Ethiopian Food and Drug Authority (EFDA)

Guideline for Medical Devices Bundling for Marketing authorization application

April 2021

Addis Ababa, Ethiopia

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1. Introduction

The Ethiopian Food and Drug Authority (EFDA) is mandated by proclamation 1112/2019 to regulate medical devices. As part of the regulatory functions, the authority is expected to register and grant marketing authorization after assessing quality, safety & effectiveness of medical devices. Article 19(1) of the same proclamation decrees that "the rigor of regulatory assessment of medicine &medical device shall be commensurate with products type, nature, & potential risk to human health". Various components or models of medical devices may be marketed individually or in different combinations as required by the end user, as convenient all in one-kit or as an individually customized pack based on the intended purpose. Hence, the authority has devised various mechanisms to carry out the assessments in a feasible and economical way that wouldn`t subject each single medical device to the same rigorous assessment procedure. Therefore, a medical device bundling criteria is needed to guide applicants during application submission for medical devices within one medical devices marketing authorization applications. In order to reduce the application processing time and to facilitate timely access of the products in the market, the authority permits bundling of medical device within a single premarket submission according to the criteria specified in this guideline. This guidelineis intended to provide general criteria for bundling medical devices within one medical devices marketing authorization application.All existing pertinent national regulatory requirements and authority`s other guidelines shall be rereferred for all medical devices marketing authorization applications submissions regardless of the way they are grouped. In the event of any contradiction between the contents of this guidelineand any written national law (proclamation, regulation and/or directives) the later should take precedence.

2. Scope

This guideline is applicable to all products that fall under the definition of medical devices for which marketing authorization applications are submitted to the Authority by applicants who wishes to bundle or group more than one medical device type, including in-vitro medical device, within one medical devices marketing authorization application. The grouping criteria described in this guideline will also be used as the guiding principles for all other device specialty or function specific grouping guidance documents that have been developed or to be developed in a distinct document.

3. Definitions

All definitions given in relation to medical devices in the proclamation 1112/2019 and subsequent regulation and directives should be applicable.

Bundling means the inclusion of multiple medical devices with the same intended purpose in a single premarket submission for the purposes of facilitating review and reasonably cut the user fee payment. Grouping is interchangeably used to describe the same concept.

Intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation. Intended useis interchangeably used to describe the same concept.

Proprietaryname means 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.Generic nameis interchangeably used to describe the same concept.

Invitro diagnosticmeans a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

Legal manufacturermeans any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.

Surgical instruments means instruments intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracing, clipping or other surgical procedure without connection to any other medical device.

4. General Principle of bundling

The major criteria for the bundlingshould consider the appropriateness of the grouped medical devices based on scientific justification and the cost effectiveness for both the applicant and the authority from the point of view of the suitability for an effective one review process. During bundling, the applicant should also consider devices specific attributes, such as those specific to invitro diagnostics devices, when categorizing devices for the purposes of grouping. To decide whether an application can be submitted for review ina single medical devices marketing authorization application, the applicant should ensure that

the supporting data are similar; review can be accomplished by primarily one reviewer and the devices are similar.

In general, the following three basic principles should be considered for grouping medical devices in to one marketing authorization application.

- The devices should have one generic name
- The devices should have one trade name (if any).
- The devices should be from one legal manufacturer or product owner.
- The devices should have one intended purpose

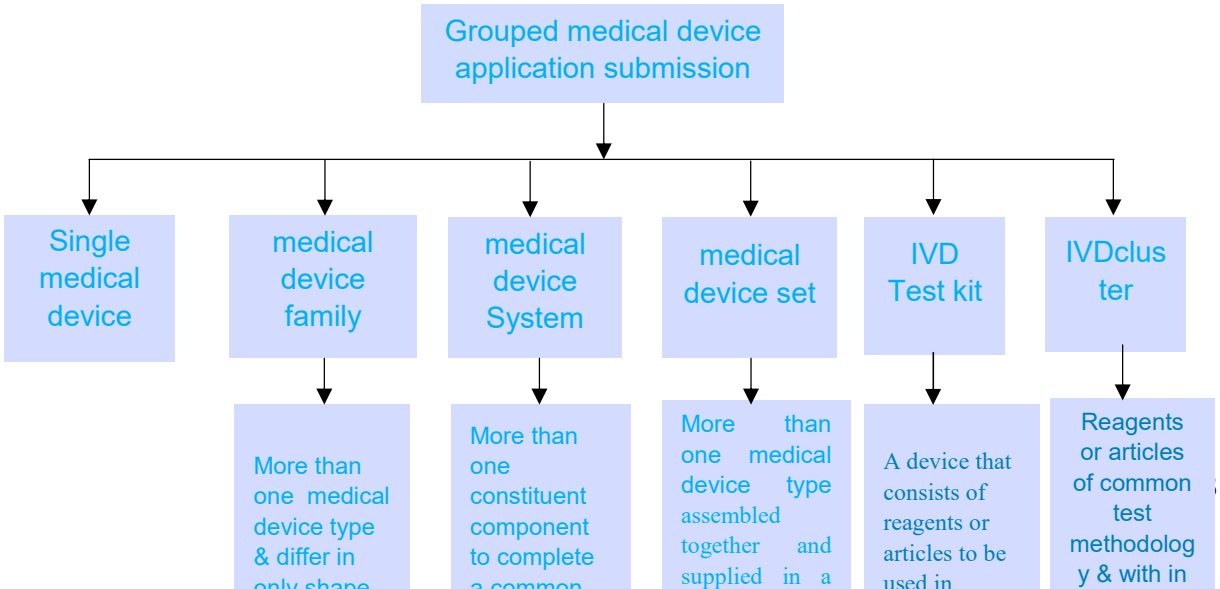
Each device or indication in a bundled submission must satisfy the applicable statutory and regulatory premarket requirements.

