NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION & CONTROL (NAFDAC)

VACCINES, BIOLOGICS AND MEDICAL DEVICES REGISTRATION AND REGULATORY AFFAIRS (VBM-R&RA) DIRECTORATE

GUIDELINES FOR GENERAL GROUPING OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS

1.0 Introduction:

1.1 These guidelines have been developed pursuant to the NAFDAC Act Cap N1, LFN, 2004, and made to guide applicants in the organization of information to be provided to the Agency in seeking marketing authorization for medical devices, including In Vitro Diagnostics (IVDs) and related products. It also provides guidance to the industry on NAFDAC's expectations regarding the classification and grouping of medical devices, including in vitro diagnostic (IVD) devices.

1.2 The National Agency for Food and Drug Administration and Control is responsible for ensuring that Medical Devices placed on the Nigerian market for use meet the requirements for quality, safety, and performance throughout the product's life cycle.

1.3 The Guidelines for the Registration of Medical Devices, including In Vitro Diagnostics, outline the process to be followed and the technical requirements that must be met before a product can be placed on the Nigerian market.

1.4 There is a wide range of medical devices, from simple to highly complex and sophisticated medical devices. The various components can be sold separately, as an individual customized pack, or in groups, and can be categorized as SINGLE, FAMILY, SYSTEM, or SET. Each of the categories mentioned can be submitted in the medical device registration application.

2.0 Scope and application

This document applies to all products that fall within the definition of a medical device, including in vitro diagnostics medical devices as defined in the NAFDAC Medical Devices and Related Products Regulations.

3.0 Terms and definitions

For the purpose of this document, the terms and definitions in the Regulations shall apply.

3.1 Accessory

For this guidance document, an accessory is an article that is specifically intended by its manufacturer to:

a) be used together with a medical device to enable that device to be used in accordance with its intended purpose as a medical device; or
b) augment or extend the capabilities of that device in fulfillment of its intended purpose as a medical device; and therefore, should be considered as a medical device

3.2 Component

For this document, 'Component' refers to several possibly unequal subdivisions that together constitute the whole medical device, enabling it to achieve its intended purpose. A component may be known as a part but not a medical device.

3.3 Proprietary name

A unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name or brand name.

3.4 Holder of Certificate of Registration

In relation to a registered medical device, this refers to the establishment on whose application the medical device is registered. A Certificate of Registration Holder is either the manufacturer or an authorized representative of the medical device's owner.

3.5 Reusable Surgical Instrument

Instruments intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping, or other surgical procedures, without connection to any active medical device, and which are intended by the manufacturer to be reused after appropriate procedures for cleaning, disinfection, and/or sterilization have been carried out.

4.0 General Principles of Grouping

4.1 General medical devices can be grouped into one of the following four categories and can be submitted in one application for medical device registration:

a) SINGLE;
b) SYSTEM
c) FAMILY
d) SET.

4.2 Basic Rule for Grouping

There are three basic rules, all of which shall be fulfilled for the grouping to apply. These are:

a) one proprietary name,
b) one manufacturer; and
c) one common intended purpose.

4.3 Categories

4.3.1 Single

A single medical device is a medical device from a manufacturer identified by a medical device proprietary name with a specific intended purpose. It is sold as a distinct packaged entity, and it may be offered in a range of package sizes, but it does not meet the criteria for family, system, or set. Examples:

a) Devices that vary in package sizes are not considered to fall within the medical device family; therefore, a single registration application for a single medical device should be filed for the various package sizes. Condoms that are sold in packages of 3, 12, and 144 can be registered as a SINGLE medical device.
b) A company manufactures a standalone software program that can be used with several CT scanners produced by other manufacturers. The standalone software program itself is deemed a medical device, which can be used on different scanners. The software can be registered as a single medical device.
c) A company that assembles and registers a first aid kit as a set 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 shall be registered separately as a single medical device.

4.3.2 System

A medical device system comprises several constituent components that are:

a) from the same manufacturer;
b) intended to be used in combination to complete a common intended purpose;
c) compatible when used as a system; and
d) 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.

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 shall be registered separately.

The decision flowchart for grouping medical devices as a system can be found in Annexure A.
Examples:

a) A hip replacement system comprising femoral and acetabular components can be registered as a system. The components shall be used in combination to achieve a common intended purpose of total hip replacement. The size of the components may vary.
b) An electrosurgical unit and its accessories that consist of forceps, electrodes, electrode holders, leads, plug adapters, when used together for a common intended purpose, can be registered as a system.
c) Optional accessories, such as wireless controllers, are part of an in-the-ear hearing aid and can be registered as a system.

4.3.3 Family

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

a) is from the same manufacturer;
b) is of the same risk classification;
c) has the same medical device proprietary name;
d) has a common intended purpose;
e) has the same design and manufacturing process; and
f) has variants that are within the scope of the permissible variants stated in Annex C.

The decision flowchart for grouping medical devices as a FAMILY can be found in Annexure B.

