnetic resonance equipment
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, Example: Nuclear camera.
- **Unless** they are specifically intended for:

- 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
- diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C. Example: Digital thermometer

Rule 10(ii). Active medical devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including medical devices which control or monitor such medical devices, or those which directly influence their performance, are in Class C. Example: Ionizing radiation.

Rule 11. All active medical devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,Example: Feeding pump.

- **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 or removal, in which case they are in Class C. Example: Dialysis equipment.

Rule 12. All other active medical devices are in Class A. Example: Examination lamps.

ADDITIONAL RULES

Rule 13. All medical devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product (as defined by the Member State), and which is liable to act on the human body with action ancillary to that of the medical devices, are in Class D. Example: Drug eluting stent.

Rule 14. All medical devices manufactured from or incorporating animal cells, tissues

and/or derivatives thereof, rendered nonviable, orcells, tissues and/or derivatives of microbial or recombinant origin are Class D, Example: Porcine heart valves.

- **Unless** such medical 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. Example: Orthopedic appliances

Rule 15. All medical devices intended specifically to be used for sterilizing medical devices, or disinfecting as the end point of processing, are in Class C. Example: Disinfectant

- **Unless** they are intended for disinfecting medical devices prior to end point sterilization or higher level disinfection, in which case they are in Class B; or Example: Washer disinfector
- **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 medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C, Example: Condoms.

- **Unless** they are implantable or long–term invasive medical devices, in which case they are in Class D. Example: Intrauterine contraceptive device.

Risk Classification Rules for IVD Medical Devices

RULE 1: IVD medical devices intended for the following purposes are classified as Class D:

- medical 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

- medical 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.

Rationale: The application of this rule as defined above should be in accordance with the rationale that follows: IVD medical devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/product will be used. Serious diseases are those that result in death or long–term disability, which are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

Examples: Tests to detect infection by HIV, HCV, HBV, HTLV. This Rule applies to first–line assays, confirmatory assays and supplemental assays.

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 system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determination which are classified as Class D.

Rationale: The application of this rule as defined above should be in accordance with the following rationale: A high individual risk, where an erroneous result would put the

patient in an imminent life–threatening situation places the medical device into Class D. The rule divides blood–grouping IVD medical devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in a transfusion setting.

Examples: HLA, Duffy system (other Duffy systems except those listed in the rule as Class D) are in Class C.

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 sexually transmitted agent (e.g. 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 (e.g. 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 (e.g. diagnostic assay for CMV, Chlamydia pneumoniae, Methicillin Resistant Staphylococcus aureus).
- in pre–natal screening of women in order to determine their immune status towards transmissible agents (e.g. Immune status tests for Rubella or Toxoplasmosis).
- 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 (e.g. Enteroviruses, CMV and HSV in transplant patients).

- in screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer (e.g. personalized medicine).

NOTE: Those IVD medical devices where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6.

- in human genetic testing (e.g. 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 (e.g. Cardiac markers, cyclosporin, prothrombin time testing).
- in the management of patients suffering from a life–threatening infectious disease (e.g. HCV viral load, HIV Viral Load and HIV and HCV geno– and subtyping).
- in screening for congenital disorders in the fetus (e.g. Spina Bifida or Down Syndrome).

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: IVD medical devices in this Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life–threatening situation, or would have a major negative impact on outcome. The IVD medical devices provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk

because of the stress and anxiety resulting from the information and the nature of the possible follow–up measures.

RULE 4: IVD medical devices intended for self–testing are classified as Class C, except those medical 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. IVD medical devices intended for blood gases and blood glucose determinations for near–patient testing would be Class C. Other IVD medical devices that are intended for near patient should be classified in their own right using the classification rules.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: In general, these IVD medical devices are used by individuals with no technical expertise and thus the labelling and instructions for use are critical to the proper outcome of the test.

Example for Self–testing Class C: Blood glucose monitoring, Example for Self–testing Class B: Pregnancy self–test, Fertility testing, Urine test strip.

RULE 5: The following IVD medical devices are classified as Class A:

- reagents or other articles that possess specific characteristics, intended by the product owner to make them suitable for in–vitro diagnostic procedures related to a specific examination.
- instruments intended by the product owner specifically to be used for in–vitro diagnostic procedures.
- specimen receptacles.

