MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

No. 39/2016/TT-BYT

Hanoi, October 28, 2016

CIRCULAR

CLASSIFICATION OF MEDICAL DEVICES

Pursuant to the Government's Decree No. 63/2012/NĐ-CP dated August 31, 2012 defining the functions, tasks, powers and organizational structure of the Ministry of Health;

Pursuant to Clause 5 Article 5 of the Government's Decree No. 36/2016/NĐ-CP dated May 15, 2016 on management of medical devices;

At the request of Director of Health Device and Work Department,

The Minister of Health promulgated a Circular on classification of medical devices.

Article 1. Classification of medical devices

1. Medical devices are classified into 4 classes (A, B, C, D) according to the rules specified in Appendix I enclosed herewith.

2. Medical devices are classified into 4 classes (A, B, C, D) according to the grouping principles specified in Appendix II enclosed herewith.

Article 2. Effect and responsibility for implementation

1. This Circular comes into force from December 15, 2016.

2. Organizations qualified for classification of medical devices shall apply the rules mentioned in Article 1 of this Circular. Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Health for consideration./.

PP MINISTER
DEPUTY MINISTER

Nguyen Viet Tien

APPENDIX I

RULES FOR CLASSIFICATION OF MEDICAL DEVICES

(Promulgated together with Circular No. *39/2016/TT-BYT dated October 28, 2016 of the Minister of Health)*

RULES FOR CLASSIFICATION OF MEDICAL DEVICES

Part I

DEFINITIONS

For the purposes of this document, the terms below are construed as follows:

1. *Active medical device* means any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements to between an active medical device and the patients, without any significant change, are not considered to be active medical devices.

Note: Standalone software (to the extent it falls within the definition of a medical device) is deemed to be an active device.

2. *Active therapeutic device means any medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.*

3. *Active device intended for diagnosis means any medical device, whether used alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.*

4. *Body orifice means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.*

5. *Central circulatory system* means the major intern blood vessels including the following:

a) Pulmonary artery (Arteriae pulmonales)

b) Ascending aorta (Aorta ascendens)

c) Coronary artery (Arteriae coro nariae)

d) Common carotid artery (Arteria carotis communis)

e) External carotid artery (Arteria carotis externa)

f) Internal carotid artery (Arteria carotis interna)

g) Cerebella arteries (Arteriae cerebrates)

h) Brachiocephalic trunk (Truncus brachiocephalicus)

i) Thoracic aorta (Thoracica aorta)

j) Abdominal aorta (Abdominalis aorta)

k) Common iliac arteries (Arteriae ilica communis)

l) Descending aorta to the bifurcation of aorta (Aorta descendens to the bifurcatio aortae)

m) Aortic arch (Arcus aorta)

n) Cardiac veins (Venae cordis)

o) Pulmonary vein (Venae pulmonales)

p) Superior vena cava (Venae cava superior)

q) Inferior vena cava (Venae cava inferior)

6. *Central nervous system* refers to the brain, meninges and spinal cord.

7. *Continuous use* of a medical device means the uninterrupted use of the medical device, not including any temporary interruption of its use during a procedure or any temporary removal or the medical device for purposes such as cleaning or disinfection; or the accumulated use of the medical device by replacing it immediately with another medical device of the same type, as intended by its product owner.

8. *Transient use* means continuous use for less than 60 minutes.

9. *Short-term use* means continuous use for between 60 minutes and 30 days.

10. *Long-term use* means continuous use for more than 30 days.

11. *Immediate danger* means a situation where the patient is at risk of either losing life or an important physiological function if no preventative measure is taken.

12. *Invasive medical device* means a medical device which, in whole or in part, penetrates inside the body either through a body orifice or through the surface of the body, including: implantable medical devices, surgically invasive medical devices, medical devices through body orifices and medical devices through body surface.

13. *Implantable medical device* means any medical device which is, through surgical intervention, intended to be totally introduced into the human body or to replace an epithelial surface or the surface of the eye, including those intended for partial introduction into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days.

14. *Surgically invasive medical device* means an invasive medical device that penetrates inside the body through the surface of the body with the aid of surgical operation, including medical devices that penetrate inside the body other than through a natural body orifice.

15. *In vitro diagnostic (IVD) medical device for self-testing* means any IVD medical device intended by the product owner for use by lay persons.

16. *Near-patient testing* means any testing performed outside a laboratory environment or at the side of the patient.

17. *Reagent* means any chemical, biological or immunological components solutions or preparations intended by the product owner to be used as IVD medical devices.

18. *Specimen receptacle* means an IVD medical device, whether vacuum-type or not, specifically intended by their product owner for the primary containment of specimens derived from the human body.

19. *Transmissible agent* means an agent capable of being transmitted to a person, as a communicable, infectious or contagious disease.

20. *Transmission* means the conveyance of a disease to a person.

21. *Life supporting or life sustaining device* means a medical device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Part II

RULES FOR CLASSIFICATION OF MEDICAL DEVICES OTHER THAN IVD MEDICAL DEVICES

A. NON-INVASIVE OF MEDICAL DEVICES

Rule 1. All non-invasive medical devices which come into contact with injured skin:

1. are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only i.e. healing they heal by primary intent.

2. are in Class B if they are intended to be used principally with wounds which have breached the dermis, including medical devices principally intended to manage the microenvironment of a wound.

3. Unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.

Rule 2. Non-invasive medical devices intended for channeling or storing

All non-invasive medical devices intended for channeling or storing body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class A, unless:

1. they may be connected to an active medical device in Class B or a higher class, in which case they are Class B.
2. they are intended for channeling blood, storing or channeling other body liquids, or storing organs, parts of organs or body tissues, in which case they are Class B.
3. they are blood bags, in which case they are Class C.

Rule 3. Non-invasive of medical devices intended for modifying the biological or chemical composition

All non-invasive medical devices intended for modifying the biological or chemical composition of blood, other bodily liquids or other liquids intended for infusion into the body are in Class C, unless the treatment consists of filtration, centrifuging or exchanges of gas or heat, in which case they are in Class B.

Rule 4. Other non-invasive of medical devices

All other non-invasive medical devices are in Class A.

B. INVASIVE OF MEDICAL DEVICES

Rule 5. Invasive of medical devices with respect to body orifices other than those surgically invasive

1. All invasive medical devices with respect to body orifices (other than those which are surgically invasive) and which are not intended for connection to an active medical device, or are intended for connection to a Class A medical device only are in Class A if they are intended for transient use. Unless they are intended by its product owner for use on the external surface of any eyeball; or it is liable to be absorbed by the mucous membrane, in which case they are in Class B.
2. All invasive medical devices with respect to body orifices (other than those which are surgically invasive) and which are not intended for connection to an active medical device, or are intended for connection to a Class A medical device only are in Class B if they are intended for short-term use. Unless they are intended for use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A.
3. All invasive medical devices with respect to body orifices (other than those which are surgically invasive) and which are not intended for connection to an active medical device, or are intended for connection to a Class A medical device only are in Class C if they are intended for long-term use. Unless they are intended for use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.
4. All invasive medical devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class are in Class B.

Rule 6. Surgically invasive medical devices intended for transient use

All surgically invasive medical devices intended for transient use are in Class B, unless:

1. They are reusable surgical instruments, in which case they are in Class A.
2. They are intended to supply energy in the form of ionising radiation, in which case they are in Class C.
3. They are intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C.
4. They are intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C.

5. they are they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D.

6. they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.

Rule 7. Surgically invasive medical devices intended for short-term use

All surgically invasive medical devices intended for short-term use are in Class B, unless:

1. They are intended to administer medicinal products, in which case they are in Class C.

2. They are intended to undergo chemical change in the body (except the medical devices are placed in the teeth), in which case they are in Class C.

3. They are intended to supply energy in the form of ionising radiation, in which case they are in Class C.

4. They are intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class D.

5. They are they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D.

6. They are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.

Rule 8. Surgically invasive medical devices intended for long-term use and implantable medical devices

All surgically invasive medical devices intended for long-term use and implantable medical devices are in class C, unless:

1. They are intended to be placed into the teeth, in which case they are in Class B.

2. They are they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D.

3. They are intended to be life supporting or life sustaining, in which case they are in Class D.

4. They are intended to be active medical devices, in which case they are Class D.

5. They are intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class D.

6. They are intended to administer medicinal products, in which case they are in Class D.

7. They are intended to undergo chemical change in the body (except the medical devices are placed in the teeth), in which case they are in Class D.

8. They are breast implants, in which case they are in Class D.

C. ACTIVE MEDICAL DEVICES

Rule 9. Active therapeutic medical devices

All active therapeutic medical devices intended to administer or exchange energy are in Class B, unless:

1. Their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionising radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.

2. They are intended to control or monitor the performance of active therapeutic medical devices in Class C, or intended directly to influence the performance of such medical devices, in which case they are in Class C.

Rule 10. Active medical devices intended for diagnosis

1. Medical devices used to illuminate the patient’s body with light in the visible or near infra-red spectrum are in Class A.

2. Active medical devices intended for diagnosis are in Class B if:

a) They are intended to supply energy which will be absorbed by the human body; except for those specified in (a);

b) They are intended to image in vivo distribution of radiopharmaceuticals;

c) They are intended to allow direct diagnosis or monitoring of vital physiological processes.

3. Active medical devices intended for diagnosis are in Class C if they are intended for:

a) Monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or

b) Diagnosing in clinical situations where the patient is in immediate danger.

4. Active medical devices intended to emit ionising radiation and intended for diagnostic and/or interventional radiology, including medical devices which control or monitor such medical devices, or those which directly influence their performance, are in Class C.

Rule 11. Active medical devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body

All active medical devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration or removal, in which case they are in Class C.

Rule 12. Other active medical devices

All other active medical devices are in Class A.

D. OTHER RULES

Rule 13. Other active medical devices

All medical devices incorporating a substance which can be considered to be a medicinal product and which is liable to act on the human body are in Class D.

Rule 14. Medical devices of animal or microbial origin

1. Active medical devices are in Class D if they are manufactured from or incorporating:

a) Animal cells, tissues and/or derivatives thereof, rendered non-viable; or

b) Cells, tissues and/or derivatives of microbial or recombinant origin.

2. Medical devices that are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only are in Class A.

Rule 15. Medical devices intended to be used for sterilizing or disinfecting

Medical devices intended to be used for sterilizing medical devices are in class C.

Medical devices intended to be used for disinfecting medical devices as the end point of processing are in Class C.

Medical devices intended to be used for disinfecting medical devices prior to end point sterilization are in Class B.

