HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-12-2: Guidance on Grouping of Medical Devices for Product Registration

– Device Specific Grouping Criteria

Revision 2

HSA
Health Sciences Authority

CONTENTS

PREFACE

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

Update Process for this Guidance Document

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

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

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

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

REVISION HISTORY

Guidance Version (Publish Date)	Revision
GN-12-2: Revision 1 (21 June 2016)	R1
R1.1 ► GN-12-2: Revision 1.1 (01 November 2017)	R1.1
R2 ► GN-12-2: Revision 2 (07 January 2022)	R2

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown*

1. INTRODUCTION

1.1. Purpose

This document is meant to provide guidance on the device specific criteria in determining whether certain models of specific medical devices can be included together and submitted in one product registration application. Grouping of medical devices for product registration facilitates the inclusion of multiple devices in one application.

1.2. Background

Under the Health Products Act (*Act*), all medical devices to be supplied locally are required to be registered with HSA prior to supply unless an exception from the registration requirement has been provided for in the regulations

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

To better cater for the diverse categories of medical devices and the multitude of models of an individual device that may differ from one another incrementally, device specific grouping criteria have been developed and are presented in this GN-12-2 guidance document. The general grouping criteria described in the GN-12-1 guidance document are also applicable to these devices in addition to the device specific grouping criteria set out in this document. Applicants should determine and perform the grouping of medical devices to be registered based

on GN-12-1 and GN-12 -2 guidance documents when preparing their medical device product registration submissions.

1.3. Scope

This document applies to medical devices for which specific grouping criteria have been described in this document.

1.4. Definition

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

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

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

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

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

PRODUCT OWNER *(as set out in the Regulations)*: in relation to a health product, means a person who —

(a) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

2. GENERAL PRINCIPLES OF GROUPING

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

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

The product owner of a medical device may incorporate as part of their device, medical devices and/or accessories from other manufacturers or product owners or intend such devices to be used together to achieve a common intended purpose. By such design and/or intended purpose, the product owner of the medical device also assumes the responsibility for such use of the other devices and accessories.

Existing regulatory requirements apply to all medical devices to be registered, regardless of the manner in which they are grouped for product registration submission. Information on all medical devices within a grouping must be submitted as part of the dossier/application for registration, such as authorisation from all medical device product owners for registration and data to substantiate the performance of these devices.

Once the medical device(s) is deemed registrable, the final appropriate device listing information on the SMDR shall be determined by HSA. For example, where submissions with device groupings which allow for

instruments/accessories from different product owners, such as IVD analysers, only the product owner of the primary device will be listed on the SMDR, although the documentation relating to other product owners are required to be submitted as part of the registration submission. Only registered medical devices listed on the SMDR shall be supplied on the market.

The Registrant shall undertake the following post-market duties and obligations for all medical devices and accessories they have registered on the SMDR either individually or as part of grouped registrations:

- comply with the conditions applicable to the registered medical device and conditions imposed on the Registrant;
- submit applications to the Authority for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Authority; and
- notify the Authority concerning field safety corrective action (FSCA), including recall.

3. DEVICE SPECIFIC GROUPING OF R2 ►--◄ CLASS B DENTAL MEDICAL DEVICES USING DENTAL GROUPING TERMS

Dental Grouping Terms (DGT) are collective generic terms used to describe a group of similar R2 ►--◄ Class B dental medical devices with a common intended purpose.

A DGT grouping of dental medical devices is a collection of dental devices and each individual device:

- is from the same product owner ;
- is of the same risk classification (R2 ►--◄ Class B only); and
- intended purpose falls within the descriptor of one DGT.

The product registration application may contain accessories of a lower risk class if they are specifically intended to be used together with the dental devices submitted under a DGT.

For R2 ►--◄ Class B only (where applicable, with accessories) dental medical devices, the applicant may choose to group their dental devices using the general grouping criteria described in GN-12-1 guidance document or this device specific grouping criteria using the DGT for product registration. DGT is not applicable to Class C and Class D dental medical devices.

