GUIDANCE FOR INDUSTRY CONSULTATION

GN-12-1: Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria

CONTENTS

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

Update Process for this Guidance Document

This version of GN-12 guidance document applies to all medical device registration applications submitted to HSA from 1 October 2015. The grouping criteria described in the GN-12-1 and GN-12-2 shall be strictly adhered to in submitting your medical devices for registration.

Any requests to reconsider or review these existing grouping criteria shall be submitted via email to hsa_md_info@hsa.gov.sg with subject header "Request for review of GN-12 grouping criteria". The email should include detailed information regarding:

(i) Device type and description
(ii) Existing grouping options and their limitations (if any)
(iii) Proposed grouping criteria and the rationale
(iv) Technical/scientific information to support the above proposal

Such requests received will be reviewed by HSA periodically and if deemed acceptable, the GN-12-1 and GN-12-2 guidance documents will be updated. Updating of the documents will only be done bi-annually (once in 6 months). Any new or revised grouping criteria shall be implemented only after these have been published online as revised versions of the GN-12-1 and GN-12-2 guidance documents.

REVISION HISTORY

Guidance Version	Revision
R1 ► GN-12: Revision 1 (January 2011)	R1
R1.1 ►GN-12: Revision 1.1 (May 2014)	R1.1
R2 ► GN-12-1: Revision 2 (draft)	R2

**Where applicable, changes and updates made in each document revision are annotated within the arrow symbol "►".*

1. INTRODUCTION

1.1. Purpose

This document is meant to provide general guidance in determining whether certain medical devices can be included together and submitted in one product registration application.

1.2. Background

Under the Health Products Act (*Act*), all medical devices to be supplied locally are required to be registered with HSA prior to supply.

Medical devices range from simple medical devices (e.g. syringe) to highly complex medical devices (e.g. implantable pacemakers) including devices that comprise of myriad components (e.g. patient monitoring systems). These various components or modules can be sold individually, in different combinations as required by the end user, as a convenient all-in-one kit, or as an individually customised pack. Individual medical devices are also typically available in various configurations including length, diameter, etc. There are also certain device specific attributes, such as those specific to *in vitro* diagnostic devices and hearing aids, which should be considered when categorising devices for the purpose of grouping.

In order to address the diverse categories of devices supplied by manufacturers, grouping criteria that applies generally to medical devices and also device specific grouping categories have been developed and are presented in this GN-12-1 and the GN-12-2 guidance documents respectively. Applicants should determine and perform the grouping of medical devices to be registered based on GN-12-1 and GN-12-2 guidance documents when preparing their medical device product registration submissions.

1.3. Scope

This document applies to all medical devices.

1.4. Definition

Definitions, which are not set out in the *Act* and Health Products (Medical Devices) Regulations (*Regulations*), are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

ACCESSORY: for the purposes of this guidance document, means an article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose. An accessory is typically intended to be used for one or more of the purposes as described in the definition of medical device and therefore should be considered a medical device.

PROPRIETARY NAME: for the purposes of this guidance document, a unique name given by the product owner to identify a medical device as a whole product, also known as the trade name or brand name.

INTENDED PURPOSE/INTENDED USE *(as set out in the Regulations)*: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the product owner of the medical device.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the *Act.*

PRODUCT OWNER *(as set out in the Regulations)*: in relation to a health product, 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, 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.

2. GENERAL PRINCIPLES OF GROUPING

Medical devices that can be grouped into one of the grouping categories specified in this GN-12-1 and also in GN-12-2 guidance documents can be submitted in one product registration application.

Grouping of medical devices is for the purpose of product registration submission. However, the listing of the medical devices on the Singapore Medical Device Register (SMDR) upon approval may differ from the initial grouping. For example, medical devices with different proprietary names or brand names may be submitted in one product registration application if they meet any of the grouping categories defined in this GN-12-1 or the GN-12-2 guidance documents. However, the devices with different proprietary names or brand names will be listed separately under different device listings on the SMDR.

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.

Only device models that are eventually listed on the SMDR shall be supplied on the market. The device listing information on the SMDR shall be determined as appropriate by HSA. For example, submissions with device groupings which allow for accessories from different product owners, only the product owner of the primary device will be listed on the SMDR, although the documentation relating to other product owners are required to be submitted as part of the registration submission. The final determination for the device listing information on the SMDR shall be made by HSA.

The Registrant shall undertake the following post-market duties and obligations for all medical devices and accessories registered on the SMDR registered by the Registrant or as part of grouped registrations (e.g. IVD 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 Registrant;
- submit applications to the Authority for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Authority; and
- notify the Authority concerning field safety corrective action (FSCA), including recall.

3. GROUPING CATEGORIES

3.1. FAMILY

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

- is from the same product owner;
- is of the same risk classification;
- 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.

1 LIST OF PERMISSIBLE VARIANTS IN A FAMILY

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

Specific products	**Permissible variants**
Abutments	Retention (e.g. cement or screw)
Antibiotic test (IVD)	Concentration
Biopsy Forceps	Formable or Non-formable
Blood Bags	(i) Anticoagulants with same composition but different concentrations (ii) Additives (different composition and concentrations)
Catheter	(i) Number of lumens in catheter (ii) Material of catheter: PVC (polyvinylchloride), PU (polyurethane), nylon and silicone (iii) Curvature (iv) Coating material for lubrication
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)
Defibrillators	Automatic or semi-automatic
Dental brackets	Material of bracket
Dental handpieces	(i) Rotational speed (ii) Material of handpiece
Dermal fillers	Same composition but different concentrations