Medical devices intended to be used for disinfecting medical devices prior to higher level disinfection are in Class B.

All medical devices used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.

Rule 16. Medical devices used for contraception or prevention of transmission of sexually transmitted diseases

All medical devices used for contraception or prevention of transmission of sexually transmitted diseases are in Class C.

Medical devices used for contraception or prevention of transmission of sexually transmitted diseases that are implantable or long-term invasive medical devices are in class D.

Part III

RULES FOR CLASSIFICATION OF IVD MEDICAL DEVICES

Rule 1. IVD medical devices intended for the following purposes are classified as Class D:

1. Medical devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation.

2. Medical devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation

Rule 2

IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation are classified as Class C, except for ABO system [A (AB01), B (AB02), AB (AB03)], rhesus system [RH 1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determination which are classified as Class D.

Rule 3. IVD medical devices are classified as Class C if they are intended for use:

1. in detecting the presence of, or exposure to, a sexually transmitted agent (e.g. Sexually transmitted diseases, such as Chlamydia trachomatis, Neisseria gonorrhoeae).

2. in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation (e.g. Neisseria meningitidis or Cryptococcus neoformans).

3. in detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested (e.g. diagnostic assay for CMV, Chlamydia pneumoniae, Methycillin Resistant Staphylococcus aureus).

4. in pre-natal screening of women in order to determine their immune status towards transmissible agents (e.g. Immune status tests for Rubella or Toxoplasmosis).

5. in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient (e.g. Enteroviruses, CMV and HSV in transplant patients).

6. in screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer (e.g. personalised medicine).

Those IVD medical devices where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into Class B under rule 6 - Part III.

7. in human genetic testing (e.g. Huntington’s Disease, Cystic Fibrosis).

8. to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient (e.g. Cardiac markers, cyclosporin, prothrombin time testing).

9. in the management of patients suffering from a life-threatening infectious disease (e.g. HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping).

10. in screening for congenital disorders in the fetus (e.g. Spina Bifida or Down Syndrome).

Rule 4

IVD medical devices intended for self-testing are classified as Class C, except those medical devices from which the result is

not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be Class C. Other IVD medical devices that are intended for near patient should be classified in their own right using the classification rules.

Rule 5. The following IVD medical devices are classified as Class A:

1. Reagents or other articles that possess specific characteristics, intended by the product owner to make them suitable for IVD procedures related to a specific examination.

2. Instruments intended by the product owner specifically to be used for IVD procedures.

3. Specimen receptacles.

Rule 6. IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

Rule 7. IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.

APPENDIX II

GROUPING OF MEDICAL DEVICES

(Promulgated together with Circular No. … /2016/TT-BYT dated … of the Minister of Health)

GROUPING OF MEDICAL DEVICES

Medical devices can grouped as single medical devices or one of the following grouping categories:

a) Family;

b) In vitro diagnostic (IVD) test kit;

c) System;

d) IVD cluster;

dd) Group;

1. Single medical devices

A single medical device is a medical device from a product owner identified by a proprietary name or brand name with a specific intended purpose and sold as a distinct packaged entity and that cannot be assigned into a family, IVD test kit, system, IVD cluster or group.

Example:

- Condoms that are sold in packages of 3, 12 and 144 can be grouped as a single medical device when submitting for registration.

- A company manufactures a standalone software program that can be used with a number of CT scanners produced by other product owners. The standalone software program itself is deemed a medical device, which can be used on different scanners. The software can be grouped as a single medical device.

2. 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 a common design and manufacturing process; and

- has variations that are within the scope of the permissible variants.

Table 1. List of permissible variants in a family

Specific products	Permissible variants
Abutments	Retention (e.g. cement or screw)
Active implantable device	MR conditional and non-MR conditional
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/densities
Diagnostic radiographic systems	(i) Number of slices (ii) Digital or Analog (iii) Biplane and Single Plane (iv) Flat Panel or Cassette (v) PET ring size
Electrophysiological Catheter	(i) Electrode spacing (ii) Number of electrodes
Gloves	Powdered 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