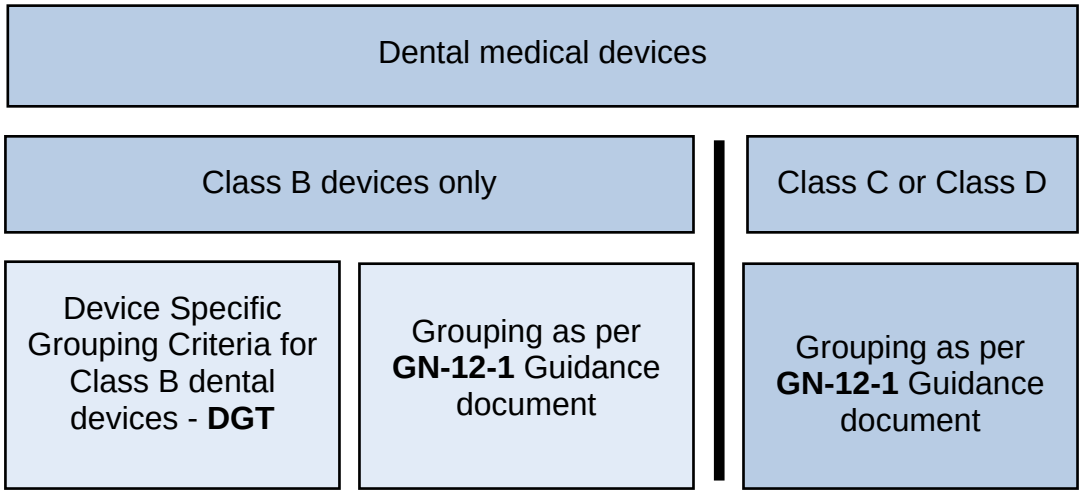


Figure 1 Dental medical device grouping consideration

When dental devices satisfy the above conditions to be grouped in one DGT application, the device name listed on the SMDR upon approval will be based on the dental grouping term used. The descriptor of the DGT will be used as the description of intended use on SMDR. The individual models will be listed on the SMDR as per product name (device label) under the section “Model Info”.

LIST OF DENTAL GROUPING TERMS (DGT) AND RESPECTIVE DESCRIPTORS

The list of DGT and respective descriptors are only applicable to R2 ►--◄ Class B dental devices only.

No	DGT	Descriptor
1.	Adhesive kit for dental composite	A kit/pack that contains a collection of devices intended to be used to bond attachments such as hooks or buttons to the teeth and/or to an orthodontic aligner during dental or orthodontic teeth adjustment.
2.	Cryoanaesthesia device, dental	A dental brace-like device that is chilled to freezing/subfreezing temperatures and then applied to the labial sulci (gums) in a patient's mouth for a period to provide a cold anaesthesia for the underlying nerves. This device may be used as a substitute for hypodermic drug delivery during dental procedures.
3.	Cryogenic spray, dental	A refrigerant use to cool down a tooth by spraying on it, mainly to find out if the pulp is vital. It can also be used as a local anaesthetic when extracting deciduous teeth in children.
4.	Cusps, dental	A device designed to provide an artificial projection on the chewing surface of the tooth to achieve a proper bite
5.	Dental abrasives	R2 ► A device intended to remove excess material or to smooth roughened surfaces of restorations, intra oral appliances and tooth structure for prophylactic and/or treatment applications. This device may be used for removal of plaque and stains, cleaning fissures, preparation of a tooth surface prior to bonding, cleaning of orthodontic appliances, removal of adhesive residue, and cleaning of implants prior to loading. It can be in various forms such as paste, powder, strip or instruments coated with abrasive particles. It may include accessories required for dental abrasion. ◄
6.	Dental absorbent	Non medicated device intended to be used to absorb fluids during dental procedures.
7.	Dental adhesives/ primers	A material used as a bonding promoting substance between dental materials. It does not include cements.

No	DGT	Descriptor
8.	Dental broach	A device that is designed with an abrasive outer surface to cut, open, enlarge, resurface with precision holes in hard tissues (e.g. bones, root canals), extirpating pulp and/or for exploring the root canal.
9.	Dental burs	A rotary cutting device designed to fit into a dental handpiece and intended to cut hard structures in the mouth, e.g. teeth or bone.
10.	Dental caries detector, electrical impedance	A device designed to measure resistance to the flow of electric current across teeth for the diagnosis of early stage dental caries and/or to monitor the progress of caries (carious areas being less resistant due to higher concentrations of fluid).
11.	Dental caries detector, optical induced fluorescence	A device designed to determine the changes in the fluorescence of teeth enamel and dentine due to mineral loss, mainly for the diagnosis of early stage dental caries and/or to monitor the progress of caries
12.	Dental caries removal solution	A substance used to detect and remove caries from an infected tooth.
13.	Dental casting materials	Compounds associated with the formation of a dental cast, i.e. a positive copy of a part of the oral anatomy made in an impression (mould).
14.	Dental cavity liner	A substance intended to be applied to the interior of a prepared cavity before insertion of restorative material, to protect the pulp of a tooth from chemical irritation.
15.	Dental cement	Compounds used to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It may include accessories to complete the cementing procedure.
16.	Dental cement kit	A kit/pack that contains a collection of components designed to complete a cementing procedure.
17.	Dental crowns/ bridges	A material used to manufacture partial or full crowns and bridges.
18.	Dental disinfectants	A substance that destroys harmful microorganisms or inhibit their activity on medical devices which are specific for dental purposes or for use in dental procedures. It is not intended for disinfection as end point of processing.

