ADDENDUM 1:**GENERAL PRINCIPLES OF GROUPING OF MEDICAL DEVICES AND INVITRO DIAGNOSTICS.**

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GENERAL PRINCIPLES OF GROUPING OF MEDICAL DEVICES AND INVITRO DIAGNOSTICS 2019

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1.0 Introduction

Application for listing/registration of medical devices and Invitro diagnostics can be made as a separate component, individual customized pack or group and the online system allow for categorizations either as SINGLE, FAMILY, SYSTEM, and GROUP/SET or ONE DENTAL GROUP. Each of the categories mentioned can be submitted in the medical device registration application.

2.0 Purpose

The purpose of this document is to provide guidance to determine the appropriate grouping for medical devices in the medical device listing/registration application.

3.0 Scope

This document applies to all products that fall within the definition of medical device and IN-Vitro Diagnostics as specified in the **Guidelines on Submission of Documentation for Registration of Medical Devices including In-Vitro-Diagnostics (IVD**

4.0 Terms and Definitions

Accessory: For the purposes of this guidance document, an accessoryis an article that isintended specifically by its manufacturer to:

- 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 to augment or extend the capabilities of that device in fulfillment of its intended purposeas a medical deviceand therefore should be considered as a medical device.

Component: One of several possibly unequal subdivisions which together constitute the wholemedical 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.

Generic Proprietary Name: A unique name given by the manufacturer to identify a medicaldevice as a whole product, also known as the trade name or brand name.

Intended Purpose: The use for which the medical device isintended according to thespecifications of its manufacturer as stated on any or all of the following:

- the label of the medical device;
- the instructions for use of the medical device;
- the promotional materials in relation to the medical device.

Local Authorised Representative (LAR): The applicant who applies to register the device mustbe a legal person incorporated in Kenya, or a natural or legal person with business registration in kenyawho has received a written mandate from the manufacturer (Letter of authorization) to act on his behalf for specified tasks with regard to the latter's obligations or jurisdiction's legislation.

Manufacturer**:** means:-

(a) any person who is responsible for:-

(i) the design, production, fabrication, assembly, processing, packaging and labeling of a medical device whether or not it is the person, or a subcontractor acting on the person's behalf, who carries out theses operations; and

(ii) assigning to the finished medical device under his own name, its intended purpose and for ensuring the finished product meets the regulatory requirement; or

(b) any other person who:-

(i) assembles, packages, processes, fully refurbishes, reprocess or labels one or more ready-made medical devices; or

(ii) assigns to them their intended purpose as a medical device under his own name;

but shall not include the following persons:

(a) any person who assembles or adapts the medical device in the market that is intended for an individual patient; and

(b) any person who assembles, packages or adapts the medical device to which the assembling, packaging or adaptation does not change the purpose intended for the medical device.

Reusable Surgical Instrument: Instrument intended for surgical use by cutting, drilling, sawing,scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning, disinfection and/or sterilisation have been carried out.

Product Owner means a person who

(a) 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

(b) is responsible for designing, manufacturing, assembling, processing, 6 labelling, packaging, refurbishing or modifying the health product, or for 7 assigning to it a purpose, whether those tasks are performed by him or on his 8 behalf.

5.0 General Principles of Grouping

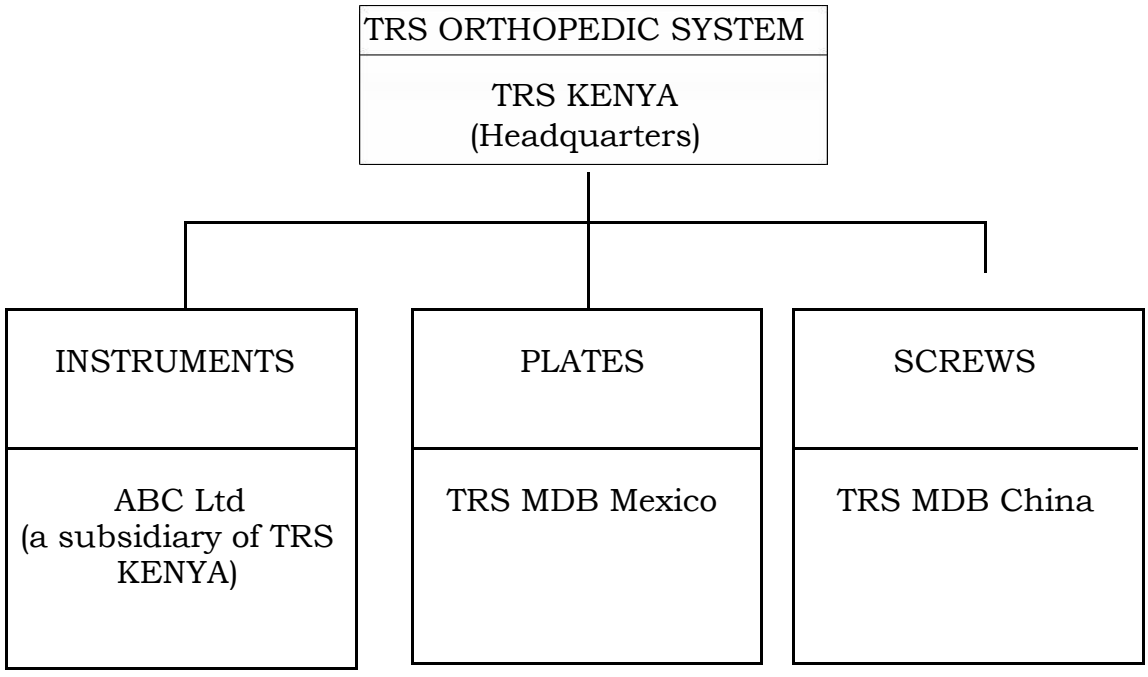
Medical devices that can be grouped into one of the following five categories can be submitted in one application for product registration and listing.

- SINGLE;
- FAMILY;
- SYSTEM;
- GROUP/SET;
- ONE DENTAL GROUPING.

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

- one generic proprietary name;
- one manufacturer; and
- one common intended purpose.

For the purpose of grouping, the corporate headquarters may be regarded as the manufacturer for its subsidiaries and regional manufacturing sites (Figure 1)



INSTRUMENTS

XYZ Ltd
(a subsidiary of TRS MDB Mexico)

Figure 1: Example of referencing the headquarters as the manufacturer for the purpose of grouping

Existing regulatory requirements apply to all medical devices to be registered, regardless of the manner in which they are grouped for product registration submission. Information on all medical devices within a grouping must be submitted as part of the requirements for registration, such as authorisation from all medical device product owners for registration and data to substantiate the performance of these devices within the grouping.

The applicant shall undertake the following post-market duties and obligations for all medical devices and accessories registered on the PPB medical devices system registered by the Applicant or as part of grouped registrations (e.g. IVD 3 TEST KIT, SYSTEM). This is regardless of whether these devices are from the same or different product owners:

- comply with the conditions applicable to the registered medical device and conditions imposed on the Applicant;
- submit applications to the Board for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Board; and
- notify the Board concerning field safety corrective action (FSCA), including recall.

6.0 Categories

6.1 Single

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 packaged entity and it may be offered in a range of package sizes.