5. Bundling Criteria

The applicant may group medical devices having same or similar intended uses, intended purposes, from the same owner, orcommonality 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 groupedin to one of the following categories to be submitted in one application for evaluation & marketing authorization.

i. Single
ii. Family
iii. System
iv. Set
v. IVD test kits
vi. IVD Cluster

Summary flow chart for grouped medical devices application submission.



5.1. Single

A. Criteria

Application formarketing authorization of a medical device from a manufacturer identified by a proprietary name with specific intended purpose and sold asa distinct packaged entityis an application for single medical device. An application submitted as a single medical device may be:

a) For a medical device that is to be sold as a distinct packaged entity that may be sold in a range of package sizes, quantity, colour and does not meet the criteria for family, IVD test kit, system, IVD cluster or a set.

b) For a medical device that cannot be assigned to family, IVD test kit, system, IVD cluster or a setand that must be registered separately.

c) For medical device which was a part of a group that needs to be licensed separately before it is sold separately as individual medical devices.

d) Medical device that have different features cannot be bundled/grouped within one marketing authorization application as a single medical device. However, they may be bundled/grouped as a medical devices family (see section 5.2 in this document).

Note: Differences in models may include color, quantity, range of size, number of units…. etc.

B. **Examples of medical devices for which MA application might be submitted as a single device**

- Condoms to be sold in package of 3, 10 or 16 can be registered as a single medical device application.
- Gloves that are sold in packages of 25, 50, and 100 pieces
- Each medical device supplied individually must be licensed as a single medical device, if a company that assembles a first aid kit that has alreadyregistered its products has now decided to also supply each of medical devices in the first aid kit individually.
- If a company manufactures a standalone software program that can be used with a number of CT scanners produced by other manufacturers, although the software cannot function on its own, it can be used on

different scanners. In such instances, the software itself is deemed as a medical device and can be registered as a single medical device.

- A catheter with multi lengths.

5.2. Family

A. Criteria

A medical device family is a collection of medical devices which might have different features but each medical device family member fulfils the following:

a) each medical device family member is from the samelegal manufactureror product owner

b) the devices in the family have the same risk classification,

c) has a common intended purpose or use

d) has a common design and manufacturing process

e) has variations that are within the scope of the permissible variants. The characteristics of a medical device may be considered as permissible variant, if

i. the physical design and material of construction of the medical device are the same or very similar.

ii. the manufacturing processes, including sterilisation method, for the medical devices are the same or very similar.

iii. differences in features may include, material, structural characteristic, design, patient groups, energy source,purpose, brand name, model name or device description, area of application, additional function, additional secondary intended use/purpose.

iv. General and specific acceptable variations are provided in annex I of this document.

f) Surgical instruments that fulfil criteria listed (a) to (c)may be bundled/grouped within a singlemarketing authorization application as a family of medical devices based on function only if theydo not exceed 50 items per application.

g) Dental products that fulfil criteria listed (a) to (c) may be bundled within one marketing authorization application only if they havesame specialty.

