Guideline for Registration of Medical Devices, 2026

MPD-G-MD-MA-

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Version History

Version	Release Date	Version History	Revised By
00	22-08-2022	Original Release	-
01	-	1. To align with current relevance of organization structure 2. Include provision for recognition of standards for the purpose of registration 3. Revise post approval variations - remove major variations, include other minor changes 4. Update and revise application forms and other letter formats aligning with the BMRR 2025	Sangay Choden

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1. Introduction

Towards ensuring the safety, quality and performance of the medical devices, the Bhutan food and drug authority (BFDA) was mandated to regulate the medical devices by the Bhutan Medicines Board vide Executive Order No. MoH/30-DRA/2019/73, dated 16 April 2019. Accordingly, the BFDA initiated the development of the medical device strategy. One of the key strategies towards enabling patient access to high quality, safe and effective medical devices is through the registration of medical devices. When appropriately implemented, it ensures the safety of patients and consumers at large.

The document is intended to guide the regulators, market authorization holders, manufacturers and other parties involved in complying with the applicable regulatory requirement for registration of medical devices with the Authority. The guidance further describes in detail the procedures to be followed in the course of registration of medical devices in Bhutan.

Medical devices are classified based on a rule based risk classification system into four risk classes i.e class A to D with class A being the lowest risk class and class D posing the highest risk to the user or patient. This is in line with the guidance document developed by the Global Harmonization Task Force (GHTF) and Health Science Authority. The actual risk classification of each medical device depends on the claims made by the product owner and on its intended purpose. Regulation and classification of medical devices is proportional to the level of risk associated with a medical device and the level of regulatory requirement increases with increasing degree of risk. Therefore Class A medical devices are exempted from registration due to relatively low risks associated thereto. The medical devices are also further grouped into four types of categories based on their intended purposes to ease-out registration processes.

The Authority reserves the right to request any additional information to establish the safety, quality and performance of a medical device in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The Authority is committed to ensure that all registered medical devices will meet the requirements of the Essential Principles relating to quality, safety and performance. It is also important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

2. Scope

1. This document is applicable to all devices which fall under the definition of a medical device as defined in this guidance document.
2. This shall not apply to Class A medical Devices.

3. **Objectives**

This guideline is developed to guide the applicant in the preparation and submission of dossiers of medical devices for the purpose of registration. The document also provides guidance to group and classify medical devices using the appropriate risk-based classification rules.

4. **Normative References**

The following documents, in whole or part, are normatively referenced in these guidelines and are indispensable for its application:

4.1. Medicines act of kingdom of Bhutan 2003
4.2. Bhutan Medicines Rules and Regulations 2019
4.3. ASEAN Medical Device Guidance
4.4. GHTF Principles of Medical Devices Classification
4.5. HSA Guidance on Grouping of Medical Devices for Product Registration

5. **Definitions**

5.1. Accessory: It refers to an article that is intended specifically by its manufacturer to:

5.1.1. be used together with a medical device to enable that device to be used in accordance with its intended purpose as a medical device; or

5.1.2. augment or extend the capabilities of that device in fulfillment of its intended purpose as a medical device; and therefore should be considered as a medical device.

5.2. Active medical device: It refers to any medical device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy, but does not include any medical device intended to transmit energy, substances or other element between that medical device and a patient without any significant change to that energy, substance or element.

Note: Standalone software is deemed to be an active medical device.

Note: The concept “act by converting energy” includes conversion of energy from the power source to another form of energy. For example, from electrical sources to thermal energy.

The application of energy from the human body does not make a device "active" unless that energy is stored within the device for subsequent release. For instance, energy generated by the human body and applied to the plunger of a syringe (thus causing a substance to be delivered to a patient) does not make this syringe an "active device". However, if a delivery system depends upon manual winding to preload a spring which is subsequently released to deliver a substance, then the device incorporating the spring is an "active device".

Medical devices using pre-stored gases and/or vacuum as a power source are regarded as active devices, e.g. a pressurized canister delivery system.

Heating/cooling pads intended only to release stored thermal energy are not active devices because they do not act by conversion of energy. However, heating/cooling pads which act by chemical action (e.g. endothermic or exothermic reaction) are active devices as they are converting chemical energy into heat energy and or vice versa.

Radioactive sources that are intended to deliver ionising radiation are regarded as active medical devices (e.g. radioactive isotopes coated beads), unless they are radiopharmaceuticals which may be infused into the body.

5.3. Authority: It refers to the Bhutan Food and Drug Authority.

5.4. Body orifice: It refers to any natural opening in a human body, the external surface of any eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

5.5. Central circulatory system*:* It refers to the major internal blood vessels including the following:

5.5.1. aorta abdominalis (abdominal aorta);
5.5.2. aorta ascendens (ascending aorta);
5.5.3. aorta descendens to the bifurcatio aortae (descending aorta to the bifurcation of aorta);
5.5.4. aorta thoracica (thoracic aorta);
5.5.5. arcus aorta (aortic arch);
5.5.6. arteria carotis communis (common carotid artery);
5.5.7. arteria carotis externa (external carotid artery);
5.5.8. arteria carotis interna (internal carotid artery);
5.5.9. arteriae cerebrates (cerebella arteries);
5.5.10. arteriae coronariae (coronary arteries);
5.5.11. arteriae pulmonales (pulmonary arteries);
5.5.12. ilica communis (common iliac arteries and veins);
5.5.13. truncus brachicephalicus (brachiocephalic trunk);
5.5.14. venae cava inferior (inferior vena cava);
5.5.15. venae cava superior (superior vena cava);
5.5.16. venae cordis (cardiac veins);
5.5.17. venae pulmonales (pulmonary vein).

5.6. Central nervous system: It refers to the brain, meninges and spinal cord.

5.7. Component: It refers to one of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended purpose. A component may be known as a part but not a medical device in its own right.

5.8. Derivative: It refers to a 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues.

5.9. Duration of contact: It refers to the uninterrupted use of the medical device, not including any temporary interruption of its use during a procedure or any temporary removal of the medical device for purposes such as cleaning or disinfection; or

the accumulated use of the medical device by replacing it immediately with another medical device of the same type, as intended by its Manufacturer.

Duration of contact	**Description**
less than 60 minutes	Transient
at least 60 minutes but not more than 30 days	short-term
more than 30 days	long-term

5.10. Family of medical devices: It refers to a collection of medical devices that are of the same design and intended purpose, but may differ in certain features (permissible variants) that do not change their safety or performance profile.

5.11. Generic Proprietary Name: It refers to a unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name or brand name.

5.12. General Medical Devices: It refers to all medical devices apart from *'In-vitro Diagnostic medical Devices'*.

5.13. Grouping: It refers to categorization of medical devices into four groups i.e. single, set, family or system based on its intended purpose, generic proprietary name and manufacturer.

5.14. Harm: It refers to any physical injury or damage to the health of a person, or any damage to property or the environment.

5.15. Hazard: It refers to any potential source of harm.

5.16. Intended purpose/intended use: It refers to the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the Manufacturer of the medical device in relation to a medical device or its process or service.

5.17. Invasive medical device: It refers to a medical device which, in whole or in part, penetrates inside a human body, either through a body orifice or through the surface of the body.

5.18. In Vitro Diagnostic device: It refers to a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

5.19. Manufacturer : It refers to a person who-

5.19.1. supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

5.19.2. is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

5.20. Market Authorization Holder: It refers to the establishment having technical authorization for sale and distribution by wholesale or the product manufacturer or a relevant government agency.

5.21. Medical device: It refers to all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

5.21.1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
5.21.2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
5.21.3. investigation, replacement, modification, or support of the anatomy or of a physiological process;
5.21.4. supporting or sustaining life;
5.21.5. control of conception;
5.21.6. disinfection of medical devices; or
5.21.7. providing information by means of in-vitro examination of specimens derived from the human or animal body.

5.22. Non-invasive medical device: It refers to a medical device other than an invasive medical device.

5.23. Non-viable: It refers to in relation to a biological entity, means that the entity is incapable of growth, development and reproduction.

5.24. Permissible variants: It refers to certain variants of medical devices which do not change the safety or performance profile.

5.25. Recognised authority: It refers to a regulatory authority, regional or international institution or assessment body whose regulatory decisions, technical assessments or approvals are accepted by the authority for reliance purposes. This may be used to refer to or leverage those decisions to support or streamline the evaluation of a medical device. These authorities will be listed in the guideline for reliance.

5.26. Reusable surgical instrument: It refers to means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device, and which is

intended to be reused after appropriate procedures for cleaning or sterilization of the instrument have been carried out.

5.27. Risk: It refers to a combination of the probability of occurrence of harm and the severity of that harm.

5.28. Single medical devices: It refers to a medical device that is sold and used as one unit, intended to perform a specific purpose on its own.

5.29. Set of medical devices : It refers to a group of medical devices packaged together and supplied for a specific medical procedure or to achieve a common purpose, even if each device could be used independently of one another. It is mainly for convenience in a procedure. Unlike a system, the devices are not necessarily designed exclusively to work together.

5.30. Sterile state: It refers to in relation to a medical device, means a state free of viable microorganisms.

5.31. System of medical devices: It refers to a combination of medical devices or components, possibly along with accessories, that are intended to be used together to achieve a common intended purpose. The combination is arranged such that it ensures compatibility.

5.32. WLA: It refers to a regulatory authority (RA) or a regional regulatory system (RRS) that complies with all the relevant indicators and requirements specified by WHO for regulatory capability as defined by an established benchmarking and performance evaluation process.

6. **Acronym**

6.1. ABR: Abridge route of registration
6.2. BFDA : Bhutan food and drug authority
6.3. GHTF: Global Harmonization task force
6.4. IMDRF: International Medical Devices Regulators Forum
6.5. IVD: In Vitro Diagnostic Devices
6.6. WLA: WHO Listed Authority

Section A: Overview of The Registration Procedures

1. **General Principles**

1.1. In accordance with section 16.2 of the act all medical devices manufactured, sold, distributed and imported shall be registered with the authority.

1.2. The medical devices shall be categorized as per their risk as class A to D based on classification rules specified by GHTF/IMDRF.

1.3. Certain documentation exemptions for registration will be provided for WHO pre-qualified medical devices and those medical devices registered with a WLA based on reliance.

1.4. The document requirements shall be proportional to the degree of risk associated with the medical devices.

1.5. The Medical devices falling under class A shall be exempted from registration.

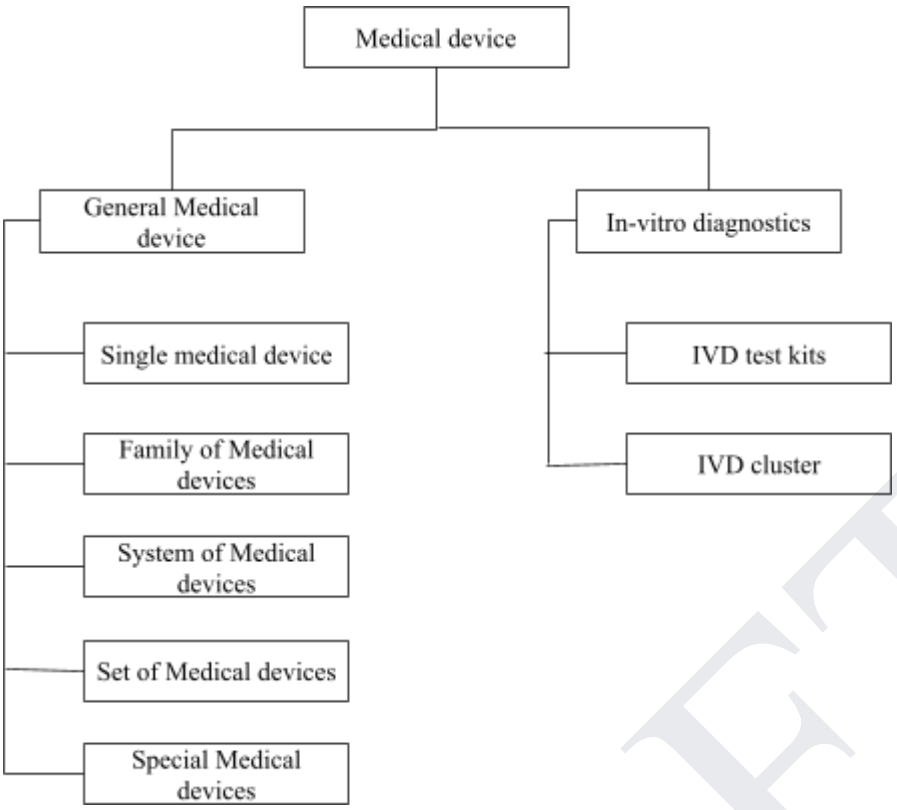
1.6. The authority may recognise relevant standards to demonstrate the safety and performance of medical devices in compliance to section 16(10) of the BMRR.