Specific products	Permissible variants
Diagnostic Radiography System	(i) Digital or analogue system (ii) Bi-plane or Single-plane
Electrophysiological Catheter	(i) Electrode spacing (ii) Number of electrodes
Gloves	Powered or powder-free
Gamma Camera	Number of detectors
Guide wire	With or without inert coating material
Orthopaedic/Dental Implants	(i) Cemented or non-cemented fixation (ii) Collar
Intra-ocular Lens	(i) Monofocal or Multifocal (ii) Multi-piece or Single-piece (iii) Aspheric or Spheric
IV Cannula	(i) Presence of injection port (ii) Presence of safety wing
IVD rapid tests	Different assembly format: cassette, midstream, strip
IVD urinalysis strips	Different combination of testing configurations
Polymer products	With or without DEHP
Pulse Generators	Number of Chambers
Stent	(i) Delivery system, that is over-the-wire or through the scope (ii) Flaps, Flares or sleeves
Suture	(i) Number of strands (ii) Pledgets (iii) Loops (iv) Dyes
Suture passer	Design of jaw, handle or needle

Specific products	Permissible variants
Wound Dressings	Different formats (e.g. Pad vs Gel)
Radiographic systems	(i) Number of slices (i) Digital vs Analog (ii) Biplane and Single Plane (iii) Flat Panel vs Cassette

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Other permissible variants in general
Diameter, Length, Width, Gauge, Shape, Size, Volume
Dimensional design differences due to paediatric versus adult use (The differences due to the different patient population are permissible, e.g. volume and length)
Colour
Flexibility
Holding force
Isotope activity level
Memory storage
Method of Sterilisation (to achieve same sterility outcome)
Radiopacity
Viscosity (The change in viscosity is solely due to changes in the concentration of constituent material)
Type of device mounting (e.g. ceiling mount, wall mount or standing)
Printing capability
Coating material for lubrication only
Sterility status* ** Sterility status (sterile vs non-sterile) is a permissible variant **only** for devices that are identical in all other aspects.*

In addition, to the above permissible variants, medical devices which are sub-set components among each other would also qualify to be submitted under a FAMILY grouping.

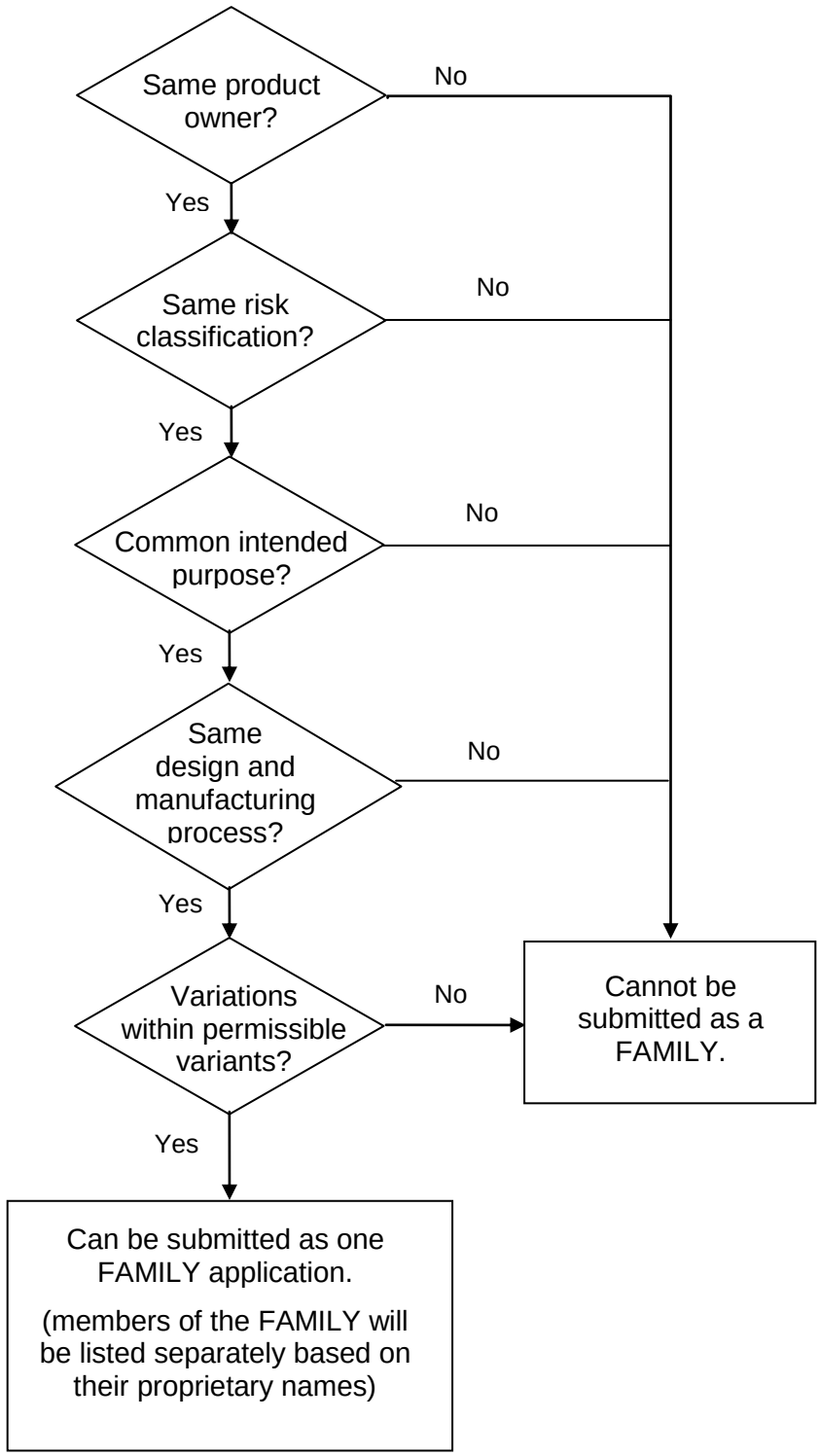
For example:

Patient monitor system A measures temperature, blood pressure and SpO_2 only. **Patient monitor system B** from the same product owner, with the same specifications, measures temperature and blood pressure only. The above two devices qualify to be grouped as a FAMILY in one product registration application as the parameters measured by **Patient monitor system B** is a sub-set of those measured by **Patient monitor system A**.

