MEDICAL DEVICE PRODUCT GROUPING

GENERAL MEDICAL DEVICE & IVD PRODUCT GROUPING

Why do we need grouping?

Important criteria to look for in grouping the devices.

- Same manufacturer or
- Different manufacturers
- Different brands
- Permissible variants

&

- intended purpose

or

additional criteria

INTRODUCTION

An application to register medical devices may be made according to their grouping.

For General Medical Device (GMD), Medical devices may be grouped into one of the following categories

i. **SINGLE**

ii. **FAMILY**

iii. **SYSTEM**

iv. **SET**

GENERAL PRINCIPLES OF GROUPING

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

i. **one generic proprietary name**

ii. **one manufacturer**

iii. **one common intended purpose**

MDA has published MDA/GD-05: Product Grouping First Edition October 2013, to provide guidance to determine appropriate grouping for medical devices

GROUPING CATEGORY : SINGLE

A medical device shall be grouped as a **SINGLE** medical device if its proprietary name is identified by the manufacturer with a

- Specific intended purpose
- It is sold as a distinct packaged entity
- It may be offered in a range of package sizes

GROUPING CATEGORY : SINGLE

Examples :

- A company manufactures a 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; universal software. The software can be registered as a **SINGLE** medical device.

GROUPING CATEGORY : SINGLE

- Condoms that are sold in packages of 3, 12, and 144 can be registered as a **SINGLE**

GROUPING CATEGORY : SINGLE

- A company that assembles and registers a first aid kit has now decided to also supply each of the medical devices in the first aid kit individually. Each medical device supplied individually as a medical device must be registered separately as a **SINGLE** medical device.

GROUPING CATEGORY : SYSTEM

A group of medical devices shall be grouped as a **SYSTEM** if it comprises of a number of constituent-components of medical devices that are:

- from the same manufacturer
- intended to be used in combination to complete a common intended purpose;
- compatible when used as a SYSTEM
- sold under a SYSTEM name or the labelling, instruction for use (IFU), brochures or catalogues for each constituent component states that the constituent component is intended for use with the SYSTEM.

GROUPING CATEGORY : SYSTEM

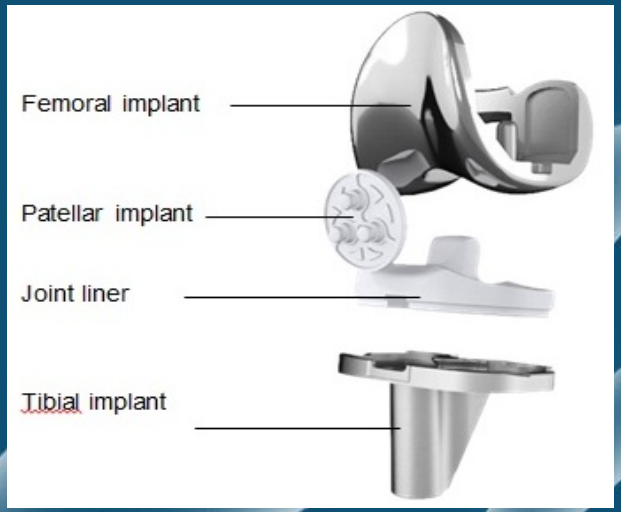
NOTE :

- *Constituent-components registered as part of a system shall only be supplied specifically for use with that SYSTEM.*
- *Any constituent-component that is meant for supply for use with multiple SYSTEMs should be registered together with each of these other SYSTEMs.*
- *Alternatively, these constituent-component(s) that are compatible for use with multiple SYSTEMs must be registered separately.*

GROUPING CATEGORY : SYSTEM

Example:

- A knee replacement **SYSTEM** comprising of femoral implant, plastic liner, patellar implant and tibial implant can be registered as **SYSTEM**. The components must be used in combination to achieve a common intended purpose of knee replacement.



GROUPING CATEGORY : SYSTEM

- 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**.