NOTE: Any product for general laboratory use not manufactured, sold or represented for use in specified in–vitro diagnostic applications are deemed to not be IVD medical devices.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These IVD medical devices present a low individual risk and no or minimal public health risk.

Examples: Selective/differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

NOTE: The performance of software or an instrument that is specifically required to perform a particular test will be assessed at the same time as the test kit.

NOTE: The interdependence of the instrument and the test methodology prevents the instrument from being assessed separately, even though the instrument itself is still classified as Class A.

RULE 6: IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These IVD medical devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The IVD medical devices give results that are usually one of several determinants. If the test result is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical

information that may guide a physician, such that classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those IVD medical devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population.

Examples: Blood gases, H. pylori and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

RULE 7: IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.

Rationale: For such controls, the user, not the product owner,

3.Medical Devices Grouping

A. Family

A medical device FAMILY is a collection of medical devices and

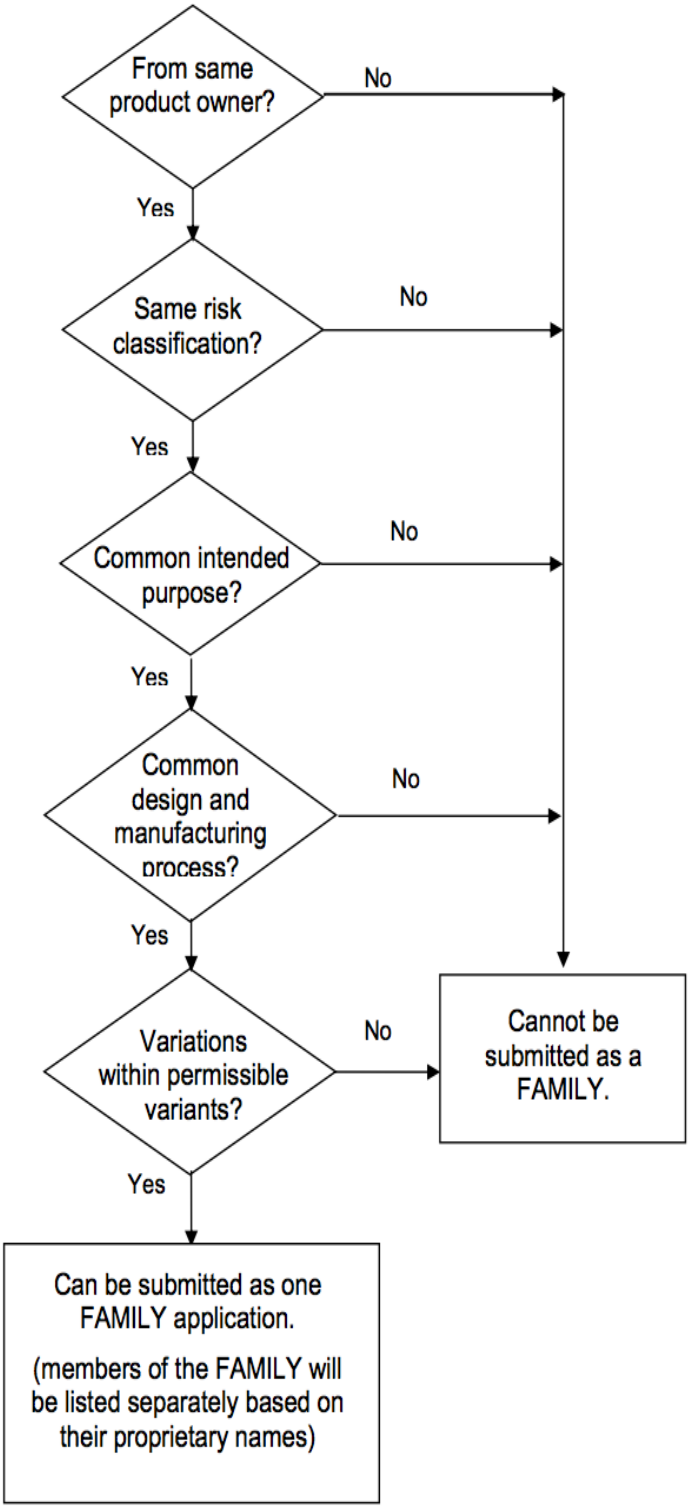
each medical device FAMILY member:

- is from the same product owner;
- of the same risk classification;
- has a common intended purpose;
- has common design and manufacturing process; and
- has variations that are within the scope of the permissible variants