No	DGT	Descriptor
19.	Dental dry field device	A device used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It forms a frame around the oral cavity and provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures
20.	Dental dry field kit	A kit/pack that contains a collection of devices used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures.
21.	Dental etching composite	A device used to create a retentive surface for a composite, an adhesive or a pit and fissure sealant.
22.	Dental file	A device that is intended for smoothing, filing or cutting during dental procedure and typically have various forms of fine-ridged cutting surfaces along part or all of their working length. This device may be used to remove gross supragingival calculus, smooth the cementoenamel junction (CEJ), finish the margins of the teeth or other dental restorations or enlarge the root canal.
23.	Dental implant debridement brush	A rotary dental instrument designed for the debridement of a patient's dental implants affected by peri-implantitis.
24.	Dental implant extractor	A device used to retrieve a dental implant from the oral cavity.
25.	Dental implant, accessories	Device designed to provide support and a means of retention for a dental prosthesis during surgical placement of a dental implant into alveolar and/ or basal bone of the mandible or maxilla.
26.	Dental implant, prosthetic teeth bar	A small rod that bears prosthetic teeth and allows them to be attached to the dental implant abutments.
27.	Dental implant, suprastructure	A prefabricated device that is incorporated into, or creates, a suprastructure on dental implants to mimic preparations of natural teeth.
28.	Dental implant/prosthesis, surgical procedure kit	A kit/pack that contains a collection of various dental instruments designed for the surgical placement of dental implants or prostheses. It does not contain pharmaceuticals.

No	DGT	Descriptor
29.	Dental precision attachments	Dental device designed for attaching a fixed or removable prosthesis to the crown of an abutment tooth, dental restoration (including implants), or dental appliance.
30.	Dental procedure console and accessories, hydraulic	An assembly of devices designed to bore/ excavate bones, teeth, and tough tissues during a dental surgical procedure. The system is powered by pressurized water via a connecting hose to the handpiece/motor water-driven turbine.
31.	Dental procedure console and accessories, line-powered	An assembly of devices designed to bore/ excavate bones, teeth, and tough tissues during a dental surgical procedure. This system is electrically-powered and supplies the handpiece/motor with low-voltage electricity through a control unit.
32.	Dental procedure console and accessories, pneumatic	An assembly of devices designed to bore/excavate bones, teeth, and tough tissues during a dental surgical procedure. The system is pneumatically-powered.
33.	Dental procedure handpiece, hydraulic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. The device is driven by a source of pressurized water.
34.	Dental procedure handpiece, line-powered	A hand-held dental device that includes a chuck or collet for attaching a dental drill, bur, reamer, and other similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. It is powered by a low-voltage electric micro-motor that is an integral part of the device.
35.	Dental procedure handpiece, pneumatic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. It is pneumatically-powered.
36.	Dental pulp testing electrode gel	A device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.
37.	Dental pulp-capping material	A dental compound designed to cover an exposed or nearly-exposed dental pulp (e.g., due to deep cavities) to provide protection against external influences and to promote healing. This compound does not have dental cement or dental cavity liner intended uses.

No	DGT	Descriptor
38.	Dental reamer	A device that is designed with fine-toothed cutting edges to cut, open, enlarge openings in, and/or resurface hard tissues (e.g. bones, root canals) with precision.
39.	Dental reinforcing fibre	A device used in general restorative dentistry and orthodontic treatment as reinforcement of dental materials, used for the construction of dental prostheses. It may also be used for the stabilization of avulsed teeth maintaining diastema closures or split-tooth syndrome.
40.	Dental restorative / cavity varnish	A substance used to cover dental filling material in the initial setting period after application typically to prevent moisture infiltration for the protection of pulpal tissue and to provide a marginal seal to newly placed amalgam restorations.
41.	Dental restorative / repair materials	A substance intended to fill dental cavities, seal pits and fissures, restore damaged dental tissues, or for inlays, onlays and veneering. It may include accessories that are used specifically with the materials. It does not include obturation of root canal.
42.	Dental restorative/ repair kit	A kit/pack that contains a collection of devices designed to fill dental cavities, seal pits and fissures, restore damaged dental tissues, or for inlays, onlays and veneering. It does not include obturation of root canal.
43.	Dental retention pin	A device intended to be placed permanently in the tooth to provide retention and/or stabilization of dental restorations, e.g. fillings or crowns.
44.	Dental retention pin kit	A kit/pack that contains a collection of devices intended for the insertion of permanent pins in healthy dentin to provide retention and/or stabilization of dental restorations, e.g. fillings and crowns.
45.	Dental scalers, pneumatic	Scaler tip/inserts which may consist of handpieces that are designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy.
46.	Dental scalers, rotary	Scaler tip/inserts which may consist of handpieces that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy.