Examples:

- **Condoms** that are sold in packages of 3, 12 and 144 can be registered as aSINGLE medical device.
- A company manufactures a **software program** that can be used with a number ofCT scanners produced by other manufacturers. Although the software cannot function on its own, it can be used on different scanners. The software can be registered as a SINGLE medical device.
- A company that assembles and registers a **first aid kit** has now decided to alsosupply each of the medical devices in the first aid kit individually. Each medical device supplied individually must be registered separately as a SINGLE medical device.

6.2 System

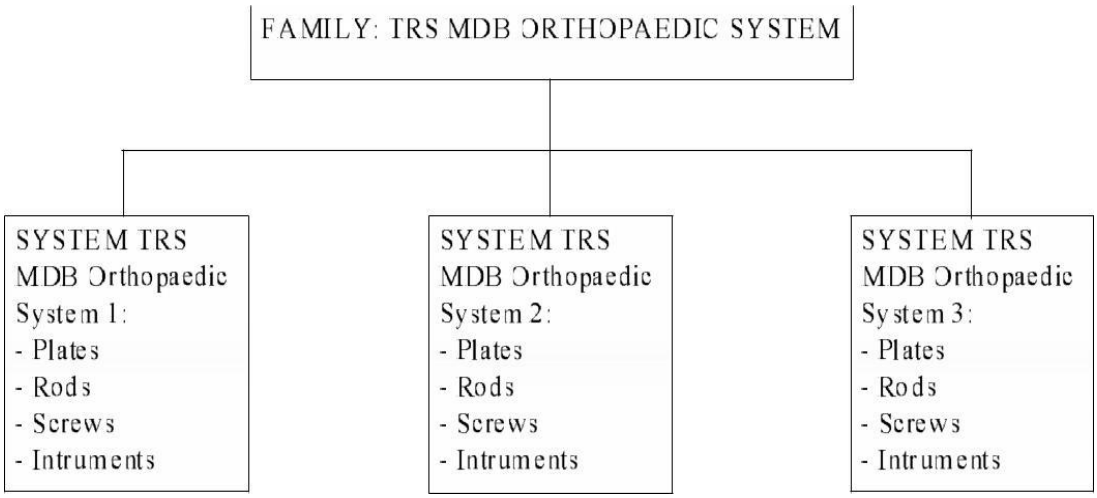
A medical device SYSTEM comprises of a number of constituent-components that are:

- 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: *Constituent-components registered 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 registered together with each of these other SYSTEMs. Alternatively, these constituent-component(s)*

that are compatible for use with multiple SYSTEMs must be registered separately.

The decision flowchart for grouping of products as an SYSTEM can be found in **Annex 1.**



Note: The key constituent-components, i.e. implantable rods, plates and screws, across the Systems are within permissible variants. For example, differences in lengths of the implantables screws are deemed permissible variants.

Figure 2: Example on Grouping of Systems as a Family

In addition, if several SYSTEMs fulfill the following conditions to be grouped as a FAMILY, they may be registered as a FAMILY:

- The SYSTEMs are from the same manufacturer
- The SYSTEMs are of the same risk classification class;
- The SYSTEMs have a common intended purpose;
- The SYSTEMs have the same design and manufacturing process; and
- Key constituent-components of the SYSTEMs have variations that are within the scope of the permissible variants.
- Has the same generic proprietary name

Individual SYSTEM names may contain additional descriptive phrases.

The Applicant has to undertake the following post-market duties and obligations for all the constituent-components in the registered SYSTEM, regardless of whether the constituent-components are from the same product owner of the SYSTEM:

- Comply with the conditions applicable to the registered medical device and conditions imposed on the Applicant;
- Submit applications to the Board for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Board, and
- notify the Board concerning field safety corrective action (FSCA), including recall.

In-Vitro Diagnostic Medical Device System

An *In Vitro* Diagnostic (IVD) Medical Device SYSTEM may typically consist of TEST KITs and instruments (e.g. an analyser designed to be used with that TEST KIT).

Examples:

A hip replacement SYSTEM comprising of femoral and acetabular components can beregistered 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, electrodeholders, leads, plug adaptor, when used together for a common intended purpose, can be registered as a SYSTEM.

Optional accessory such as wireless controller is part of **In-the-ear hearing aid** can be registered as a SYSTEM.

A glucose monitoring SYSTEM comprising of a glucose meter, test strips, controlsolutions and linearity solutions can be registered as a SYSTEM.

6.3 Family

A medical device FAMILY is a collection of medical devices and each medical device FAMILY member:

- is from the same manufacturer;
- is of the same risk classification;
- has the same generic 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.

The decision flowchart for grouping of products as an FAMILY can be found in **Annex 2.**

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.

See **Annex 3** for a list of permissible variants in a FAMILY.

If medical devices satisfy the above conditions to be grouped as a FAMILY, but have different device proprietary names, the products will be listed separately**)** based on their proprietary name.
Information on all medical devices within a FAMILY must be submitted as part of one product registration application. Only members of a FAMILY that are eventually listed/registered on the register shall be supplied on the market. Those that are not listed/registered shall not be supplied on the market.
The medical device proprietary name must appear on the label of each of the member medical devices. Individual medical device names may contain additional descriptive phrase.

A special grouping rule is applicable for Class A reusable surgical instruments. See **Annex 4** for this grouping rule.
Examples:

- **Condoms** that differ in colour, size and texture but are manufactured from the samematerial and manufacturing process and share a common intended purpose can be registered as a FAMILY.
- **IV administrative sets** that differ in features such as safety wings and length oftubing, but are manufactured from the same material and manufacturing process and share a common intended purpose can be registered as a FAMILY.
- **Steerable guidewires** that are available in various lengths and possess various tip
- **shapes and tip flexi**bilities can be registered as a FAMILY if their variations fall within the scope of permissible variants.
- **Spherical contact lens** with additional features of UV protection, can be registeredas 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 registered as a FAMILY.

- **Automated blood pressure monitors** with optional featuressuch as memorystorage and print capability can be considered as part of a FAMILY.
- **Cardiac catheters** that are available in a different number of lumens, lengths anddiameters can be registered as a FAMILY.
- **Contact lenses** are available as toric lens and spherical lens. These products havedifferent intended purposes and performances. They are designed and manufactured differently. Due to these differences, they shall not be considered as members of a FAMILY.

6.4 Set

A medical device SET is a collection of two or more medical devices, assembled together as one package by a manufacturer. The medical device SET has the following:

- a single proprietary SET name, and
- a common intended purpose
- classification allocated to the set is at the level of the highest classified device within the set.

Each medical device in the SET may have different design and manufactured by different manufacturers.

When the SET is registered, the manufacturer is able to customize the set for particular hospitals or physicians, while maintaining the same SET name and intended purpose. When the SET is registered, all other combinations in that SET can be supplied on the market.

Information on all medical devices within a SET must be submitted as part of one product registration application. Only medical devices within a SET that are eventually listed on the register shall be supplied on the market. Those that are not listed/registered shall not be supplied on the market. Medical devices that are registered as part of a SET must have a SINGLE

medical device registration before they are sold separately as individual medical devices.

If a medical device in a SET is supplied for use in another SET, such a medical device shall be included in the registration application of that other SET.

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 SET name. Individual medical devices in the SET may contain additional descriptive phrases.
The applicant has to undertake the following post-market duties and obligations for all the constituent-components in the registered SET, regardless of whether the constituent-components are from the same manufacturer of the SET:

- comply with the conditions applicable to the registered medical device and conditions imposed on the Applicant;
- submit applications to the Board for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Board and
- notify the Board concerning field safety corrective action (FSCA), including recall.