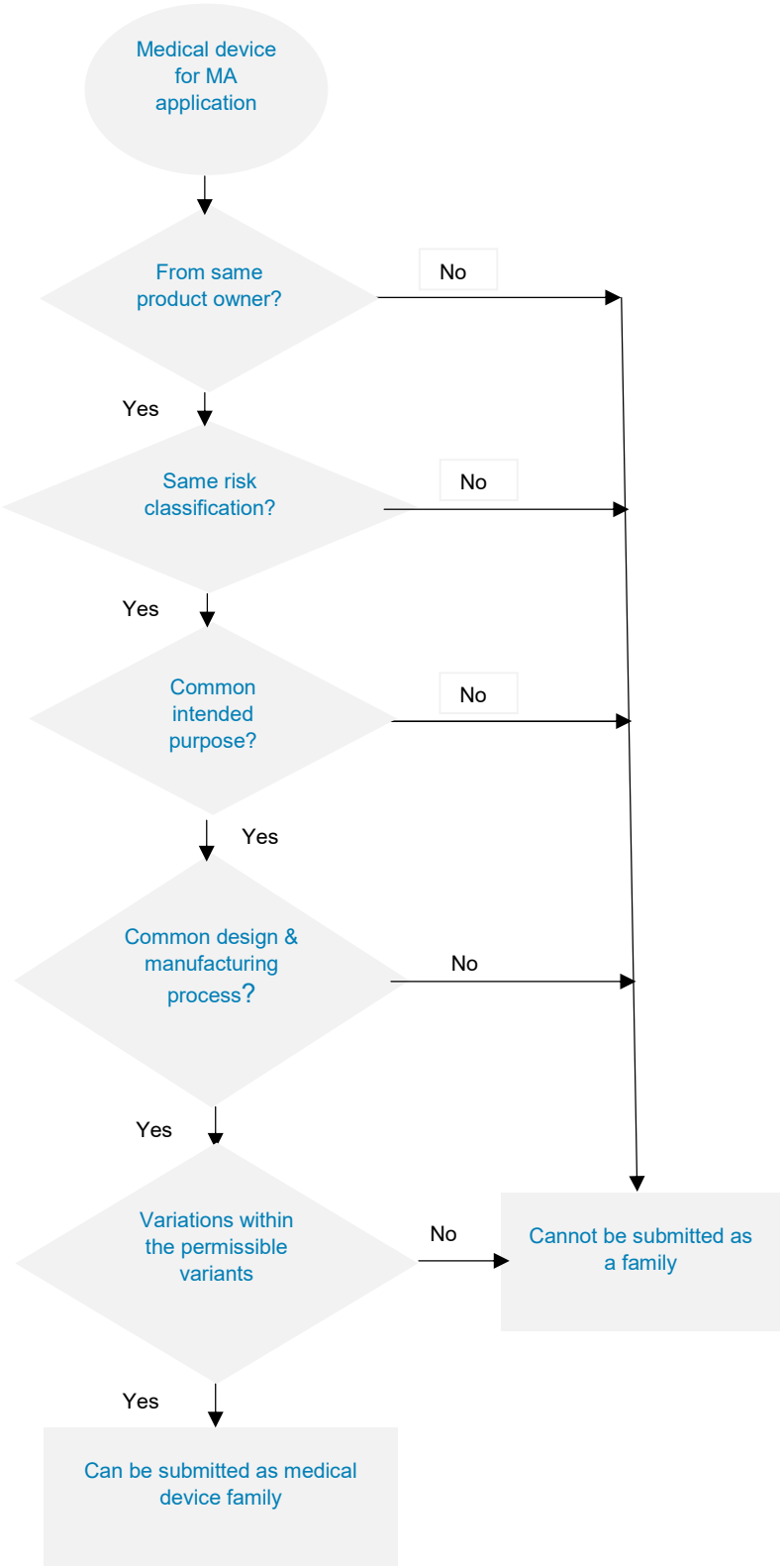
h) A special grouping rule is applicable for class I/ reusable surgical instruments(see annex III for this grouping rule).

B. Examples of medical devices for which the MA might be submitted in a single application as a family

a) Cardiac catheters that are available in a different numbers of lumens lengths & diameters can be grouped or bundled with in a single application as a family medical device
b) IV administration sets that differ in features such as safety features and lengths of tubing but are manufactured from the same material & manufacturing process and share a common intended purpose
c) Condoms that differ in colour, size and texture but are manufactured from the same material and manufacturing process and share a common intended purpose can be registeredas a family.
d) 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 or manufacturing of the lens. However, contact lens which are available as toric lens and spherical lens are designed and manufactured differently, and have different intended purposes and performances cannot be considered as members of a family due to these differences.
e) Other examples of Medical device family
    i. X-ray and mobile x-ray
    ii. Basic bedside monitor, bedside monitor with EEG module and bedside monitor with paper printer
f) Examples of surgical instruments that may be bundled within a single marketing authorization application as a "family of medical devices" based on function are as listed in table 1 below.

Function	**Examples**
cut or incise	scissors, knives, saws and blades
retract	traction and bone hooks
grasp, hold or occlude	tissue and bone holding forceps, also needle holders
dilate or probe	punch
cannulate or drain	catheters or any instrument used for drain
aspirate, inject or infuse	instrument to remove unwanted fluids as well as to inject fluids such syringes or some needles
suture or ligate	sutures, clips as well as suture needles and ligating blades

C. Decision flow chart for grouping of medical devices as a family



5.3. System

A. Criteria

A medical devices system comprises of several constituent components to complete a common intended purpose. To submit marketing authorization applications as a single application for such members(components) of a medical device, which might have their own distinctive intended uses/purposes but bundled to complete an overall common intended purpose, the following criteria/ principles shall apply:

a) General requirements for medical device system
   i. should be sold as medical device system under a single proprietary system name.
   ii. should be from same legalmanufacturer/ license holder
   iii. should be intended to be used in combination to complete a common intended purpose;
   iv. should be compatible when used as system; and
   v. should have a constituent component labelling instruction for use (IFU) brochures or catalogues which states that each constituent component is intended for use with the medical devicesystem.

b) For a constituent component in a system which is supplied for use in more than one system, such constituent components shall be included in the application for registration of each ofother system.

c) If several systems fulfil the following conditions to be grouped as afamily, they may be registered as a family:
   i. the systems are from the same manufacturer;
   ii. the systems are of the same risk classification class;
   iii. the systemshave a common intended purpose;
   iv. the systems have the same design and manufacturing process; and
   v. key constituent-components of the systems have variations that are within the scope of the permissible variants.
   vi. has the same generic name
   vii. has the same trade name

d) An In Vitro Diagnostic (IVD) Medical Device systems may typically consist of Test kits and instruments (e.g. an analyzer designed to be used with that Test kit).

e) Medical devices and/or accessories from other product owners (or manufacturers) may be incorporated as part of a product owners 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 all 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.