Patient monitor system C from the same product owner that has the same specifications, which measures temperature, blood pressure and ECG, would not qualify as a sub-set of **Patient monitor system A** or **B**. Hence, **Patient monitor system C** will not qualify to be grouped with the above two devices.

If **Patient monitor system A** is registered on SMDR, then a sub-set device (e.g. **Patient monitor system B**) can be submitted for registration via change notification – Addition of models submission. However, devices which are not sub-set of the registered devices (e.g. **Patient monitor system C**) will not qualify for CN but will require a new product registration submission.

DECISION FLOWCHART FOR GROUPING OF MEDICAL DEVICES AS A FAMILY



When medical devices satisfy the above conditions to be grouped as a FAMILY during the product registration submission, but have different device proprietary names or brand names, the devices will be listed separately on the SMDR based on their proprietary names upon approval of the application.

The addition of new medical devices to an SMDR device listing through a CHANGE NOTIFICATION is only permissible if the new medical devices being added carry the same device proprietary name or brand name as the SMDR-listed medical devices. Although, the new medical devices satisfy the criteria to be grouped as a FAMILY with the registered medical devices, a new product registration application has to be submitted for the registration of these new medical devices. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

Examples:

- **Condoms** that differ in colour, size and texture but are manufactured from the same material, 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 of tubing, 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 flexibilities can be registered as a FAMILY if their variations fall within the scope of permissible variants.
- **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 registered as a FAMILY.

- **Contact lenses** with additional features of UV protection can be registered as part of a FAMILY, as this feature does not affect the basic design and manufacturing of the lens.
- **Contact lenses** are available as toric lens and spherical lens. These products have different intended purposes and performances. They are designed and manufactured differently. Due to these differences, they shall not be considered as members of a FAMILY.

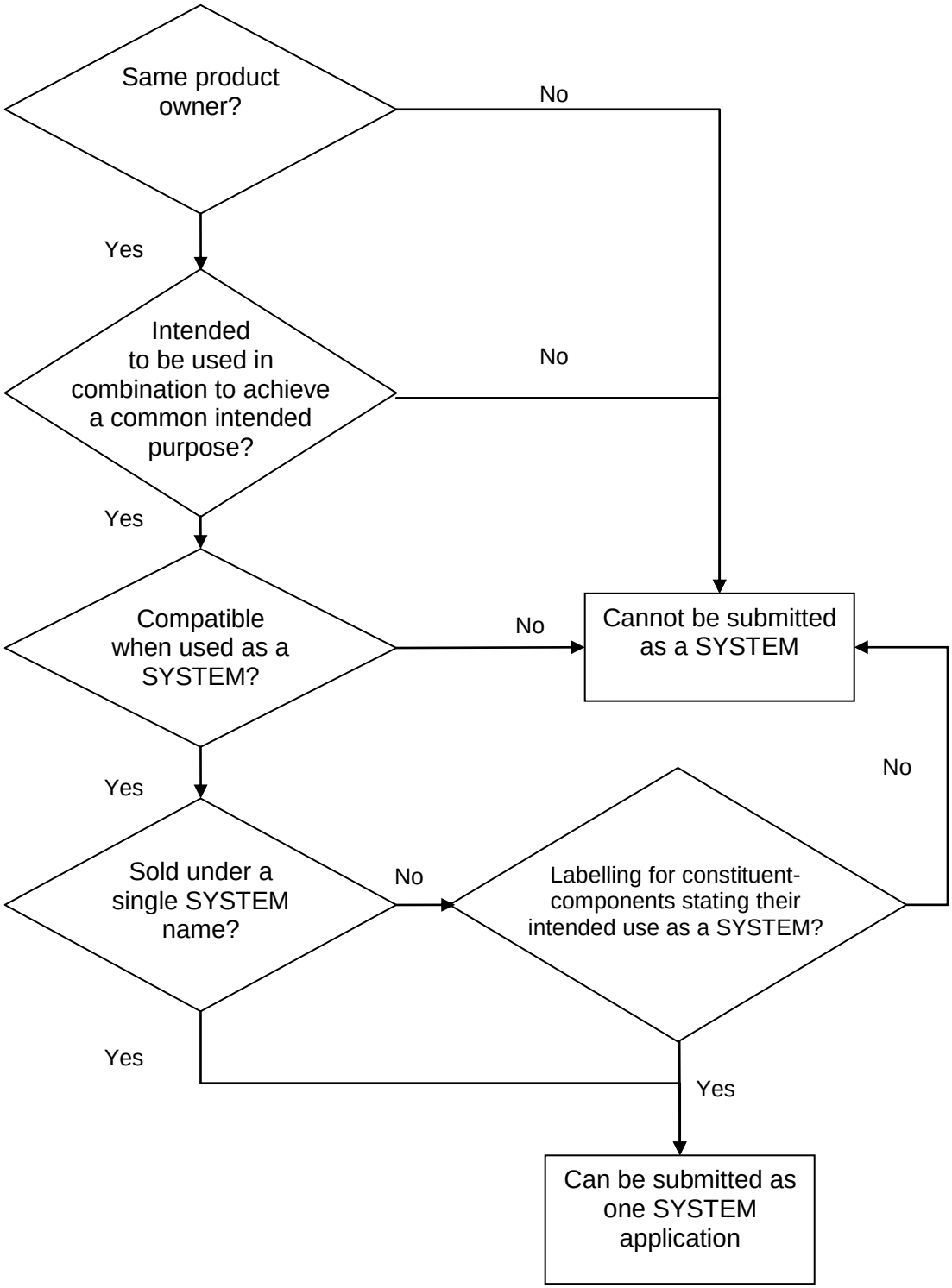
3.2. SYSTEM

A medical device SYSTEM comprises of a number of medical devices or accessories that are:

- from the same product owner;
- intended to be used in combination to achieve a common intended purpose;
- compatible when used as a SYSTEM; and
- sold under a single SYSTEM name or the labelling, IFU, brochures or catalogues for each constituent component states that the constituent component is intended for use with the SYSTEM.