Examples:

1. Surgical sutures
2. Catheters (Intravenous, Urinary, Urethral)
3. Tubes (Endotracheal tube, Nasopharyngeal tube, etc.,)
4. Syringes Needles
5. Gloves

Decision Flowchart for Grouping of Medical Devices as a FAMILY



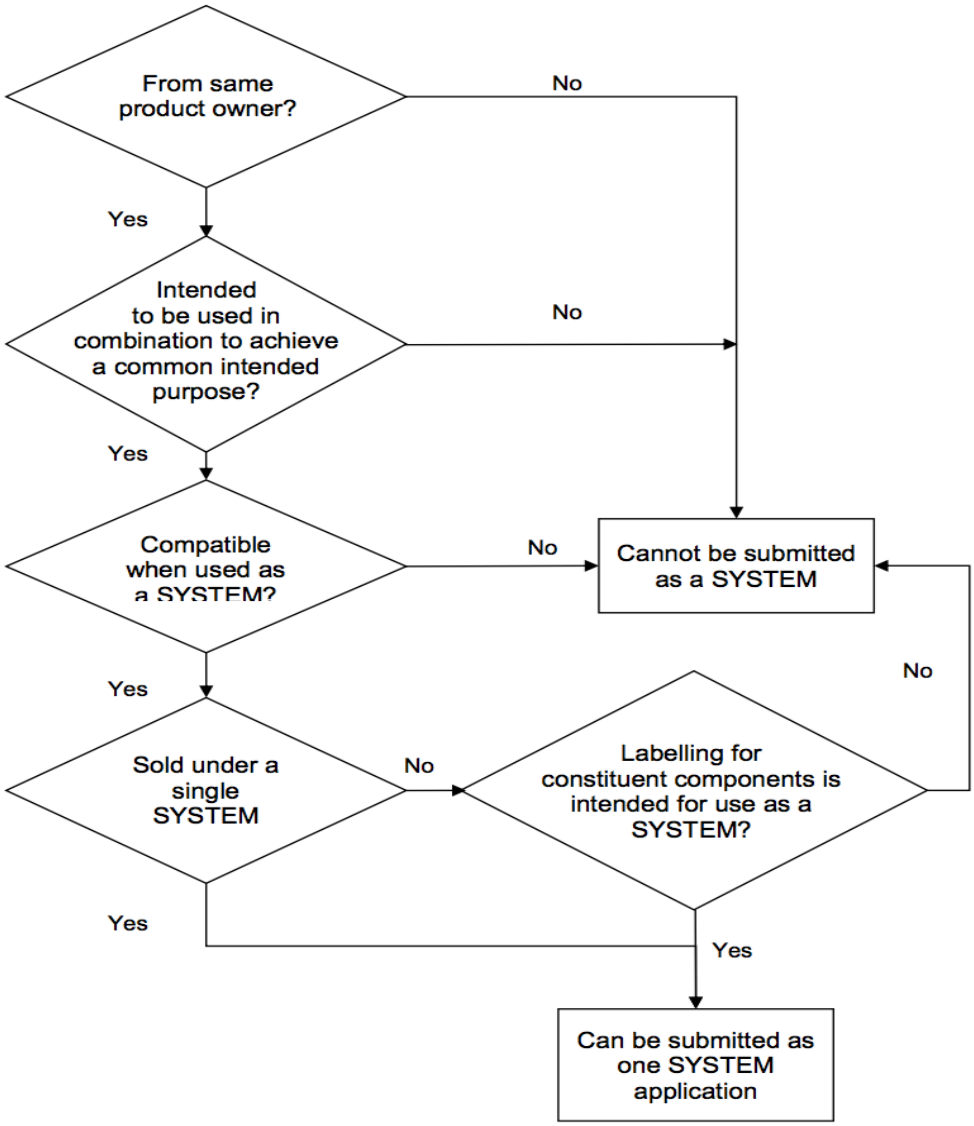
B. System

- comprises of a number of medical devices and/or accessories from the same product owner;
- intended to be used in combination to achieve a common purpose;
- compatible when used as a SYSTEM; and sold under a single SYSTEM name or the labelling, IFU, or catalogues for each constituent indicating to be used together or for use with the SYSTEM.
- Devices applied as part of a SYSTEM shall only be supplied specifically for use with that SYSTEM.
- Any device that is meant for supply for use with multiple SYSTEMs should be applied together with each of these other SYSTEMs.