Examples:

- 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 registered 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 can be registered 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.

- A promotional pack consisting of different number of medical devices, for example multi-purpose solution, saline solution, and contact lens case, will not require a SET registration. Individual medical devices shall require registration as SINGLE medical devices

6.5 IVD Test Kit

An IVD TEST KIT is an *in vitro* diagnostic (IVD) 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.

An IVD TEST KIT does not include the instruments, such as analysers, needed to perform the test.

The decision flowchart for grouping of products as an IVD TEST KIT can be found in **Annex 5.**

Information on all reagents or articles within an IVD TEST KIT must be submitted as part of one product registration application. Only those reagents or articles within an IVD TEST KIT that are eventually listed on the register shall be supplied on the market. Those that are not listed shall not be supplied on the market.

Individual reagents or articles can be supplied separately as replacement items for the kit. If the reagents or articles in a TEST KIT are supplied for use in more than one TEST KIT, suchreagents or articles shall be included in the product registration application of each of the other TEST KITS.

Reagents or articles from another manufacturer may be registered with the IVD-TEST KIT. The Applicant has to undertake the following post-market duties and obligations for all the reagents and articles in the registered IVD

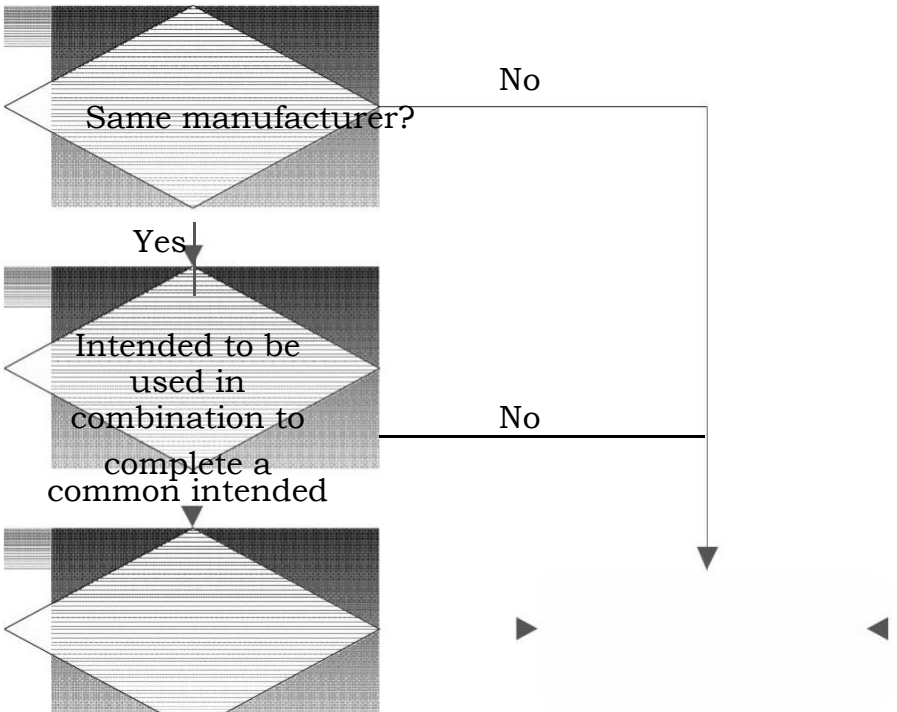
TEST KIT, regardless of whether the reagents or articles are from the same manufacturer of the IVD TEST KIT:

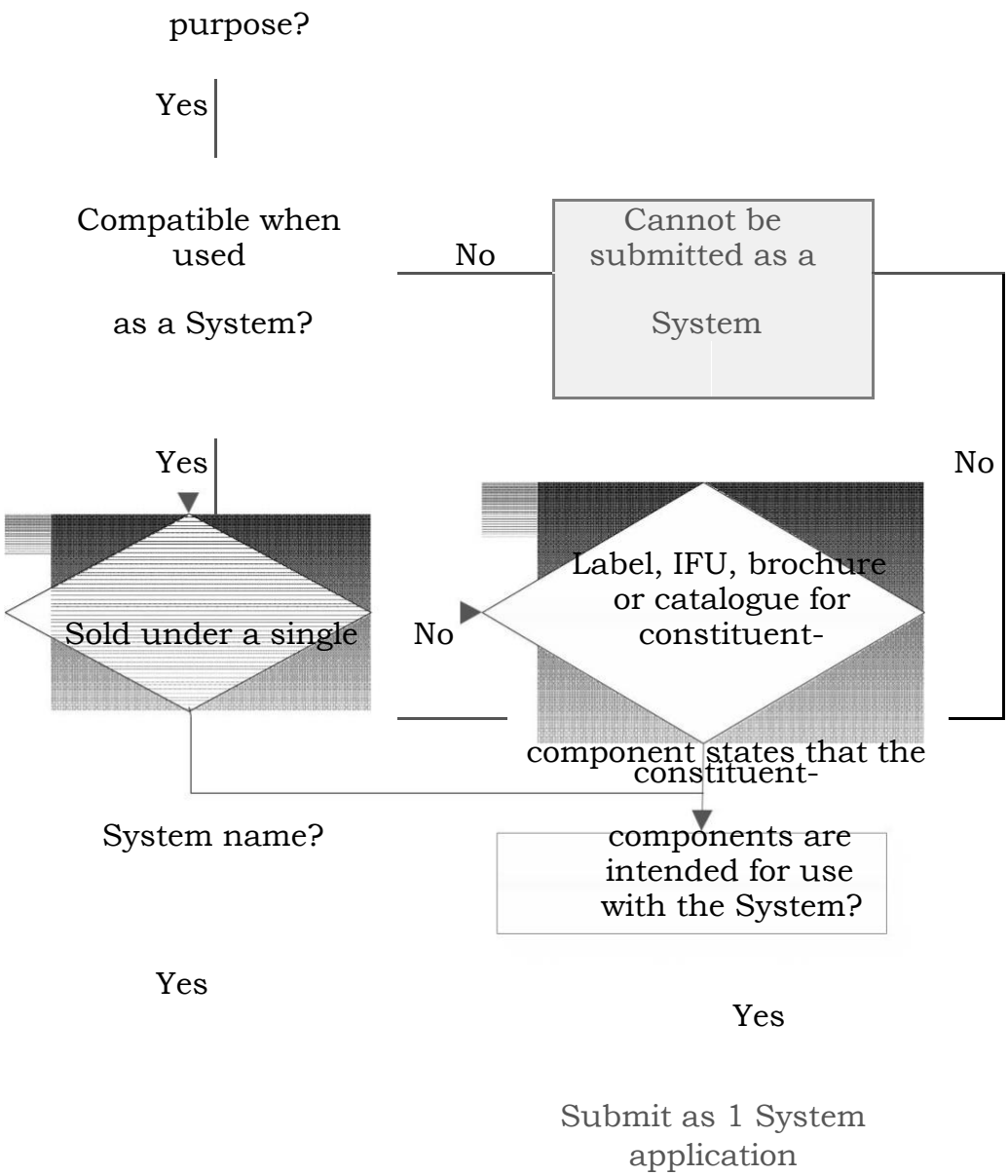
- comply with the conditions applicable to the registered medical device and conditions imposed on the Applicant;
- submit applications to the Board for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Board and
- notify the Board concerning field safety corrective action (FSCA), including recall.