Devices registered as part of a SYSTEM shall only be supplied specifically for use with that SYSTEM. Any device that is meant for supply for use with multiple SYSTEMs should be registered together with each of these other SYSTEMs. However, if these devices are compatible for use with one or multiple SYSTEMs from different product owners, they can be registered separately.

Decision Flowchart for Grouping of Medical Devices as a SYSTEM



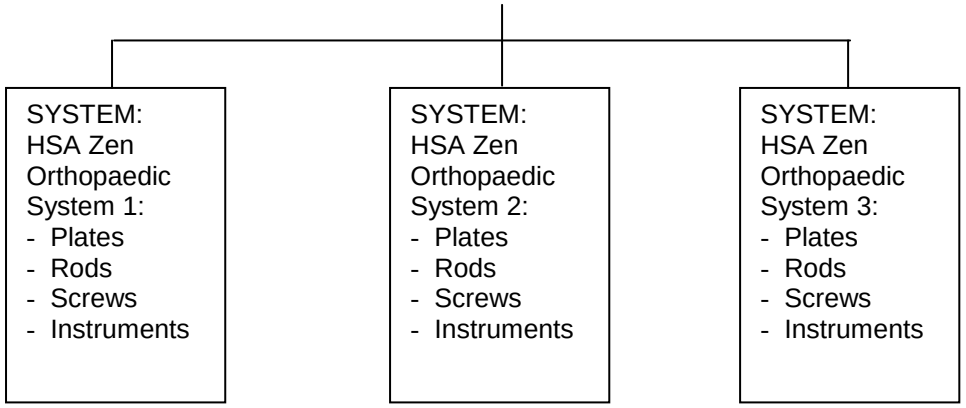
A product owner of a medical device SYSTEM may incorporate medical devices and/or accessories from other product owners as part of their SYSTEM to achieve the intended purpose of the device. These medical devices and/or accessories should be registered together under the SYSTEM grouping, and information on all these devices and accessories, such as authorisation from the other product owners for registration within the SYSTEM, evidence on use and compatibility with the SYSTEM shall be submitted.

Example:
A patient monitoring SYSTEM from **product owner A** is intended to be used specifically with vital signs sensors and probes from **product owner B**. These accessories are used in combination to achieve a common intended purpose in accordance with **product owner A's** specifications, and should be registered as part of the patient monitoring SYSTEM.

In addition, if several SYSTEMs fulfil the following conditions to be grouped as a FAMILY, they may be registered as a FAMILY (of SYSTEMs):

- the SYSTEMs are from the same product owner;
- the SYSTEMs are of the same risk classification;
- 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.

Individual SYSTEM names may contain additional descriptive phrases.



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

Figure 1 Example on Grouping of SYSTEMS as a FAMILY.

Examples:

- **A hip replacement SYSTEM** comprising of femoral and acetabular components can be registered 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 registered as a SYSTEM.
- **A catheter placement SET** 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 registered as a SYSTEM.

3.3. 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 product owner;
- 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.

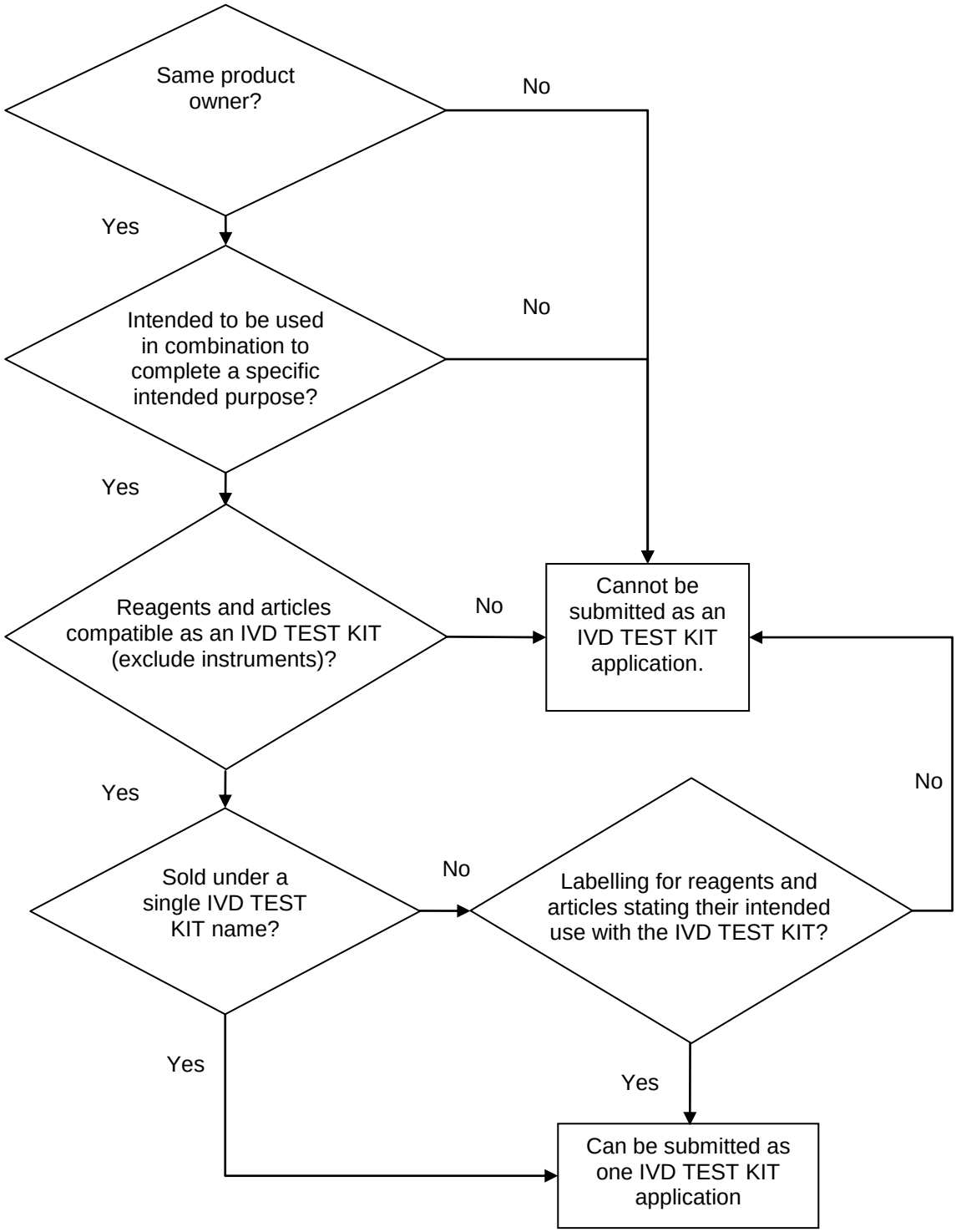
An IVD TEST KIT does not include the instruments, such as analysers, needed to perform the test.