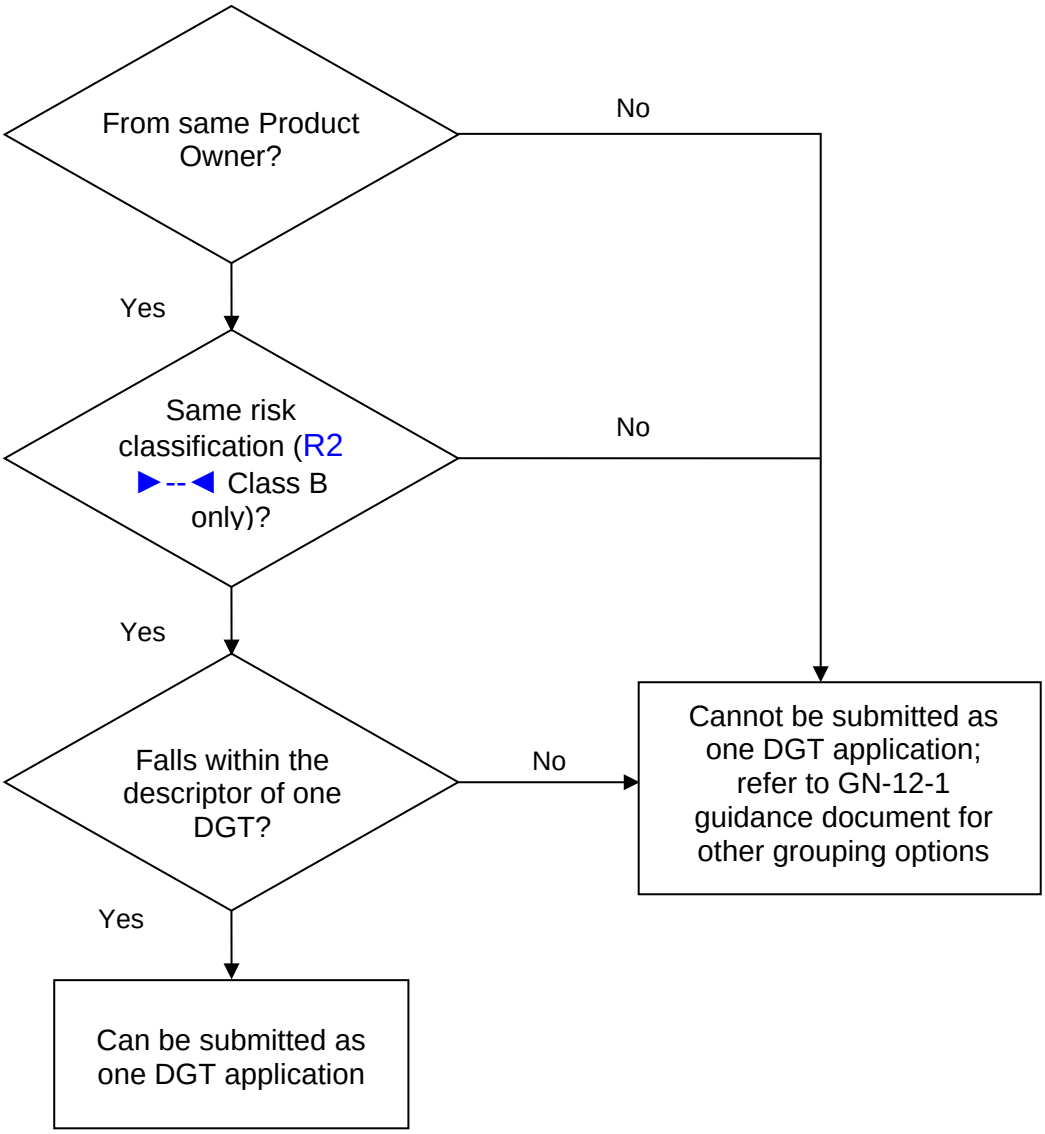
No	DGT	Descriptor
47.	Dental scalers, ultrasonic	Scaler tip/inserts (which function as part of an ultrasonic scaler system) which may consist of handpieces that together transmit ultrasonic energy from a generator to the oral cavity for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy.
48.	Dental scaling system, pneumatic	An assembly of devices designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. The handpiece may connect to an existing air driven handpiece tubing and the water spray for lavage. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
49.	Dental scaling system, rotary	An assembly of powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
50.	Dental scaling system, ultrasonic	An assembly of devices that uses ultrasonic energy at its point of patient contact to remove accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
51.	Dental sealants, endodontic	A substance used in endodontics to fill or permanently obturate the root canal of a tooth. The substance may be intended for orthograde use (i.e., a root filling placed from the coronal aspect).
52.	Dental sealants, pit/fissure	A material intended for sealing pits and fissures on teeth. It may include accessories to complete the sealing procedure.
53.	Dental shaded pontic kit	A kit/pack that contains a collection of devices intended to be used to produce artificial tooth veneers (shaded pontics) typically inside clear plastic custom-made teeth aligners (retainer-style orthodontic appliances). This is used to create the appearance of teeth inside the aligner to cover spaces where teeth may be missing for aesthetic and/or therapeutic purposes during treatment to realign teeth.

