Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By: _____ 09/12/2024

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Director - Product Evaluations and Registration

Date of approval (DD/MM/YY)

Revision status sheet

Page	Changes made	Issue No	Process owner	Reviewer's name	Date
5	3.2 Added Abbreviations of DEHP, IgG, IgM, MR, PET and UV	2.0	Director, DPER	Medical Devices Unit	04/11/2024
6	4.1 Added sub point "vi"	2.0	Director, DPER	Medical Devices Unit	04/11/2024
7	5.1 Removed one example	2.0	Director, DPER	Medical Devices Unit	04/11/2024
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13	6.0 Added flow diagram	2.0	Director, DPER	Medical Devices Unit	04/11/2024
7	Removed section 5.1.2	1.0	Director, DPER	Medical Devices Unit	08-09-2023

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1. Purpose

The intention and purpose of this guideline is to provide general guidance in determining whether certain medical devices including In-Vitro Diagnostics (IVD) medical device can be included together and submitted in one product application. In this document medical devices including In-Vitro Diagnostics (IVD) medical devices will be referred to as medical devices.

2. Scope

This guideline applies to all medical devices. Grouping of medical devices facilitates the inclusion of multiple devices in one application.

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

3.1.1 Accessory

An article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that that device to be used in accordance with its intended purpose.

3.1.2 Authority

Botswana Medicines Regulatory Authority (BoMRA).

3.1.3 Intended use/purpose

The objective intent of the manufacturer regarding the use of a device, process, or service as reflected in the specifications, instructions and information provided by the manufacturer of the medical device.

3.1.4 In Vitro Diagnostic

Means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimen derived from the human or animal; solely or principally to provide information for diagnostic, monitoring or compatibility purposes which includes but not limited to – reagents used for IVD purposes, calibrators, control chemicals, specimen receptacles, software and related instruments or apparatus or other articles and are used for the following test purposes; diagnosis; aid to diagnosis; screening; monitoring; predisposition; prognosis; prediction; determination of physiological status.

3.1.5 Manufacturer

A company that carries out at least one step of the manufacture of a medical device, which includes the responsible person and/or company that designs and/or manufactures a medical device with the intention of making the medical device available

for use, under his/her/its name, whether or not such medical device is designed and/or manufactured by that person or on behalf of that person by another person(s).

3.1.6 **Medical device**

It means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article -

a) intended by the manufacturer to be used, alone or in combination, for humans or animals for-

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

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

iii. investigation, replacement, modification or support of the anatomy or of a physiological process;

iv. supporting or sustaining life;

v. control of conception;

vi. cleaning, disinfection or sterilization of medical devices; or

vii. providing information for medical or diagnostic purpose by means of in vitro examination of specimens derived from the human body; and

b) which do not achieve its primary intended action in or on human or animal body by pharmacological, immunological or metabolic means but which may be assisted in its intended function by such means.

3.1.7 **Product Owner**

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, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

3.2 Abbreviations

The following abbreviations shall apply:

3.2.1 **DEHP**- Di(2-ethylhexyl) phthalate

3.2.2 **FSCA** - Field Safety Corrective Action

3.2.3 **HIV** - Human Immunodeficiency Virus

3.2.4 **IFU** - Instructions for use

3.2.5 **IgG**- Immunoglobulin G

3.3.6 **IgM**- Immunoglobulin M

3.2.7 **IVD** - In Vitro Diagnostic

3.2.8 **MAH**- Marketing Authorization Holder

3.2.9 **MR**- Magnetic Resonance

3.2.10 **PET**- Positron Emission Tomography

3.2.11 **PU**- Polyurethane

3.2.12 **PVC**- Polyvinylchloride

3.2.13 **UV**- Ultraviolet

4. General Principle of Grouping

4.1 The applicant may group medical devices having the same or similar intended uses, intended purposes, from the same owner, or commonality of technology and submit in a single application. The grouping of medical devices is for the purpose of submission of single application for getting marketing authorization prior to import or marketing locally manufactured devices. Medical devices can be grouped into one of the following categories to be submitted in one application for evaluation & marketing authorization.

i. Medical Device Family
ii. System
iii. IVD test kits
iv. IVD Cluster
v. Single Medical device
vi. Medical Device Group/ Set

4.2 The product owner/manufacturer of a medical device may incorporate as part of their device, medical devices and/or accessories from other manufacturers or product owners or intend such devices to be used together to achieve a common intended purpose. By such design and/or intended purpose, the product owner of the medical device also assumes the responsibility for such use of the other devices and accessories.

4.3 Once the medical device(s) is approved for registration, the final appropriate device information on the register shall be determined by Authority. For example, where submission with device grouping allow for instrument/accessories from different devices, such as IVD analyser, only the product owner/manufacturer of primary device will be registered. Although the documentation relating to other products owners/manufacturer are required to be submitted as part of the registration submission.

4.4 The MAH shall undertake the following post-market duties and obligations for all medical devices and accessories they have registered either individually or as part of grouped registrations:

I. comply with the conditions applicable to the registered medical device and conditions imposed on the MAH.

II. submit applications to the Authority for changes made to the registered medical device.

III. maintain records of supply.

IV. maintain records of complaints.

V. report defects and adverse effects to the Authority.

VI. notify the Authority concerning FSCA including recall.

5 Grouping Categories

5.1 Medical Device Family- A medical device family is a collection of medical devices and each medical device family member:

i. Is from same product owner/manufacturer.

ii. Is of the same risk classification.

iii. Has a common intended purpose.

iv. Has a common design and manufacturing process.

v. Has variation within scope of permissible variants. List of permissible variants in a family is provided in annexure I.