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

Example:

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

Decision Flowchart for Grouping of Medical Devices as an IVD TEST KIT



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, such reagents or articles shall be included in the product registration application of each of the other TEST KITS.

Reagents or articles from another product owner may be registered with the IVD TEST KIT if the applicant furnishes all information on these reagents or articles required for registration, such as authorisation from the other product owners for registration and data to substantiate the performance of these reagents when used in the test kit.

Example:

- A **Human Immunodeficiency Virus (HIV) Enzyme Linked ImmunoSorbent 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 registered as a TEST KIT. These reagents and articles can be supplied separately as replacement items for that particular TEST KIT.

3.4. IVD CLUSTER

An IVD CLUSTER comprises of a number of *in vitro* diagnostic reagents or articles that are:

- from the same product owner;
- within risk classification of Class A or Class B;
- of a common test methodology as listed below; and
- of the same IVD CLUSTER category as listed below

The IVD CLUSTER may include analysers that are designed for use with the reagents in the IVD CLUSTER.

LIST OF IVD CLUSTER CATEGORIES

This list of IVD CLUSTER categories is only applicable to **Class A and Class B IVD** devices. 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:

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
1	Clinical Chemistry	Enzymes	(i) Acid Phosphatase (ii) Alpha-Amylase (iii) Creatine Kinase (iv) Gamma-Glutamyl Transferase (v) Lactate Dehydrogenase (vi) Lipase
2		Substrates	(i) Albumin (ii) Bilirubin (iii) Urea/Blood Urea Nitrogen (iv) Cholesterol (v) Creatinine (vi) Glucose

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
3		Electrolytes Reagents	(i) Ammonia (ii) Bicarbonate (iii) Calcium (iv) Chloride (v) Magnesium (vi) Phosphate Inorganic/Phosphorus
4		Electrolyte Electrodes	(i) Ammonia Electrodes (ii) Carbon Dioxide (Bicarbonate) Electrodes (iii) Calcium Electrodes (iv) Chloride Electrodes (v) Magnesium Electrodes (vi) Potassium Electrodes
5		Substrate Electrodes/ Biosensors	(i) Creatinine Electrodes (ii) Glucose Electrodes (iii) Glycated Hemoglobin Electrodes (iv) Lactate Electrodes (v) Urea Electrodes (vi) Bilirubin Electrodes
6	Immunochemistry	Immunoglobulins (without IgE).	(i) Immunoglobulin A (ii) Immunoglobulin D (iii) Immunoglobulin G (iv) Immunoglobulin M (v) Kappa and Lambda chain (vi) Immunofixation kits

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
7		Complement Components	(i) Complement Component C1q (ii) Complement Component C1 inactivator (iii) Complement Component C3/C3c (iv) Complement Component for Bb (v) Complement Component C4 (vi) Complement Component C5a
8		Transport Proteins	(i) Albumin (ii) Ceruloplasmin (iii) Haptoglobin (iv) Hemopixin (v) Lactoferrin (vi) Pre-albumin/Transthyretin
9		Lipoproteins	(i) Apolipoprotein A I (ii) Apolipoprotein A II (iii) Apolipoprotein B (iv) Apolipoprotein E Sub-typing (v) Lipoprotein (a)
10		Other Specific Proteins	(i) a1-Acid Glycoprotein (ii) a1-Antitrypsin (iii) a2-Macroglobulin (iv) a1-Microglobulin (v) Fibronectin (vi) Immuno Reactive Trypsin
11		Allergy	(i) Immunoglobulin E – Total (ii) Immunoglobulin E – Screen (iii) Immunoglobulin E – Specific, monotest/monoresult (iv) Allergen specific IgA (v) Allergen specific IgG

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
12		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
13		Thyroid Function Markers	(i) Free Triiodothyronine (ii) Free Thyroxine (iii) Thyroid Stimulating Hormone (iv) T – Uptake (v) Thyroglobulin (vi) Neonatal Thyroxine
14		Fertility/Pregnancy Hormones/ Proteins	(i) Androstenedione (ii) Estradiol (iii) Prolactin (iv) Human Chorionic Gonadotropin Total (v) Human Placental Lactogen (vi) Estriol
15		Diabetes Assays (Hormones)	(i) C-Peptide (ii) Glucagon (iii) Insulin (iv) Glycosylated/Glycated Haemoglobin (v) Islet Cell Ab (vi) Proinsulin