Examples:

1. Cardiac catheterization system
2. Orthopedic implant system
3. Electrosurgical unit and its appliances
4. Imaging system
5. system Stent system

Decision Flowchart for Grouping of Medical Devices as a SYSTEM



C.Group

- is a collection of two or more medical devices, that is labelled and supplied in a single packaged unit by a product owner.
- The medical device GROUP comprises of the following:
- a single proprietary GROUP name;
- labelled and supplied in a single packaged unit by the product owner; and
- a common intended purpose.

Examples

1. Surgical instrument set
2. First Aid Kit
3. Dressing Kit
4. Resuscitation Kit
5. Delivery Kit
6. Blood Lines (Hemodialysis blood tubing set)
7. CVC Kit

Responsibilities

1. A product owner supplies dressing trays customized with different quantity and type to different hospitals.
2. When the closed list of medical devices in the GROUP are applied, the product owner is able to customize the trays, from the list of devices, for other hospitals,

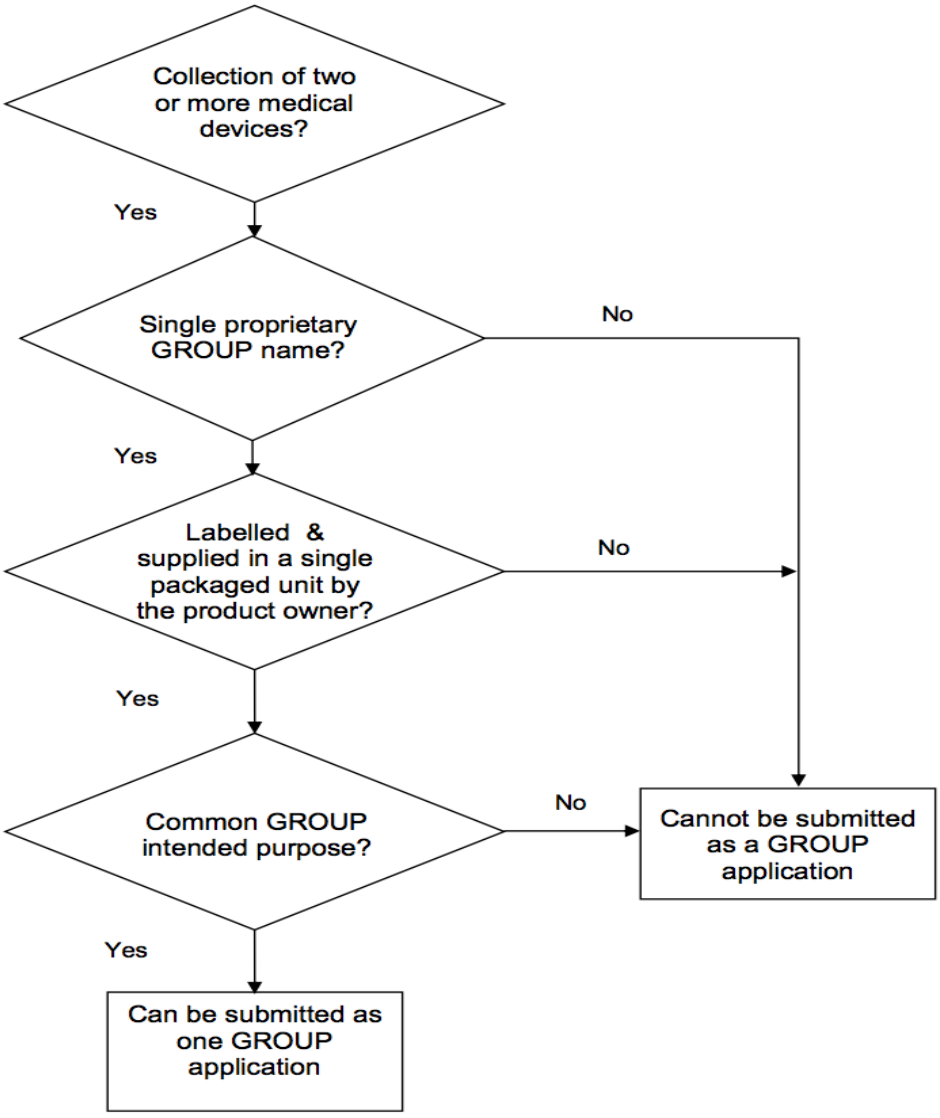
while maintaining the same GROUP name for the trays and the registered intended purpose.