5.1.1 When medical devices satisfy the family conditions to be grouped as one product registration submission, they will be registered as such upon approval of the application.

5.1.2 The addition of new medical devices to the medical devices register shall be carried out according to the Guidelines on Submission of Application for Variation to Registered/Listed Medical Devices (BOMRA/ER/MED/P09/G01).

Examples:

Condoms that differ in flavor, colour, size and texture but are manufactured from same material, using common manufacturing process and share a common intended purpose can be grouped as a family.

IV administration sets that differ in features such as safety wings and length of tubing, but are manufactured from same material, using common manufacturing process and share a common intended purpose can be grouped as a family.
Steerable guidewires that are available in various lengths and possess various tip shapes and tip flexibilities can be grouped as a family.
Cardiac catheters that are available in a different number of lumens, lengths and diameters can be grouped as a family.
Contact lenses with additional features of UV protection can be grouped as a family, as this feature does not affect the basic design and manufacturing of lens.

5.2 **System**- A medical device system comprises of a number of a medical devices and/or accessories, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose that are

i. Intended to be used in combination to achieve a common intended purpose.

ii. Compatible when used as a system.

iii. Sold under a single system name or the labelling, IFU, brochure or catalogues for each constituent component indicates that the constituent component is intended to be used together or for use with the system.

iv. Devices registered as a part of a system shall only be supplied specifically for use with that system. Any devices that are meant for supply for use with multiple systems should be registered together with each of these systems. Alternatively, if these devices are compatible for use with one or multiple systems from different product owners, they can be registered separately.

5.2.1 A manufacturer (or product owner) of a medical device system may incorporate medical devices and /or accessories from other product owners (or manufacturers) as part of their system to achieve the intended purpose of the device. These medical devices and/or accessories should be grouped together as a system and information on these devices and accessories such as authorization from their product owners for registration with the system, evidence on use and compatibility with the system shall be submitted.

Examples:

A patient monitoring system from product owner/manufacturer XYZ is intended to be used specifically with vital signs sensors and probes from product owner/manufacturer ABC. These accessories are used in combination to achieve a common intended purpose in accordance with product owner/manufacturer XYZ's

specifications and can be grouped together with the patient monitoring system in one application.
A hip replacement system comprising of femoral and acetabular components can be grouped as system. The component must be used in combination to achieve a common intended purpose of total hip replacement. The size of component may vary.
The electrosurgical unit and its accessories that consist of forceps, electrodes, electrode holders, lead, plug adaptor, when used together for a common intended purpose, can be grouped as a system.
A catheter placement set/kit comprising of scalpels, syringes, needles, surgical gloves, gauze, drapes and flushing solution that is validated for compatibility and assembled by a single product owner under a single system name for use in combination during a surgical catheter placement procedure can be grouped as a system.
A glucose monitoring system comprising a glucose meter, test strips, control solutions and linearity solutions can be grouped as system.

5.3 IVD Test Kit- An IVD test kit is an IVD device that consists of reagents or articles that are:

i. From the same product owner.

ii. Intended to be used in combination to complete a specific intended purpose.

iii. Sold under a single test kit name or labelling, IFU, brochure or catalogues for each reagent or article states that the component is intended for use with the IVD test kit.

iv. Compatible when used as a test kit.

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

5.3.1 Individual reagent 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, such reagents or article shall be included in the product registration application of each of other test kits.

5.3.2 Reagents or articles from another manufacturer/ product owner may be grouped with IVD test kit if the application furnishes all information on these reagents or articles required for registration and data to substantiate the performance of these reagents when used with test kit.

Example: A HIV enzyme linked immunosorbent assay (ELISA) test kit may contain controls, calibrators and washing buffers. All the reagents and articles are used together, and articles can be supplied separately as replacement items for particular test kit.

5.4 IVD Cluster- An IVD cluster comprises of a number of IVD reagents or articles that are:

i. From same manufacturer/ product owner.

ii. Same risk classification (class A only or class B only).

iii. A common test methodology.

iv. Same IVD cluster category as mentioned in annexure II.

v. Sold under a single proprietary name

5.4.1 A list of common test methodologies and IVD cluster categories is provided in Annex II of this document.

5.4.2 The IVD cluster grouping is only to be used for product registration and would not be applicable as a grouping criterion for the addition of models through a variation procedure.

5.4.3 Information on the reagents or article within an IVD cluster must be submitted as part of product registration application.

5.4.4 If a reagent or article is intended for multiple usage categories such that it can be grouped in more than one IVD cluster, the MAH can choose to group the reagent or article as part of any one of the IVD clusters it qualifies. Information to support all the intended purpose of the reagent or article must be submitted as part of medical devices registration application.

5.5 Single Medical Device

5.5.1 A single medical device is a medical device from a manufacturer/ product owner identified by a brand name with specific intended purpose. Medical devices that cannot be assigned to a family, system, IVD cluster, IVD test kit, Group.

5.5.2 A single medical device is sold as a distinct packaged entity and may also be offered in a range of package sizes.

5.5.3 Medical devices, or parts, components that cannot be assigned to a System, Test Kit, Medical Device Family, Medical Device Group, or a Medical Device Group Family must be registered individually.