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
16		Renal Metabolism Assays	(i) Aldosterone (ii) Angiotensin I / II (iii) Angiotensin Converting Enzyme (iv) Cortisol (v) Renine
17		Bone and Mineral Metabolism Assays	(i) Bone Alkaline Phosphatase (ii) Calcitonin (iii) Cross-linked C-Telopeptides (iv) Cross-linkded N-Telopeptides (v) Cyclic Adenosin Monophosphate (vi) Hydroxyproline
18		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
19		Neuroendocrine Function Assays	(i) Bombesin (ii) 17-Hydroxy-Ketosterone (iii) β-Endorphin (iv) Neurotensin (v) Somatostatin (vi) Substance P

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
20		Other Individual and Specified Hormones	(i) Gastrin (ii) Gonadotropin-Releasing Hormone (iii) Melatonin (iv) Pepsinogen (v) Adrenalin (vi) Dopamine
21		Anaemia	(i) Erythropoietin (ii) Ferritin (iii) Folate (iv) Iron (v) Iron Binding Capacity (vi) Soluble Transferrin Receptor
22		Vitamins	(i) Vitamin B1 (ii) Vitamin B2 (iii) Vitamin B6 (iv) Vitamin B12 (v) Vitamin D (Cholecalciferol) (vi) Intrinsic Factor (Blocking Antibody)
23		Non-Immuno Suppressive Therapeutic Drug Monitoring	(i) Phenobarbitol (ii) Digitoxin (iii) Gentamicin (iv) Valproic Acid (v) Caffeine (vi) Theophylline (vii) Methotrexate

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
24		Immunosuppressive Therapeutic Drug Monitoring	(i) Cyclosporine (ii) Tacrolimus (iii) Rapamycin (Sirolimus) (iv) Mycophenolate
25		Toxicology	(i) Amphetamines (ii) Cocaine (iii) Barbiturates (iv) Morphine (v) Phencyclidine (vi) Acetaminophen (vii) Catecholamines (viii) Ethanol (ix) Salicylate
26		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
27		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 Screening
28		Liver Function	(i) MEGX (ii) Carbohydrate Deficient Transferrin

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
29		Cardiac Markers	(i) BNP/proBNP (ii) Creatine Kinase - MB (iii) Myoglobin (iv) Troponin I/T (v) Homocysteine (vi) High-Sensitivity C-Reactive Protein
30		Bacterial Infection - Immunology	(i) *Bacillus subtilis* (ii) *Escherichia coli*
31		Viral Infection - Immunology	(i) Influenza virus
32		Parasitic Infection - Immunology	(i) *Entamoeba histolytica* (ii) *Leishmania*
33		Fungal Infection - Immunology	(i) *Candida albicans* (ii) *Aspergillus*
34	Haematology/ Histology/ Cytology (Blood tests for transfusions excluded)	Hemoglobin Testing	(i) Hemoglobin determinations (Total Hb) (ii) Fractional oxyhemoglobin (FO2Hb) (iii) Fractional carboxyhemoglobin (FCOHb) (iv) Fractional methemoglobin (FMetHb) (v) Fractional deoxyhemoglobin (FHHb)
35		General Coagulation Tests	(i) Prothrombin Time (ii) Thrombin Time (iii) Activated Clotting Time (iv) Activated Partial Thromboplastin Time

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
36		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 XIII (x) Platelet Factor 4 (xi) Plasminogen
37		Other Hematology Tests	(i) Complete Blood count (ii) Hematocrit (iii) Erythrocyte Sedimentation rate
38		Cytokines (Lymphokines)/ Immunomodulators	(i) Interferons (ii) Soluble Antigens/Receptors (iii) Tumor Necrosis Factors (iv) Interleukins (v) Colony Stimulating Factors (vi) Tumor Necrosis Factors Receptors (vii) Interleukins Receptors
39		Histology/ Cytology Reagents	(i) Cytochemical Staining (ii) Embedding, Fixing, Mounting media (iii) Stain solutions (iv) Immunohistology kits

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
40	Microbiology - culture	Culture Media	(i) Dehydrated culture media (DCM) (ii) Additives for DCM (iii) Prepared Media (Tubes, bottles, Plates) (iv) Cells, Media, Serum for Viral culture
41		Susceptibility Testing Identification of bacteria by testing for the susceptibility of the bacteria to the certain antibiotics.	(i) Erythromycin susceptibility test for *Staphylococcus aureus* (ii) Tobramycin susceptibility test for *Pseudomonas aeruginosa* (iii) Fungal susceptibility testing
42		Biochemical culture Identification (ID)	(i) Gram Negative Manual ID (ii) Gram Positive Manual ID (iii) Other ID Kits Manual - Anaerobes, Fastidious (iv) Mycoplasma
43		Immunological culture Identification (ID)	(i) Streptococci Grouping Slide tests (ii) Serotyping (E.coli, Salmonella, Shigella etc.)
44		Nucleic Acid (NA) based culture identification (ID)	(i) NA Identification – MRSA (ii) NA Identification – Other resistance markers
45		Serological identification (ID)	(i) For Parasitology and Mycology (Fungi and Yeast)
46	Molecular Biology	Oncogenes Genes, whose mutation or enhanced expression, turns a normal cell into a cancer cell.	(i) p53 (ii) MYC (8q24) (iii) TERC (3q26)

S/N	Methodology	CLUSTER Category (closed list)	Examples of Analytes (non-exhaustive list)
47		Bacterial Infections (Detection by NA Reagents)	(i) Staphylococcal detection (ii) E.coli detection
48		Viral Infections (Detection by NA Reagents)	(i) Influenza and Para-influenza NA Reagents
49		Fungal Infections	(i) Fungi NA Reagents