GROUPING CATEGORY : SYSTEM

- Scaler dental system which consist of main unit, hand piece, footswitch and list of tips (accessories); for the purpose of prophylaxis, periodontology, endodontology, etc, may be grouped together as **SYSTEM.**

GROUPING CATEGORY : Family

A group of medical device shall be grouped as a **FAMILY** if it consists of a collection of medical devices and each medical device **FAMILY** member:

- is from the same manufacturer
- same risk classification
- same medical device proprietary name (trade name/brand name)
- has a common intended purpose
- same design and manufacturing process
- has variations that are within the scope of the permissible variants

GROUPING CATEGORY : Family

A characteristic of a medical device may be considered a permissible variant if:

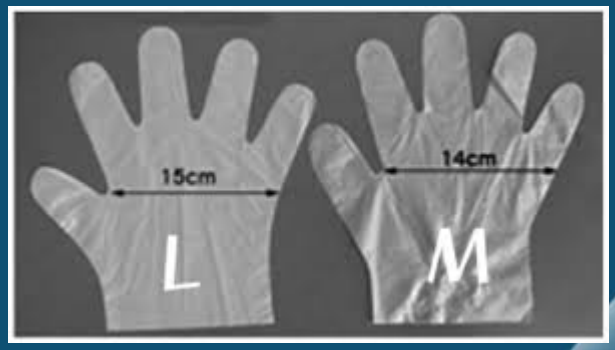
- the physical design and construction of the medical devices are the same, or very similar
- the manufacturing processes for the medical devices are the same, or very similar
- the intended purpose of the medical devices is the same
- the risk profile of the medical devices, taking into account the above factors, is the same.

**Refer to Guidance on Product Grouping for list of permissible variant*

GROUPING CATEGORY : FAMILY

Examples:

- Gloves 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 registered as a **FAMILY**.

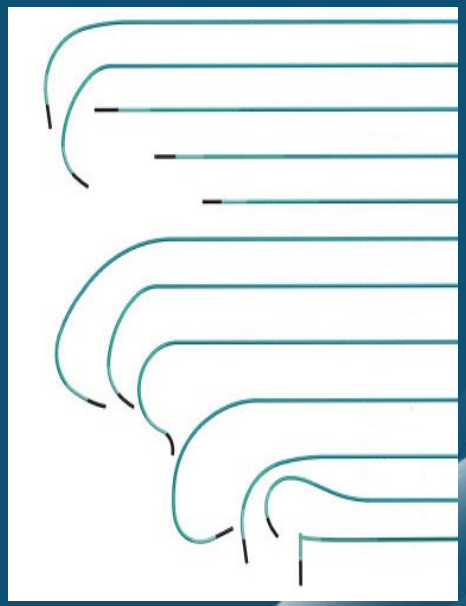


GROUPING CATEGORY : Family

- Surgical light from the same manufacturer and same brand may be grouped together as ***FAMILY*** under permissible variant of type of monitoring; ceiling mount, portable and wall mount

GROUPING CATEGORY : Family

- Cardiac catheters that are available in a different number of lumens, lengths and diameters can be registered as a **FAMILY**.



Grouping Category : SET

A group of medical devices shall be grouped as a **SET** if it consist of a collection of two or more medical devices, assembled together as one package by manufacturer and have :-

- a single proprietary SET name
- a common intended purpose
- a classification which is allocated based on the highest class of the device within the set

❖ *Each medical device in the SET may have different medical device proprietary names and intended purposes, may be designed and manufactured by different manufacturers.*

Grouping Category : SET

Examples:

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

Grouping Category : SET

- A dressing tray consisting of a number of medical devices; when packaged together for convenience to meet a specific purpose by a manufacturer can be can be registered as a **SET**.