Example:

A company manufacturer a standalone software program that can be used with a number of CT scanners produced by other manufacturers. The standalone software itself is deemed a medical device, which can be used on different scanners. The software can be grouped as single medical device.
Condoms that are sold in package of 3 or 12 can be grouped as single medical device when submitting for registration.
A manufacturer has a first aid kit registered as a "procedure pack", where the manufacturer wishes to market any member/ item of the first aid kit separately, applicant shall apply as a single medical device.
Gloves that are sold in packages of 25, 50 and 100 pieces can be registered as a single medical device

5.6 Medical device Group/Set

5.6.1 A medical device group/set is a collection of two or more medical devices, that is labelled and supplied in a single packaged unit by a product owner. The medical device group comprises of the following:

i. A single brand group/set name

ii. Labelled and supplied in a single packaged unit by the product owner

iii. A common intended purpose.

5.6.2 For the purpose of grouping for product registration, the collection of medical devices in a group is the closed list of devices included in a product registration application. This closed list of medical devices in a group (single packaged unit) may differ in the quantity and combination of medical devices that comprise the group, while maintaining the same brand group name and the group's intended purpose.

5.6.3 For a medical device group, the manufacturer/product owner intends to supply a collection of customized medical devices for a specific medical purpose within a single packed unit, such as convenience pack or tray, which is under a single name.

5.6.4 A manufacturer/product owner of the group who assembles a group together also assumes responsibility for medical device group and its intended purpose. The manufacturer/product owner of a medical device group may incorporate medical devices obtained from other manufacturer/product owner as part of their group to achieve the common intended purpose. In manufacturing and assembling this group of medical devices, evidence to substantiate the safety, quality and efficacy of collection

of devices shall be provided in the submission. Relevant information for submission may include sterility, shelf life, evidence on use and compatibility as a group, quality management systems, etc., labeling, IFU, where applicable shall clearly describe the common intended purpose of the group.

5.6.5 Medical devices that are registered within a group must have a single medical device registration before they are sold separately as individual medical devices for their specific individual intended purpose or as replacement.

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

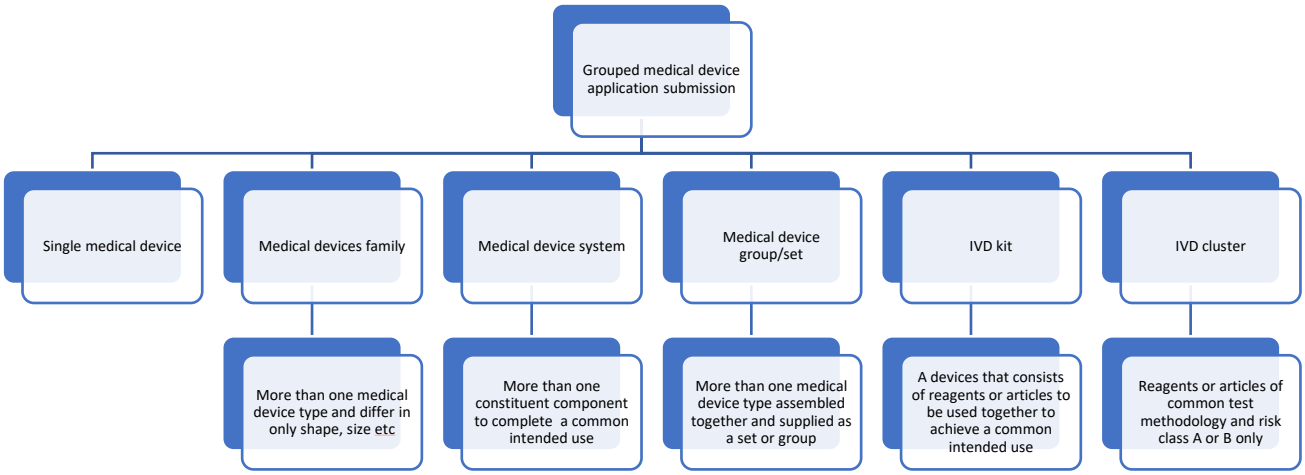
5.6.7 When the group is registered, the MAH is able to customize for supply, in a single packaged unit, from the closed list of devices for particular facility/hospital while maintaining the same group name and intended purpose. When a medical devices group is registered, any other single packaged unit combination of devices in that group can be supplied on the market for the registered intended purpose of the group.

5.6.8 The group name indicated for medical device must appear in the product label affixed on the external package unit of the group. The content list of devices within the single packaged unit for supply should also appear on the external package of the group or supplied with the group. Individual medical devices in the group do not require to be labelled with that group name.

Example:

A promotional pack or convenience pack, without a GROUP name and without a common medical intended purpose, consisting of different number of medical devices, for example multi-purpose solution, saline solution, and contact lens case, will NOT qualify as a GROUP registration. Individual medical devices shall require registration as SINGLE medical devices
First aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package for a common medical purpose by a product owner, can be grouped as a GROUP/Set
A MAH supplies dressing trays customized with different quantities and type of gauze and sutures to different hospitals. When the closed list of medical devices in the GROUP are registered, the product owner is able to customize the trays, from the list of devices, for other hospitals, while maintaining the same GROUP name for the trays and the registered intended purpose. The product label for the trays shall bear the content list of devices within the package for supply. Some of the medical devices in the GROUP may be individually packaged and labelled, while others remain in bulk form and may not be labelled. The product owner shall account for these during the assembling of the GROUP and ensure compliance to existing regulatory requirements including traceability of individual devices packaged into the trays and record keeping