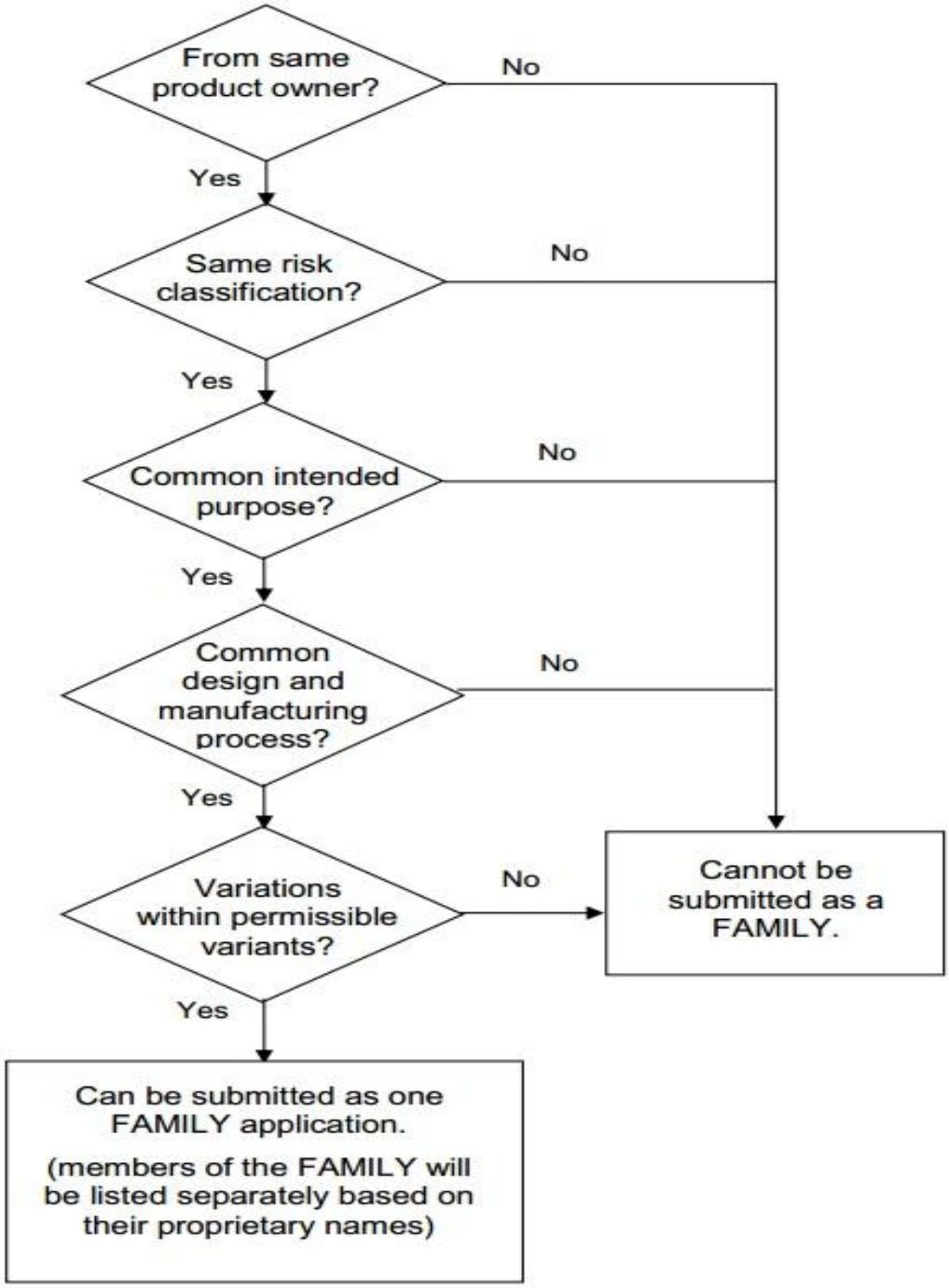
	(ii) Collar
Intra-ocular Lens	(i) Monofocal or multifocal (ii) Multi-piece or single-piece (iii) Aspheric or spheric
Implantable pulse generators	Number of chambers (cardio)
IV cannula	(i) Presence of injection port (ii) Presence of safety wing
IVD rapid tests	Different assembly format: cassette, midstream, strip
IVD urinalysis strips	Different combination of testing configurations
Polymer products	With or without plasticisers (e.g. DEHP)
	(i) Stent 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
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 in a family

Coating material for lubrication only
Colour
Diameter, length, width, gauge
Concentration with same indication and mechanism (same composition different amount of constituent)
Dimensional design differences due to paediatric versus adult use (The differences due to the different patient population permissible, e.g. volume and length)
Flexibility
Holding force
Isotope activity level
Memory storage
Method of Sterilisation (to achieve same sterility outcome)
Printing capability
Radiopacity
Shape, size, volume

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)
Sterility status (sterile vs. non-sterile)

Decision flowchart for grouping of medical devices as a family



A medical device may be added as a new product to a registered family if the conditions specified by this principle are satisfied, unless such product satisfies the same requirements applied to another product of the same family but their names are different.

Common name of a product is the name given by the product owner to a category, group or family. Example: “Dimension” is the common name for a family of testing products produced by Siemens.

Dimension® LOCI® FT3/Free Triiodothyronine Flex®
Dimension® LOCI® FT4L/Free Thyroxine Flex®
Dimension® LOCI® Thyroid Calibrator
Dimension® LOCI® TSHL/TSH Flex®

Examples:

- Condoms that differ in colour, size and texture but are manufactured from the same material, using common manufacturing process and share a common intended purpose can be grouped 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, 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 if their variations fall within the scope of permissible variants.
- 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 the lens.
- Contact lenses are available as toric lens or 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.