1.7. For the context of this guideline, the term “Product registration” and “Marketing authorization” is used interchangeably.

2. **Grouping of Medical Devices**

Medical devices range from simple products like syringes to complex products with complex applications like patient monitoring systems which include many devices for the same purpose of monitoring vital signs. To simplify regulatory review and ease registration process, medical devices are grouped under one application submission instead of multiple applications and assessing each one individually.

Grouping for medical devices is different for general medical devices and IVDs considering the difference in the applicability of the medical devices.



2.1. General Medical Devices

General medical devices is classified into groups as follows:

a. Single;
b. Family;
c. System;
d. Set; and
e. Special Group.

The following basic rules must all be fulfilled for the grouping to apply. These are:

a. Same generic proprietary name(brand name/trade name);
b. Same manufacturer; and
c. Same common intended purpose.

2.1.1. Single medical devices

A **single** medical device is a medical device from a manufacturer identified by a medical device proprietary name with a specific intended purpose. It is sold as a distinct single packaged entity to perform a specific purpose on its own. It may be offered in a range of package sizes.

Examples:

- Condoms that are sold in packages of 3, 12 and 144 can be grouped as a **single** medical device.
- A company manufactures a software program that can be used with a number of CT scanners produced by other manufacturers. Although the software cannot

function on its own, it can be used on different scanners. The software can be grouped as a **single** medical device.

- A company that assembles and registers a first aid kit has now decided to also supply each of the medical devices in the first aid kit individually. Each medical device supplied individually as a medical device must be grouped separately as a **single** medical device.

2.1.2. Family of medical devices

Family of medical devices are a collection of medical devices and each medical device in the family must fulfill the following:

- is from the same manufacturer;
- is of the same risk classification;
- has the same medical device proprietary name;
- has a common intended purpose;
- has the same design and manufacturing process; and
- has variations that are within the scope of the permissible variants.

A characteristic of a medical device may be considered a permissible variant if:

- the physical design and construction of the medical devices are the same, or very similar;
- the manufacturing processes for the medical devices are the same, or very similar;
- the intended purpose of the medical devices is the same; and
- the risk profile of the medical devices, taking into account the above factors, is the same.

Table 1: General permissible variants

General permissible variants
Colour
Coating material (for lubrication only)
Concentration with same indication and mechanism (same concentration, different amount of constituents)
Diameter, length, width, gauge
Dimensional design differences for child and adult use (differences due to different patient populations are allowed. Eg. volume and length)
Flexibility
Holding force
Isotope activity level
Method of sterilization (to achieve same sterility outcome)
Memory storage
Printing capability

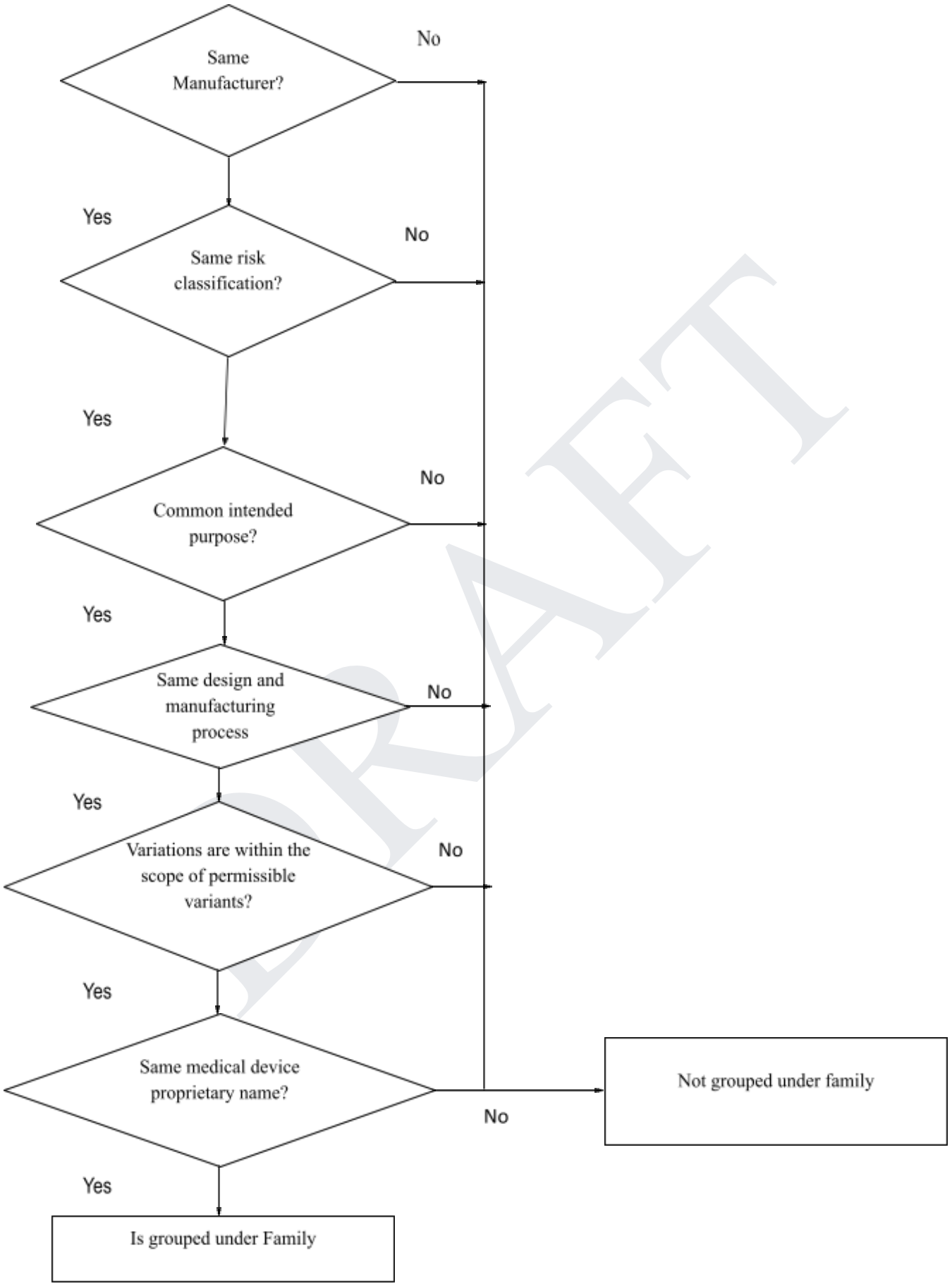
Radiopacity/Radiodensity
Shape, size, volume
Sterility status (sterile vs. non-sterile)
Type of device mounting (Eg. ceiling mount, wall mount, standing)
Viscosity (the change in viscosity is solely due to changes in the concentration of constituents)

Table 2: The list of permissible variants for specific products

Specific products	**Permissible variants**
Antibiotic test	(i) Concentrations
Biopsy forceps	(i) Formable or non-formable
Blood bags	(i) Anticoagulants (same composition and different concentration) (ii) Additives (different composition and concentration)
Catheter	(i) Number of lumens in catheter (ii) Material of catheter: PVC (polyvinyl chloride), PU (polyurethane), nylon and silicone (iii) Curvature (straight or pigtail) (iv) Coating material for lubrication Polymer products-with or without DEPTH Stent- delivery system, that is over-the –wire or through the scope
IV Cannula	(i) Presence of injection port (ii) Presence of safety features(wing)
Condoms	(i) Texture (ii) Flavour
Contact lens	(i) Diopter, (ii) UV protection (iii) Tinting (iv) Colour (v) Wearing schedule (i.e. daily wear, extended wear) (vi) Replacement schedule (i.e. daily, weekly, monthly)
Electrophysiological Catheter	(i) Electrode spacing (ii) Number of electrodes
Suture	(i) Number of strands (ii) Pledgets (iii) Loops (iv) Dyes
Suture passer	(i) Design of jaw, handle or needle
Dental handpieces	(i) Rotational speed (ii) Material of handpiece

Dental brackets	(i) Material of bracket
Wound dressings	(i) Different formats (eg.solutions, creams, gels loaded onto pads)
Gloves	(i) Powdered or powder free
IVD rapid tests	(i) Different assembly format: cassette, midstream, strip
IVD urinalysis strips	(i) Different combination of testing configurations
Polymer Products	(i) With or Without plasticizers(eg.DEHP)
Stent	(i) Delivery system, that is over –the-wire or through the scope (ii) Flaps, flares or sleeves

Figure 1: Decision Flowchart for Grouping of Medical Devices as a Family



Examples:

- Condoms that differ in color, size and texture but are manufactured from the same material and manufacturing process and share a common intended purpose can be grouped as a **family**.
- IV administrative sets that differ in features such as safety features and length of tubing, but are manufactured from the same material and manufacturing process and share a common intended purpose can be grouped as a **family**.
- Steerable guide wires that are available in various lengths and possess various tip shapes and tip flexibilities can be grouped as a **family** if their variations fall within the scope of permissible variants.
- Spherical contact lenses with additional features of UV protection , can be grouped as part of a **family**, as this feature does not affect the basic design and manufacturing of the lens.
- In-the-ear hearing aids which are designed in different sizes to be fitted in the ear (i.e. outer ear, middle ear, and inner ear canal), and have been designed using the same main components including the signal processor and compression circuit, microphone, amplifiers, and receiver, can be grouped as a **family**.
- Automated blood pressure monitors with optional features such as memory storage and print capability can be considered as part of a **family**.
- Cardiac catheters that are available in a different number of lumens, lengths and diameters can be grouped as a **family**.