3. The label for those trays shall describe the content list of devices within the package for supply.

4. Some of the medical devices in the GROUP may be individually packaged and labelled, while others remain in bulk form and may not be labelled.

5. The product owner shall account for these during the assembling of the GROUP and ensure compliance to existing regulatory requirements including traceability of individual devices packaged into the trays and record keeping.

Decision Flowchart for Grouping of Medical Devices as a GROUP



IVD Test Kit

- From the same product owner
- To be used in combination to complete specific intended purpose
- Sold under a single test kit name or labeling IFU or catalogues for each reagents or articles
- Compatible to be used as TEST KIT
- IVD TEST KIT does not include instruments, s/as Analyzers

IVD Cluster

- From the same product owner
- Of the same risk classification
- Common test methodology
- IVD Cluster may include analyzers for use with reagents in IVD CLUSTER

(IVD Medical Device SYSTEM IVD test kit + INSTRUMENTS(Analyzers to be used with that TEST KIT)

4. Letter Of Authorization Format

Letterhead of Product Owner

Date

Letter of Authorization

Forwarding

Product owner (name) ……authorized to Distributor/Importer (Myanmar), Address……..

Authorized product list …….

(Product name, Brand name, Model, Type, size, ...)

Validity – valid at least 3 years from the date of submission

Product owner agree to assist Myanmar FDA with any request for information on the above medical devices.

*You give authorization to this importer/distributor exclusively or not, if not please mention detail information. (Name of company, name of product, model)

Signature
……...
Full Name
……...
Designation
……...
Seal/Stamp
……...

5. Declaration of Product Safety Format

Letterhead of Local Importer/ Distributor

Date ……..

Declaration of Product Safety

Forwarding

I, *local Importer/ distributor*, of the medical devices stated below, hereby declare for any safety issues globally associated with the use of medical device(s) when used as intended by Product Owner, in the last three years from (*dd/mm/yyyy*) to (*dd,mm,yyyy*).

- *Any* reported deaths

  ……

- *Any* reported serious deterioration of health and

  ……

- *Any* field safety corrective actions and recalls at the time of this application.

  ……

I, *applicant*, agree to report to Myanmar FDA for any form of safety issues related with stated medical devices after importing to Myanmar.

I, *applicant*, clearly aware that any mis–conduct in reporting process may result in the cancellation of Import approval issued by Myanmar FDA.

Signature ……..

Full name ……..

Designation ……..

Company Stamp ….……..

6. Declaration of Conformity Format

(from AMDD Pg–79,80)

[*To be printed on Company Letterhead of Product Owner or Physical Manufacturer*]

We hereby declare that the below mentioned medical devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the [*state the applicable statute of the Member State*].

Name and Address of Product Owner:
<*Person responsible for manufacturing the medical device*>

Name and Address of Physical Manufacturer:
<*Person responsible for manufacturing the medical device*>

Authorised Representative (if required by a particular Member State):
<*Local authorised representative responsible for placing the medical device on the market of the ASEAN Member State*>

Medical Device(s):
<*e.g. medical device name and model number*>

Risk Classification: e.g. Class B, rule
<*Class of Medical device according to the classification rule, and the rule used to determine the classification*>

Quality Management System Certificate:
<*Certification Body and Certificate Number, issue date, expiry date*>

Standards Applied:
<*International standards; OR Regional Standard; OR See Attached Schedule for multiple standards*>

This declaration of conformity is valid from<*Day Month Year*>

Authorised Signatory:

Name,

Position,

Date

MEDICAL DEVICES

FOR OFFICIAL USE ONLY Date received : Product Registration No.