B. **Examples of medical devices for which the MAapplication might be submitted in a single application as a system**

i. 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.

ii. 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.

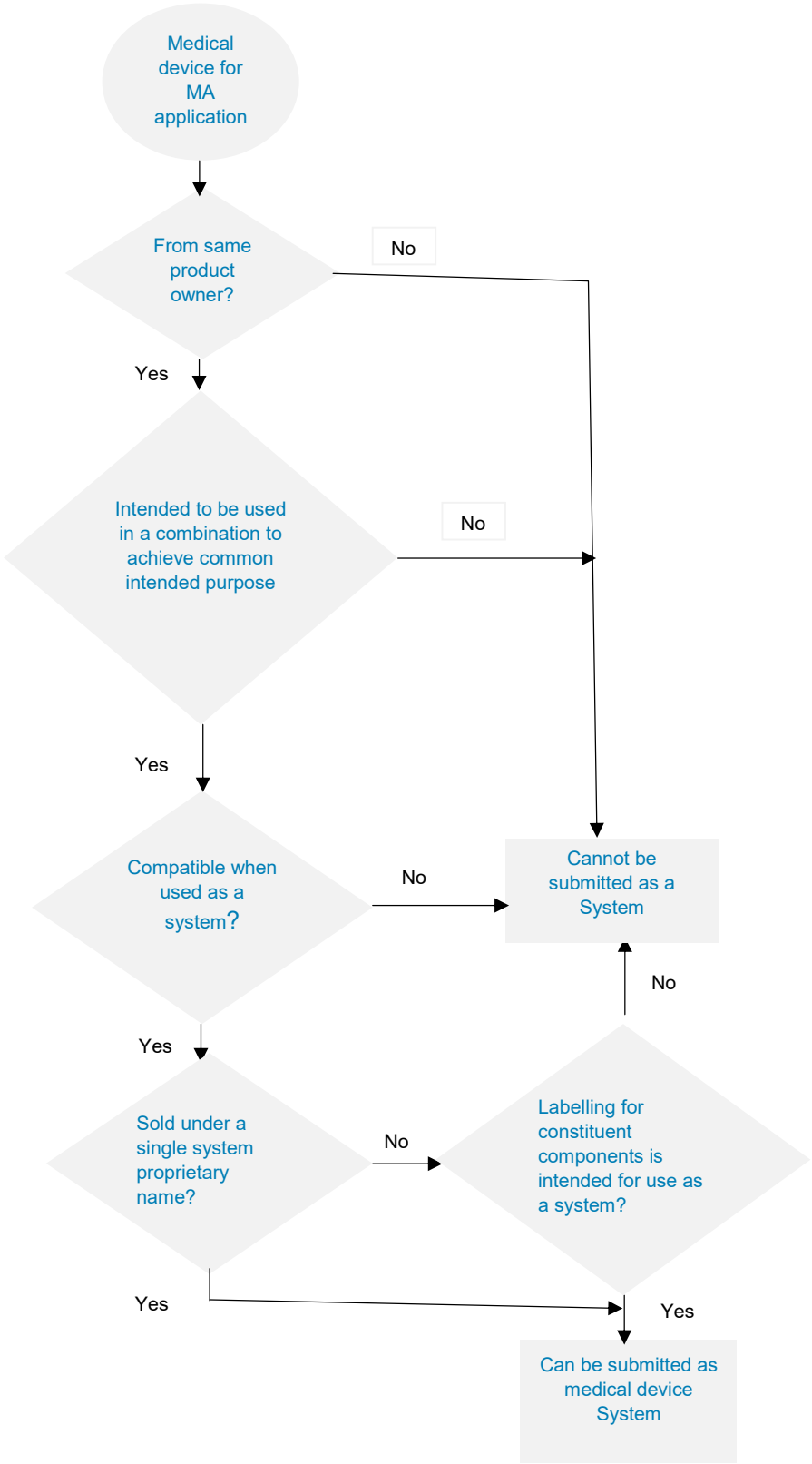
iii. Optional accessory such as wireless controller that is part of In-the-ear hearing aid can be registered as a system.

iv. A glucose monitoring system comprising of a glucose meter, test strips, control solutions and linearity solutions can be grouped/bundled with in a single application of marketing authorization and registered as a system.

f) If the items of the system have different risk-classes, the highest risk-class will be considered.

g) If the applicant wishes to market any item of the system separately, he shall apply for another marketing authorization application.

C. Decision flow chart for grouping of medical devices as a system



5.4. Set

A. Criteria

A medical device set is a collection of two or more medical devices, assembled together and supplied in a single package by the same legal manufacturer /license holder.

a. The medical devices set should:

(i) Be sold under a single proprietary name

(ii) Have a common intended use

b. The collection of medical devices in a set may differ in the number and combination of products that comprises each group, while maintaining the same proprietary group name and group's intended purpose.