6. Summary flow chart for grouped medical devices application.



Annexure I

List of Permissible Variants in a Family (this list is not exhaustive)

Specific Product	Permissible Variants
Active Implantable Devices	MR conditional and Non-MR conditional
Antibiotic Test (IVD)	Concentrations
Biopsy Forceps	Formable or Non-formable
Blood Bags	a) Anticoagulants with same composition but different concentration b) Additives (different composition and concentrations)
Catheter	a) Number of lumens in catheter b) Material of catheter: PVC, PU, nylon and silicone c) Curvature d) Coating material for lubrication
Condom	a) Texture b) Flavour c) Size d) Colour
Contact lens	a) Diopter b) UV protection c) Tinting d) Colour e) Wearing schedule (e.g. daily wear, extended wear) f) Replacement schedule (e.g. daily, weekly, monthly)
Defibrillators	Automatic or Semi-automatic
Dental handpieces	a) Rotational speed b) Material of handpiece
Dermal fillers	Same composition but different concentration/ densities
Diagnostic Radiographic system	a) Number of slices b) Digital vs Analog c) Biplane and Single plane d) Flat panel vs Cassette e) PET ring size
Electrophysiological Catheter	a) Electrode Spacing b) Number of electrode
Gloves	Powdered or Powder-free

Gamma Camera	Number of detectors
Guide wire	With or without inert coating material
Orthopaedic/ Dental Implants	a) Cemented or non-cemented fixation b) Collar
Intra-ocular Lens	a) Monofocal or Multifocal b) Multi-piece or Single-piece c) Aspheric or Spheric
Implantable Pulse Generators	Number of Chambers (Cardio)
IV Cannula	a) Presence of injection port b) Presence of safety wing
IVD rapid tests	Different assembly format: cassette, midstream, strip
IVD urinalysis strips	Different combination of testing configurations
Polymer Product	With or without plasticisers (e.g. DEHP)
Stent	a) Delivery system, that is over-the-wire or through the scope b) Flaps, Flares or sleeves
Suture	a) Number of strands b) Pledgets c) Loops d) Dyes
Suture passer	Design of jaw, handle or needle
Tracheal Tube (endotracheal tube, tracheostomy tube)	With or without cuff
Wound Dressings	Different formats (e.g. solution, creams, gels loaded onto pads, etc.)
X-ray detector	Scintillator material
Other permissible variants	a) Coating material for lubrication only b) Colour c) Diameter, Length, Width, Gauge d) Concentration with same indication and mechanism (same composition different amount of constituent) e) Dimensional design differences due to paediatric versus adult use (The differences due to the different patient population are permissible, e.g. volume and length) f) Flexibility

	g) Holding force h) Isotope activity level i) Memory storage j) Method of Sterilisation (to achieve same sterility outcome) k) Printing capability l) Radiopacity m) Shape, Size, Volume n) Viscosity (The change in viscosity is solely due to changes in the concentration of constituent material) o) Type of device mounting (e.g. ceiling mount, wall mount or standing)

Annexure II

List of IVD Cluster Categories

This list IVD cluster categories only applicable to Class A only or Class B only IVD medical devices.

Methodology	Cluster category (closed list)	Example Analytes (non-exhaustive list)
Clinical Chemistry	Enzymes	a) Acid Phosphatase b) Alpha-Amylase c) Creatine Kinase d) Gamma-Glutamyl Transferase e) Lactate Dehydrogenase f) Lipase
	Substrates	a) Albumin b) Bilirubin c) Urea/Blood Urea Nitrogen d) Cholesterol e) Creatinine f) Glucose
	Electrolytes Reagents	a) Ammonia b) Bicarbonate c) Calcium d) Chloride e) Magnesium f) Phosphate Inorganic/Phosphorus
	Electrolyte Electrodes	a) Ammonia Electrodes b) Carbon Dioxide (Bicarbonate) c) Electrodes d) Calcium Electrodes e) Chloride Electrodes f) Magnesium Electrodes g) Potassium Electrodes
	Substrate Electrodes/ Biosensors	a) Creatinine Electrodes b) Glucose Electrodes c) Glycated Haemoglobin Electrodes

		d) Lactate Electrodes e) Urea Electrodes f) Bilirubin Electrodes
Immunochemistry	Immunoglobulins (without IgE)	a) Immunoglobulin A b) Immunoglobulin D c) Immunoglobulin G d) Immunoglobulin M e) Immunofixation kits
	Complement Components	a) Complement Component C1q b) Complement Component C1 inactivator c) Complement Component C3/C3c d) Complement Component for Bb e) Complement Component C4 f) Complement Component C5a
	Transport Proteins	a) Albumin b) Ceruloplasmin c) Haptoglobin d) Hemopixin e) Lactoferrin f) Pre-albumin/Transthyretin
	Lipoproteins	a) Apolipoprotein A I b) Apolipoprotein A II c) Apolipoprotein B d) Apolipoprotein E Sub-typing e) Lipoprotein (a)
	Other Specific Proteins	a) a1-Acid Glycoprotein b) a1-Antitrypsin c) a1-Microglobulin d) Fibronectin e) Immuno Reactive Trypsin