No	DGT	Descriptor
54.	Dental solution, scaling	A substance used to soften and partially solubilize a dental calculus (a hard deposit that forms on the teeth) before scaling mechanically so that less force is required, especially when teeth are loose.
55.	Denture base resins	A material used for the fabrication of a denture base or repair of a denture.
56.	Denture clasps	Dental devices designed to retain and stabilize removable partial dentures to stationary teeth.
57.	Denture reliners	A device that is applied as a permanent coating or lining on the base or tissue-contacting surface of a denture to provide a new fitting surface to a denture.
58.	Dental suction system cannula	A component of a dental suction system designed to be inserted into the oral cavity for the aspiration and removal of blood, pus, saliva, debris, and water during a dental procedure.
59.	Facebow	A caliper-like dental instrument used to record the relative position of the maxillary arch to the temporo-mandibular joint (TMJ), or the opening axis of the jaw. It is used to orient dental casts in the same relationship to the opening axis of the articulator.
60.	Fixture/appliance dental drill	A device intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the implantation of a dental fixture/appliance. It is attached to a motorized handpiece or other power source that provides rotation.
61.	Gingiva bleaching protector	A substance designed to protect a patient's gums from the hydrogen peroxide found in teeth whitening agents used during chairside light-curing bleaching of the teeth.
62.	Gingival retraction cord, non-medicated	A non-medicated device used to temporarily hold off the gingiva during abutment preparation.
63.	Gingival retraction kit	A kit/pack that contains collection of devices used to temporarily hold off the gingiva during abutment preparation.
64.	Gingival retraction solution	A substance used in dentistry to induce gingival retraction by in situ impregnation of a non-medicated gingival retraction cord. It induces contraction of the upper strata of the free gingiva. This device may also induce a local stasis of gingival exudates and gingival haemorrhages.

No	DGT	Descriptor
65.	Non-medicated dental surgical procedure kit,	A kit/pack that contains a collection of dental instruments, dressings and the necessary materials used to perform a dental surgical procedure. It does not contain any pharmaceuticals.
66.	Oral wound dressing	A device intended as a protective cover for the oral mucosa to manage wounds and sores in the mouth. It is used for various types of dental wounds, sores and lesions caused by dental prostheses/orthodontic braces; it may also be used to treat mucosal irritations/inflammation, dryness and gingivitis. This does not include pharmaceuticals.
67.	Orthodontic appliance archwire-cooling device	A device used in orthodontic dentistry to intra-orally chill or cool thermally-activated archwires when placing bends in an orthodontic appliance.
68.	Orthodontic appliances	Dental devices designed to influence the shape and/or function of the stomatognathic system through the application of physical force.
69.	Orthodontic space maintainer	A dental prosthetic replacement for prematurely lost deciduous teeth intended to prevent closure of the space before eruption of the permanent successors.
70.	Periodontal dressing	A material which is placed over the periodontal tissues as a dressing, normally after surgery. This does not include pharmaceuticals.
71.	Root canal filling-removal solution	A substance used in endodontic procedures for the softening and removal of root canal fillings.
72.	Root canal irrigation/ rinsing solution	A substance used to facilitate cleansing/irrigation of the root canal (the canal space) during and/or after endodontic instrumentation for the removal of the smear layer, pulpal tissue, necrotic materials, and bacteria from the instrumented root canal, before placement of the endodontic filling.
73.	Root canal obturation kit	A kit/pack that contains a collection of devices designed to permanently prime, seal, and/or fill a tooth undergoing a root canal procedure.
74.	Root canal post kit	A kit/pack that contains collection of root canal posts and devices used for the insertion of root canal posts.
75.	Root canal posts	A device intended to be inserted and cemented into a prepared root canal of a tooth to stabilize and support a restoration.

No	DGT	Descriptor
76.	Root canal preparation kit	A kit/pack that contains a collection of dental devices designed to be used in root canal preparation.
77.	Root surface conditioner	A material used for topical application on exposed/scaled root surfaces for the removal of the smear layer during dental/periodontal surgery. The material is removed after the recommended period to expose the collagenous matrix of dentine surfaces.
78.	Tooth preservation kit	A kit/pack that contains a collection of devices designed to preserve and transport a tooth that has been knocked out (i.e., avulsed) so it can be reimplanted. It is used to avoid tooth cell crushing and/or dehydration by immersing the tooth in a pH balanced solution compatible with periodontal cells, and is used in field emergency situations after traumatic knock out of teeth.
79.	Warm-bonded endodontic obturation system	Devices designed to deliver preheated sealing, filling, and core materials into a root canal for direct warm bonding during an endodontic obturation procedure.

Decision Flowchart for Grouping of Dental Medical Devices using Dental Grouping Terms (DGT)



The following examples provide a comparison between the grouping of dental medical devices using the general grouping criteria in GN-12-1 guidance document and using the device specific grouping - DGT.

Example:

Product Owner “HSA Zen” manufactures 3 different dental cements of different cement materials as follows:

Product name	Description
HSA Zen 1 dental cement	Main Constituent: Zinc Phosphate Available as 2g and 4g syringes
HSA Zen 2 dental cement	Main Constituent: Polycarboxylate Available as 2g syringe and 2g kit (dispenser, mixing pad)
HSA Zen 3 dental cement	Main Constituent: Glass Ionomer Available as 2g and 4g syringes

Using the general grouping criteria in GN-12-1

Based on general grouping criteria in GN-12-1 guidance document, these 3 products cannot be grouped together as a FAMILY because of the different product material which does not qualify as having a common design and manufacturing process.

Using device specific grouping - DGT

In order to submit a product registration using the device specific grouping criteria in GN-12-2 guidance document - DGT, the applicant has to determine if the dental medical devices fulfill the DGT requirements:

From the same product owner	**Yes** ("HSA Zen" is the common product owner)
Risk classification Class B?	**Yes** (all cement products are Class B medical devices)
Falls within the descriptor of one DGT	**Yes;** all 3 products fall under the DGT of : **DGT - Dental Cement** *Descriptor for Dental Cement*: Compounds used to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It may include accessories to complete the cementing procedure.