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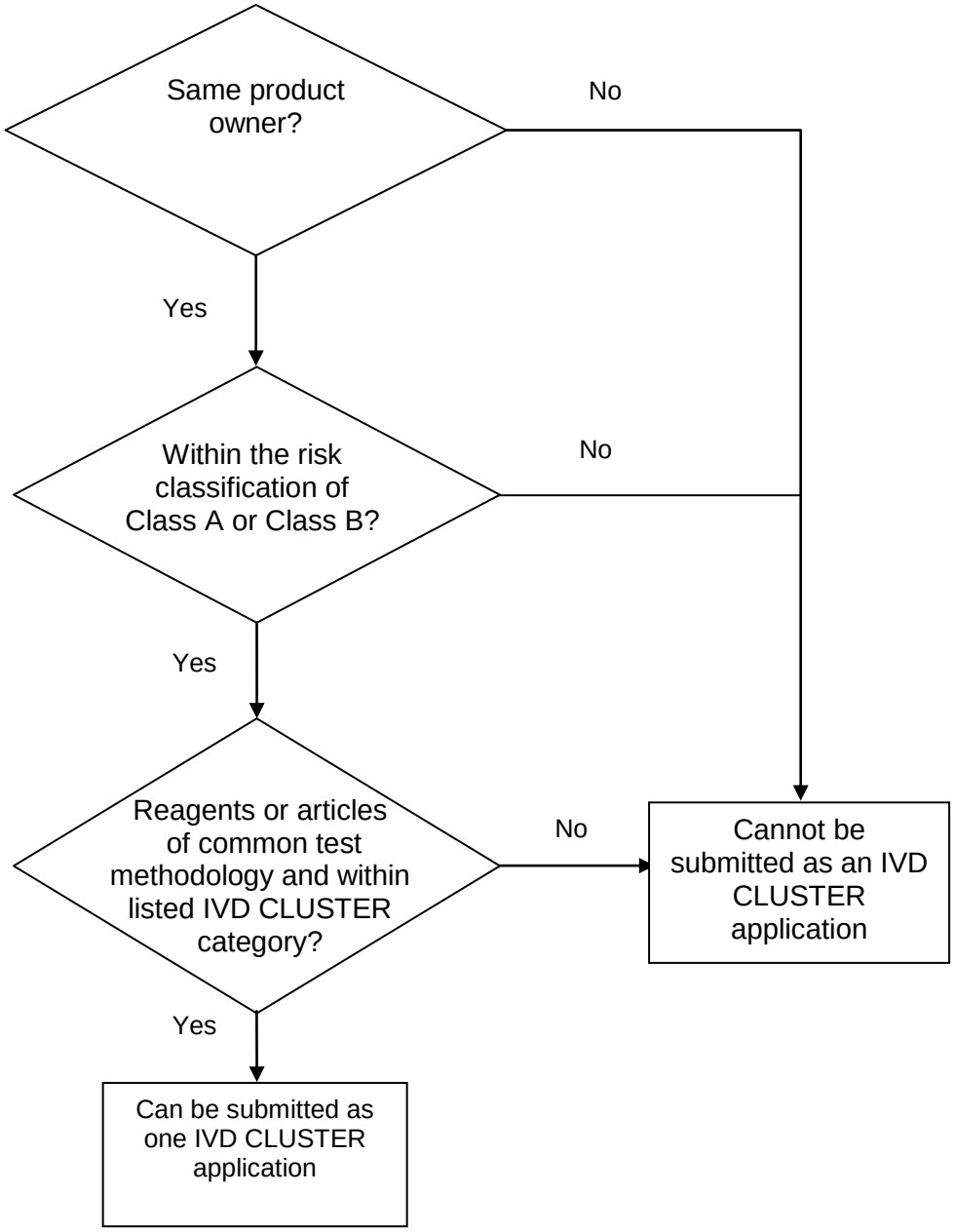
Decision Flowchart for Grouping of Medical Devices as an IVD CLUSTER



Information on all reagents or articles within an IVD CLUSTER must be submitted as part of one product registration application. Devices and articles that are listed as part of a CLUSTER can be supplied separately but solely for the registered intended purpose.

If a reagent or article is intended for multiple usage categories such that it can be grouped in more than one IVD CLUSTER, the Registrant 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 purposes of the reagent or article must be submitted as part of the product registration application.

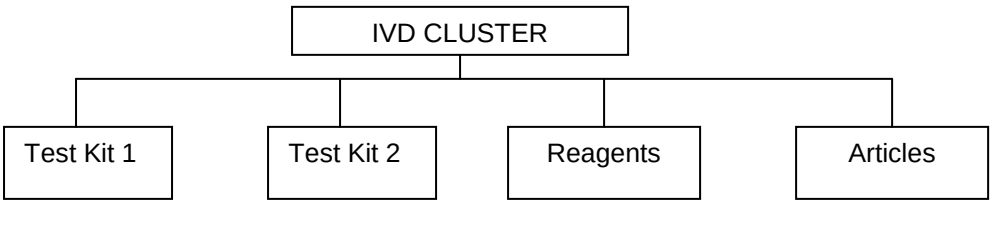


Figure 2 Example of an IVD CLUSTER.

Individual (single) reagents or articles, test kits or families of reagents or articles within an IVD CLUSTER (Figure 2), shall be listed separately on the SMDR.

3.5. GROUP

A medical device GROUP is a collection of two or more medical devices, supplied in a single package unit by a product owner. The medical device GROUP has the following:

- a single proprietary GROUP name, and
- a common intended purpose.

Each medical device in the GROUP may have different medical device proprietary names and intended purposes, and may be designed and manufactured by different product owners.

For the purposes of grouping for product registration, the collection of medical devices in a GROUP is the **closed list** of devices included in a product registration submission. This closed list of medical devices in a GROUP (single packaged unit) may differ in the number (quantity) and combination (permutation within the closed list) of products that comprise the GROUP, while maintaining the same proprietary GROUP name and the GROUP's intended purpose.