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

a) The physical design and construction of the medical devices are the same or very similar;
b) The manufacturing processes for the medical devices are the same, or very similar;
c) The intended purpose of the medical devices is the same; and
d) The risk profile of the medical devices, considering the above factors, is the same.

See Annexure C for a list of permissible variants in a FAMILY.
Examples:

a) Condoms that differ in color, 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.

b) Intravenous fluid administration sets that differ in features such as length of tubing but are manufactured from the same material and manufacturing process and share a common intended purpose can be registered as a FAMILY.
c) Steerable guidewires, available in various lengths and possessing different tip shapes and flexibilities, can be registered as a family if their manufacturing process is the same and they share a common intended purpose.
d) A spherical contact lens with additional features, such as UV protection, can be registered as part of a FAMILY, as this feature does not affect the basic design and manufacturing of the lens.
e) In-the-ear hearing aids which are designed in different sizes to be fitted in the ear (i.e. outer ear, middle ear, and inner ear canal), and have been designed using the same main components including the signal processor and compression circuit, microphone, amplifiers, and receiver, can be registered as a FAMILY.
f) Cardiac catheters, available in various numbers of lumens, lengths, and diameters, can be registered as a FAMILY.
g) Contact lenses are available as Toric and spherical lenses. These medical devices have different intended purposes and performances. They are designed and manufactured differently. Due to these differences, they are **NOT** to be considered as members of a FAMILY.

4.3.3.3 Information on all medical devices within a FAMILY should be submitted as part of one medical device registration application. Only members of a FAMILY that are eventually listed on the Certificate of Registration can be placed on the market. Those that are not listed shall not be placed on the market.

4.3.3.4 The medical device's proprietary name should appear on the label of each individual medical device in the family, if packaged or supplied separately. Individual medical device names may contain additional descriptive phrases.

4.3.4 Set

4.3.4.1 A medical device SET is a collection of two or more medical devices assembled together as one package by a manufacturer. The medical device SET has the following:
a) a single proprietary set name;
b) a common intended use;
c) the classification allocated to the set is at the level of the highest classified device within the set.

The decision flowchart for grouping medical devices as a set can be found in Annexure D.

4.3.4.2 The collection of medical devices in a SET may differ in number (quantity) and combination (permutation within the list of medical devices in a SET of medical devices that comprise each SET while maintaining the same proprietary SET name and SET's intended use.

4.3.4.3 Information on all medical devices within a SET shall be submitted as part of one medical device registration application. Medical devices that are registered as part of a SET shall have a single medical device registration.

4.3.4.4 The SET name indicated for the medical device should appear on the product label affixed on the external package of the SET. Individual medical devices in the SET

do not need to be labelled with the SET name. Individual medical devices in the SET may contain additional descriptive phrases.

4.3.4.5 The product label for medical devices in a set should bear the content list of devices within the package for supply. Some of the medical devices in the SET may be individually packaged and labeled, while others may not require individual packaging and labeling. The manufacturer should account for these during the assembly of the SET and ensure compliance with existing regulatory requirements, including traceability of individual devices packaged into the set and record keeping.

Examples of medical devices in a set:

a) A first aid kit consisting of medical devices such as bandages, gauze, drapes, and thermometers, when assembled together as one package by a manufacturer, can be registered as a SET.
b) A dressing tray consisting of several medical devices, when packaged together for convenience to meet a specific purpose by a manufacturer, can be registered as a SET.