Hands on activity

Axis™ mobile x-ray

Omega™ mobile x-ray

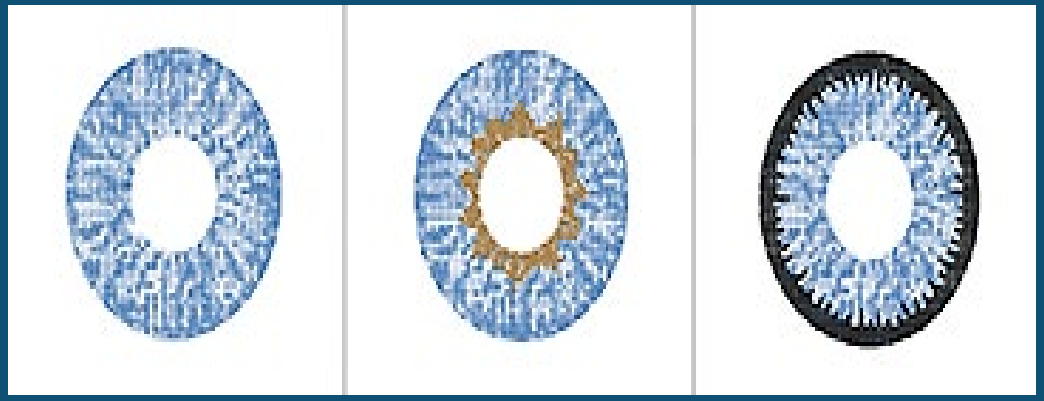
Picard™ mobile x-r

Manufactured by Imaging Co.

Hands on activity

AQUBUE CONTACT LENS

Hands on activity



AQUBUE +20.00D

AQUBUE +10.00D
WITH UV PROTECTION

AQUBUE -10.00D
TINTED


Thank you

Medical Device Authority

MINISTRY OF HEALTH

Grouping of IVD Medical Device

INTRODUCTION

IVD Medical Device

A 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.

Medical Device Grouping

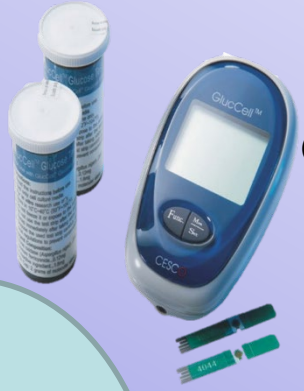
- An application to register medical devices may be made according to their grouping.
- The information regarding Rules of Grouping of Medical Device Grouping refer to SECOND SCHEDULE [*Paragraph*

SINGLE

Microtome Blade

Pasteur Pipette

SYSTEM



Glucose Monitoring System

General Principles of Grouping

Pregnancy Test Kit

FAMILY

SET

IVD Test Kit

- Same manufacturer
- Combine to complete a specific intended use
- Compatible
- All reagent in IVD Test Kit must be submitted as part of one product registration application.

Dengue IgM Test Kit

RPR Latex Test Kit

General Principles of Grouping

Rheumatoid-inflammatory diseases markers

- Same manufacturer
- Within Class A or B
- Common test methodology
- Same IVD Cluster category.

(refer to Guidance documents-An

- All reagent in IVD Cluster must b

submitted as part of one product registration application.

IVD CLUSTER

IVD Cluster Category

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:

	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-GlutamylTransferase (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		Electrolyte Electrodes	(i) Ammonia Electrodes (ii) Carbon Dioxide (Bicarbonate) Electrodes (iii) Calcium Electrodes (iv) Chloride Electrodes (v) Magnesium Electrodes (vi) Potassium Electrodes
5		Substrate	(i) Creatinine Electrodes