	Allergy	a) Immunoglobulin E – Total b) Immunoglobulin E – Screen c) Immunoglobulin E – Specific, monotest/monoresult d) Allergen specific IgA e) Allergen specific IgG
	Cancer markers	a) GI-marker CA242 b) p53
	Thyroid Function Markers	a) Free Triiodothyronine b) Free Thyroxine c) Thyroid Stimulating Hormone d) T – Uptake e) Thyroglobulin f) Neonatal Thyroxine
	Fertility/Pregnancy Hormones / Proteins	a) Androstenedione b) Estradiol c) Prolactin d) Human Placental Lactogen e) Estriol
	Diabetes Assays (Hormones)	a) C-Peptide b) Glucagon c) Insulin d) Glycosylated/Glycated Haemoglobin e) Islet Cell Ab f) Proinsulin
	Renal Metabolism Assays	a) Aldosterone b) Angiotensin I / II c) Angiotensin Converting Enzyme d) Cortisol e) Renine

	Bone and Mineral Metabolism Assays	a) Bone Alkaline Phosphatase b) Calcitonin c) Cross-linked C-Telopeptides d) Cross-linkded N-Telopeptides e) Cyclic Adenosin Monophosphate f) Hydroxyproline
	Endocrine Hormones and Peptides	a) Adrenocorticotropic Hormone b) Human Growth Hormone c) Insulin-like Growth Factor I d) Insulin-like Growth Factor Binding Protein 1 e) Vasointestinal Peptide f) Vasopressin
	Neuroendocrine Function Assays	a) Bombesin b) 17-Hydroxy-Ketosterone c) β-Endorphin d) Neurotensin e) Somatostatin f) Substance P
	Other Individual and Specified Hormones	a) Gastrin b) Gonadotropin-Releasing Hormone c) Melatonin d) Pepsinogen e) Adrenalin f) Dopamine
	Anaemia	a) Erythropoietin b) Ferritin c) Folate d) Iron e) Iron Binding Capacity f) Soluble Transferrin Receptor

	Vitamins	a) Vitamin B1 b) Vitamin B2 c) Vitamin B6 d) Vitamin B12 e) Vitamin D (Cholecalciferol) f) Intrinsic Factor (Blocking Antibody)
	Drug Monitoring	• Caffeine • Benzodiazepines • Penicillin • Tetracyclines
	Toxicology	a) Amphetamines b) Cocaine c) Morphine d) Phencyclidine e) Acetaminophen f) Catecholamines g) Ethanol h) Salicylate
	Auto-immune Diseases	a) Anti-nuclear antibodies (ANAs) b) Anti-topoisomerase c) Organ-specific autoantibodies d) Circulating Immuno-complex e) TSH Receptor antibodies f) Anti-Cardiolipin antibodies
	Rheumatoid- Inflammatory Diseases Markers	a) Anti-Streptococcal Hyaluronidase b) Anti-Streptokinase c) Anti-Streptolysin O d) C-Reactive Protein e) Anti-Staphylolysin f) Anti-Streptococcal Screening
	Liver Function	a) MEGX b) Carbohydrate Deficient

		Transferrin
	Cardiac Markers	a) Homocysteine b) ST2 c) Galectin-3 d) Myeloperoxidase (MPO)
	Bacterial Infection - Immunology	a) Bacillus subtilis b) Pseudomonas Aeruginosa c) Helicobacter Pylori d) Lactobacillus casei
	Viral Infection - Immunology	a) Norovirus b) Rotavirus c) Hantavirus
	Parasitic Infection - Immunology	Leishmania
	Fungal Infection - Immunology	a) Candida albicans b) Aspergillus
Haematology / Histology/ Cytology (Blood tests for transfusions excluded)	Haemoglobin Testing	a) Haemoglobin determinations (Total Hb) b) Fractional oxyhaemoglobin (FO2Hb) c) Fractional carboxyhaemoglobin (FCOHb) d) Fractional methemoglobin (FMetHb) e) Fractional deoxyhaemoglobin (FHHb)
	General Coagulation Tests	a) Prothrombin Time b) Thrombin Time c) Activated Clotting Time d) Activated Partial Thromboplastin Time
	Haemostasis (Coagulation)	a) Fibrinogen b) Protein C and Protein S reagents c) C1-inhibitors d) Alpha-Antiplasmin

		e) Fibrin f) Factor XIII g) Platelet Factor 4 h) Plasminogen
	Other Haematology Tests	a) Complete Blood count b) Haematocrit c) Erythrocyte Sedimentation rate
	Cytokines (Lymphokines)/ Immunomodulators	a) Interferons b) Soluble Antigens/Receptors c) Tumour Necrosis Factors d) Colony Stimulating Factors e) Tumour Necrosis Factors Receptors
	Histology/ Cytology Reagents	a) Cytochemical Staining b) Embedding, Fixing, Mounting media c) Stain solutions d) Immunohistology kits
Microbiology - culture	Culture Media	a) Dehydrated culture media (DCM) b) Additives for DCM c) Prepared Media (Tubes, bottles, Plates) d) Cells, Media, Serum for Viral culture
	Susceptibility Testing	a) Erythromycin susceptibility test for Staphylococcus aureus b) Tobramycin susceptibility test for Pseudomonas aeruginosa c) Fungal susceptibility testing
	Biochemical culture Identification (ID)	a) Gram Negative Manual ID b) Gram Positive Manual ID c) Other ID Kits Manual-Anaerobes, Fastidious
	Immunological culture Identification (ID)	a) Streptococci Grouping Slide tests

		b) Serotyping (Shigella etc.)
	Nucleic Acid (NA) based culture identification (ID)	a) Streptococci b) Shigella
	Serological identification (ID)	For Parasitology and Mycology (Fungi and Yeast)
	Bacterial Infections (Detection by NA Reagents)	a) Streptococci b) Shigella
	Viral Infections (Detection by NA Reagents)	Para-influenza NA Reagents
	Fungal Infections	• Fungi NA Reagents • Candida albicans • Aspergillus