Examples:

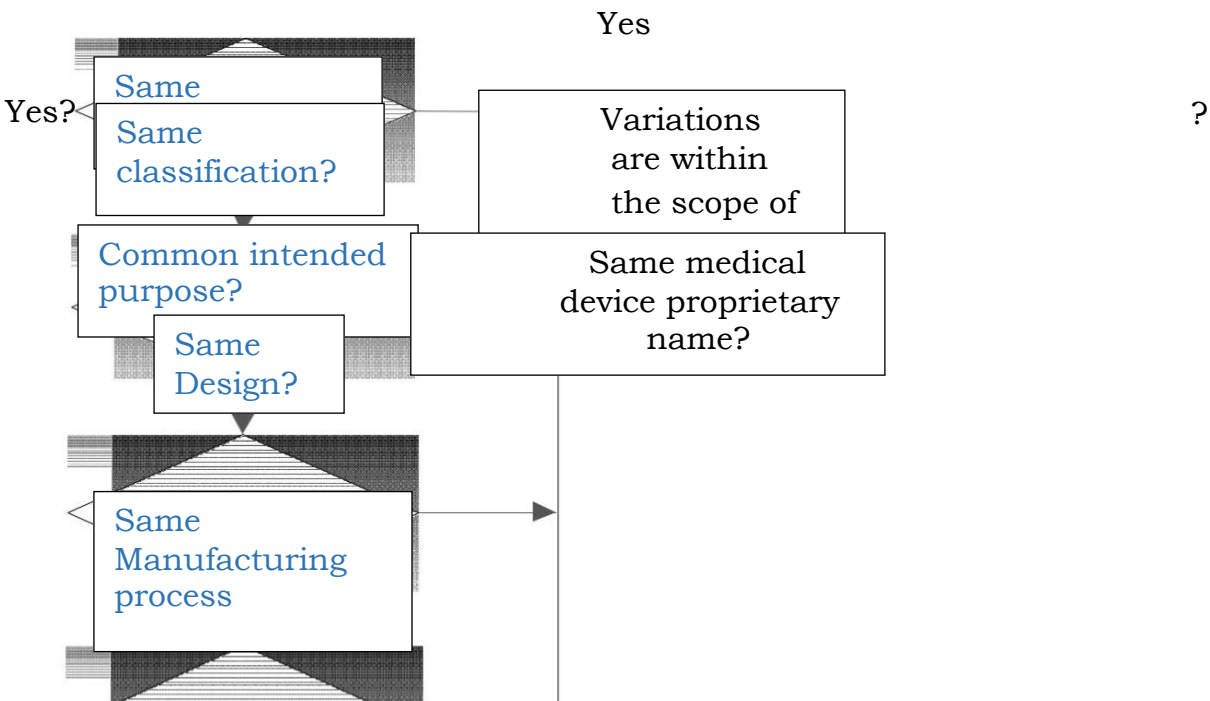
- A **Human Immunodeficiency Virus (HIV) Enzyme Linked ImmunoSorbent Assay(ELISA) TEST KIT** may contain controls, calibrators and washing buffers. All the reagentsand articles are used together to detect HIV and therefore can be registered as a TEST KIT. These reagents and articles can be supplied separately as replacement items for that particular TEST KIT but must be registered as a SINGLE IVD device.

ANNEX 1 : Decision Flowchart For Grouping of Products as a System





ANNEX 2: Decision Flowchart for Grouping of Medical Devices as a Family



No

No

No

No

No

Cannot be submitted as a FAMILY

Yes

Submit as 1 FAMILY application

ANNEX 3: Permissible Variants in a Family

The list of permissible variants is a closed and positive list.

Specific products	**Permissible variants**
Antibiotic test	(i) Concentrations
Catheter	(i) Number of lumens in catheter (ii) Material of catheter: PVC (polyvinylchloride), PU (polyurethane), nylon and silicone
IV Cannula	(i) Presence of injection port (ii) Presence of safety wing
Condoms	(i) Texture (ii) Flavour
Contact lens	(i) Diopter, (ii) UV protection (iii) Tinting
Electrophysiological Catheter	(i) Electrode spacing (ii) Number of electrodes
Suture	(i) Number of strands (ii) Pledgets
Suture passer	(i) Design of jaw, handle or needle
Dental handpieces	(i) Rotational speed (ii) Material of handpiece
Dental brackets	(i) Material of bracket
IVD rapid tests	(i)Different assembly format: cassette, midstream, strip
IVD urinalysis strips	(i) Different combination of testing configurations

Other permissible variants in general

Colour
Diameter
Flexibility
Gauge
Holding force
Isotope activity level
Length
Memory storage
Print capability
Radiopacity
Shape
Size
Volume
Width
Viscocity(The change in viscocity is solely due to changes in the concentration of consituent material)

ANNEX 4: Special Grouping Rule for Class A Reusable Surgical Instruments

A special grouping rule is applicable to Class A reusable surgical instruments.

The special grouping rule states that reusable surgical instruments can be grouped together as FAMILY if they satisfy the following conditions:

- Are from the same manufacturer
- Same overall intended purpose (This refers to the overall intended purpose of the instrument, regardless of location of the body they are used on).

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

This special grouping rule is only applicable to Class A reusable surgical instruments. It is not applicable to Class B, C and D reusable surgical instruments.

Example:

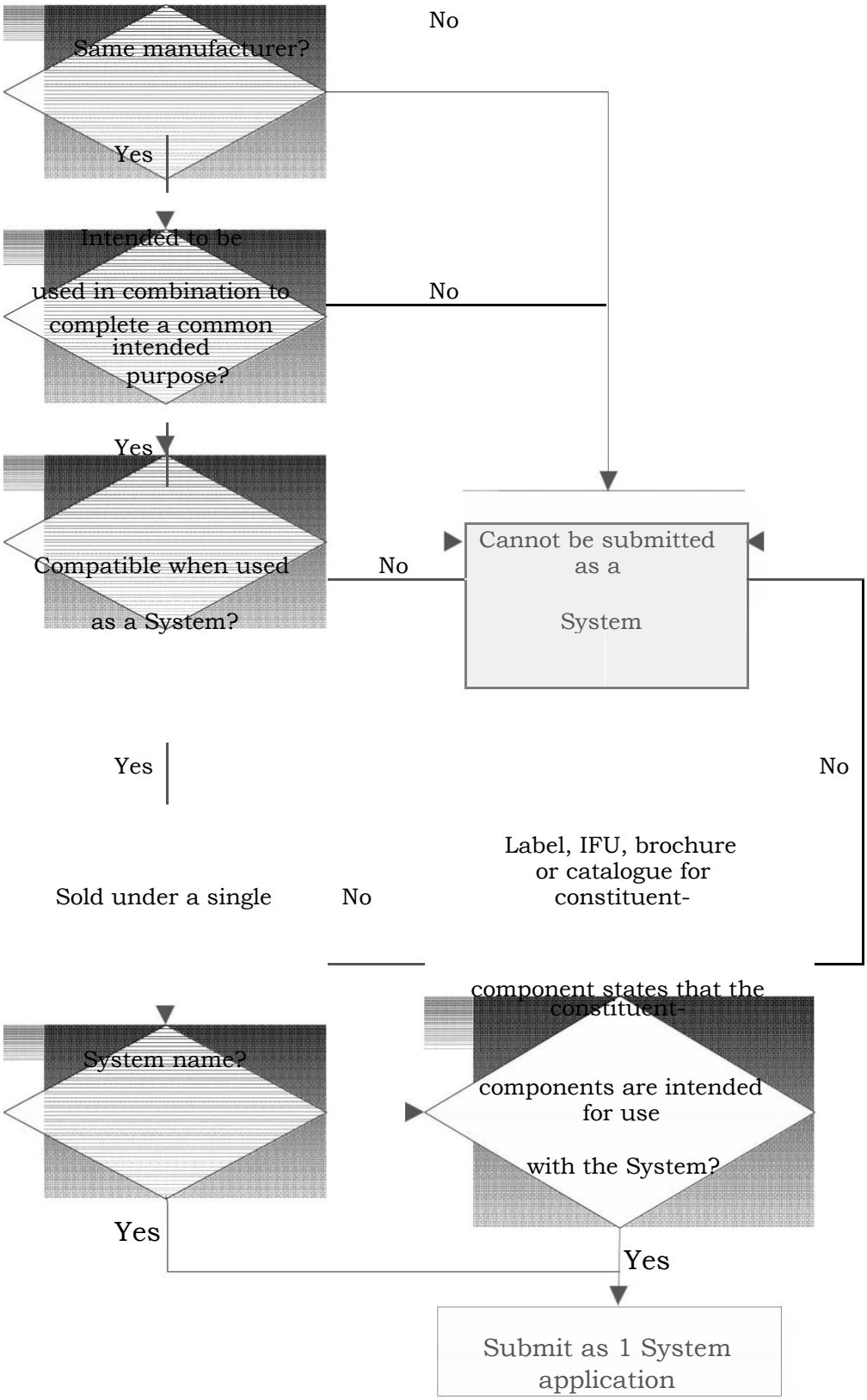
Instrument name	**Description**	**Intended purpose**
ABC Dressing Forceps	Delicate, Serrated Tips, Straight, 4¾"	To pick up or grasp tissue or items in the surgical wound
DEF Kidney Forceps	Half curved, 222 mm Length	To grasp renal polyps
HIJ Lung Forceps	Triangular jaws, jaw width 11", length 8"	To 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

In the example above, the forceps have the same product owners, 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 as a FAMLY and registered as part of one application on the basis of the special grouping rule for Class A reusable surgical instrument because:

- they are Class A reusable surgical instruments,
- the product owner is the same for all instruments, and
- they have the same overall intended purpose (i.e. to grasp).

ANNEX 5: Decision Flowchart for Grouping of Products as a IVD Test Kit



7 DEVICE SPECIFIC GROUPING OF CLASS A AND CLASS B DENTAL MEDICAL DEVICES USING DENTAL GROUPING TERMS FAMILY

Dental Grouping Terms (DGT) are collective generic terms used to describe a group of similar Class A and Class B dental medical devices with a common intended purpose.

A DGT grouping of dental medical devices is a collection of dental devices and each individual device:

- Is from the same product owner ;
- Within the risk classification of Class A or Class B; and
- Intended purpose falls within the descriptor of one DGT

The product registration application may contain accessories of a lower risk class if they are specifically intended to be used together with the dental devices submitted under a DGT.

LIST OF DENTAL GROUPING TERMS (DGT) AND RESPECTIVE 1 DESCRIPTORS

No	Dental Grouping Term	Definition
1.	Adhesive kit for dental composite	A collection of devices intended to be used to bond attachments such as hooks or buttons to the teeth and/or to an orthodontic aligner during dental or orthodontic teeth adjustment. The contents of this kit may include etchant, bonding resin, bonding paste, spatula, brushes, and a paper pad.
2.	Cryoanaesthesia device, dental	A dental brace-like device that is chilled to freezing/subfreezing temperatures and then applied to the labial sulci (gums) in a patient's mouth for a period to provide a cold anaesthesia for the underlying nerves. It is typically made of a thermoplastic elastomer (TPE) and cryogenic materials. This device may be used as a substitute for hypodermic drug delivery during dental procedures.
3.	Cryogenic spray, dental	A refrigerant typically contained in an aerosol dispenser and used to cool down a tooth by spraying on it, mainly to find out if the pulp is vital. It can also be used as a local anaesthetic when extracting deciduous teeth in children.
4.	Cusps, dental	A device designed to provide an artificial projection on the chewing surface of the tooth to achieve a proper bite.
5.	Dental abrasives	A dental material made from various base substances having some abrasive qualities [e.g., treated sodium bicarbonate (NaHCO3) or aluminium oxide (Al2O3)] and applied with an appropriate device (e.g., a dental abrasive air jet system) to the surface of teeth or dental devices. It has a wide variety of both prophylactic and treatment applications such as the removal of plaque and stains, cleaning fissures (above and below the gingiva), the preparation of a tooth surface prior to bonding, the cleaning of orthodontic appliances (bands and brackets), the removal of adhesive residue, and the cleaning of implants prior to loading. It includes accessories e.g. mixing pad, dispenser and other components required for dental abrasion.

6.	Dental adhesives/ primers	A material primarily used as a bonding promoting substance between dental materials. It does not include cements.
7.	Dental burs	A dental bur is a rotary cutting device designed to fit into a dental handpiece and intended to cut hard structures in the mouth, e.g. teeth or bone. It can also be used to cut hard metals, plastics, porcelains and similar materials.
8.	Dental caries detector, electrical impedance	A device designed to measure resistance to the flow of electric current across teeth for the diagnosis of early stage dental caries and/or to monitor the progress of caries (carious areas being less resistant due to higher concentrations of fluid). It typically consists of a probe with an electrode placed in contact with the tooth to be tested and a second counter electrode, separate from the probe, which is placed in contact with another part of the patient's body to complete an electrical circuit connecting the two electrodes; and an electronic control unit that quantifies the resistance. This procedure is also known as electronic caries monitoring/measurement (ECM).
9.	Dental caries detector, optical induced fluorescence	A device designed to determine the changes in the fluorescence of teeth enamel and dentine due to mineral loss, mainly for the diagnosis of early stage dental caries and/or to monitor the progress of caries. It consists of a light source (typically a laser) that elicits fluorescence in teeth, and a unit that quantifies the altered fluorescence of the carious tooth tissue.
10.	Dental caries removal solution	A liquid substance used in dentistry to detect and remove caries from an infected tooth.
11.	Dental casting materials	Compounds associated with the formation of a dental cast [i.e. a positive copy of a part of the oral anatomy made in an impression (mould)].
12.	Dental cavity liner	A substance intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth from chemical irritation. The device is typically a thin layer of zinc oxide (ZnO) and eugenol (C10H12O2), or calcium hydroxide (Ca(OH)2).
13.	Dental cement	Compounds used in dentistry/ orthodontics typically to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It includes accessories e.g. mixing pad, dispensor and other components required to complete the cementing procedure.
14.	Dental cement kit	A collection of components designed to complete a cementing procedure.
15.	Dental crowns/ bridges	Solid blocks or liquid materials used to manufacture partial or full crowns and bridges.
16.	Dental dry field device	A pre-assembled device used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It forms a frame around the oral cavity and provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures (e.g., bonding orthodontic brackets, bleaching, applying veneers or pit and fissure sealants, posterior restorations). It typically consists of cheek retractors, a tongue guard, suction adaptors, and tubing with Y-piece connection to a suction system.
17.	Dental dry field kit	A collection of devices used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures (e.g., bonding orthodontic brackets, bleaching, applying veneers or pit and fissure sealants, posterior restorations). It typically consists of bite blocks, pad extenders, suction tips of varying sizes, and tubing that connects to a suction system.
18.	Dental etching composite	A device, typically in form of solution or gel, used to create a retentive surface for a composite, an adhesive or a pit and fissure sealant.