Therefore, these 3 Class B dental cements, which are different in design and manufacturing process, can be grouped together in one application using the DGT "Dental Cement". Devices will be listed on SMDR as "HSA Zen Dental Cement".

Addition of New Models to a DGT Listing on the SMDR

The addition of new dental device models to an existing SMDR DGT device listing through a Change Notification is only permissible if the new models being added fulfill the device specific grouping criteria to be grouped using the same DGT. Registrant can submit a Change Notification if all DGT requirements are met. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

4. DEVICE SPECIFIC GROUPING OF HEARING AIDS

This section applies only to Class B hearing aids and excludes implantable hearing devices.

Generally, hearing aids can be categorised based on:

- Design (i.e Behind the ear (BTE) vs In the ear (ITE) (e.g. ITE devices have all components of the hearing aids are contained in tiny case shell that fits in the ear or canal))
- Technology for sound amplification (i.e. analogue vs digital)
- Communication technology (i.e Wireless vs Non-wireless communication)

A device specific grouping of hearing aids comprises of a collection of hearing aids that are:

- from the same product owner;
- within risk classification Class B only (hearing aids not including the implantable hearing devices);
- have the same design type (i.e. behind the ear **or** in the ear);
- have the same technology for sound amplification (i.e. analogue **or** digital); and
- have the same communication technology (i.e. wireless **or** non-wireless).

The product registration application may contain accessories of a lower risk class if they are specifically intended to be used together with the hearing aids.

For Class B only hearing aids, the applicant may choose to group their devices using the general grouping criteria described in GN-12-1 guidance document

or this device specific grouping criteria for hearing aids. This device specific grouping criteria for hearing aids would not be applicable for Class C and Class D medical devices (e.g. cochlear implant systems), as well as Class B hearing devices that are used in conjunction as part of an implantable hearing system (e.g. sound processors of a bone-anchored hearing system).

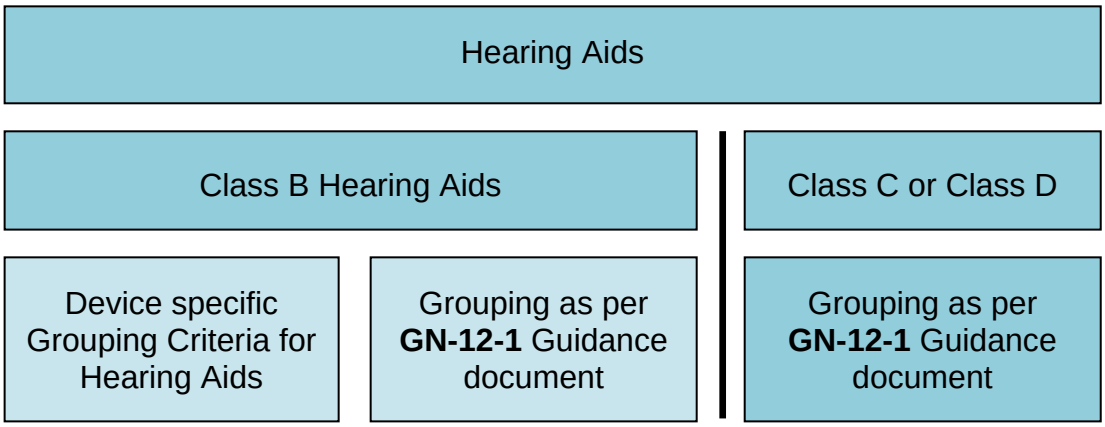
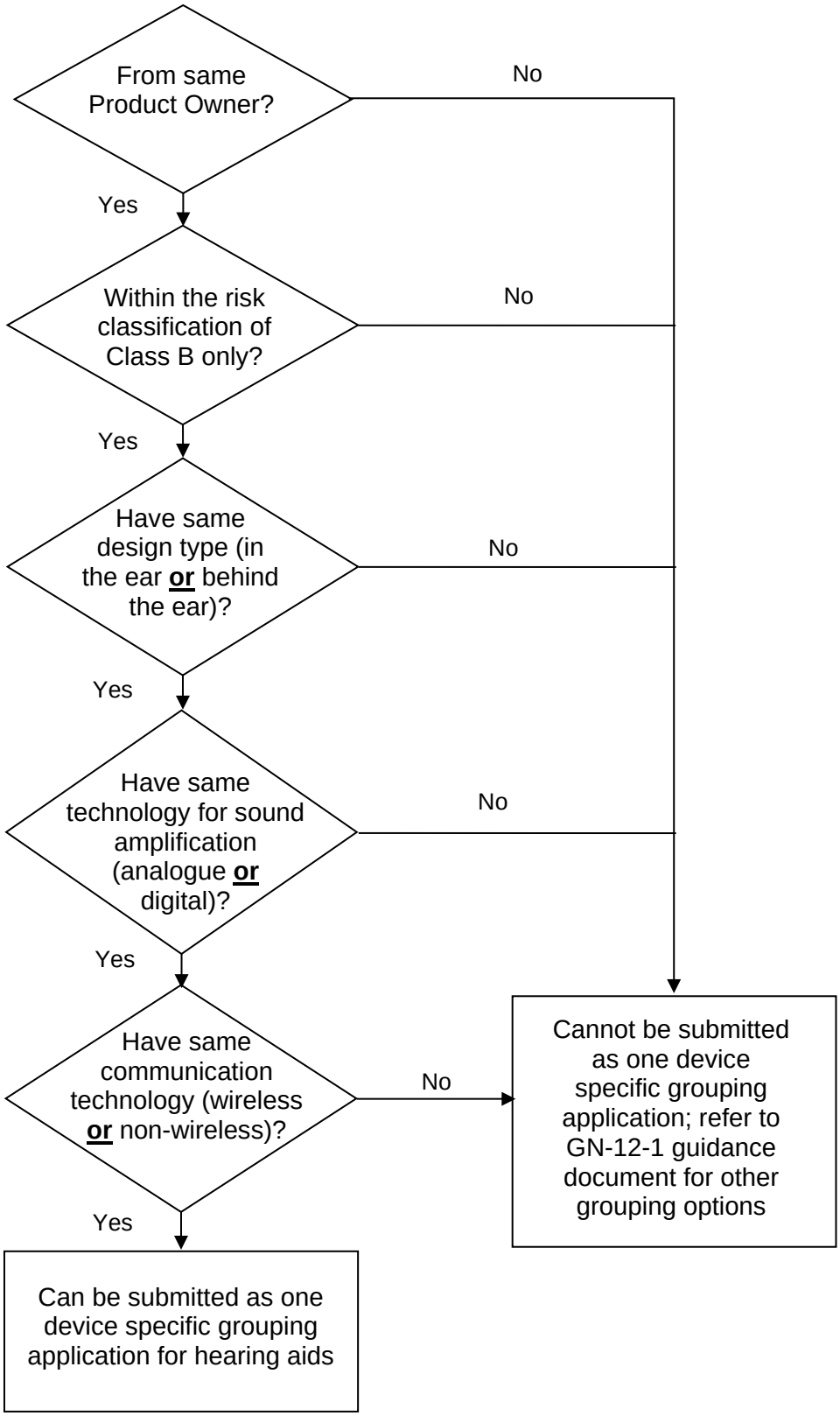