2.1.3. **System of medical devices**

A **system** of medical devices comprises a number of constituent-components that are:

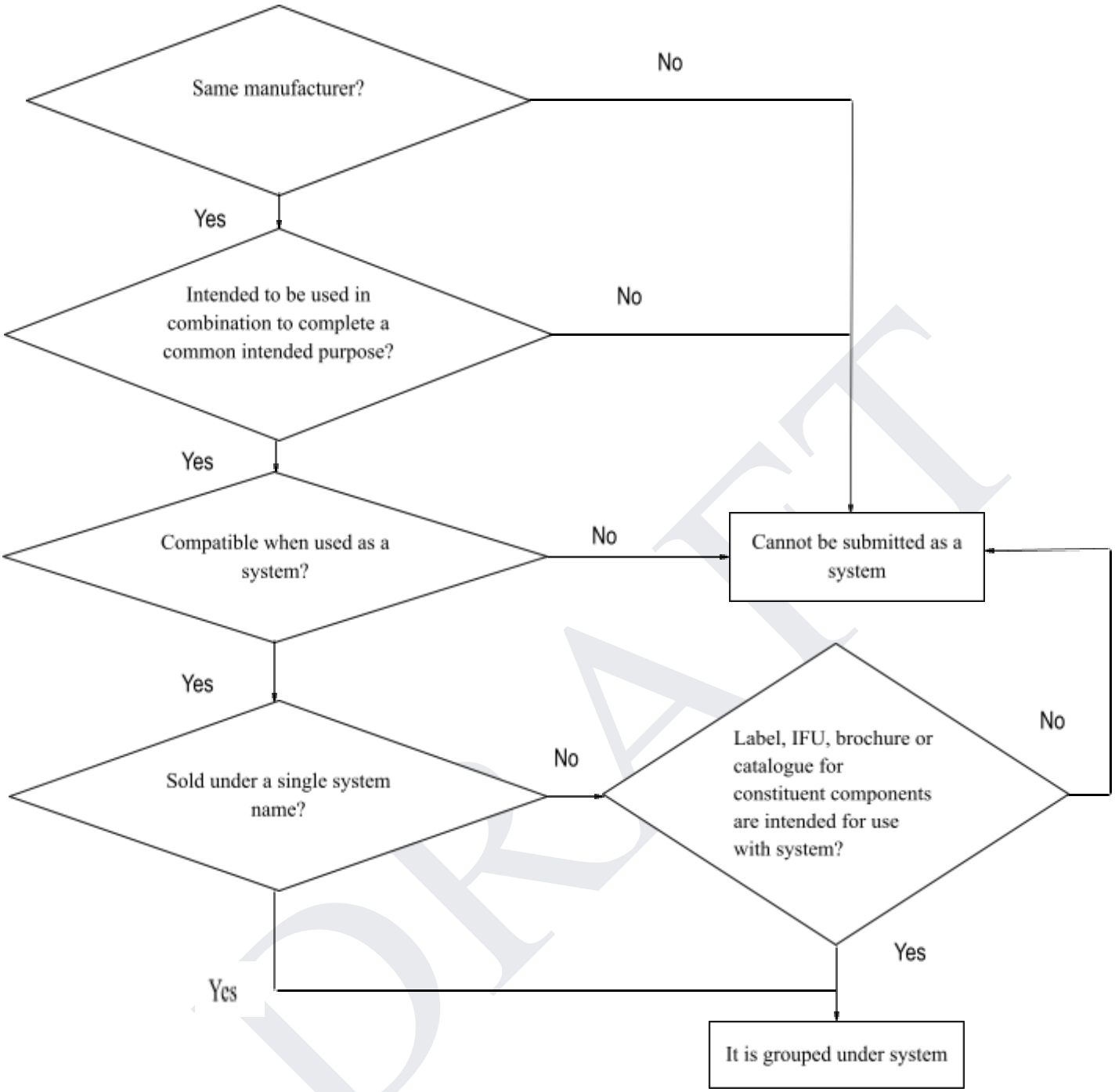
- from the same manufacturer;
- intended to be used in combination to complete a common intended purpose;
- compatible when used as a **system**; and
- Sold under a system name or the labeling, instruction for use (IFU), brochures or catalogues for each constituent-component states that the constituent-component is intended for use with the **system**.

Note: Individual names for a **system** of medical devices may contain additional descriptive phrases and are acceptable.

Constituent-components grouped as part of a system shall only be supplied specifically for use with that system. Any constituent-component that is meant for supply for use with multiple systems should be grouped together with each of these other systems. Alternatively, these constituent-component(s) that are compatible for use with multiple systems must be grouped separately.

In addition, if several **systems** fulfill the following conditions as given in section 9.2, they may be grouped as a family of systems.

Figure 2: Decision Flowchart for Grouping of Products as a System



Examples:

- A hip replacement system consisting of femoral and acetabular components can be grouped as a system. The components must be used in combination to achieve a common intended purpose of total hip replacement. The size of the components may vary.
- An electrosurgical unit and its accessories that consist of forceps, electrodes, electrode holders, leads, plug adaptor, when used together for a common intended purpose, can be grouped as a system.

- Optional accessories such as wireless controllers that are part of In-the-ear hearing aid can be grouped as a system.
- A glucose monitoring system consisting of a glucose meter, test strips, control solutions and linearity solutions can be grouped as a system.

2.1.4. **Set of medical devices**

A set of medical devices is a collection of two or more medical devices, assembled together as one package by a manufacturer. The medical devices are usually packaged together for convenience in a procedure, but not necessarily functionally interdependent.

A set of medical devices is characterised by the following:

- a single proprietary set name;
- a common intended use;
- risk classification allocated to the set is at the level of the highest classified device within the set.

Considerations for a set of medical devices:

- Each medical device in the set may have different medical device proprietary names and intended purposes, may be designed and manufactured by different manufacturers.
- When the set is grouped, the manufacturer is able to customize the set for particular medical procedures or clinicians, while maintaining the same set name with a desired common intended purpose.
- The collection of medical devices in a set may differ in number and combination of products that comprise each set while maintaining the same proprietary set name and set's intended use.
- The set name indicated for the medical device must appear in the product label affixed on the external package of the set. Individual medical devices in the set do not require to be labelled with that sets' name. Individual medical devices in the set may contain its own additional descriptive phrases.

Examples of set of medical devices:

- A first aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package by a manufacturer, can be grouped as a set.
- A dressing tray consisting of a number of medical devices when packaged together for convenience to meet a specific purpose by a manufacturer can be grouped as a set.
- A manufacturer supplies dressing trays customised with different quantity and type of gauze and sutures to different hospitals while maintaining the same SET name and intended purpose.

2.1.5. **Special Group**

This is applicable for all the medical devices which can't be grouped with other medical devices. The basis of this group is primarily on the functionality.

For example: Class A lung retractor and Class A kidney retractor have the same overall intended purpose as they are both retractors. However, kidney retractor and lung retractors do not have the same overall intended purpose and therefore cannot be grouped together as a FAMILY.

Table 3: Examples for Special Group

Instrument name	Description	Intended purpose
ABC Dressing Forceps	Delicate, Serrated Tips, Straight, 4¾"	To pick up or grasp tissue or items in the surgical wound
DEF Kidney Forceps	Half curved, 222 mm Length	To grasp renal polyps
HIJ Lung Forceps	Triangular jaws, jaw width 11", length 8"	To grasp lung tissue
XYZ Uterine Biopsy Forceps	Oblong basket jaw, jaw size 3x10mm, shaft length 10"	To grasp tissue during transvaginal or transrectal tissue biopsy

Note: In the example above, the forceps have the same manufacturer, but have different proprietary names (ABC, DEF, HIJ and XYZ) and different intended purposes. These forceps are Class A medical devices. These forceps can be grouped under special group.

2.2. In Vitro Diagnostic Medical Device grouping

2.2.1. **An IVD test kit**

It is an in-vitro diagnostic device that consists of reagents or articles that are:

- from the same manufacturer;
- intended to be used in combination to complete a specific intended purpose;
- sold under a single test kit name or the labeling, instructions for use (IFU), brochures or catalogues for each reagents or article states that the component is intended for use with the IVD test kit; and
- compatible when used as a test kit.

2.2.1.1. An IVD test kit does not include the instruments, such as analyzers, needed to perform the test.

2.2.1.2. Information on all reagents or articles within an IVD test kit must be as part of one product.

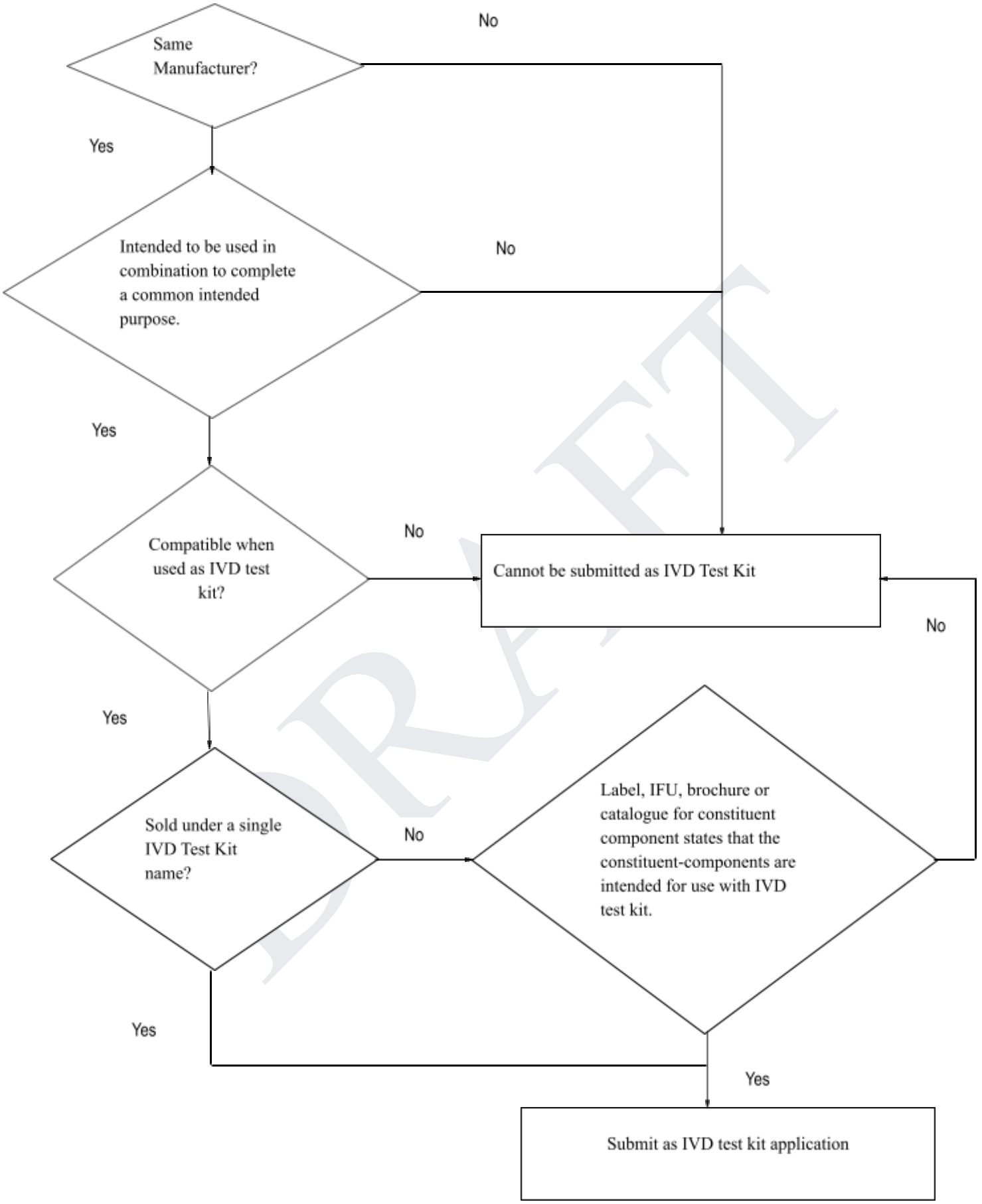
2.2.1.3. Reagents or articles from another manufacturer may be grouped with the IVD test kit.

2.2.1.4. Some test kits may involve the use of an analyser which is used in combination to achieve a common intended purpose.

2.2.1.5. Examples: A Human Immunodeficiency Virus (HIV) Enzyme Linked Immuno Sorbent Assay (ELISA) test kit may contain controls, calibrators and washing buffers. All the reagents and articles are used together to detect HIV and therefore can be grouped as a test kit. These reagents and articles can be supplied separately as replacement items for that particular test kit.

2.2.1.6. Example of test kit with analyser - A glucose monitoring system consisting of a glucose meter, test strips, control solutions and linearity solutions can be grouped as an IVD system.

Figure 3: Decision Flowchart for Grouping of Products as a IVD Test Kit



2.2.2. An IVD CLUSTER

It comprises a number of *in vitro* diagnostic reagents or articles that are:

- from the same manufacturer;
- within risk classification A or B;
- of a common test methodology ; and
- of the same IVD CLUSTER category.