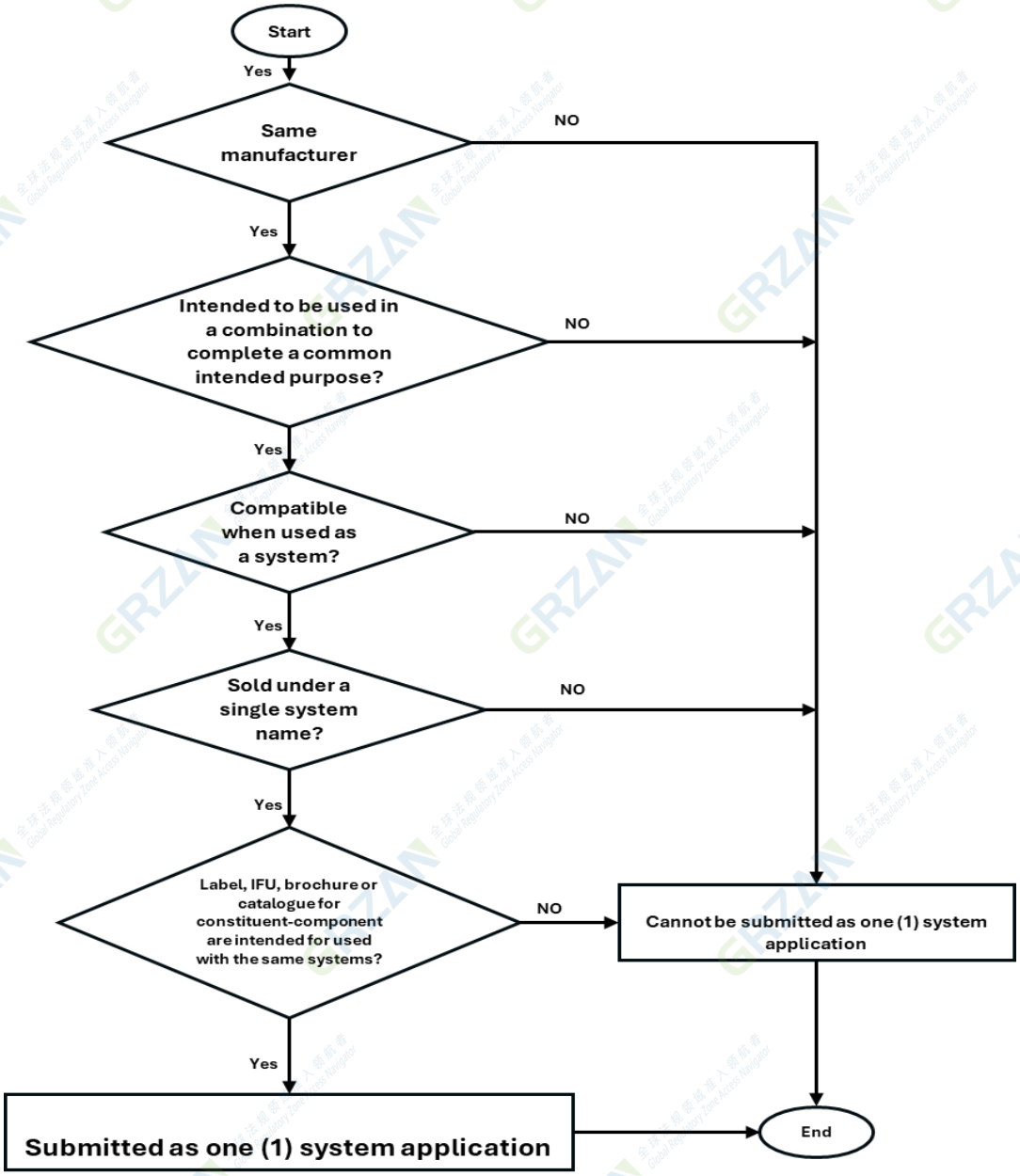
All correspondences should be addressed to:
The Director-General (NAFDAC)
Attn: The Director (Vaccines, Biologics and Medical Devices Registration and Regulatory Affairs) Directorate
National Agency for Food and Drug Administration and Control
NAFDAC Office Complex
Isolo Industrial Estate,
Apapa-Oshodi Expressway, Isolo, Lagos

Email: bvmregistration@nafdac.gov.ng

NAFDAC website: www.nafdac.gov.ng

Annexure A

Decision Flowchart for Grouping of Medical Devices as a SYSTEM



Annexure B

Decision Flowchart for Grouping of Medical Devices as a FAMILY



Annex C

List of Permissible Variants in a Family

Specific products	**Permissible variants**
Abutments	Retention (e.g. cement or screw)
Active Implantable Devices	MR conditional and Non-MR Conditional
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) Curvature (straight or pigtail) (iii) Coating material for lubrication
Condoms	(i) Texture (ii) Flavour
Contact lens	(i) Diopter, (ii) UV protection (iii) Tinting (iv) Color (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 the bracket
Dental handpieces	(i) Rotational speed (ii) Material of the handpiece

Specific products	**Permissible variants**
Dermal fillers	Same composition but different concentrations/densities
Diagnostic Radiographic Systems	(i) Number of slices (ii) Digital vs Analog (iii) Biplane and Single Plane (iv) Flat Panel vs 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
Orthopedic/ 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 a safety wing
Polymer products	With or without plasticizers (e.g., DEHP)
Stent	(i) Delivery system, that is over-the-wireor through the scope (ii) Flaps, Flares or sleeves

Specific products	**Permissible variants**
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
Hearing aid	(i) Design a) Behind the ear (BTE) b) In the ear (ITE). ITE devices have all components of the hearing aid contained in a case shell that fits in theear or canal. (ii) By technology for sound amplification a) Analogue b) Digital (iii) By communication technology a) Wireless b) Non-wireless

Other permissible variants in general
Coating material for lubrication only
Colour
Diameter, Length, Width, Gauge

Concentration with the same indication and mechanism (same composition, different amount of constituent)
Dimensional design differences due to pediatric versus adult use (Thedifferences due to the different patient population are permissible, e.g. volume and length)
Flexibility
Holding force
Isotope activity level
Memory storage
Method of Sterilization (to achieve same sterility outcome)
Printing capability
Radiopacity
Shape, Size, Volume
Viscosity (The change in viscosity is solely due to changes in theconcentration of constituent material)
Type of device mounting (e.g. ceiling mount, wall mount or standing)

Annex D

Decision Flowchart for Grouping of Medical Devices as a SET