Figure 2 Hearing Aid grouping consideration

When hearing aids satisfy the above conditions to be grouped in one device specific hearing aid grouping application, but have different device proprietary names or brand names, the devices will be listed separately on the SMDR based on their proprietary names upon approval of the application.

Decision Flowchart for Grouping of Hearing Aids



The following example clarifies the possible grouping combinations using the Device Specific Grouping of Hearing Aids.

Example:

Product Owner “HSA Zen” manufactures a collection of Class B hearing aids, they:

(i) have the **same** design type – all are **in the ear** design

(ii) have the **same** technology for sound amplification - **digital**

(iii) comes in ***two variants*** in communication technology – using **wireless** and **non-wireless technology**

Table 1 Grouping consideration using the Device Specific Grouping of Hearing Aids for this example

GN-12-2 Grouping Criteria	Behind the Ear		In the Ear	
	Analogue	Digital	Analogue	Digital
Wireless	✗	✗	✗	✓
Non-wireless	✗	✗	✗	✓

Using Device Specific Grouping of Hearing Aids

Based, on the tabulated consideration, the hearing aids, which differ in the communication technology criteria, they cannot be grouped together in a single application. Hence, **two** product registration applications have to be submitted separately.

1. HSA Zen hearing aids (non-wireless), and
2. HSA Zen hearing aids (wireless).

Addition of New Models to a device specific Hearing Aid Listing on the SMDR

The addition of new hearing aids to an existing SMDR hearing aid device listing through a Change Notification is only permissible if the new models being added fulfill the device specific grouping criteria and carry the same device proprietary as the SMDR-listed devices. Although, the new medical devices may satisfy the criteria to be grouped as a FAMILY with the registered medical devices, a new product registration application has to be submitted for the registration of these new medical devices that have different proprietary names from those registered on the SMDR. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

5. DEVICE SPECIFIC GROUPING OF IMMUNOHISTOCHEMISTRY IN VITRO DIAGNOSTIC REAGENTS

Immunohistochemistry (IHC) IVD reagents are *in vitro* diagnostic (IVD) products consisting of polyclonal or monoclonal antibodies labelled with directions for use and performance claims, which may be packaged with ancillary reagents in kits. Their intended use is to identify, by immunological techniques, antigens in tissues or cytologic specimens, and excludes reagents specifically intend to be used with flow cytometry. This section applies to IHC IVD reagents and their accessories only.

A device specific IHC IVD grouping category comprises of a collection of IVD reagents and their accessories that are:

- from the same product owner;
- is of the same risk classification (either Class B only or Class C only);
- based on IHC methodology; and
- within the same IHC IVD Grouping Category as listed below.