19.	Dental implant debridement brush	A rotary dental instrument designed for the debridement of a patient's dental implants affected by peri-implantitis; a destructive inflammatory process of the soft and hard tissues surrounding dental implants. It is a brush-like device, typically consisting of titanium bristles at the distal end of a high-grade steel shaft, that is held in a dental handpiece which provides its rotation for the mechanical removal of biofilm from the surface of the implants. This is a single-use device.
20.	Dental implant extractor	A manually-operated, dental device used to retrieve a dental implant, typically because of damage (e.g., a broken collar) or malfunction, from the oral cavity. It is typically made of toughened, high-grade steel and has a cylindrical design with a coarse, left-handed fluting with a steep pitch that spirals up the tapered working end and a hexagonal head at the proximal end that fits a torque wrench socket. Such a device is inserted into the implant to be removed and turned anticlockwise (counterclockwise). The anticlockwise torque exerted makes this device grip into the implant, which is then unscrewed. It is a single-use device.
21.	Dental implant, accessories	Device designed to provide support and a means of retention for a dental prosthesis (e.g., bridge, single-tooth, overdenture) during surgical placement of a dental implant into alveolar and/ or basal bone of the mandible or maxilla.
22.	Dental implant, prosthetic teeth bar	A small rod, usually cast or brazed, that bears prosthetic teeth and allows them to be attached to the dental implant abutments.
23.	Dental implant, suprastructure	A prefabricated device that is incorporated into, or creates, a suprastructure on dental implants to mimic preparations of natural teeth. It is used during dental implant restorative procedures. It typically includes burnout/temporary cylinders, fixture impression pick-ups, replica devices.
24.	Dental implant/prosthesis, surgical procedure kit	A collection of various dental instruments designed for the surgical placement of dental implants or prostheses. It does not contain pharmaceuticals. It typically contains various dental drills (drill bits), drill extensions, depth gauges, wrenches and torque wrench, screwdrivers, forceps, trays and osteotomes.
25.	Dental precision attachments	Dental devices designed for attaching a fixed or removable prosthesis to the crown of an abutment tooth, dental restoration (including implants), or dental appliance.
26.	Dental procedure console and accessories, hydraulic	An assembly of devices designed to bore/excavate bones, teeth, and tough tissues during a dental surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, polishing disks). The system is powered by pressurized water via a connecting hose to the handpiece/motor water-driven turbine.
27.	Dental procedure console and accessories, line-powered	An assembly of devices designed to bore/excavate bones, teeth, and tough tissues during a dental surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, polishing disks). This system is electrically-powered, typically from the mains and supplies the handpiece/motor with low-voltage electricity (through a control unit.
28.	Dental procedure console and accessories, pneumatic	An assembly of devices designed to bore/excavate bones and tough tissues during a surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, screwdriver bits). The system is pneumatically-powered (gas-powered) by either nitrogen (N2) or surgical-grade air via a connecting hose to the handpiece/motor.
29.	Dental procedure handpiece, hydraulic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. The

		device incorporates a small water-powered turbine motor that is driven by a source of pressurized water; it will typically have a built-in water spray for cooling the rotating instrument. It is typically connected to a dental delivery system or a free-standing independent system.
30.	Dental procedure handpiece, line-powered	A mains electricity, hand-held, dental device that includes a chuck or collet for attaching a dental drill, bur, reamer, and other similar rotating instruments used in dentistry to bore/excavate bones, teeth, and tough tissues. It is powered by a low-voltage electric micro-motor that is an integral part of the device. It is typically connected through the dental delivery system or a free-standing independent control unit.
31.	Dental procedure handpiece, pneumatic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. It will typically include a built-in motor. The device may be cannulated to allow for use of a guidewire and may be of the micro or macro design. It is pneumatically-powered (gas-powered) by either nitrogen (N2) or surgical-grade air via a connecting hose to the handpiece.
32.	Dental pulp testing electrode gel	An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.
33.	Dental pulp-capping material	A dental compound designed to cover an exposed or nearly-exposed dental pulp (e.g., due to deep cavities) to provide protection against external influences and to promote healing. This compound does not have dental cement or dental cavity liner intended uses. This is a single-use device.
34.	Dental reinforcing fibre	A device used in general restorative dentistry and orthodontic treatment typically as reinforcement of dental polymer-based materials, used for the construction of dental prostheses, i.e., splints, posts, crowns, and bridges. This device is typically made of polyethylene fibres supplied in strands, braid, or ribbon in a variety of sizes. It may also be used for the stabilization of avulsed teeth maintaining diastema closures or split-tooth syndrome. The fibres increase the strength of composite materials, and provide improved safety by assisting in the retention of pieces in the event that a dental prosthesis is broken. This is a single-use device.
35.	Dental restorative / cavity varnish	A liquid substance used to cover dental filling material in the initial setting period after application typically to prevent moisture infiltration, especially when a dental silicate or glass ionomer cement is used as a filling material. The device typically consists of dissolved artificial resins. It is used for the protection of pulpal tissue and to provide a marginal seal to newly placed amalgam restorations.
36.	Dental restorative/ repair materials	Liquid compounds specially designed to fill dental cavities, seal pits and fissures, restore damaged dental tissues, or for inlays, onlays and veneering. It includes accessories that are used specifically with the materials. It includes accessories e.g. mixing pad, dispenser and other components required to complete the restorative procedure. It does not include obturation of root canal.
37.	Dental restorative/ repair kit	A collection of devices designed to fill dental cavities or restore dental tissues. It does not include obturation of root canal.
38.	Dental retention pin	A device intended to be placed permanently in the tooth to provide retention and/or stabilization for a dental restoration, e.g. a filling or a crown. It is typically made of stainless steel or titanium and comes in a variety of sizes. The device is inserted into a pre-drilled hole in the tooth and is secured by threading, friction and/or cementing.
39.	Dental retention pin kit	A device intended to be placed permanently in the tooth to provide retention and/or stabilization for a dental restoration, e.g. a filling or a crown. It is typically made of stainless steel or titanium and comes in a variety of sizes. The device is inserted into a pre-drilled hole in the tooth and is secured by threading, friction and/or cementing.