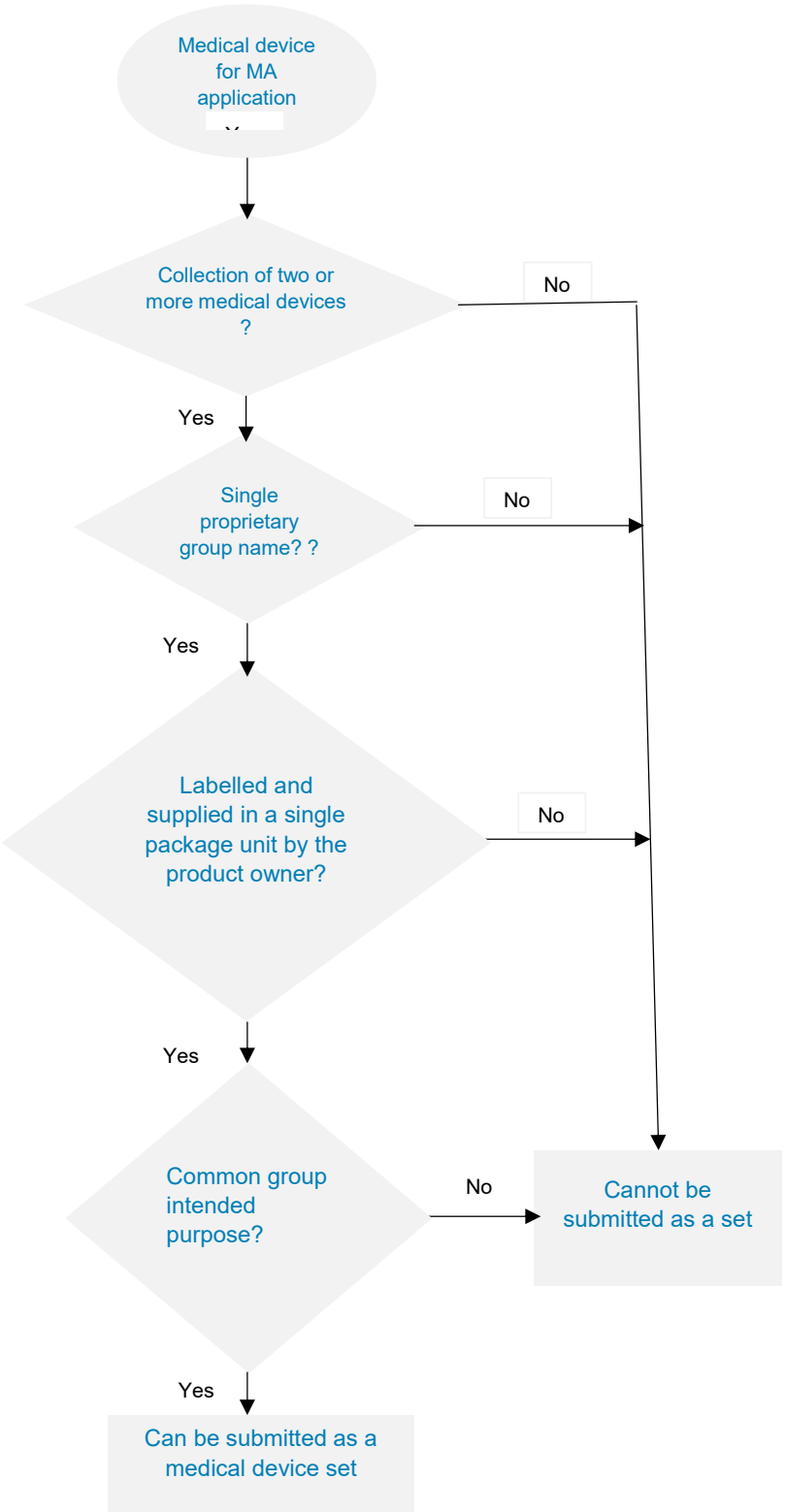
c. If the medical device in a setis supplied for use in another group, such a medical device shall be included in the application of that other set.

B. **Exampleof medical devices for which the MA application might be submitted in a single application as a set**

A first aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package, can be registered as a set.

Dialysis kit consisting of medical devices such as blood tubing lines and dialysers when packaged together for convenience to meet a specific purpose by a manufacturer can be applied as a set in a single marketing authorization application.

C. Decision flow chart for grouping of medical devices as a set



5.5. IVD test Kit

A. Criteria

An *in-vitro* diagnostics kit that consists of reagents or articles may be bundled/grouped within one marketing authorization application only if:

a. theyconsists of reagents or articles which are:-

(i) from same legal manufacturer/ license holder

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

(iii) sold under single proprietary Test Kit name or the labelling instructions for use (IFU) brochures or catalogues for each reagent or article states that component is intended for use with the IVD test kit; and

(iv) compatible when used as a Test Kit.

b. An *in-vitro* diagnostics kit does not include the instruments, such as analysers, needed to perform the test.