A product owner of the GROUP who assembles a GROUP together also assumes responsibility for the medical device GROUP and its intended purpose. The product owner of a medical device GROUP may incorporate medical devices from other product owners as part of their GROUP to achieve the common intended purpose. In manufacturing and assembling this GROUP of medical devices, the documents to substantiate the safety, quality and efficacy of the 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. Labelling, particularly the instructions for use (IFU), where applicable, shall clearly describe the common intended purpose of the GROUP.

Only medical devices within a GROUP that are eventually listed on the SMDR shall be supplied on the market as a single package unit. 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 replacements.

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

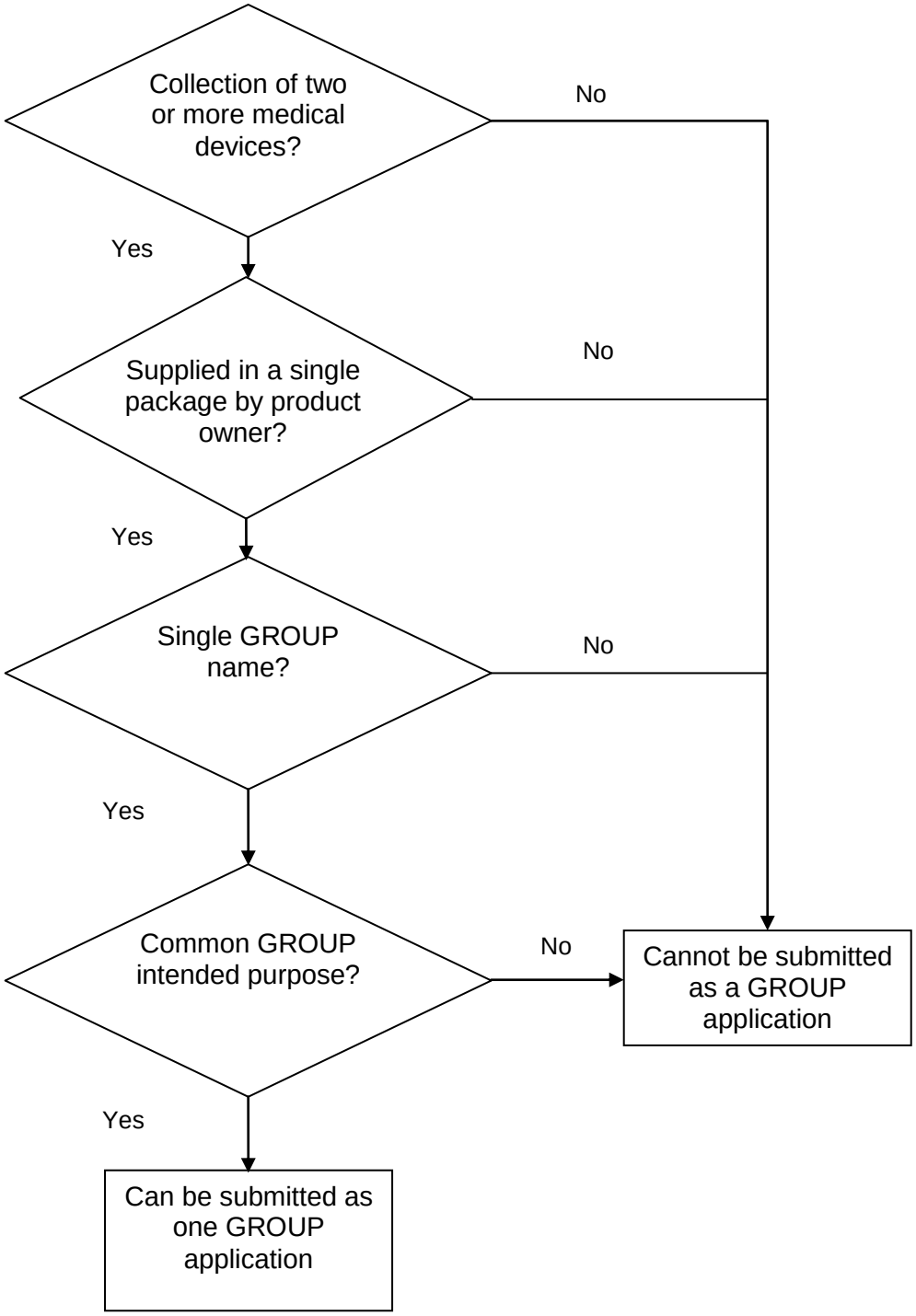
When the GROUP is registered, the product owner is able to customise for supply, any single packaged unit, from the closed list of devices for particular hospitals or physicians, while maintaining the same GROUP name and intended purpose. Thus, when the medical device GROUP is registered, any other combination (permutation within the closed list) in that GROUP can be supplied on the market for the registered intended purpose of the GROUP.

The GROUP name indicated for the medical device must appear in the product label affixed on the external package of the GROUP. The content list of devices within the single packaged unit for supply shall 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. Individual medical devices in the GROUP may contain additional descriptive phrases.

Examples:

- A **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 registered as a GROUP.
- A product owner supplies **dressing trays customised** with different quantity and type of gauze and sutures to different hospitals. When all the medical devices in the GROUP are registered individually, the product owner is able to customise the trays, from the closed 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.
- 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.

1 Decision Flowchart for Grouping of Medical Devices as a GROUP



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3.6. SINGLE

A SINGLE medical device is a medical device from a product owner identified by a medical device proprietary name or brand name with a specific intended purpose. Medical devices that cannot be assigned to a FAMILY, SYSTEM, IVD TEST KIT, IVD CLUSTER, GROUP or any other device specific grouping category defined in the GN-12-2 guidance document must be registered individually.

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

Medical devices that are registered as part of a GROUP must have a SINGLE medical device registration before they can be sold separately as individual medical devices.

Examples:

- Condoms that are sold in packages of 3, 12 and 144 can be registered as a SINGLE medical device.
- A company manufactures a standalone software program that can be used with a number of CT scanners produced by other product owners. 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.