40.	Dental scalers, pneumatic	Scaler tip/inserts which may consist of handpiences that are designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. Water is also fed through the handpiece and attached tip to assist in the process. It is typically designed to connect to an existing air driven handpiece tubing and the water spray for lavage.
41.	Dental scalers, rotary	Scaler tip/inserts which may consist of handpieces, intended to be attached to a powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy.
42.	Dental scalers, ultrasonic	Scaler tip/inserts (which function as part of an ultrasonic scaler system) which may consist of handpieces that together transmit ultrasonic energy from a generator to the oral cavity for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. Water or a rinsing solution (e.g., chlorhexidine) is also fed through the handpiece and attached tip to assist in the process. This device is typically designed with permanently attached cables in the form of a pen or pencil.
43.	Dental scaling system, pneumatic	An assembly of devices designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. It typically consists of a scaler handpiece and self-locking, removable tip. The handpiece may connect to an existing air driven handpiece tubing and the water spray for lavage. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
44.	Dental scaling system, rotary	An assembly of powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy. It typically consists of an energy-generating unit [which may contain a water or rinsing solution (e.g., chlorhexidine) source], a handpiece with connecting cable, an insert tip (the distal end of the system used in the oral cavity), and a foot control. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
45.	Dental scaling system, ultrasonic	An assembly of devices that uses ultrasonic energy at its point of patient contact to remove accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. It typically consists of an energy-generating unit [which may contain a water or rinsing solution (e.g., chlorhexidine) source], a handpiece with connecting cable, an insert tip (the distal end of the system used in the oral cavity), and a foot control. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
46.	Dental sealants, endodontic	A prefabricated, solid dental substance used in endodontics to fill or permanently obturate the root canal of a tooth. The substance may set without assistance of moisture, and is typically intended for orthograde use (i.e., a root filling placed from the coronal aspect). The device has various metallic or polymeric compositions that include, but are not limited to, silver (Ag), methylmethacrylate, zinc oxide eugenol, glass alkenoate, and calcium hydroxide (Ca(OH)2).
47.	Dental sealants, pit/fissure	A resin-based dental material suitable for sealing pits and fissures on teeth. It may be chemically cured or external energy cured. It may include accessories e.g. mixing well, brush etc or other components required to complete the sealing procedure.
48.	Dental shaded pontic kit	A collection of devices intended to be used to produce artificial tooth veneers (shaded pontics) typically inside clear plastic custom-made

		teeth aligners (retainer-style orthodontic appliances). This is used to create the appearance of teeth inside the aligner to cover spaces where teeth may be missing for aesthetic and/or therapeutic purposes during treatment to realign teeth. The contents of the device may include polymer-based materials, dispenser gun, mixing tips, applicator brushes and practice aligner.
49.	Dental solution, scaling	A liquid substance used in dentistry to soften and partially solubilize a dental calculus (a hard deposit that forms on the teeth) before scaling mechanically so that less force is required, especially when teeth are loose. It will typically contain acid as a solvent (e.g., hydrochloric) and include other elements (e.g., iodine and excipients).
50.	Denture clasps	Dental devices designed to retain and stabilize removable partial dentures to stationary teeth.
51.	Denture reliners	A device consisting of polymer based material, e.g. plastic resin, that is applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. Denture relining is defined as a process of providing a new fitting surface to a denture.
52.	Facebow	A caliper-like dental instrument used to record the relative position of the maxillary arch to the temporo-mandibular joint (TMJ), or the opening axis of the jaw. It is used to orient dental casts in the same relationship to the opening axis of the articulator.
53.	Fixture/appliance dental drill, single-use	A shaft of metal (a drill bit) intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the implantation of a dental fixture/appliance. It is typically made of a high-grade stainless steel alloy. The device is typically available in a set of graduated sizes and various forms and functions (e.g., guide, pilot, twist, cortical, conical). It is attached to a motorized handpiece or other power source that provides rotation. This is a single-use device.
54.	Gingiva bleaching protector	A paste or gel-like substance designed to protect a patient's gums from the hydrogen peroxide found in teeth whitening agents used during chairside light-curing bleaching of the teeth. It is typically supplied in a disposable syringe and is applied with an applicator along the gingiva leaving the teeth exposed for treatment.
55.	Gingival retraction cord, non-medicated	A non-medicated, cotton string used to temporarily hold off the gingiva during abutment preparation.
56.	Gingival retraction kit	A collection of dental instruments and other items used to hold off the gingiva during abutment preparation.
57.	Gingival retraction solution	A liquid substance used in dentistry to induce gingival retraction by in situ impregnation of a non-medicated gingival retraction cord. It induces contraction of the upper strata of the free gingiva. This device may also induce a local stasis of gingival exudates and gingival haemorrhages.
58.	Non-medicated dental surgical procedure kit, single-use	A collection of various dental instruments, dressings and the necessary materials used to perform a dental surgical procedure. It does not contain any pharmaceuticals. This is a single-use device.
59.	Oral wound dressing, non - animal/ microbial- derived	A compound intended as a protective cover for the oral mucosa to manage wounds and sores in the mouth. It is used for various types of dental wounds, sores and lesions caused by dental prostheses/orthodontic braces; it may also be used to treat mucosal irritations/inflammation, dryness and gingivitis. It is supplied in various forms (e.g., gel, paste, fluid, spray solution of water/oil). It is normally available over-the-counter (OTC) for use in healthcare facilities or home. It is not derived from animal or microbial sources. This does not include pharmaceuticals.
60.	Orthodontic appliance archwire-cooling device	An instrument used in orthodontic dentistry to intra-orally chill or cool thermally-activated archwires when placing bends in an orthodontic appliance. The device, after it has been precooled (typically with a cryogenic spray), is applied to a desired point of contact on the wire to extract heat and allow easy bending. As the

		archwire warms to body temperature it attempts to return to its former shape, and thus contributes to the application of forces within the mouth. The device is typically formed as a heavy-duty stainless steel rod with an insulated plastic handle and a slot at the distal end to accept wire.
61.	Orthodontic appliances	Dental devices designed to influence the shape and/or function of the stomatognathic system through the application of physical force. It includes orthodontic anchor plate, orthodontic anchoring screw, orthodontic archwire, orthodontic archwire/bracket fixation ring, orthodontic bands, orthodontic brackets, orthodontic bracket adhesive, orthodontic clasps, orthodontic chin cap, orthodontic extraoral headgear, orthodontic face bow, orthodontic ligature, orthodontic magnet, orthodontic spring, orthodontic tube, orthodontic wire.
62.	Orthodontic space maintainer	Dental devices designed to influence the shape and/or function of the stomatognathic system through the application of physical force. It includes orthodontic anchor plate, orthodontic anchoring screw, orthodontic archwire, orthodontic archwire/bracket fixation ring, orthodontic bands, orthodontic brackets, orthodontic bracket adhesive, orthodontic clasps, orthodontic chin cap, orthodontic extraoral headgear, orthodontic face bow, orthodontic ligature, orthodontic magnet, orthodontic spring, orthodontic tube, orthodontic wire.
63.	Orthodontic space maintainer	A dental prosthetic replacement for prematurely lost deciduous teeth intended to prevent closure of the space before eruption of the permanent successors. Often an urgent necessity in the buccal segment to prevent impaction of the permanent teeth and other complications.
64.	Root canal filling-removal solution	A liquid substance used in endodontic procedures for the softening and removal of root canal fillings. It will typically be introduced into the root canal using instruments. The device typically contains solvents and other elements (e.g., tetra chloroethylene, formamide, eucalyptol, excipients).
65.	Root canal irrigation/ rinsing solution	A substance used in dentistry to facilitate cleansing/irrigation of the root canal (the canal space) during and/or after endodontic instrumentation for the removal of the smear layer, pulpal tissue, necrotic materials, and bacteria from the instrumented root canal, before placement of the endodontic filling. It is typically available as an aqueous solution delivered into the canal with an irrigation needle or similar device, providing mechanical and possibly chemical cleansing of the canal.
66.	Root canal obturation kit	A collection of dental devices, synthetic materials, and solutions designed to permanently prime, seal, and/or fill a tooth undergoing a root canal procedure. This device typically includes materials such as a primer (for bonding to the walls of the canal), a sealer (for bonding to the primer), and endodontic points and pellets (for the filling). This bonding process creates a monoblock filling resulting in increased resistance to bacteria penetration and fracture for root canal-treated teeth.
67.	Root canal post kit	A collection of root canal posts and devices used for the insertion of root canal posts. These are typically prefabricated and made in a variety of shapes, dimensions and materials, e.g., they can be non-threaded, pre-threaded, or self-tapping, straight or tapered, and made of alloy, ceramic and fibre reinforced polymers. This device typically includes the root canal posts, drills and thread cutter.
68.	Root canal posts	A dental device (rod) intended to be inserted and cemented into a prepared root canal of a tooth to stabilize and support a restoration. Pre-fabricated root canal posts come in various shapes, dimensions, and materials, e.g. metal, fibre reinforced polymer and ceramic.