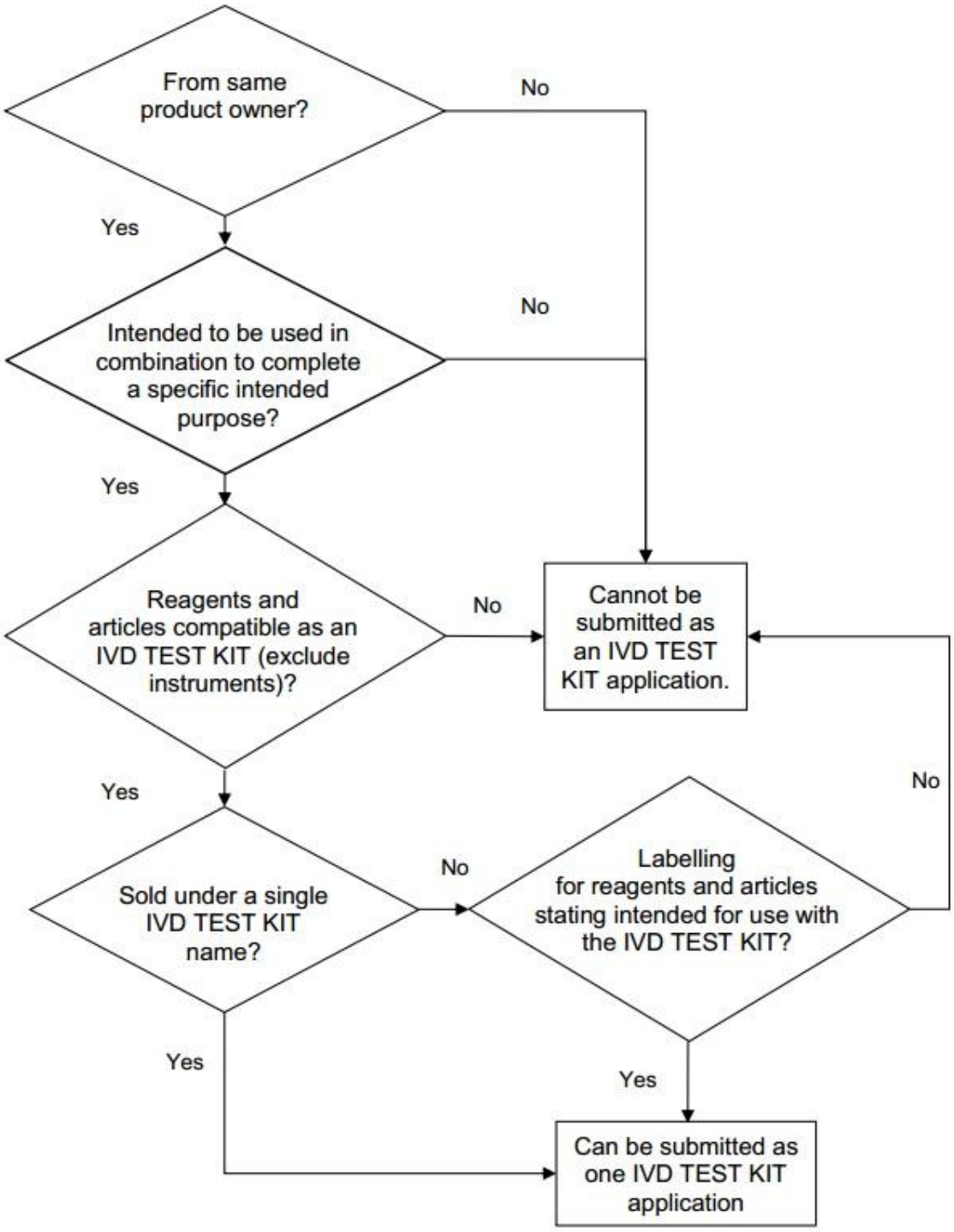
3. IVD test kit

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, 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).

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 grouped 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 grouped as a test kit. These reagents and articles can be supplied separately as replacement items for that particular test kit.

4. System

A medical device system comprises of a number of medical devices and/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, instructions for use, brochures or catalogues for each constituent component indicates that the constituent component is intended to be used together or 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 or they can be registered separately.

A 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.