IVDs in a cluster may have different proprietary names while fulfilling the above criteria and may include analyzers that are designed for use with the reagents in the IVD cluster.

This list of IVD cluster categories as provided below is only applicable to **Class A and Class B IVD**. It should be clearly stated in the label or IFU of each reagent or article that it is intended for use, whether alone or in combination, for the same category.

Methodology	Cluster Category (closed list)	Examples of Analytes (non-exhaustive list)
Clinical Chemistry	Enzymes	i. Acid Phosphate ii. Alpha-Amylase iii. Creatine Kinase iv. Gamma-Glutamyl Transferase v. Lactate Dehydrogenase vi. Lipase
	Substrates	i. Albumin ii. Bilirubin iii. Urea/Blood Urea iv. Cholesterol v. Creatinine vi. Glucose
	Electrolytes Reagents	i. Ammonina ii. Bicarbonate iii. Calcium iv. Chloride v. Magnesium vi. Phosphate Inorganic/ Phosphorus
	Electrolyte Electrodes	i. Ammonia Electrodes ii. Carbon Dioxide (Bicarbonate) Electrodes iii. Calcium Electrodes iv. Chloride Electrodes v. Magnesium Electrodes vi. Potassium Electrodes

	Substrate Electrodes/Biosensors	i. Creatinine Electrodes ii. Glucose Electrodes iii. Glycated Haemoglobin Electrodes iv. Lactate Electrodes v. Urea Electrodes vi. Bilirubin Electrodes
Immunochemistry	Immunoglobulins (Without IgE)	i. Immunoglobulin A ii. Immunoglobulin D iii. Immunoglobulin G iv. Immunoglobulin M v. Kappa and Lambda chain vi. Immunofixation kits
	Complement Components	i. Complement Component C1q ii. Complement Component C1 in-activator iii. Complement component C3/C3c iv. Complement component C4 v. Complement component C5a
	Transport Proteins	i. Albumin ii. Ceruplasmin iii. Haptoglobin iv. Hemopixin v. Lactoferrin vi. Pre-albumin/Transthyretin
	Lipoproteins	i. Apolipoprotein A I ii. Apolipoprotein A II iii. Apolipoprotein B iv. Apolipoprotein E Sub-typing v. Lipoprotein(a)
	Other Specific Proteins	i. a1- Acid Glycoprotein ii. a1-Antitrypsin iii. a2-Macroglobulin iv. a1-Microglobulin v. Fibronectin vi. Immuno Reactive tRYPSIN
	Allergy	i. Immunoglobulin E- Total ii. Immunoglobulin E- Screen iii. Immunoglobulin E-Specific, monotest/monoresult iv. Allergene specific IgA v. Allergene specific IgG
	Cancer Markers	i. BR-marker CA15-3 ii. GI-marker CA19-9. CA242 iii. Carcinoembryonic Antigen iv. Total Prostatic Specific Antigen v. Alphafetoprotein (AFP) vi. P53

	Thyroid Function Markers	i. Free Triiodothyronine ii. Free Thyroxine iii. Thyroid Stimulating Hormone iv. T-Uptake v. Thyroglobulin vi. Neonatal Thyroxine
	Fertility/Pregnancy Hormones/ Proteins	i. Androstenedione ii. Estradiol iii. Prolactin iv. Human Chorionic Gonadotropic Total v. Human Placental Lactogen vi. Estriol
	Diabetes Assays (Hormones)	i. C-Peptine ii. Glucagon iii. Insulin iv. Glycosylated. Glucated Haemoglobin v. Islet Cell Ab vi. Proinsulin
	Renal Metabolism Assays	i. Aldosterone ii. Angiotensin I/II iii. Angiotensin Converting Enzyme iv. Cortisol v. Renine
	Bone and Mineral Metabolism Assays	i. Bone Alkaline Phosphate ii. Calcitonin iii. Cross-linked C-Telopeptides iv. Cross-linked N-Telopeptides v. Cyclic Adenosine Monophosphate vi. Hydroxyproline
	Endocrine Hormones and Peptides	i. Adrenocorticotropic Hormone ii. Human Growth Hormone iii. Insulin-like Growth Factor I iv. Insulin-like Growth Factor Binding Protein 1 v. Vasointestinal Peptide vi. Vasopressin
	Neuroendocrine Function Assays	i. Bombesin ii. 17-Hydroxy-Ketosterone iii. B-Endorphin iv. Neurotensin v. Somatostatin vi. Substance P
	Other Individual and specified Hormones	i. Gastrin ii. Gonadotropin-Releasing Hormone iii. Melatonine iv. Pepsinogen v. Adrenaline vi. Dopamine

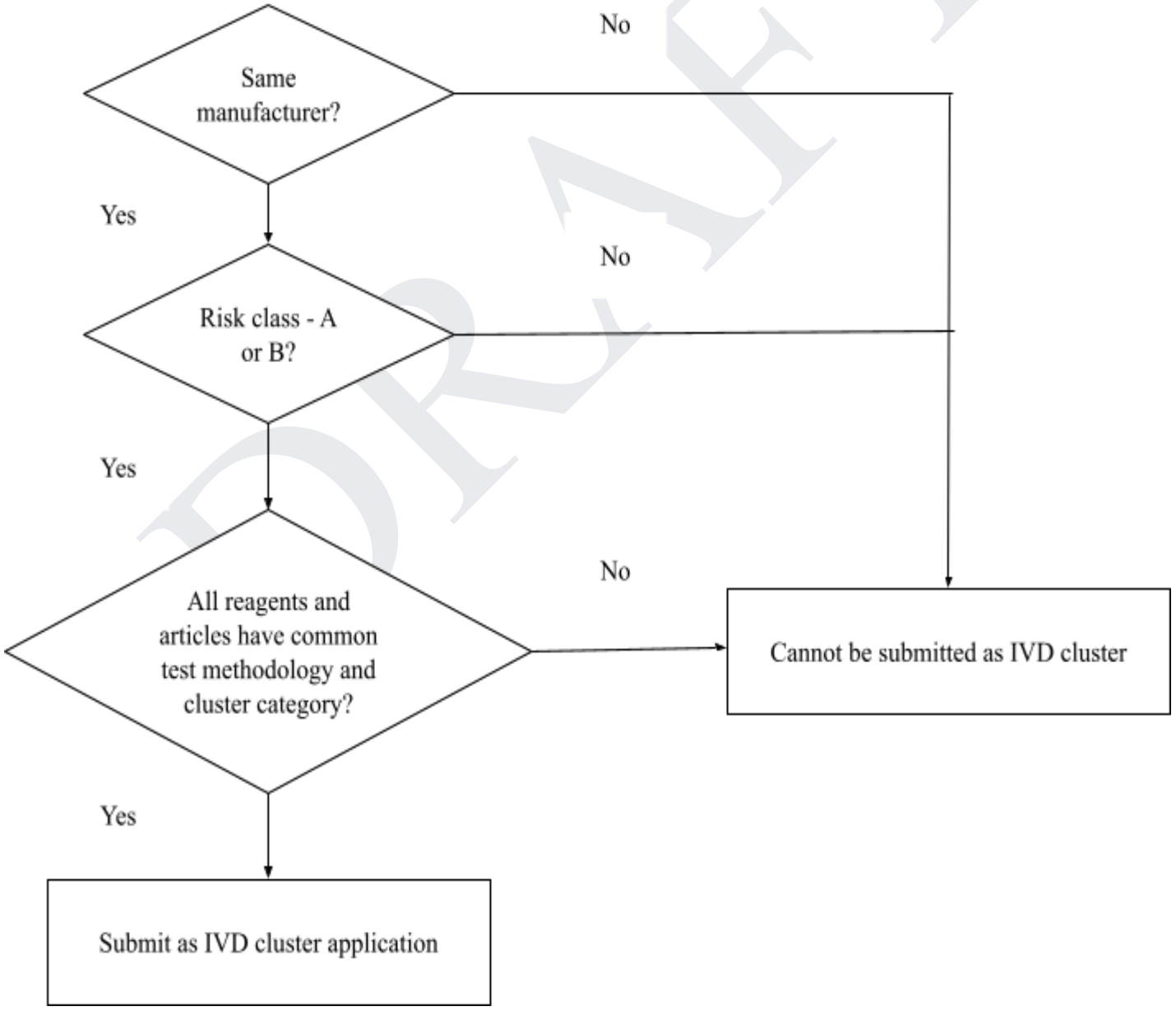
	Anaemia	i. Erythropoietin ii. Ferritin iii. Folate iv. Iron v. Iron Binding Capacity vi. Soluble Transferrin Receptor
	Vitamins	i. Vitamin B1 ii. Vitamin B2 iii. Vitamin B6 iv. Vitamin B12 v. Vitamin D (Cholecalciferol) vi. Intrinsic Factor(Blocking Antibody)
	Non-Immuno Suppressive Therapeutic Drug Monitoring	i. Phenobarbitol ii. Digitoxin iii. Gentamicin iv. Valproic Acid v. Caffeine vi. Theophylline vii. Methotrexate
	Immunosuppressive Therapeutic Drug Monitoring	i. Cyclosporine ii. Tacrolimus iii. Rapamycin(Sirolimus) iv. Mycophenolate
	Toxicology	i. Amphetamines ii. Cocaine iii. Babiturates iv. Morphines v. Phencyclidine vi. Acetaminophen vii. Catecholamines viii. Ethanol ix. Salicyclate
	Auto-Immune Diseases	i. Anti-nuclear antibodies(ANAs) ii. Anti-topoisomerase iii. Organ-specific autoantibodies iv. Circulating Immuno-complex v. TSH Receptor antibodies vi. Anti-Cardiolipin antibodies
	Rheumatoid Inflammatory Diseases Markers	i. Anti-Streptococcal Hyaluronidase ii. Anti-Streptokinase iii. Anti-Streptolysin O iv. C-Reactive Protein v. Anti-Staphylolysin vi. Anti-Streptococcal vii. Screening
	Liver Function	i. MEGX ii. Carbohydrate Deficient Transferrin

	Cardiac Markers	i. BNP/proBNP ii. Creatine Kinase-MB iii. Myoglobin iv. Troponin I/T v. Homocysteine vi. High-Sensitivity C-Reactive Protein
	Bacterial Infection Immunology	i. Bacillus subtilis ii. Escherichia coli
	Parasitic Infection Immunology	i. Entamoebahistolytica ii. Leishmania
	Fungal Infection Immunology	i. Candida albicans ii. Aspergillus
Haematology (Blood tests for transfusion excluded)	Haemoglobin Testing	i. Hemoglobin determinations (Total Hb) ii. Fractional oxyhemoglobin (O2Hb) iii. Fractional carboxyhemoglobin (FCOHb) iv. Fractional methemoglobin (FMetHb) v. Fractional deoxyhemoglobin (FHHb)
	General Coagulation Tests	i. Prothrombin Time ii. Thrombin Time iii. Activated Clotting Time iv. Activated Partial Thromboplastin Time
	Haemostasis (Coagulation)	i. Prothrombin ii. Thrombin iii. Fibrinogen iv. Protein C and Protein S reagents v. C1-inhibitors vi. Heparin vii. Alpha-Antiplasmin viii. Fibrin ix. Factor XII x. Platelet Factor 4 xi. Plasminogen
	Other Hematology Tests	i. Complete Blood Count ii. Hematocrit iii. Erythrocyte Sedimentation rate