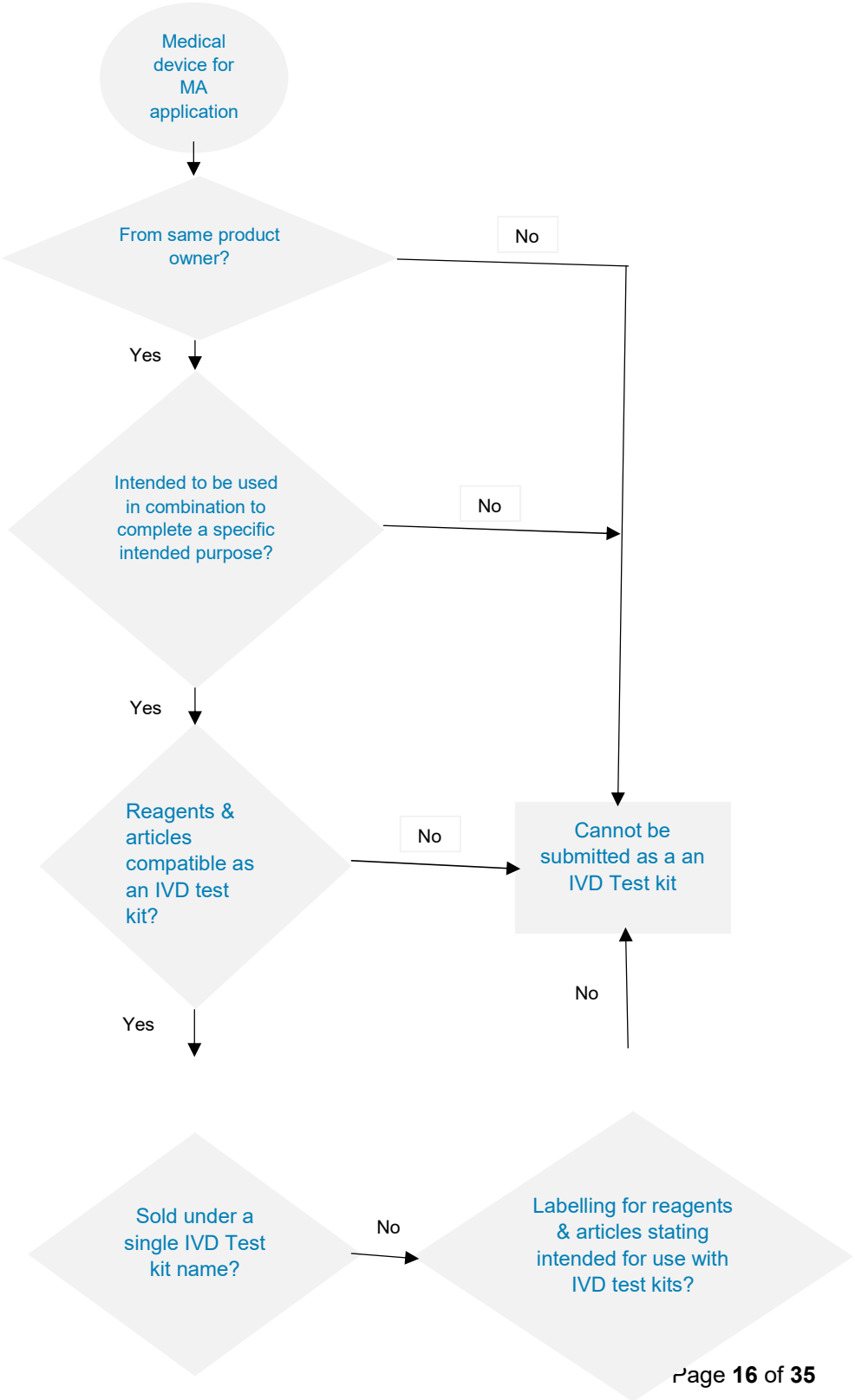
c. Individual reagents or articles can be supplied separately as replacement items for kit. If the reagents or articles in a Test Kit are supplied for use in more than one Test Kit, such reagents or articles shall be included in the application of the other Test Kits.

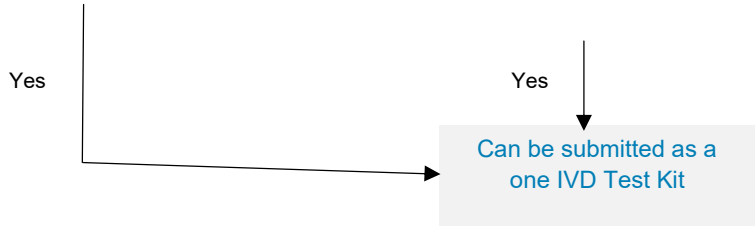
d. Total number of IVD medical device that are grouped/bundled within a single application of grouped medical devices shall not exceed 50 items within a single application.

B. **Exampleof medical devices for which the MA application might be submitted in a single application as IVD**

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 Test Kit. These reagents and articles can be supplied separately as replacement items for that particular Test Kit.

C. Decision flow chart for grouping of medical devices as a IVD Test Kit





5.6. *In vitro* diagnostics cluster

A. Criteria

An in-vitro diagnostics cluster comprises of a number of*in-vitro* diagnostics reagents or articles and they should fulfil the following criteria to be submitted as one application.