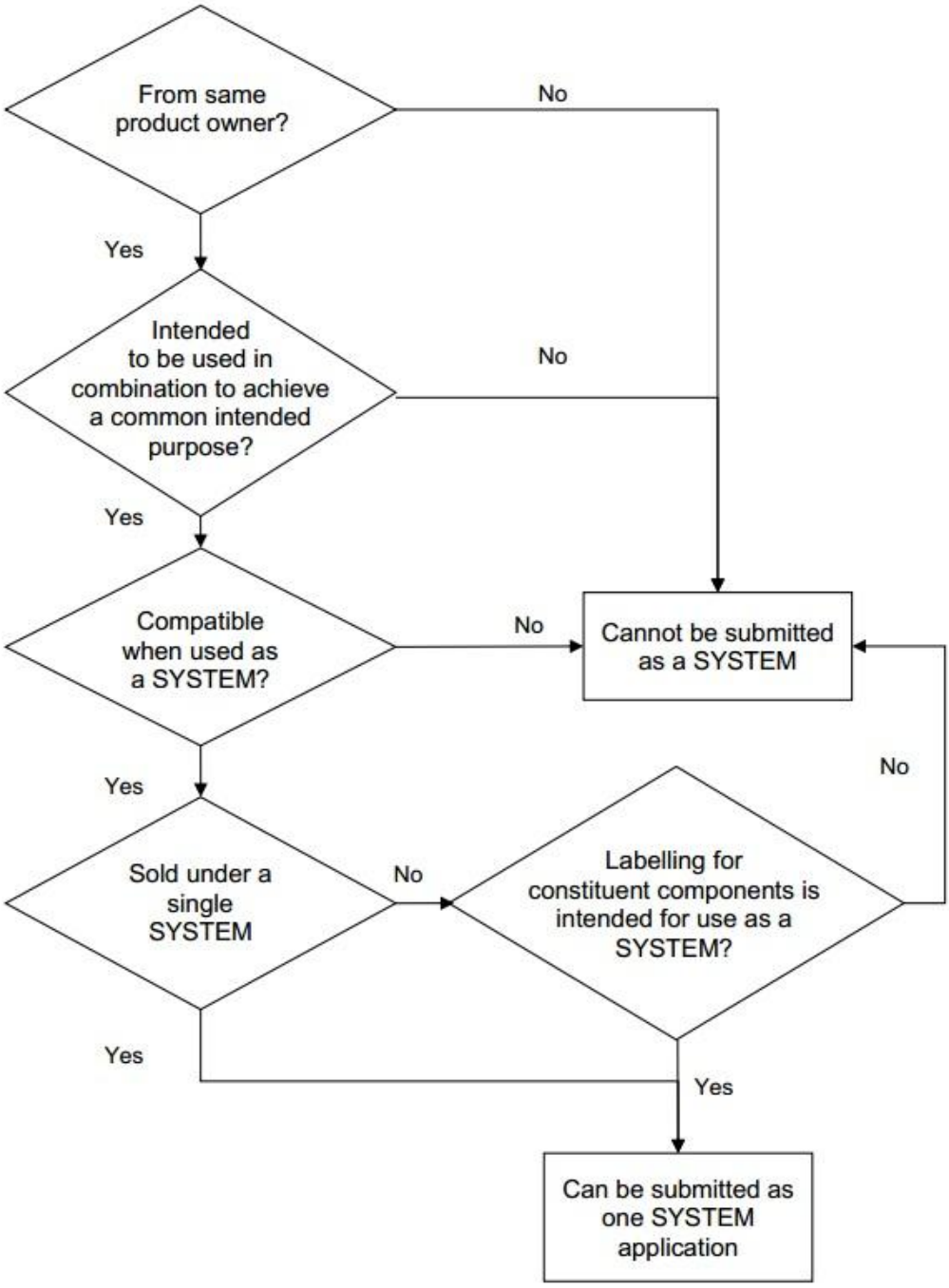
Example: A patient monitoring system from product owner A is intended to be used specifically with vital signs sensors and probes from product owner B. These accessories are used in combination to achieve a common intended purpose in accordance with product owner A's specifications, and can be grouped together with the patient monitoring system in one application for registration.

In addition, if multiple systems fulfill the following conditions to be grouped as a family, they may be grouped as a family (of systems):

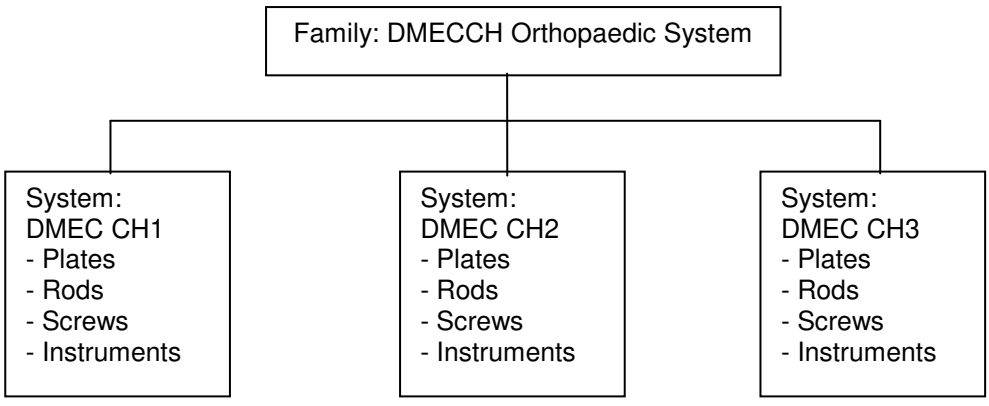
- the systems are from the same product owner;
- the systems are of the same risk classification;
- the systems have a common intended purpose;
- the systems have a common design and manufacturing process; and
- key constituent components of the systems have variations that are within the scope of the permissible variants.

Individual system names may contain additional descriptive phrases.

Decision flowchart for grouping of medical devices as a system



Example on grouping of systems as a family:



Note: the key constituent-components, i.e. implantable rods, plates and screws, across the systems are within the permissible variants. Differences in lengths of the implantable screws are deemed permissible variants.

- A hip replacement system comprising of femoral and acetabular components can be grouped as a system. The components must be used in combination to achieve a common intended purpose of total hip replacement. The size of the components may vary.
- An electrosurgical unit and its accessories that consist of forceps, electrodes, electrode holders, leads, plug adaptor, when used together for a common intended purpose, can be grouped as a system.
- 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.
- Automated blood pressure monitors with optional features such as memory storage and print capability for various models can be considered as part of a family of systems.

5. IVD cluster

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

- from the same product owner;
- is of the same risk classification (either Class A only or Class B only);
- of the same IVD cluster category and a common test methodology as listed in Table 2; and

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

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:

Table 2. List of common test methodologies and IVD cluster categories

No.	Methodology	Cluster category (closed list)	Examples of analytes
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
3		Electrolytes reagents	(i) Ammonia (ii) Bicarbonate (iii) Calcium (iv) Chloride

			(v) Magnesium (vi) Phosphate Inorganic/Phosphorus
4		Electrolytes 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) 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 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) a1-Microglobulin

			(iv) Fibronectin (v) 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
12		Cancer markers	(i) GI-marker CA242 (ii) 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 placental lactogen (v) 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 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	(i) Adrenocorticotropic Hormone