Histology/Cytology	Cytokinesis (Lymphokinesis)/ Immunomodulators	i. Soluble Antigens/Receptors ii. Interferons iii. Tumor Necrosis Factors iv. Interleukins v. Colony Stimulating Factor vi. Tumor Necrosis Factors Receptors vii. Interleukins Receptors
	Histology/ Cytology Reagents	i. Embedding, Fixing, Mounting medica ii. Cytochemical Staining iii. Stain Solutions iv. Immunohistology kits
Microbiology culture Cytochemical Staining Embedding, Fixing, Mounting media Stain Solutions Immunohistology kits	Culture Media	i. Additives for DCM ii. Prepared Media(Tubes, bottles, plates) iii. Cells. Media, Serum for Viral Culture iv. Dehydrated culture media (DCM)
	Susceptibility Testing	i. Erythromycin susceptibility test for Staphylococcus aureus
	Identification of bacteria by testing for the susceptibility of the bacteria to the certain antibiotics	i. Tobramycin susceptibility test for pseudomonas aeruginosa ii. Fungal susceptibility testing
	Biochemical Culture Identification	i. Gram Negative Manual ID ii. Gram Positive Manual ID iii. Other ID Kits Manual-Anaerobes, Fastidious iv. Mycoplasma
	Immunological culture identification (ID)	i. Streptococci Grouping slide tests ii. Serotyping(E.Coli, Salmonella, Shigella etc)
	Nucleic Acid (NA) based culture identification	i. NA Identification-MRSA ii. NA Identification-other resistance markers
	Serological Identification (ID)	i. For Parasitology and Mycology (Fungi and Yeast)
	Oncogenes: Genes whose mutation or enhanced expression turns normal cell into cancer cell	i. Streptococci Grouping slide tests ii. P53 iii. Myc(8Q24) iv. TERC (3q26)

	Bacterial Infection (Detection by NA Reagents)	i. Staphylococcal detection ii. E.coli detection
	Viral infections (Detection by NA reagents)	i. Influenza and Para-influenza Nucleic acid reagents
	Fungal Infections	i. Fungi Nucleic acid reagents

Figure 4: Decision Flowchart For Grouping Of IVD Cluster



3. Risk classification of medical devices

The classification of medical devices is a 'risk based' system based on the vulnerability of the recipient body taking account of the potential risks associated with the use of medical devices. This approach allows the use of a set of criteria that can be combined in various ways in order to determine classification, e.g. duration of contact with the body, degree of invasiveness and local vs. systemic effect. These criteria can then be applied to a vast range of different medical devices and technologies.

The risks presented by a particular device will depend on:

- the intended purpose;
- effectiveness of risk management techniques applied during design, manufacture and use;
- its intended user(s);
- mode of operation; and
- type of technology(ies).

3.1. Factors influencing risk classification

Along with the risks presented by the device, the following factors may be considered during the risk classification of a medical device.

3.1.1. General medical devices

- the duration of medical device contact with the body,
- the degree and site of invasiveness into the body,
- whether the medical device delivers medicines or energy to the patient,
- whether the medical device incorporates human or animal tissues or cells,
- whether they are intended to have a biological effect on the patient's body
- local *versus* systemic effects (e.g. conventional *versus* absorbable sutures)
- whether medical device is to be used alone or in combination,
- whether it could modify blood or other body fluids,
- intended action on the human body,
- whether device comes in contact with injured skin,
- ability to be reused or not and whether the medical device is used for diagnosis or for the purpose of treatment.

3.1.2. In vitro diagnostics medical devices

- Technical expertise of the intended user;
- Importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a healthcare professional; and

- the impact of the result (true of false) on the individual and/or public health.

Table 5: Risk Classification of General Medical Devices

Risk Class	**Risk Level**	**Examples**
A	Low Risk	Wheelchairs / Tongue depressors
B	Low-moderate Risk	Hypodermic needles / Suction equipment
C	Moderate-high Risk	Ventilators / Bone fixation plates
D	High Risk	Heart valves / Implantable defibrillator

Table 5 indicates the four risk classes of medical devices. The examples given are for illustration only and risk classification rules must be applied to each medical device according to its intended purpose.

Table 6: Risk Classification of IVD medical devices

Risk Class	**Risk Level**	**Examples**
A	Low individual risk and low public health risk	Clinical chemistry analyser
B	Moderate individual risk and low public health risk	Anti nuclear antibody test
C	High individual risk and moderate public health risk	HLA typing
D	High individual risk and high public health risk	HIV blood donor screening;HIV/AIDs diagnosis

3.2. General Principles for classifying medical devices

The following is a list of general principles which should be kept in mind when classifying a device.

3.2.1. Medical devices are defined as articles which are intended to be used for a medical purpose.

3.2.2. It is the intended purpose that determines the class of device and not the particular technical characteristics of the device.

3.2.3. The intended purpose of the device should be substantiated (if required) and be representative of the technical characteristics of the device.

3.2.4. It is the intended and not the accidental use of the device that determines its class.

3.2.5. It is the intended purpose assigned by the manufacturer to the device that determines the class of device and not the class assigned to other similar products.

3.2.6. Accessories are classified separately from their parent device.

3.2.7. The mode of action of a medical device should be clear and evidenced with appropriate data to confirm this mode of action.

3.2.8. If the device can be classified according to several rules then the highest possible class applies.

3.2.9. Multipurpose equipment which may be used in combination with medical devices are not themselves classed as medical devices unless the manufacturer places them on the market with the specific intended purpose as a medical device.

3.2.10. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

3.2.11. Standalone software is regarded as driving or influencing the use of a device and so falls automatically into the same class. Software is classified on a case-by-case basis. If the output of the software is general patient information, the software is generally not a device. If the output of the software is based on analysing/manipulating clinical data to facilitate diagnosis or determine treatment schedules, the software is more likely to be a medical device.

3.2.12. It is the manufacturer that determines the appropriate class for their product. Consequently, the primary responsibility for the classification of a medical device is placed on the manufacturer. The authority may review the manufacturer's decision and reserves the right to challenge the risk classification.

3.3. Risk classification rules

3.3.1. The classification rule will be adopted as per **IMDRF guidance document** for classification of general and IVD medical devices.

3.3.2. The classification rules must be considered to determine the classification of the medical device.

3.3.3. If a medical device is intended to be used in more than one part of a patient's body, the medical device is classified on the assumption that it will be used in the part of the body that poses the highest risk. For invasive devices, this may be the central circulatory or central nervous systems.

3.3.4. For groups, systems and sets, the classification for the entire group, system or set is the highest classification of any individual device in the group, system or set.

3.3.5. If the device is to be used in combination with another medical device, the classification rules must be applied separately to each device.

3.3.6. In the event of a dispute between the manufacturer and the notified body concerned, resulting from application of the classification rules, the Bhutan food and drug authority shall determine the classification.

3.4. Special Cases

3.4.1. Software

3.4.1.1. Where it drives, controls or influences the use of a separate medical device, it is classified according to the intended use of the combination. Where intended as an accessory to a medical device should be classified separately from the device with which it is used. It is classified in its own right using the classification rules for medical devices.

3.4.1.2. Standalone software (to the extent it falls within the definition of a medical device) is deemed to be an active device since it relies on an energy source for its operation.

3.4.2. **Medical devices with a measuring function**

A medical device is considered to have a measuring function if the device is intended by the manufacturer to measure:

- quantitatively a physiological or anatomical parameter (or)
- a quantity or a qualifiable characteristic of energy, (or)
- substances delivered to or removed from the human body.

The measurements given by a medical device must:

- Display units of measurement acceptable to the Authority, or be compared to at least one point of reference indicated in Bhutan's legal units of measurement or
- other units of measurement acceptable to the Authority, and be accurate to enable the device to achieve its intended purpose.

Section B: General Requirements for Registration

1. General Requirements of a dossier

The dossier should be:

1.1. submitted in an acceptable format as notified by the Authority from time to time;
1.2. arranged properly in a chronological order (including page numbers) as per the guidelines.
1.3. complete as per the requirements specified in this guideline;
1.4. should either be in English or Dzongkha. For documents in foreign local language, the English translation may be accepted provided it is authenticated with a public notary of the country of origin.
1.5. 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.
1.6. for performance reports and certificate of analysis the standards used must be clearly reflected.
1.7. all copies of labeling, certificates, reports and other documents submitted must be legible.
1.8. all certificates/license/authorizations submitted must be within its validity period with a minimum of three months from the date of renewal or expiry during the time of submission.

2. Routes of Registration

There are two evaluation routes for Class B, C and D medical devices as follows:

2.1. Full Evaluation

2.2. Abridged Evaluation

Evaluation Route	**Eligibility Criteria**
Abridged Evaluation(ABR)	For medical devices that are WHO prequalified or has obtained at least one approval from recognised authorities..
Full Evaluation	For medical devices that isn't eligible for ABR.

3. Process flow for registration

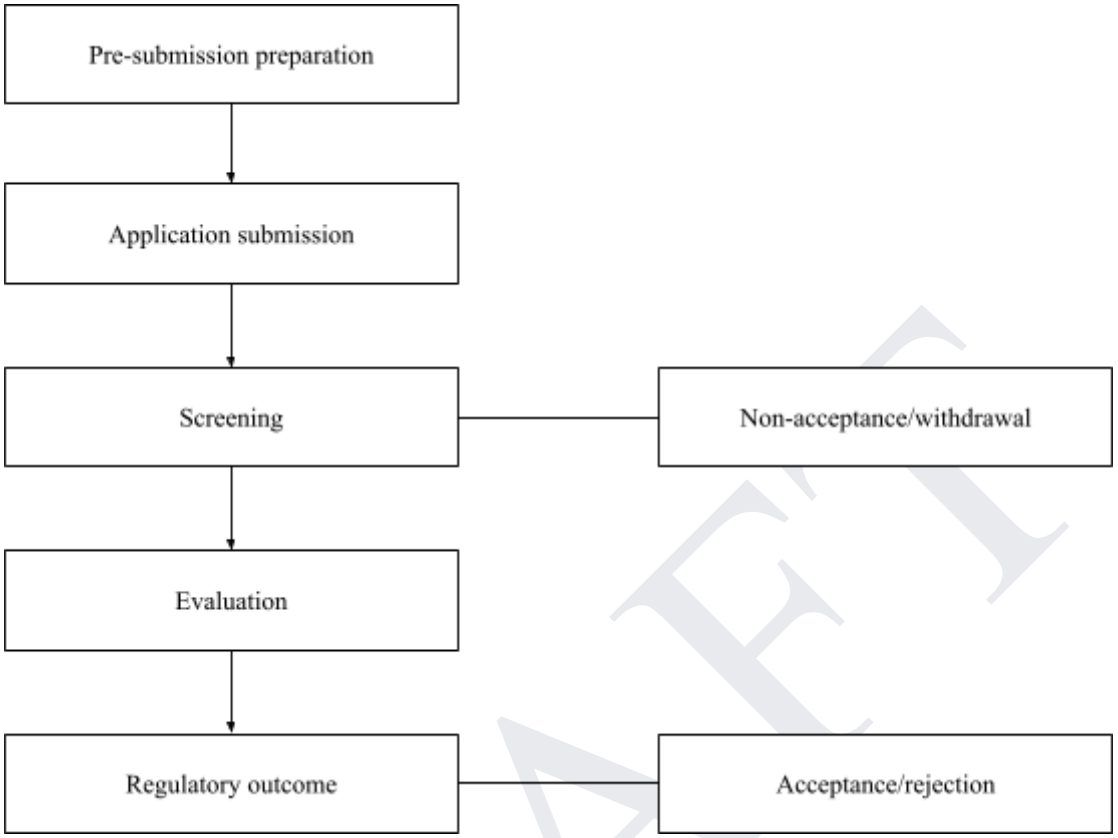


Figure 5: Registration process

4. Procedure for Registration

4.1. Pre-submission Preparation

During this phase, the applicant may discuss with the Authority regarding:

- Document required against respective application type and evaluation routes
- Selection of evaluation route
- Product sample requirement

4.2. Application Submission

The applicant submits dossier along with prescribed fee and application form(Annexures).