To:

Director General

Department of Food and Drug Administration

Pyigyi Zeya Road, Zeya Theiddhi Ward, Zabuthiri Township,

Nay Pyi Taw

Telephone No. 0673403871

Fax no. 0673403874

Email Address. fdanpt1@gmail.com

MANDATORY PROBLEM REPORTING FORM (ဆေးပစ္စည်းနှင့်ဆက်စပ်၍ စိုးရိမ်ဖွယ်ဖြစ်စဉ်တွေ့ရှိက သတင်း/မှတ်တမ်းပေးပို့ခြင်း) This reporting form is to be used by medical device manufacturers , authorized representatives or distributors, to report any suspected problem with medical device that may be a health hazard. (ဤသတင်းပေးပို့မှု မှတ်တမ်းပုံစံသည် ဆေးပစ္စည်းထုတ်လုပ်သူများ၊ တရားဝင် ကိုယ်စားလှယ်များ (သို့မဟုတ်) ဆေးပစ္စည်းဖြန့်ဖြူးသူများမှ မိမိတို့၏ ထုတ်လုပ်/ တင်သွင်း/ဖြန့်ဖြူးသည့် ဆေးပစ္စည်းသည် ကျန်းမာရေးအန္တရာယ်ထိခိုက်နိုင်သည်ဟု သံသယရှိပါက ပေးပို့ရန်ဖြစ်သည်။)	
Type of report (မှတ်တမ်းပုံစံ)	☐ Initial (ကနဦး) ☐ Follow-up (နောက်ဆက်တွဲ) ☐ Final (အပြီးသတ်)
Background Information (နောက်ခံသတင်းအချက်အလက်များ)	
Report Category (မှတ်တမ်းအဆင့်)	☐ Serious public health thread (ပြည်သူ့ကျန်းမာရေးကို ပြင်းထန်စွာ ခြိမ်းခြောက်ခြင်း) ☐ Death (အသက်သေဆုံးခြင်း)

	☐ Serious Injury (အပြင်းအထန်ထိခိုက်စေခြင်း) ☐ Non–Serious Injury (သာမန်ထိခိုက်မှု)
Date of report (မှတ်တမ်းပေးပို့သောရက်စွဲ)	
Date of Incident (ဖြစ်ပျက်ခဲ့သောရက်စွဲ)	
Date of establishment awareness on the incident (ဖြစ်ပျက်သည်ဟုသတိပြုမိသည့်ရက်စွဲ)	
Was this incident reported to other Regulatory Authorities? (ဤဖြစ်ရပ်နှင့်ပတ်သက်၍ အခြားသောကြီးကြပ်ကွပ်ကဲရေးဆိုင်ရာ အဖွဲ့အစည်းများသို့ သတင်းပေးပို့ထားခြင်း ရှိ/မရှိ)	☐ Yes (ရှိ) ☐ No (မရှိ)
If Yes, please specify (ရှိပါကဖော်ပြရန်)	

Details of Reporting Person (သတင်းပေးပို့သူ၏ အသေးစိတ်အချက်အလက်များ)			
Name of reporting person (သတင်းပေးပို့သူအမည်)			
Name of establishment (ဌာန/အဖွဲ့အစည်းအမည် : ဆေးရုံ/ဆေးခန်း/အခြား)			
Establishment license no. (လိုင်စင်အမှတ်ရှိက ဖော်ပြရန်)			
Address (လိပ်စာ)			
Telephone No. (တယ်လီဖုန်း)		Fax No. (ဖက်စ်)	
Email(အီးမေးလ်)			
Incident Information (ဖြစ်စဉ်သတင်းအချက်အလက်များ)			
Description of incident (ဖြစ်စဉ်အသေးစိတ်ဖော်ပြချက်)			
Location of Incident (ဖြစ်ပွားခဲ့သောနေရာ)			
Name of institution (လုပ်ငန်းအဖွဲ့အစည်းအမည်)			
Address(လိပ်စာ)			