(i) They should be from same legalmanufacturer/ license holder;

(ii) They should be sold under single proprietary name;

(iii) They should be within the risk classification of A or B

(iv) They should be intended for a common test methodology;

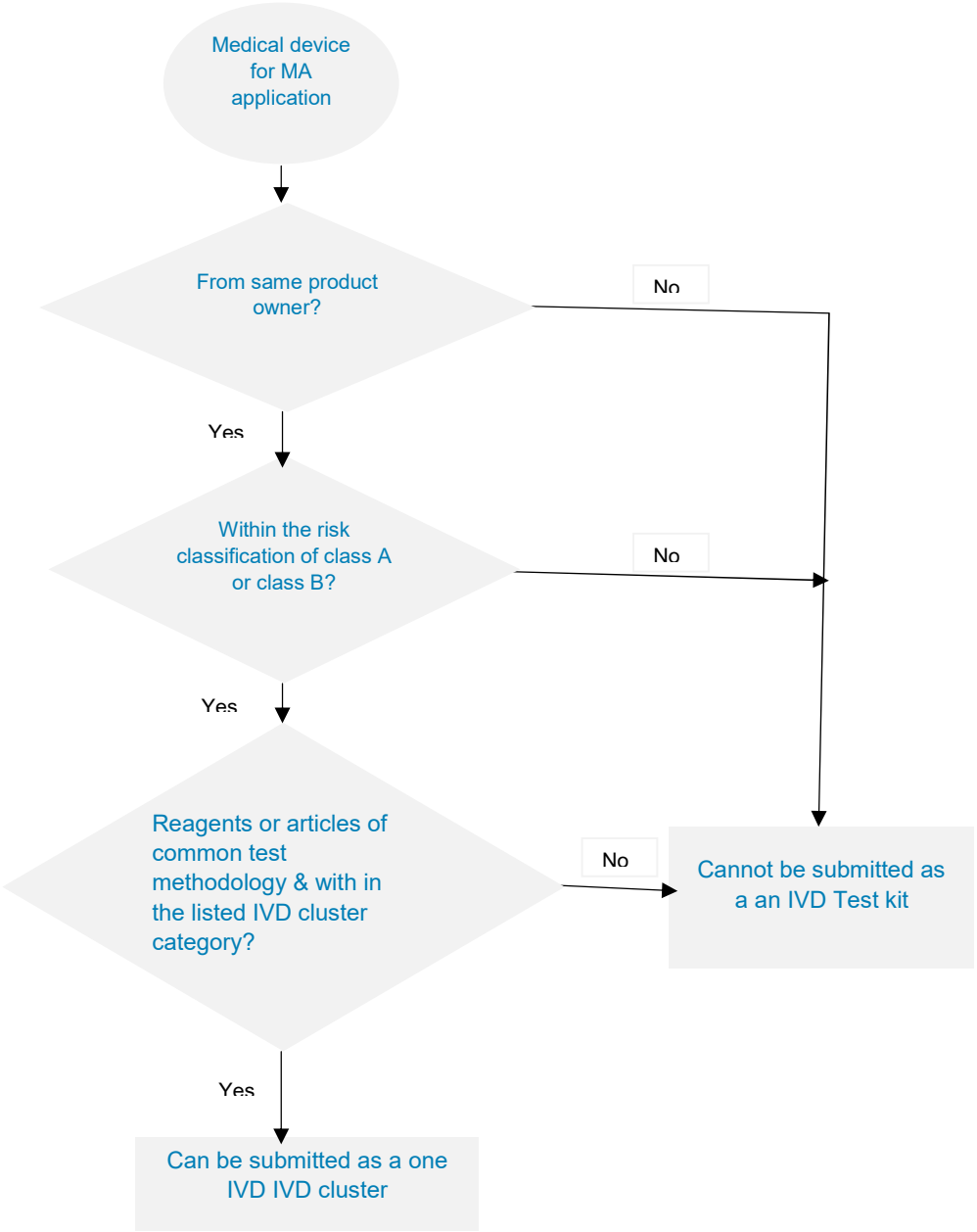
(v) They shouldbe under the same cluster category

(vi) Should be compatible when used as anIVD cluster.

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

A closed list of common test methodologies and IVD cluster categories is provided in AnnexII of this document.

B. Decision flow chart for grouping of medical devices as a IVD cluster



6. Application submission process

a) Applicants shall refer to other relevant guidelines for the administrative and technical documents to be submitted and service fees.

b) The authority will not accept adding more devices or indications for use to a submission which is under review and hence bundling should occur before the application is submitted to the authority. If they have to submit more devices or indications with justifiable scientific reasons and intended use of the grouped medical devices as addition to the submission under review, the applicant can request for such addition provided that the added devices comply with the relevant grouping criteria.

c) Applicants may withdraw a device(s) (or indication for use) from a bundled submission if they have satisfactory reason. But, if they resubmit the device(s) or indication for use in a new application, it will be considered as new application and they will be required to pay the service fee for theresubmission.

d) Applicants should not bundle multiple intended uses of a single test system (or indications for use such as professional and to be used by lay person), because it is unlikely that such multiple uses would be supported by the same data sets.

e) If a submission includes a device or indication that should not be bundled because it presents disparate scientific/clinical or regulatory issues (from the other devices or indications in the submission), the authority will notify the applicant to withdraw the device or indication from the bundled submission. The applicant may resubmit the device or indication for use in a separate submission, withdraw the device or indication for use, withdraw the entire application, or appeal the decision. However, the frequency of resubmissions shall not exceed a maximum of two times.