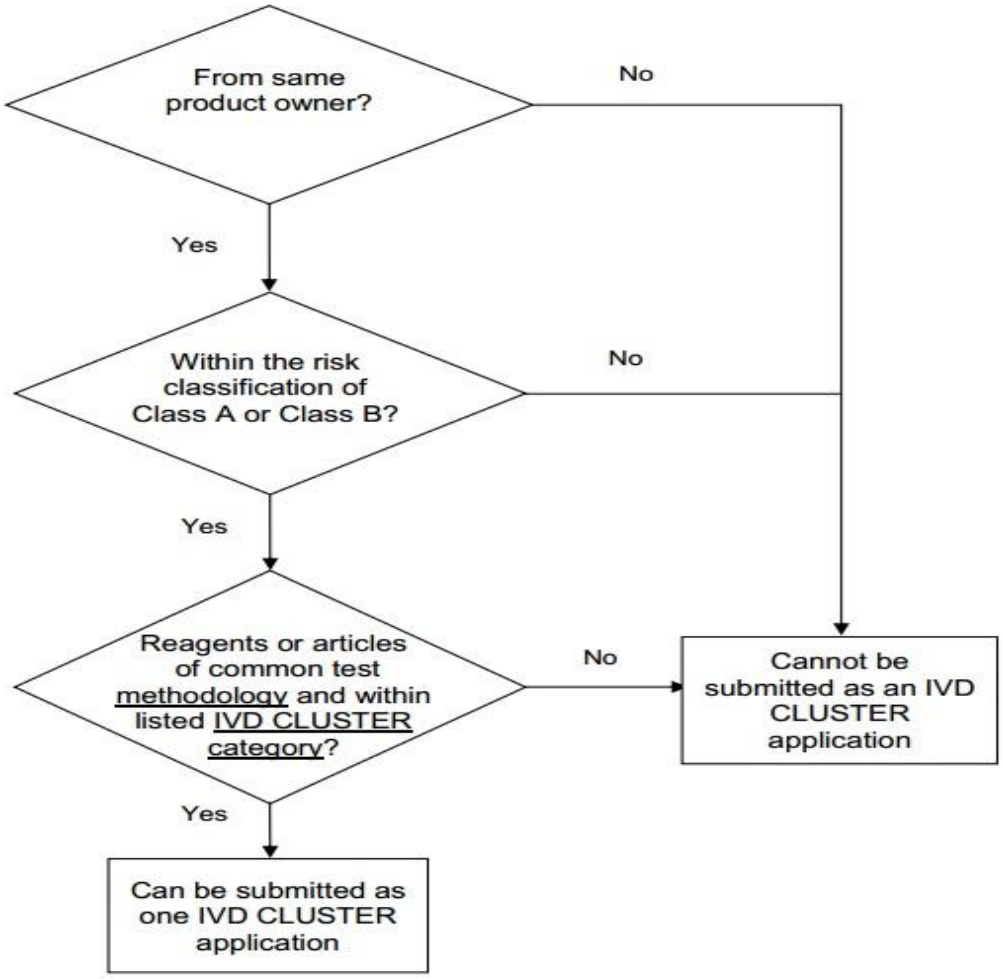
		Peptides	(ii) Human Growth Hormone (iii) Insulin-like growth factor I (iv) Insulin-like Growth Factor Binding Protein 1 (v) Vasointestinal Peptide (vi) Vasopressin
19		Neuroendocrine function assays	(i) Bombesin (ii) 17-Hydroxy-Ketosterone (iii) β-Endorphin (iv) Neurotensin (v) Somatostatin (vi) Substance P
20		Other individual and specified hormones	(i) Gastrin (ii) Gonadotropin-releasing hormone (iii) 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		Drug monitoring	(i) Caffeine (ii) Benzodiazepines (iii) Penicillins (iv) Tetracyclines
24		Toxicology	(i) Amphetamines (ii) Cocaine (iii) Morphines (iv) Phencyclidine (v) Acetaminophen (vi) Catecholamines

			(vii) Ethanol (viii) Salicylate
25		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
26		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
27		Liver function	(i) MEGX (ii) Carbohydrate Deficient Transferrin
28		Cardiac markers	(i) Homocystcinc (ii) ST2 (iii) Galectin-3 (iv) Myeloperoxidase (MPO)
29		Bacterial infection - Immunology	(i) *Bacillus subtilis* (ii) *Pseudomonas Aeruginosa* (iii) *Helicobacter Pylori* (iv) *Lactobacillus casei*
30		Viral infection - Immunology	(i) Norovirus (ii) Rotavirus (iii) Hantavirus
31		Parasitic infection – Immunology	(i) *Leishmania*
32		Fungal infection - Immunology	(i) Candida albicans (ii) Aspergillus
33	Histology/Cytology (Blood tests for transfusions excluded)	Hemoglobin testing	(i) Hemoglobin determinations (ii) Fractional oxyhemoglobin (FO2Hb) (iii)Fractional carboxyhemoglobin (FCOHb) (iv) Fractional methemoglobin (FMetHb) (v) Fractional deoxyhemoglobin (FHHb)
34		General coagulation tests	(i) Prothrombin time (ii) Thrombin time (iii) Activated clotting time