Telephone No. (တယ်လီဖုန်း)		Fax No.(ဖက်စ်)	
Contact person at site of incident (ဖြစ်ပွားခဲ့သောနေရာရှိ ဆက်သွယ်ရမည့်သူ)			
Device Information (ဆေးပစ္စည်းဆိုင်ရာသတင်းအချက်အလက်များ)			
Device name(ဆေးပစ္စည်းအမည်)			
Brand name (အမှတ်တံဆိပ်အမည်)			
Manufacturer name (ထုတ်လုပ်သူအမည်)			
Batch/ Lot/ Serial no. (ထုတ်လုပ်မှုအပါတ်စဉ်နံပါတ်)		Expiry date (သက်တမ်းကုန်ဆုံးရက်)	
Medical device Import Recommendation/Notification no. (ဆေးပစ္စည်းတင်သွင်းခွင့်ထောက်ခံချက်အမှတ်/ မှတ်တမ်းတင်အမှတ်)			
Operator of device at time of incident (ဖြစ်ပွားချိန်၌ဆေးပစ္စည်းကို အသုံးပြုသူ)		☐ Healthcare Professional (ဆရာဝန်/ဆရာမ/ကျွမ်းကျင်သူများ) ☐ Patients (လူနာ) ☐ Others (အခြား) _____	
Usage of device (ဆေးပစ္စည်းကို သုံးစွဲပုံ)		☐ Single use(တစ်ခါသုံးခြင်း) ☐ Reuse of Single Use (တစ်ခါသုံးအား ထပ်မံအသုံးပြုခြင်း) ☐ Re-serviced / Refurbished (ပြုပြင်ပြင်ဆင်၍ အသုံးပြုခြင်း)	
Device disposition / current location (ဆေးပစ္စည်း၏ အနေအထား/လက်ရှိတည်နေရာ)		☐ Implanted (ခန္ဓာကိုယ်တွင်းသို့ ထည့်သွင်းထားပြီး) ☐ Explanted (ခန္ဓာကိုယ်တွင်းမှ	

	ထုတ်ဖယ်ပြီး) ☐ Disposed (စွန့်ပစ်ပြီး) ☐ Returned to manufacturer (ထုတ်လုပ်သူထံ ပြန်လည်ပေးပို့ပြီး) ☐ Others , please specify (အခြားရှိက ဖော်ပြရန်) _____
List of other devices involved in the incident (if applicable) (ဖြစ်ပွားချိန်တွင် အခြားသော ဆေးပစ္စည်းများကို အသုံးပြုခဲ့ပါက စာရင်းဖြင့်ဖော်ပြရန်)	
Result of manufacturer investigation (ထုတ်လုပ်သူ၏ စုံစမ်းစစ်ဆေးမှုရလဒ်)	
Patients information (လူနာ၏ သတင်းအချက်အလက်များ)	
Age (အသက်)	
Gender (ကျား/မ)	
Patient outcome (လူနာ၏ ဆေးကုသမှုရလဒ်)	☐ Death (အသက်သေဆုံးခြင်း) ☐ Life threatening (အသက်အန္တရာယ်စိုးရိမ်ရခြင်း) ☐ Hospitalized (ဆေးရုံတင်ကုသရခြင်း) ☐ Congenital anomaly (မွေးရာပါမူမမှန်ခြင်း) ☐ Required intervention to prevent permanent impairment / damage ရေရှည်ချို့ယွင်းခြင်း / ပျက်စီးခြင်းမှ ကာကွယ်ရန်လိုအပ်သော ဖေးမဆောင်ရွက်မှုပေးခြင်း ☐ Others, please specify (အခြား) _____
Corrective action taken to the care of patient	

(လူနာအား ပြန်လည်၍ အရေးယူစောင့်ရှောက်ကုသမှု)	
Other information (အခြားသတင်းအချက်အလက်များ)	
Manufacturer / authorised representative aware of other similar incident (frequency, number) (ထုတ်လုပ်သူ/တရားဝင်ကိုယ်စားလှယ်မှ အလားတူဖြစ်ရပ်နှင့်ပတ်သက်၍ သတိပြုမိသည့်) (အကြိမ်/အရေအတွက်)	
Countries where these similar incident occurred (အလားတူဖြစ်ရပ် ဖြစ်ဖူးသော နိုင်ငံများ)	
Other related information (အခြားဆက်စပ်သော သတင်းအချက်အလက်များ)	

I attest that the information submitted is true and correct (အထက်ဖော်ပြအချက်အလက်များသည် စစ်မှန်၊ မှန်ကန်ပါကြောင်း ဝန်ခံကတိပြုပါသည်။)

Signature(လက်မှတ်) : ----------

Name of reporting person : ----------
(မှတ်တမ်းပေးပို့သူအမည်)

Date of this notification : ----------
(မှတ်တမ်းတင်သည့်ရက်စွဲ)
(dd/mm/yyyy)(ရက်/လ/နှစ်): ----------

Establishment stamp

(ဌာန/အဖွဲ့အစည်း၏ တံဆိပ်တုံး)

7. References

1. ASEAN Medical Device Directives
2. Guidance for Medical Device Grouping, Health Science Authority, Singapore
3. Guidance for Medical Device Specific Grouping, Health Science Authority, Singapore