7. Post registration

The registrant is always required to comply with the conditions applicable to the registered medical device and conditions imposed on the MA holder. The MA holder shall undertake the following post-market activities for all medical devices and accessories approved by the authority as part of grouped/bundled medical devices registrations. Such duties and obligations shall include all the constituent-components registered in a group, regardless of whether the constituent components are from the same product owner or no

7.1. Post approval Notification

The MA holder shall submit post approval change notifications to the authority for any changes made to the registered medical device in accordance with the guideline for post approval notification. Whenever a product; include a single member of a bundled medical devices, has been withdrawn from the market for any reason (such as deficiencies in product quality defect or ADE reports) in other countries, the local agent or the manufacturer should notify EFDA as per the article 67(17) of proclamation No 1112/2019.

7.2. **Re-registration**

As per article 20(6) of the currently in force EFDA`s law, every medical devices registered in accordance with the proclamation shall have its registration renewed every five years (Marketing authorizations granted by EFDA will be valid for 5 years. Hence, marketing authorization holders should submit applications for re-registration of allmedical devices in accordance with the requirements for re-registration stated in the Authority`s guideline for re-registration of medical devices.

7.3. Retaining Records and reporting

The registrant is expected to maintain records of supply and any complaints, as well as to report any defects and adverse effects to the Authority. The MA holder shall notify the authority any actions taken concerning field safety corrective action (FSCA), including recall

8. Annexes

Annex 1: 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 (iii) Curvature (straight or pigtail) Polymer products-with or without DEPH Stent- delivery system, that is over-the –wire or through the scope
I V 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 hand-piece
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
Polymer Products	(i) With or Without DEHP
Stent	1)Delivery system, that is over –the-wire or through the scope

Other permissible variants

Other permissible variants in general
Colour
Diameter
Flexibility
Gauge
Holding force
Isotope activity level
Length
Memory storage
Print capability
Radiopacity
Shape
Size
Volume
Width

Viscosity (The change in viscosity is solely due to changes in the concentration of constituent material
Type of monitoring (e.g. ceiling mount, wall mount or standing) Dimensional design differences due to pediatric versus adult use (the differences due to the different patient population are permissible, e.g. volume and length)

ANNEX II: List of IVD Cluster Categories

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

S. No	Methodology	Cluster Category (closed list)	Examples of Analytes (non-exhaustive list)
1	Clinical Chemistry	Enzyme	(i) Acid Phosphatase (ii) Alpha-Amylase (iii) Creatine Kinase (iv) Gamma-GlutamylTransferase (v) Lactate Dehydrogenase (vi) Lipase
2		Substrate	(i) Albumin (ii) Bilirubin (iii) Urea/Blood Urea Nitrogen (iv) Cholesterol

			(v) Creatinine (vi) Glucose
3		Electrolyte 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) GlycatedHemoglobin 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
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 Protein	(i) Albumin (ii) Ceruloplasmin (iii) Haptoglobin (iv) Hemopixin (v) Lactoferrin (vi) Pre-albumin/Transthyretin
9		Lipoprotein	(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) Allergene specific IgA (v) Allergene specific IgG
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
16		Renal metabolism assay	(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
20		Other Individual and Specified Hormones	(i) Gastrin (ii)Gonadotropin-Releasing Hormone (iii) Melatonine (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
24		Immunosuppressive Therapeutic Drug Monitoring	(i) Cyclosporine (ii) Tacrolimus (iii) Rapamycin (Sirolimus) (iv) Mycophenolate
25		Toxicology	(i) Amphetamines (ii) Cocaine (iii) Barbiturates (iv) Morphines (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
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) Entamoebahistolytica (ii) Leishmania
33		Fungal Infection - Immunology	(i) Candida albicans (ii) Aspergillus
34	Haematology (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
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	Histology/Cytology	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
40	Microbiology -	Culture media	(i) Dehydrated culture media

	culture (i) Cytochemical Staining (ii) Embedding, Fixing, Mounting media (iii) Stain solutions (iv) Immunohistology kits		(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	(i) p53

		enhanced expression, turns a normal cell into a cancer cell.	(ii) MYC (8q24) (iii) TERC (3q26)
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

Annex III: Special Grouping Rule for Class I ReusableSurgical Instruments

A special grouping rule is applicable to Class I reusable surgical instruments. The special grouping rule states that reusable surgical instruments can be grouped together as 1 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 I lung retractor and Class I 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 I reusable surgical instruments. It is not applicable to Class II, III and IV 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		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 I medical devices.

These forceps can be grouped as a family and registered as part of one application on the basis of the special grouping rule for Class I reusable surgical instrument because:

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