Diagram 1: Decision Flowchart For Grouping Of Medical Devices As A Family

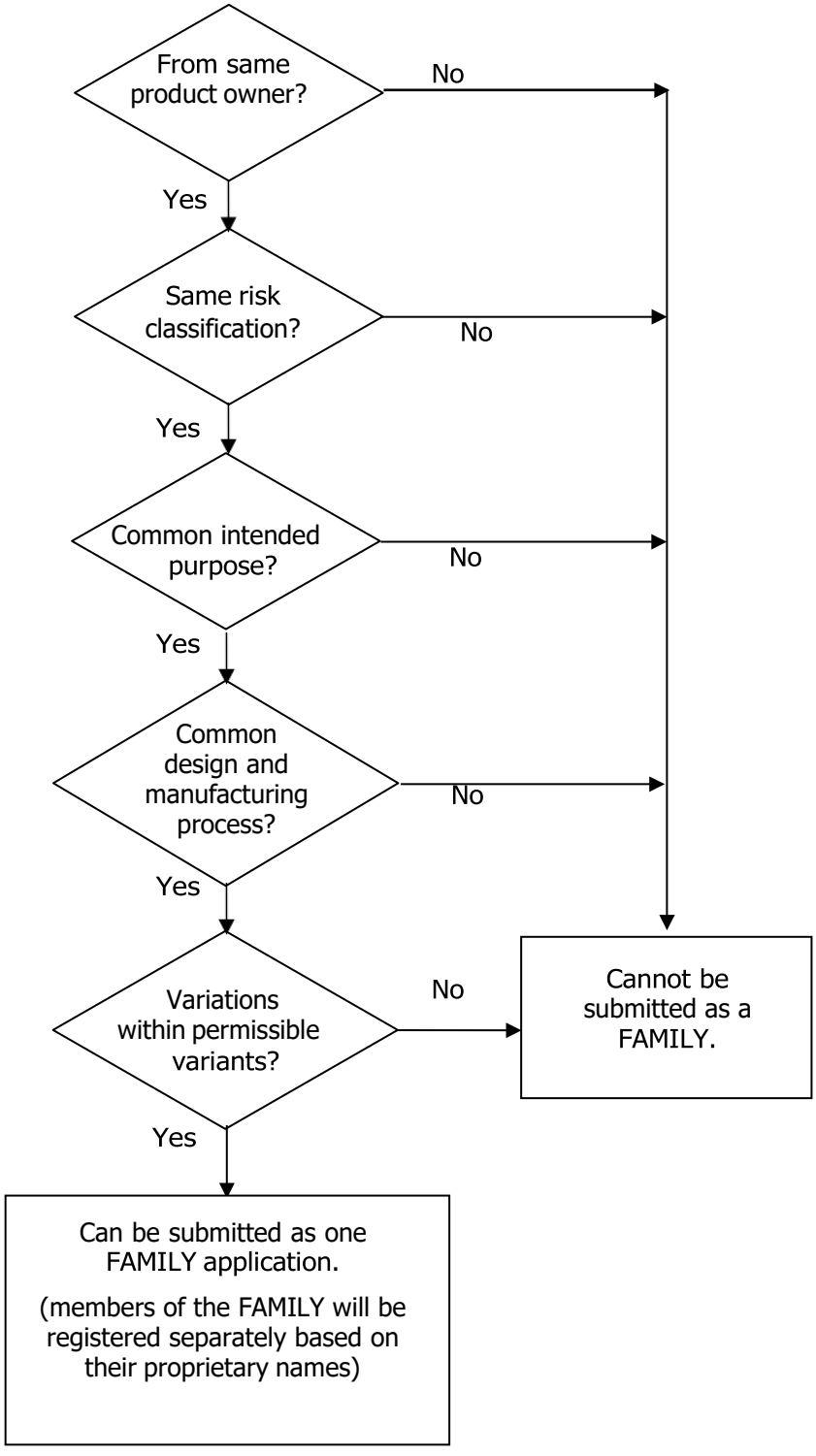


Diagram 2 : Decision Flowchart For Grouping Of Medical Devices As A System