69.	Root surface conditioner	A dental material, typically of neutral pH, used for topical application on exposed/scaled root surfaces for the removal of the smear layer (adherent debris produced when cutting the enamel or dentin in cavity or endodontic preparation, Circa 1 micron thick) during dental/periodontal surgery. The material is removed (washed off) after the recommended period to expose the collagenous matrix of dentine surfaces. It is typically presented in the form of a gel and consists of, e.g., edetate disodium (EDTA) and carboxymethylcellulose (CMC) with a neutral pH.
70.	Tooth preservation kit	A collection of devices designed to preserve and transport a tooth that has been knocked out (i.e., avulsed) so it can be reimplanted. It typically includes instruments, preserving solutions, a container (e.g., a vial or cup with a plastic net inside to hold the tooth suspended in the preservation solution), and swabs/bandages. It is used to avoid tooth cell crushing and/or dehydration by immersing the tooth in a pH balanced solution compatible with periodontal cells, and is typically used in field emergency situations after traumatic knock out of teeth.
71.	Warm-bonded endodontic obturation system	An assembly of devices designed to deliver preheated resin-based sealing, filling, and core materials into a root canal for direct warm bonding during an endodontic obturation procedure. It typically consists of a mains electricity oven specifically used to heat the preloaded oburators, a series of root canal sizers (verifiers) used for the selection of the appropriate obturator, and preloaded obturators; other materials may be included (e.g., self-etch sealer).
72.	Denture base resins	A polymer-based dental material used for the fabrication of a denture base (the portion of a complete or removable partial denture which rests on the oral mucosa and retains the artificial teeth) or repair of a denture. This is a single-use device.
73.	Dental disinfectants	A substance, typically in liquid, wipes or powder (reconstituted in water) form that destroys harmful microorganisms or inhibit their activity on medical devices which are specific for dental purposes or for use in dental procedures. It is not intended for disinfection as end point of processing. The medical device is typically bathed by the substance for a specified period of time, or the substance is sprayed on, or manually applied to the medical device, in order to achieve disinfection.
74.	Dental suction system cannula, single-use	A semi-rigid or rigid hollow tubular component of a dental suction system designed to be inserted into the oral cavity for the aspiration and removal of blood, pus, saliva, debris, and water during a dental procedure. This is a single-use device.

8 DEVICE SPECIFIC GROUPING OF HEARING AIDS

This section applies only to Class B hearing aids and excludes implantable hearing devices.

Generally, hearing aids can be categorised based on:

- Design (i.e Behind the ear (BTE) vs In the ear (e.g. al components of the hearing aids are contained in tiny case shell that fits in the ear or canal))
- Technology for sound amplification (i.e. analogue vs digital)
- Communication technology (i.e Wireless vs Non-wireless communication)

A device specific grouping of hearing aids comprises of a collection of hearing aids that are:

- from the same product owner;
- within risk classification Class B (hearing aids not including the implantable hearing devices);
- have the same design type (i.e. behind the ear or in the ear);
- have the same technology for sound amplification (i.e. analogue or digital); and
- have the same communication technology (i.e. wireless or non-wireless)

The product registration application may contain accessories of a lower risk class if they are intended to be used together with the hearing aids.

For Class B hearing aids, the applicant may choose to group their devices using the general grouping criteria described in the guidelines or this device specific grouping criteria for hearing aids or devices.

This device specific grouping criteria for hearing aids would not be applicable for Class C and Class medical devices (e.g. cochlear implant systems), as well as Class B hearing devices that are used in conjunction as part of an implantable hearing system (e.g. sound processors of a bone-anchored hearing system).

9 DEVICE SPECIFIC GROUPING OF IMMUNOHISTOCHEMISTRY IN VITRO DIAGNOSTIC REAGENTS

Immunohistochemistry (IHC) IVD reagents are in vitro diagnostic (IVD) products consisting of polyclonal or monoclonal antibodies labelled with directions for use and performance claims, which may be packaged with ancillary reagents in kits. Their intended use is to identify, by immunological 6 techniques, antigens in tissues or cytologic specimens, which excludes reagents specifically intend to be used with flow cytometry. This section applies to IHC IVD reagents and their accessories only.

A device specific IHC IVD grouping category comprises of a collection of IVD reagents and their accessories that are:

a. from the same product owner;

b. within the risk classification of Class B or Class C;
c. based on IHC methodology; and
d. within the same IHC IVD Grouping Category as listed below

When IHC IVD reagents and their accessories satisfy the criteria to be grouped under one of the six prescribed IHC IVD grouping categories, they can be submitted in one product registration application. However, the listing of the IHC IVD reagents and their accessories on the SMDR upon approval may differ from the initial grouping. The device name listed on the SMDR upon approval will be based on the IHC IVD grouping category used during product registration. The individual models will be listed on the SMDR as per product name (device label). Alternatively, the product owner and their applicants may choose to group these devices using the general grouping criteria described in the guidelines.

If any reagent and their accessories are intended for multiple usage categories such that it can be grouped in more than one IHC IVD grouping category, the applicant can choose to group the reagents and their
accessories as part of any one of the IHC IVD categories it qualifies. Information to support the intended purposes of all the reagents and their accessories must be submitted as part of the product registration application.

LIST OF IHC IVD GROUPING CATEGORIES

The list of IHC IVD categories for the device specific grouping of Class B and Class C IHC reagents and their accessories is a closed and positive list.

S/N	**IHC IVD Grouping Category(closed list)**	**Examples of Analytes (non-exhaustive list)**
1.	Selective Therapy	HER2/neu EGFR
2.	Hematologic Disorder and Blood Cancer Markers	Immunoglobulin Kappa Chain Immunoglobulin Lamda chain
3.	Other Cancer Markers	Alpha fetoprotein (AFP) Cytokeratins CD117
4.	Pathogen Markers	Escherichia coli Candida albicans Herpes simplex virus protein VP22
5.	Immune Disorders	Antinuclear antibodies (ANAs) Anti-topoisomerase

		Organ-specific autoantibodies Anti-streptokinase Anti-Streptolysin 0 C-Reactive Protein
6.	Other Pathology Markers	P57 Growth Hormone

References

1. *HEALTH SCIENCES BOARD GN-12-2: Guidance on Grouping of Medical Devices for Product Registration – Device Specific Grouping Criteria*
2. *International Medical Devices regulators Forum- Grouping of medical devices*