4.3. Application Screening

4.3.1. The dossier will be screened to ensure the correctness of the application type and the completeness of the dossier following its receipt.

4.3.2. The date of receipt of the application including the checklist will be taken as the submission date and the start of the screening timeline.

4.3.3. The turnaround time for the application screening (pre-screening) is 10 working days.

4.3.4. During screening, the application type/evaluation route may be reassigned to a more appropriate one. The applicant will be informed of this change and the Authority will take necessary actions.

4.3.5. Applications will not be accepted for the following deficiencies which is not exhaustive to:

- If any required section as per the guideline is not submitted.
- The dossier contains unexplained information from different manufacturers - inconsistent product and quality information.
- Documents are not legible.
- Documents not in Dzongkha or English.
- Documents not submitted in chronological order.
- Banned Medical devices.

4.3.6. If deficiencies or discrepancies are identified in an application, a screening query will be sent to the applicant.

4.3.7. If the applicant fails to address the deficiencies raised during screening, the application will not be accepted for evaluation.

4.3.8. The stop-clock starts when a query is sent and ends upon receipt of a complete and satisfactory response to the query from the applicant.

4.3.9. The total number of queries sent during screening will be capped at two.

4.3.10. An applicant has fifteen (15) working days to respond to each query starting from the date of dispatch of the query.

4.3.11. The application will only be accepted when all deficiencies or discrepancies have been adequately addressed and the Authority is satisfied that the dossier is complete for evaluation.

4.3.12. If the application is subsequently re-submitted, it will be processed as a new application.

4.4. Application Evaluation

4.4.1. Once the application is accepted after screening, the evaluation stage begins.

4.4.2. Evaluation queries may be issued to the applicant if clarification or additional information is required. The maximum number of queries from the Authority will be capped at two.

4.4.3. The stop-clock starts whenever the Authority issues a query and stops upon the receipt of a response from the applicant.

4.4.4. The registration certificate will be issued within sixty (60) calendar days from the date of receipt of complete required documents from the date of evaluation.

4.4.5. The application shall be rejected if the submitted information in the dossier is completely different against the application made.

4.4.6. The Authority may engage external evaluators, experts and advisory committee in the evaluation process, when deemed necessary. These experts may be included from both local or/and overseas institutions. All external evaluators and experts are bound by conflict of interest and non-disclosure agreement to protect the information made available to them.

4.4.7. The qualification and experience of the evaluators shall be based on the provision of the Quality Manual of the Authority.

4.4.8. Rejection of the Application after evaluation - An application for registration will be rejected after evaluation in following conditions which is not exhaustive to:

4.4.8.1. The applicant fails to respond to the queries or submit the required additional documents within six months from the date of last correspondence.

4.4.8.2. Submission of manipulated or fraudulent documents.

If the application is subsequently re-submitted, it will be processed as a new application.

4.4.9. Regulatory Outcome

A regulatory decision is made following the conclusion of the risk-benefit assessment by the Authority based on the data submitted. Applicants will be notified of one of the following outcomes:

- ***Approval***: the application satisfies the requirements of registration.
- ***Pending***: the application can be approved subject to adequate response to deficiencies and/or testing reports.
- ***Rejection***: the application does not satisfy the requirements of registration.

Section C: Dossier Requirements

The following are the required documents for the registration of a medical device. All documents must be present for the application to be accepted for evaluation. The dossier content has been referred and customised as per ASEAN guidance on Common Submission Dossier Template.

1. Full Registration

1.1. Part 1: Administrative Document Requirements

1.1.1. Application form

The application form for registration of a Medical Device is provided in Annexure 1 of this Guideline. The date of application should correspond to the date of submission of the registration dossier to the Authority with all the required Information.

1.1.2. Letter of Authorisation from the manufacturer

The letter of authorization (LOA) is a legal document that authorizes an eligible local supplier to be the representative of the manufacturer to Bhutan and will be responsible for the product performance. A prescribed format is provided in annexure 5 of this guideline.

1.1.3. Declaration of Conformity

The manufacturer should attest that its medical device complies fully with all applicable Essential Principles for Safety and Performance as documented in a written Declaration of Conformity (DOC). At a minimum, this declaration should contain the following information:

- statement that each device that is the subject of the declaration;
- complies with the applicable Essential Principles for Safety and Performance(for class **C and D** only);
- has been classified according to the classification rules set by the GHTF;
- has met all the applicable conformity assessment elements;
- A Global Medical Device code and term for the device(s) if applicable;
- Description of Conformity assessment procedure;
- Date from which the Declaration of Conformity is valid;
- Name and address of the device manufacturer; and
- The name, position, and signature of the responsible person who has been authorized to complete the Declaration of Conformity on behalf of the manufacturer.

1.1.4. Letter of authorization

1.1.4.1. The letter of authorization from the manufacturer should be submitted in the specified format as per Annexure 5 of this guideline.

1.1.4.2. The regional offices of the principal manufacturer or the authorised marketer may provide a letter of authorization. In such cases, the letter of authorization

from the principal manufacturer to these offices or the marketer must be submitted as well.

1.1.4.3. In case of more than one letter of authorization for the same product, the letter of authorization from the principal company shall be considered.

1.1.4.4. In case of more than one letter of authorization from equivalent offices of the same manufacturer for the same product(s), the initial one shall be considered.

1.1.5. Quality System Certificates

These refer to formal certifications issued by notified bodies that verify a manufacturer's quality management system **(QMS)** to ensure that it complies with applicable standards for design, development, manufacturing and post-marketing activities. Any of the following certificates are required to be submitted to demonstrate compliance.

- A valid Good Manufacturing Practice Certificate issued by the competent national regulatory authority should, at least, bear the name of manufacturer, address, medical device name, scope of audit, device category, and class.
- Valid quality system **(ISO 13485)** or conformity assessment certificates issued by a recognized certifying authority.

1.1.6. Free sale certificate

A confirmatory letter issued by the competent national regulatory authority, which indicates the name(s) of the device(s) (with model if applicable) and explains whether the products are freely sold in the country of origin, should be provided; if not, the reasons thereof should be clearly stated with appropriate justification.

1.1.7. Manufacturing Process

The following information should be provided about the manufacturer of the product:

- Name of the manufacturer;
- Complete address, including telephone number, e-mail, and website;
- Background information, including year of establishment, development since establishment, capital, total work force, organogram, and subsidiaries (if any); and,
- Quality control and quality management system, including quality control and general quality management system of source and authorization of raw materials, component handling, packaging, release, recall procedures, and handling of compliance and out of specifications.
- Information on the manufacturing process should be provided in sufficient detail to allow a general understanding of the manufacturing processes. Detailed proprietary information on the manufacturing process is not required. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing and packaging of the finished medical device. If the manufacturing process is carried out at multiple sites, the manufacturing activities carried out at each site should be clearly identified. For example:

i. if the manufacturing process of a product consists of a number of sub-assembly processes, the manufacturing sites where each of these sub-assembly processes are carried out must be identified, and the relationship between these processes must be shown; or
ii. if multiple sites manufacture the same product, each of these sites must be identified.

1.1.8. Sample of actual product

Where applicable, a sample of actual products may be requested for the purpose of visual confirmation.

1.1.9. Price structure of the product

1.1.9.1. The price structure containing minimum information as per annexure 4 should be submitted.

1.1.9.2. The Currency of the price structure should be in USD, INR or BTN.

1.1.9.3. The MRP reflected in the price structure will be considered as the MRP of the product in the kingdom of Bhutan.

1.2. Part 2: Technical Document Requirements

1.2.1. Essential Principles and Method Used to Demonstrate Conformity (Only for class C and D medical devices)

The essential principles of safety and performance (EPSP) of medical devices are a set of fundamental regulatory requirements that every medical device must meet before introduction to the market. These ensure that devices are safe, perform as intended, and do not compromise the health of patients, users or others when it is used as instructed by the device manufacturer.

The manufacturer should identify and conform to the requirements as per Essential Principles of Safety and Performance of Medical Devices that are applicable to the device. Appropriate methods should be used to demonstrate conformity to each applicable Essential Principle(s). Relevant documentations should then be reflected in the checklist, consistent with the methods used to demonstrate conformity.

1.2.1.1. Essential Principles and Evidence of Conformity

- The evidence of conformity can be provided in tabular form with supporting documentation available for review as required. Templates for the essential principles conformity checklist are included in Annexure 6 of this guideline.. Not all the essential principles will apply to all devices and it is for the manufacturer of the device to assess which are appropriate for their particular device product. In determining this, account must be taken of the intended purpose of the device.
- Essential Principle checklist is applicable only to class C and D medical devices only.

1.2.1.2. Recognition of standards

The authority will identify and recognize applicable standards to ensure and establish the safety and performance of the medical device.

Standards may be identified and reviewed for the purpose of recognition. The criteria for recognition will be based on:

- regulatory purview of notified medical devices for registration by the authority
- market prevalence of medical devices
- recognition by WHO and WLAs

The effective versions of recognised standards will be communicated and disseminated via regulatory notifications and through the website of the authority(www.bfda.gov.bt), for information to manufacturers, marketing authorization holders and relevant stakeholders.

However, conformance to recognised standards by manufacturers is voluntary as long as the manufacturer meets an equivalent or better standard or provides alternate evidence of safety or effectiveness, usually through clinical investigation data or comparisons to similar marketed devices. For such cases, the manufacturer must clearly reflect the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. This applies for internal standards as well.

1.2.2. Device Description

1.2.2.1. Device description and features

The following information shall be submitted to meet the requirements of this section:

- A complete description of the medical device and a description or complete list of the various accessories and/or components. This will include labeled pictorial representation clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams if applicable;
- A complete description of the key functional elements including its formulation, composition, functionality and connectivity capabilities if applicable;
- Principles of operation or mode of function;
- Risk class and applicable classification rule for the medical device as per GHTF;
- A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical devices.
- An explanation of any novel features.
- Intended use of the device
- Indications - General description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate and include a description of the target patient population for which the device is intended.
- Contraindications - General description of the disease or condition and the

patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating.Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

- Warnings and precautions (if applicable)
- Potential adverse effects - These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions.

1.2.2.2. Materials

The following information shall be submitted to meet the requirements of this section:

- List of materials of the medical device making either direct or indirect contact with a human body;
- Complete chemical, biological and physical characterisation of the materials;
- Where there are specific concerns related to the safety of materials used in the medical device, additional information to address these safety concerns shall be provided.

1.2.3. Performance Data/ Report or Certificate of Analysis

The functional characteristics and technical performance specifications for the device including, relevant data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the medical device. Some performance parameters are as follows:

- Accuracy;
- Clinical Sensitivity and/or Analytical Sensitivity (if applicable);
- Clinical Specificity and/or Analytical Sensitivity of measuring and diagnostic medical devices;
- reliability and other factors;
- Biocompatibility Category of Finished product (If applicable);
- engineering tests;
- laboratory tests;
- simulated use;
- software validation; and
- other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant standards.

1.2.4. Clinical Evidence (Only for class C and D medical devices)

This section should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar medical devices, or by clinical investigation. Clinical investigation is most likely to be required for higher risk class medical devices, or for medical devices where there is little or no clinical experience.

1.2.5. Device Labeling

1.2.5.1. This is the descriptive and informational product literature of the device made available for the user and patient. This section should contain the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as "labelling":

- Labels on the device and its packaging;
- Instructions for use (electronic/physical);
- Physician's manual; and
- Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable).

1.2.5.2. The labels on the medical device and its packaging are to be provided for the primary and secondary levels of packaging and shall be provided for the commercial version. The labels can be provided in the form of artwork.

1.2.5.3. Labels provided must be in English.

1.2.5.4. Labels must be provided for all the components of a medical device system, members of a medical device family and accessories submitted for registration. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated.