Case
study
Shift

Case 1

Alanine Aminotransferase Reagents Kit

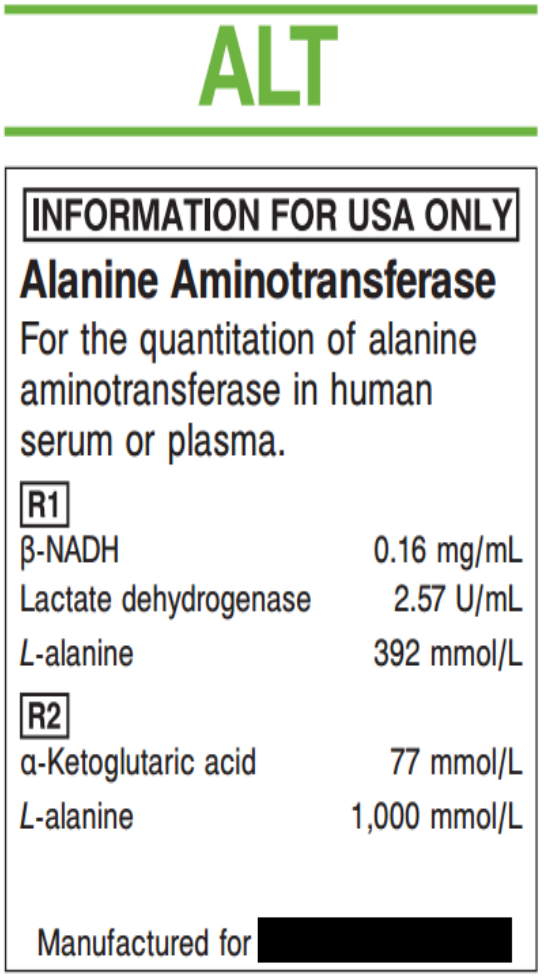
Materials Provided:

- Reagent 1 (R1)
- Reagent 2 (R2)

Intended Use

- Used for the quantitation of Alanine Aminotransferase in human serum or plasma.

What is the most suitable grouping for this IVD MD?



Case 2

Family Grouping

MD included in this application:

- Dengue Combo NS1-IgG/IgM Rapid Test-Cassette
- Zika, Dengue & Chikungunya Real Time PCR Detection Kit

Intended Use

- **Dengue Combo IgG/IgM Rapid Test-Cassette** - To aid in the diagnosis and management of patients suspected of dengue by detection of IgM and IgG
- **Zika, Dengue & Chikungunya Real Time PCR Detection Kit** - Aid in the diagnosis of the zika, dengue and/or chikungunya viruses in combination with clinical and epidemiological risk factors

Is this the correct grouping?

Case 3

Grouping IVD Cluster

MD included in this application:

- **Anti-Streptolysin O (ASO)**

An ASO test system is a device intended for the quantitative in vitro determination of Anti-Streptolysin O (ASO) in human serum. Detection of ASO in serum may aid in the diagnosis of streptococcal infections.

- **Rheumatoid Factor (RF) Test**

A RF test system is a device intended for the quantitative in vitro determination of Rheumatoid Factors (RF) concentration in serum

- **High Sensitivity C-Reactive Protein**

A HS-CRP test system is a device intended for the quantitative in vitro determination of C-Reactive Protein concentration in serum. HS-CRP is a reliable test to evaluate the cardiovascular risk because the **crp level is increased for low-level**, chronic systemic inflammations.

Is this the correct grouping?

Case 4

Creatine kinase-MB

MD included in this application:

- **CK-MB (500 Test)**
- **CK-MB (100 Test)**
- **CK-MB Diluent (2-pack)**
- **CK-MB Diluent (10 mL bottle)**
- **CK-MB Calibrator**

Intended Use

- For in vitro diagnostic use in the quantitative determination of CK-MB in serum or heparinized plasma.

What is the most suitable grouping for this IVD MD?

Case 5

Fertility/Pregnancy Hormones/Protien

MD included in this application:

- **Follicular-stimulating hormone (FSH)**

The kit has been designed for the quantitative determination of follicular-stimulating hormone (FSH) in human serum.

- **Luteal Hormone (LH)**

The kit has been designed for the quantitative determination of luteal hormone (LH) in human serum.

- **Prolactin (PRL)**

The kit has been designed for the quantitative determination of Prolactin (PRL) in human serum.

What is the most suitable grouping for this IVD MD?


Thank
you!!

Any Further Questions:

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