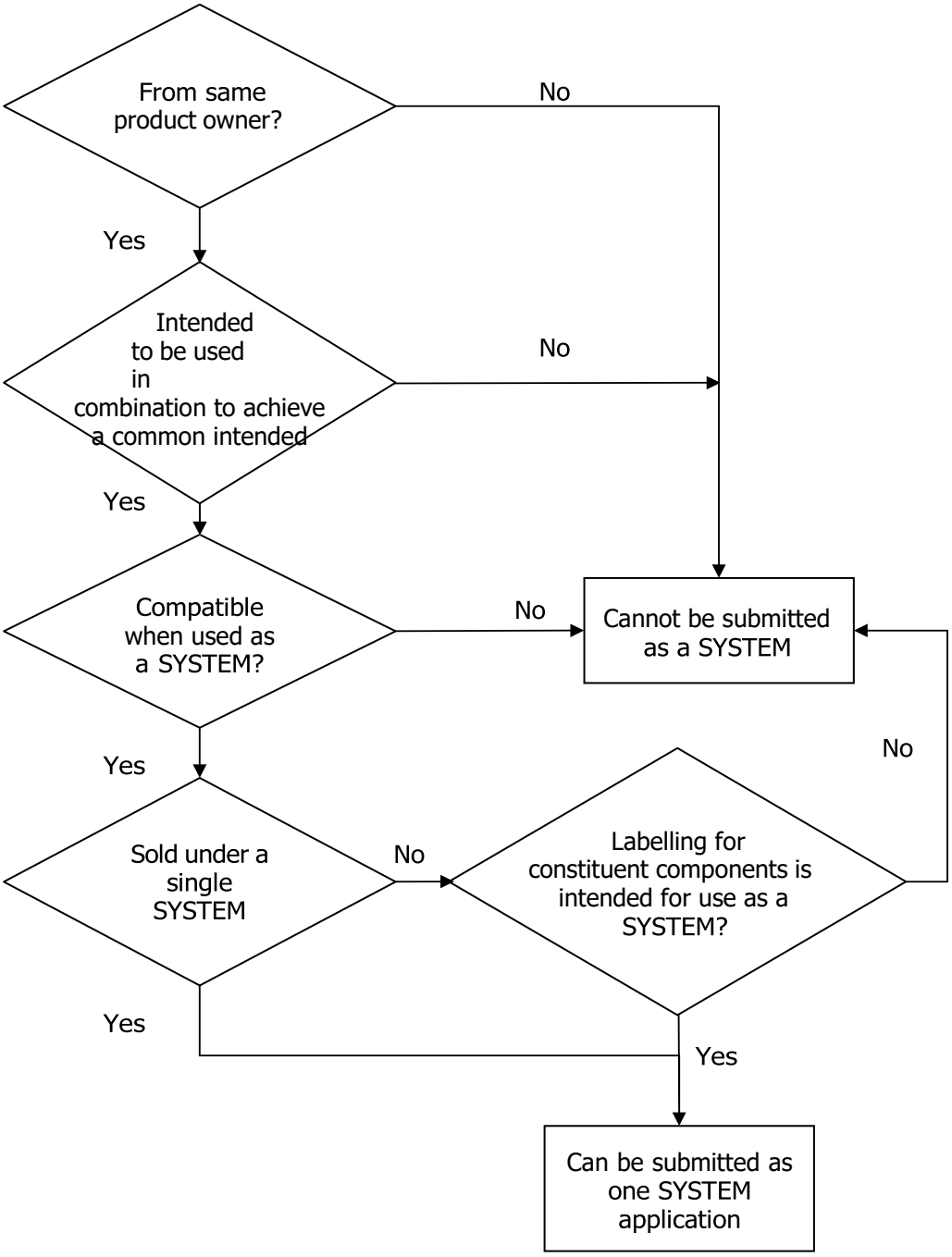


Diagram 3: Decision Flowchart for Grouping of Medical Devices as IVD Test Kit

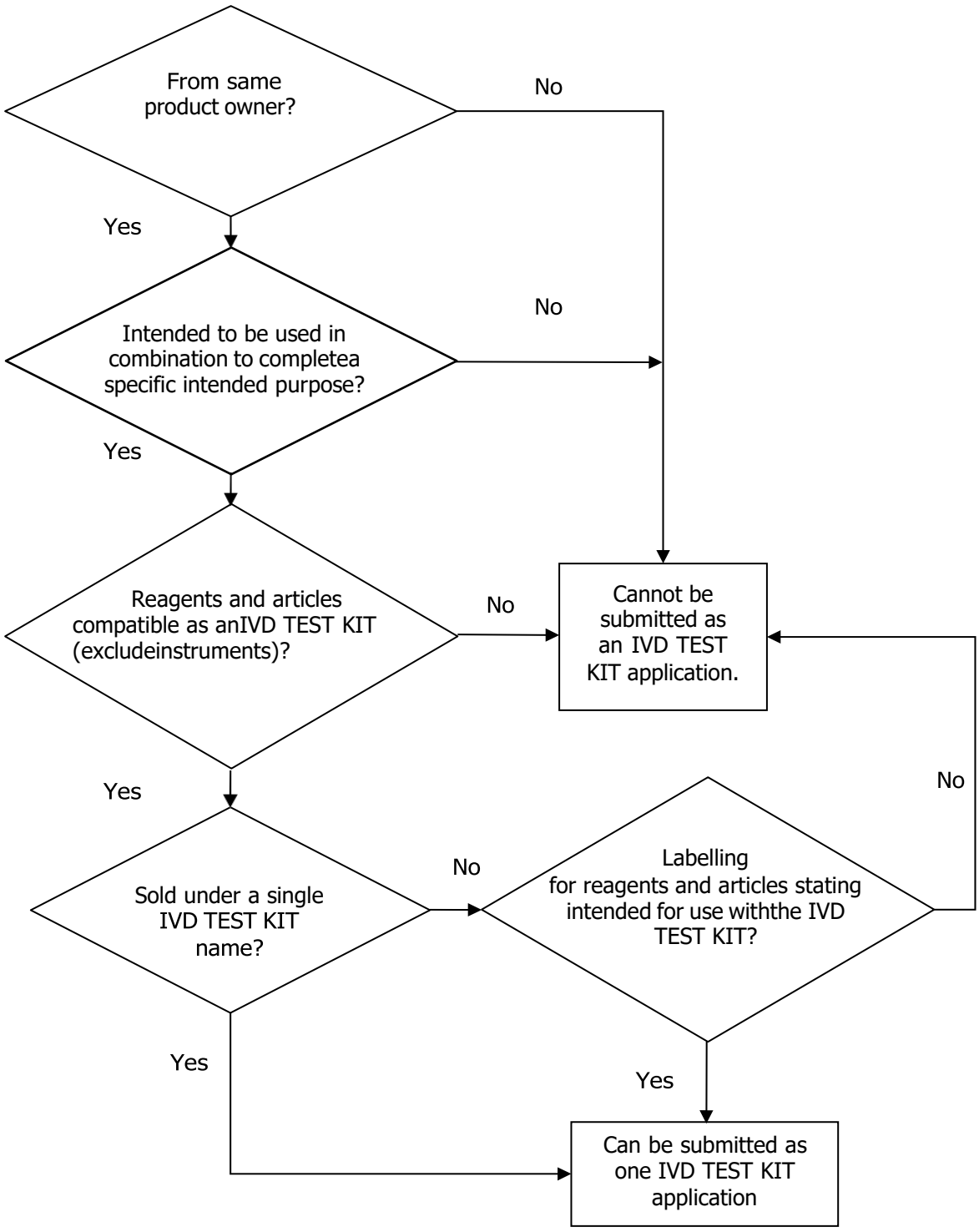