1.2.5.5. If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.

1.2.6. Risk Analysis

Information required in this section is to be provided in the form of a risk management protocol and a report. It is recommended that the risk management activities be conducted according to recognized standards. A risk management report will contain details of the risk analysis, risk evaluation, risk control conducted for the medical device. The risks and benefits associated with the use of the medical device should be described.

2. Abridged Registration

This route is a shortened pathway for registration as the name implies, with basis on reliance. The same medical device, if registered/licensed for market by a recognised authority (Refer guideline for reliance), is eligible to be registered through this pathway.

The documents required for registration are as follows:

2.1. Evidence of registration by a recognised authority(ies) - A valid marketing authorization certificate, letter of approval, assessment reports will be considered.
2.2. Application form
2.3. Letter of authorization
2.4. Sample of product
2.5. Price structure
2.6. Device description
2.7. Performance report/certificate of analysis
2.8. Device labelling

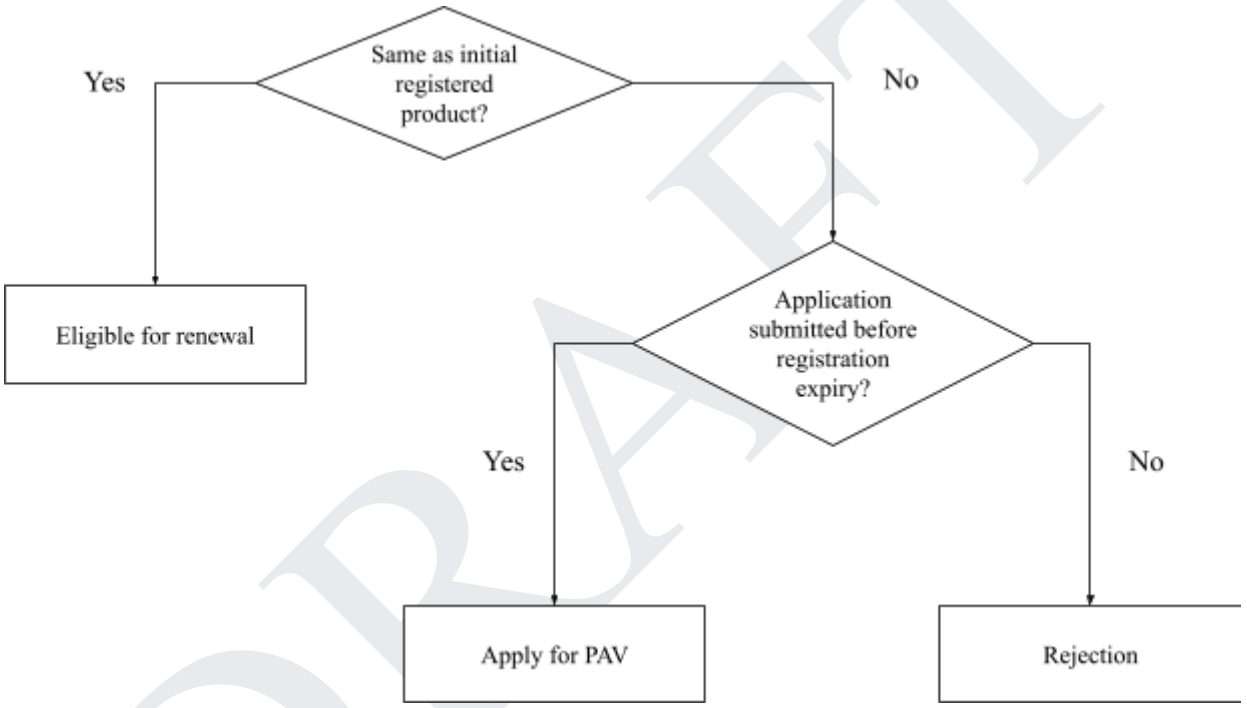
Please refer to Section C - 1.1.1, 1.1.2, 1.1.7, 1.1.8, 1.2.3, 1.2.4, and 1.2.6 for more information.

Section D: Renewal, Registration Transfer and Post Approval Variations

1. Renewal of Registration

1.1. Criteria for renewal

The product should be the same as the initially registered product. In cases of differences during renewal period, the applicant may submit a PAV dossier as long as the submission has been made during active registration status of the product, i.e., within the validity period of marketing authorization.



1.2. The process flow for the renewal, after acceptance of application, will be the same as initial registration - refer section 4 and figure 5 of Section B of this guideline.

1.3. Application for renewal shall be submitted using Annexure 1 of this guideline within 90 calendar days before the expiry date of registration along with the processing fee and samples.

1.4. A grace period of 30 working days may be given if the current MAH provides a written justification with evidence of having carried out the renewal process with the manufacturers prior to the date of expiry.

1.5. Upon the completion of the grace period or failure to provide the evidence of having carried out the renewal process, the product registration shall be canceled and the renewal application will be rejected.

1.6. The procedure for evaluation will be the same as initial registration as given in section B 4.2, 4.3 and 4.4.

1.7. Following documents are required for renewal:

1.7.1. Declaration Letter from the company stating that there is no change in all aspects of the registered product and the product submitted for renewal.

1.7.2. A copy of initial registration certificate

1.7.3. Specimen of package, label and insert where applicable

1.7.4. Product Sample where applicable

1.7.5. ISO/GMP certificate if the certificate has expired.

2. Product Registration Transfer

The marketing authorization of a registered product may be transferred if the manufacturer authorizes a new MAH when the registered product has a remaining validity of at least one month.

Following documents are required for product registration transfer:

2.1. Application form using annexure 3 of this guideline.

2.2. An original letter of authorization from the principal manufacturer to the new MAH specifying the name of the product.

2.3. No Objection Certificate/letter from the current MAH

3. Post-approval variation

3.1. Post approval variations are any changes made to a medical device after it has been approved by the authority. These changes must be evaluated, documented and where required, submitted for approval to ensure continued compliance with safety, quality and performance requirements.
Any changes to the product's quality, safety and effectiveness of the medical device must be notified to the authority prior to implementation.

3.2. The variations to the initial dossier submitted will be classified as follows:

3.2.1. Minor variations

3.2.1.1. Variations not requiring approval/Prior notice variation - 1a variation

3.2.1.2. Variations requiring prior approval - 1b variation

3.2.2. Major variations

3.3. Minor variations will be accepted after fulfilling the conditions and requirements for variations.

3.4. 1a variations are minor variations which do not affect the quality, safety and performance of the medical device and are low-risk in nature however requires notifying the authority for implementation. For such variation notifications, if no responses or clarifications from the authority are received within 30 calendar

days from the date of receipt by the authority, the applicant may consider the variation application to be accepted.

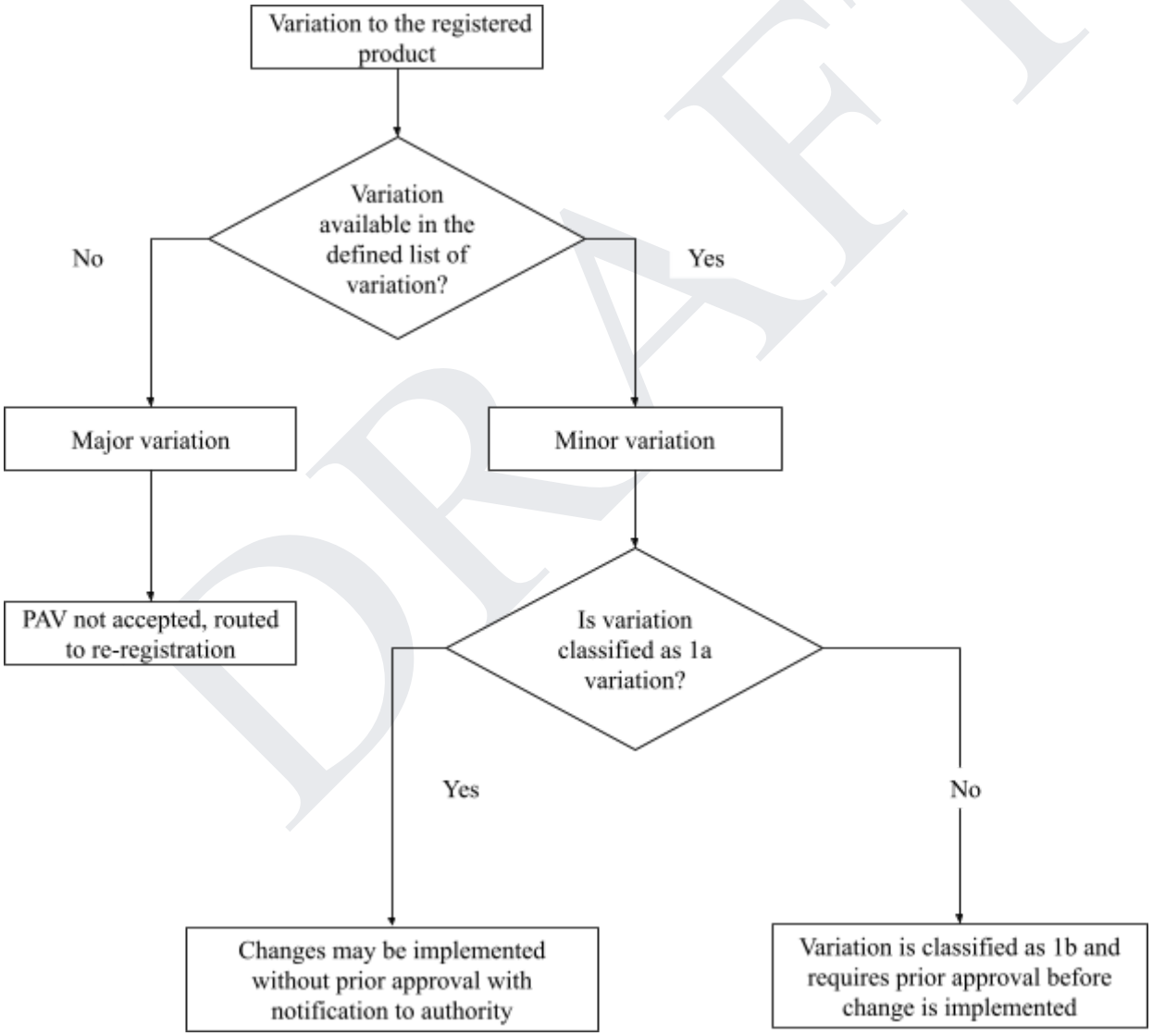
3.5. 1a variations may be bundled together and notified to the BFDA in one variation application. While bundling 1a variations, any such change shall be submitted within a maximum of 6 months from the point of first implementation.

3.6. 1b variations are minor variations which require review and prior approval for the variation to be implemented.

3.7. For major variations, the applicant will be required to submit a new application for registration following the procedure given in Section B.

3.8. The authority will accept a defined list of minor variations as given in table 8 and any other changes to the product will not be accepted.