			(iv) Activated partial thromboplastin
35		Haemostasis (Coagulation)	(i) Fibrinogen (ii) Protein C and Protein S reagents (iii) C1 inhibitors (iv) Alpha-Antiplasmin (v) Fibrin (vi) Factor XIII (vi) Platelet Factor 4 (vii) Plasminogen
36		Other hematology tests	(i) Complete blood count (ii) Hematocrit (ii) Erythrocyte sedimentation rate
37		Cytokines (Lymphokines)/ Immunomodulators	(i) Interferons (ii) Soluble antigens/Receptors (iii) Tumor necrosis factors (iv) Colony stimulating factors (vi) Tumor Necrosis Factors receptors
38		Histology/Cytology reagent	(i) Cytochemical staining (ii) Embedding, fixing, mounting media (iii) Stain solution (iv) Immunohistology kits
39		Culture media	(i) Dehydrated culture media (DCM) (ii) Additives for DCM (iii) Prepared media (tubes, bottles, plates) (iv) Cells, media, serum for viral culture
40		Testing for the susceptibility of the bacteria to certain antibiotics	(i) Erythromycin susceptibility test for Staphylococcus aureus (ii) Tobramycin susceptibility test for Pseudomonas aeruginosa (iii) Fungal susceptibility testing
41		Biochemical culture Identification (ID)	(i) Gram Negative Manual ID (ii) Gram Positive Manual ID (iii) Other ID Kits Manual - Anaerobes, Fastidious
42		Immunological culture Identification (ID)	(i) Streptococci Grouping Slide tests (ii) Serotyping (E.coli, Salmonella, Shigella vv.)
43		Nucleic Acid (NA) based culture identification (ID)	(i) Streptococci (ii) Shigella
44		Serological identification (ID)	(i) For Parasitology and Mycology
45		Bacterial infections	(i) Streptococci

		(Detection by NA Reagents)	(ii) Shigella
46		Viral Infections (Detection by NA Reagents)	(i) Para-influenza NA Reagents
47		Fungal infections	(i) Fungi NA Reagents (ii) Candida albicans (iii) Aspergillus

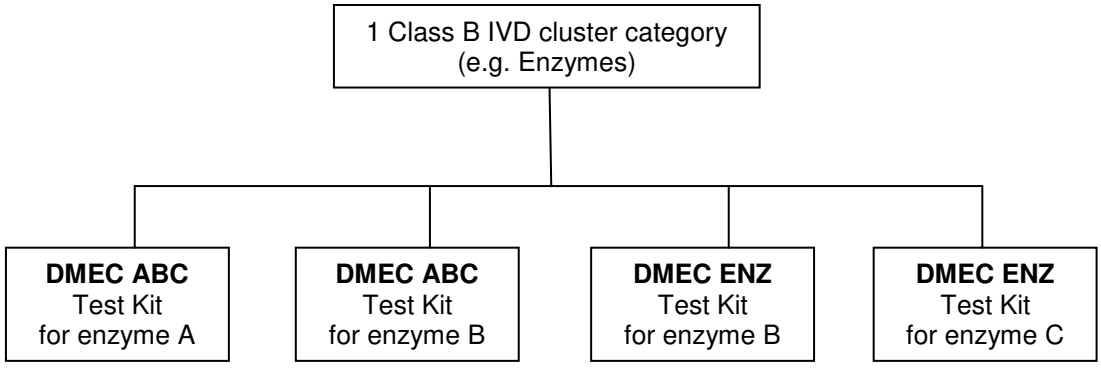
Decision flowchart for grouping of medical devices as an IVD cluster



If a reagent or article is intended for multiple usage categories, it can be grouped into more than one IVD cluster.

Example of a Class B IVD cluster grouping with 4 products within the Cluster category - Enzymes

Example: Product owner is "DMEC"



Based on the example, the 04 IVD products qualify to be submitted as one IVD cluster category (Enzymes) and would be listed as follows:

1. DMEC ABC Test Kit for Enzyme A*
2. DMEC ABC Test Kit for Enzyme B**
3. DMEC ENZ Test Kit for Enzyme B***
4. DMEC ENZ Test Kit for Enzyme C****

* DMEC ABC Test Kit for enzyme A is under one listing in which DMEC is the product owner and ABC is the proprietary name.

I* DMEC ABC Test Kit for enzyme B is under one listing in which DMEC is the product owner and ABC is the proprietary name.

*** DMEC ENZ Test Kit for enzyme B is under one listing in which DMEC is the product owner and ENZ is the proprietary name.

**** DMEC ENZ Test Kit for enzyme C is under one listing in which DMEC is the product owner and ENZ is the proprietary name.

6. Group of other medical devices

A medical device group is a collection of two or more medical devices other than IVD medical devices that is labeled and supplied in a single packaged unit by a product owner. The medical device group comprises of the following:

- a single proprietary group name;
- labeled and supplied in a single packaged unit by the product owner; and
- a common intended purpose.

This list of medical devices in a group may differ in the number (quantity) and combination 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 assumes responsibility for the medical device GROUP and its intended purpose. The product owner of a medical device group may incorporate medical devices obtained from other manufacturers/product owners as part of their group to achieve the common intended purpose. In manufacturing and assembling this group of medical devices, the evidence 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.

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.

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 in the group must appear on the external package of the group or supplied with the group. Individual medical devices in the group do not require to be labeled with that GROUP name.

Example:

- 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 the medical devices in the group are registered, the product owner is able to customise 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 labeled, while others remain in bulk form and may not be labeled.
- 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.

Decision flowchart for grouping of medical devices as a group