Diagram 4: Decision Flowchart For Grouping Of Medical Devices As An IVDs Cluster

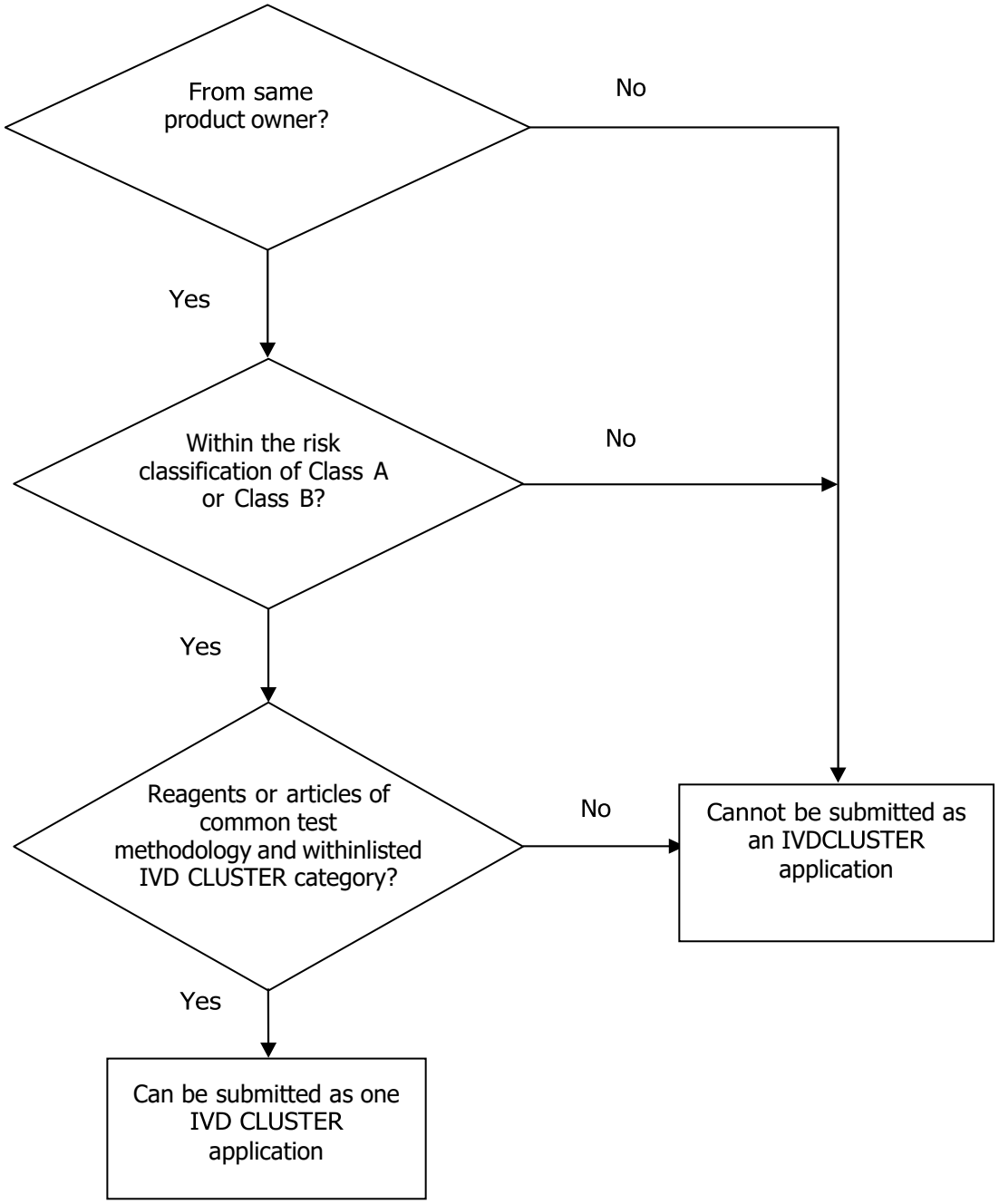


Diagram 5: Decision Flowchart for Grouping of Medical Devices as a GROU