3.9. Process flow chart



3.10. The procedure for evaluation will be the same as initial registration as given in section B - 4.3 and 4.4.

3.11. The following changes to the product will be accepted in a PAV application -

3.11.1. proprietary name of the product;
3.11.2. pack size;
3.11.3. product labeling due to safety updates;
3.11.4. Secondary and tertiary packaging material;
3.11.5. Addition of family,
3.11.6. Change in name and address of the manufacturer (excluding change in site)
3.11.7. Labelling -
  3.11.7.1. changes that only involve changes in layout, colour, font sizes and design, without change in prominence of precautions, warnings, contraindications and/or adverse events,
  3.11.7.2. changes that involve the addition and/removal of languages not required by the authority,
  3.11.7.3. changes that involve the addition/removal of reference agency approvals (eg. CE markings),
  3.11.7.4. changes that involves the update of distributor information, including EU authorised representative, and which does not affect the device repository information,
  3.11.7.5. changes that involve the addition/change or removal of barcodes, and which does not change the device repository information,
  3.11.7.6. changes that involve the addition of a Unique Device Identifier (UDI), and which does not change the device repository information,
  3.11.7.7. change with no new information related to safety and performance (e.g. addition of symbols to harmonise information between label and IFU, addition of warnings/precautions related to safe disposal of the device, change in design of existing symbol),
  3.11.7.8. changes that involve the change in date format of an existing labelling date field (e.g. from MMYY to DDMMYY),
3.11.8. Change involves only a design change that does not affect performance characteristics and/or specifications of the medical device (e.g. changes that improve ergonomics, aesthetic modifications),
3.11.9. Change in scope of the quality management system (QMS) certification which does not affect the registered medical device,
3.11.10. Change in certification body with no change in scope of QMS certificate
3.11.11. Changes based on reliance (for products approved via abridged pathway)
3.11.12. Changes in price structure.

Note: All the documentary evidence, as required, must be submitted with the application for post approval variation using annexure 2 of this guideline . The documents shall be evaluated based on the evidence.

Table 8: Document requirements for post approval variation

Sl No	Type of PAV	Documents Required
1b variations		

1	Changes for products approved via abridged pathway	1. Application form 2. Document detailing out the changes made to the product registered via abridged pathway 3. Evidence for acceptance of PAV proposed, by the recognised NRA. 4. Medical device safety and performance declaration from the manufacturer and MAH stating that no other changes on the label except for the intended change along with safety declaration.
2	Proprietary name	1. Application form 2. Official letter from principal manufacturer requesting for the change of product proprietary name. 3. Medical device safety and performance declaration from the manufacturer and MAH stating that no other changes on the label except for the intended change along with safety declaration. 4. Revised draft product artwork and label incorporating the proposed variation. 5. Product sample as per proposed proprietary name
3	Product labeling due to safety updates	1. Application form 2. Official letter from principal manufacturer requesting for the change of product proprietary name. 3. Medical device safety and performance declaration from the manufacturer and MAH stating that no other changes on the label except for the intended change along with safety declaration. 4. Supporting document for inclusion of safety updated in the product label 5. Revised draft product artwork and label incorporating the proposed variation. 6. Product sample as per proposed proprietary name
4	Addition of family	1. Application form 2. Updated device description and labelling, performance report of the new variant 3. Medical device safety and performance declaration from the manufacturer and MAH stating that no other changes on the label except for the intended change along with safety declaration. 4. Product samples 5. Revised price structure

5	Change involves only design change that does not affect performance characteristics and/or specifications of the medical device (e.g. changes that improve ergonomics, aesthetic modifications	1. Application form 2. Justification for the proposed change. 3. Performance report of the medical devices. 4. Medical device safety and performance declaration from the manufacturer and MAH stating that no other changes on the label except for the intended change along with safety declaration.
6	Price structure	1. Application form 2. Justification for the proposed change.
1a Variations		
1	Pack size	1. Application form 2. Justification for the change proposed 3. Medical device safety and performance declaration from the manufacturer and MAH stating that no other changes on the label except for the intended change along with safety declaration.
2	Secondary and tertiary packaging material	
3	Change in name and address of the manufacturer (excluding change in site)	
4	Labelling - a. changes that only involve changes in layout, colour, font sizes and design, without change in prominence of precautions, warnings, contraindications and/or adverse events, b. changes that involve the addition and/removal of languages not required by the authority, c. changes that involve the addition/removal of reference agency approvals (eg. CE markings) d. changes that involves the update of distributor information, including EU authorised representative, and which does not affect the device repository information e. changes that involve the addition/change or removal of barcodes, and which does not change the device repository information	

	f. changes that involve the addition of a Unique Device Identifier (UDI), and which does not change the device repository information g. change with no new information related to safety and performance (e.g. addition of symbols to harmonise information between label and IFU, addition of warnings/precautions related to safe disposal of the device, change in design of existing symbol) h. changes that involve the change in date format of an existing labelling date field (e.g. from MMYY to DDMMYY)	
5	Change in certification body with no change in scope of QMS certificate	
6	Change in scope of the quality management system (QMS) certification which does not affect the registered medical device	

Annexure 1: Application form registration and renewal of marketing authorization

BMRR X-MA

APPLICATION FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

M/s …….....….hereby apply for registration of the product specified below for sale/distribution in Bhutan.

Route of registration (Tick the appropriate one):

- ☐ Abridged registration Please specify eligibility……
- ☐ Full registration
- ☐ Renewal registration

Type of medicinal product (Tick the appropriate one):

- ☐ Human Allopathic
- ☐ Herbal
- ☐ Veterinary Allopathic
- ☐ API for extemporaneous preparation
- ☐ Sowa-Rigpa
- ☐ Medical device

Brand name (Generic name)	Pack size	Material of construction or Composition	Manufacturer	Permissible variants (in case of FAMILY) - For medical devices only

Please provide information as requested below for medical devices only:
Medical Device Classification:
Medical Device group:
Intended Indication:

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravene the provision(s) of the act and regulations made there under.

☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant
Name:
Contact No.

Date:.....

Annexure 2: Application form for post approval variations

BMRR XI-PAV MA

APPLICATION FOR POST APPROVAL VARIATION OF MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

I/we……hereby apply for post approval changes of the following product:

Product Registration no:
Generic Name:
Brand Name:
Product Code (If applicable, for medical devices only):
Date of Expiry of the Registration:

Proposed Variations and supporting documents (as per relevant guideline):

Current Specification or details	**Proposed Variation(s)**	**Reason for Variation**

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravene the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant
Name:
Contact No.

Date:……..

Annexure 3: Application form for product registration transfer

BMRR XIII-Trans MA

APPLICATION FOR TRANSFER OF MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

I/we……(Recipient MAH) hereby apply for transfer of marketing authorization of the following product:

Registration number	Brand name (Generic name)	Manufacturer	Current MAH

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravene the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant
Name:
Contact No.

Date:……..

Annexure 4: Sample Format for price structure

Letter Head of the MAH

Date:.....

Price Structure

Sl.no	Brand Name (International non-proprietary name)	Pack Size	Price to Distributor	Price to Retailer	MRP

Authorised signatory
(Proprietor of MAH)
Name of the firm

(Seal and logo of the company)

Authorised signatory
(Managing Director/Head of the Company)
Name of the firm

(Seal and logo of the company)

Annexure 5: Letter of Authorization Template

[To be printed on Company Letterhead of Product Owner]

Bhutan Food and Drug authority

Ministry of Health

Kawangjangsa, Thimphu

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for *[name of Firm(Company Name)]*

We, *[name of Principal manufacturer (Company Name)]*, hereby authorize *[name of local MAH (Firm Name and proprietor name)],* as the Registrant to submit applications for the registration of the medical device(s) to the Bhutan Food and Drug Authority on our behalf.

This authorization shall apply to the following medical devices:

[List containing product names of medical devices]

We also authorize *[name of Registrant (Firm Name)]* to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements set in the guidelines for registration of medical devices and any other applicable legislations of Bhutan.

This authorization shall remain in effect until *DD/MM//YYYY* or further notice.

We undertake to provide post-market support and assistance to the local MAH as may be required in relation to any matter involving the above medical devices. We acknowledge that any non-compliance with any registration condition issued by the Bhutan Food and Drug Authority in relation to medical devices may result in the suspension or cancellation of the registration.

We agree to assist the Bhutan food and drug authority with any request for information on the above medical devices.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]
[Name, contact details and address of company]

Annexure 6: Essential Principle Checklist

EP Checklist control number:

Product Owner Name:

Product Name:

No.	Essential Principles – General requirements	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			

2.	The solutions adopted by the product owner for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the product owner should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The product owner should apply the following principles in the priority order listed: ● identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, ● eliminate risks as far as reasonably practicable through inherently safe design and manufacture, ● reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, ● inform users of any residual risks.			
3.	Devices should achieve the performance intended by the product owner and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device.			

4.	The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the product owner, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the product owner's instructions.			
5.	The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the product owner.			
6.	The benefits must be determined to outweigh any undesirable side effects for the performances intended.			
7.	Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the			

	essential principles. A clinical evaluation should be conducted.			
Essential Principles – Design and Manufacturing Requirements				
8.1	The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 6 of the 'General Requirements'. Particular attention should be paid to: ● the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, ● the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device, the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
8.2	The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be			

	paid to tissues exposed and to the duration and frequency of exposure.			
8.3	The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.			
8.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.			
8.5	The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.			

8.6	Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.			
9.1	The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: ● allow easy handling, and, where necessary: ● reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use, ● prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.			

9.2	Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.			
9.3	Products incorporating non-viable tissues, cells and substances of animal origin falling within the definition of a medical device, should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. The product owner is required to retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			

9.4	For products incorporating cells, tissues and derivatives of microbial or recombinant origin falling within the definition of a medical device, the selection of sources/donors, the processing, preservation, testing and handling of cells, tissues and derivatives of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
9.5	For products incorporating non-viable human tissues, cells and substances falling within the definition of a medical device, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			

9.6	Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the product owner.			
9.7	Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the product owner, until the protective packaging is damaged or opened.			
9.8	Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilised by appropriate, validated methods.			
9.9	Devices intended to be sterilised should be manufactured in appropriately controlled (e.g. environmental) conditions.			

9.10	Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilisation indicated by the product owner.			
9.11	The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
10.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.			

10.2	Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: ● the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; ● risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; ● the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; ● the risks of accidental penetration of substances into the device; ● the risk of incorrect identification of specimens; ● the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; ● risks arising where maintenance or			

	calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
10.3	Devices should be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
10.4	Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			
11.1	Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the product owner.			

11.2	Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.			
11.3	Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.			
11.4	Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
11.5	Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.			

12.1.1	Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			
12.2.1	Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
12.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.			

12.3.1	Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.			
12.4.1	The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.			
12.5.1	Devices intended to emit ionising radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.			
12.5.2	Devices emitting ionising radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.			

12.5.3	Devices emitting ionising radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.			
13.1	Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
13.2	Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.			
13.3	Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			

13.4	Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.			
13.5	Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.			
13.6	Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			
13.7.1	Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the product owner.			

14.1	Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.			
14.2	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			
14.3	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.			
14.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimise all possible risks.			

14.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.			
15.1	Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
15.2	Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			
15.3	The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.			

16.1	Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the product owner should be easy for the user to understand and apply.			
16.2	Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
16.3	Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the product owner.			
17.1	Users should be provided with the information needed to identify the product owner, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.			

18.1	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.			

EP Checklist prepared by (name/signature/date):

EP Checklist approved by (name/signature/date):

Annexure 7: Medical Device Safety and Performance Declaration Template

[To be printed on Company Letterhead of the manufacturer]

Bhutan food and drug authority

Ministry of Health

Thimphu, Bhutan

[Date]

Subject: Declaration of Medical Device Safety and Performance on Change Notification

Dear Sir/Madam,

I, the manufacturer of the medical device(s) stated below, hereby declare that the medical device(s) in this change notification -

- Conform(s) to the Essential Principles for Safety and Performance as per the statutory requirements of the Medicines Act of Kingdom of Bhutan, 2003 and existing guidelines for registration of medical devices.
- There are no other changes to the product than those applied to the authority.

This declaration shall apply to the following medical device(s*):[List containing medical devices names and registration number]*

I am aware that a false declaration is an offence and will result in the cancellation of registration of the above medical devices under Section 18 d) of the Medicines Act of Kingdom of Bhutan, 2003.

Yours Faithfully,

[Signature]

[Full Name and Title (Top Management Official)]

We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers' satisfaction and confidence.

Bhutan food and drug authority
Royal Government of Bhutan
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Phone: 337074/337075, Fax: 33580
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