When IHC IVD reagents and their accessories satisfy the criteria to be grouped under one of the six prescribed IHC IVD grouping categories, they can be grouped together and submitted in one product registration application. In cases where the IHC IVD reagents have different device proprietary names, they may be grouped together during the product registration submission. However, the products will be listed separately on the SMDR based on their proprietary names.

The device name listed on the SMDR upon approval will be based on the proprietary name and the IHC IVD grouping category used during product registration. The individual models will be listed on the SMDR as per product name (device label) under the section “Model Info”. Alternatively, product owners and applicants may choose to group these devices using the general grouping criteria described in GN-12-1 guidance document.

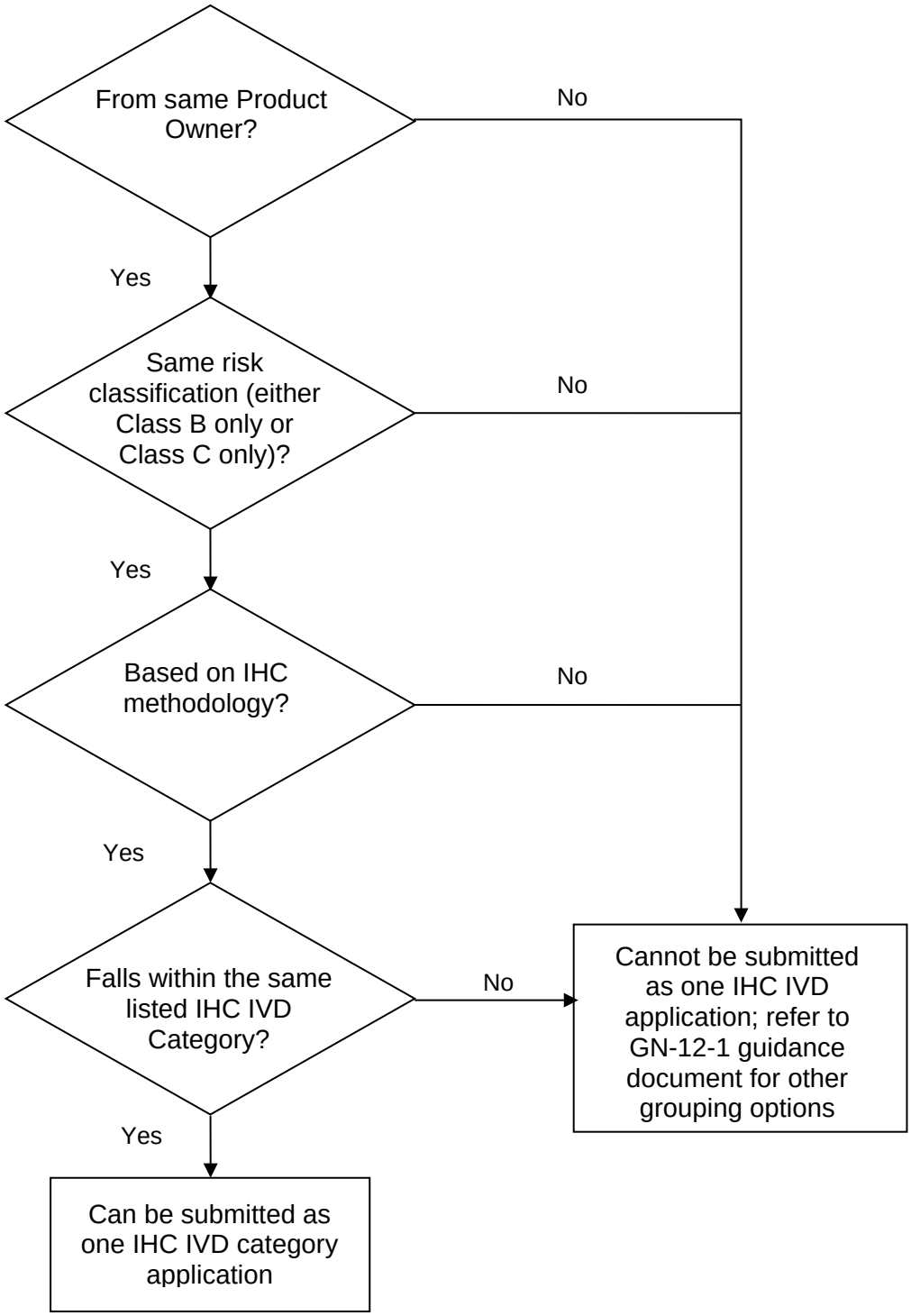
If any reagent and its accessories are intended for multiple usage categories such that it can be grouped in more than one IHC IVD grouping category, the applicant can choose to group the reagents and their accessories as part of any one of the IHC IVD categories it qualifies. Information to support the intended purposes of all the reagents and their accessories must be submitted as part of the product registration application.

LIST OF IHC IVD GROUPING CATEGORIES

The list of IHC IVD categories for the device specific grouping of Class B only or Class C only IHC reagents and their accessories is a closed and positive list.

S/N	IHC IVD Grouping Category (closed list)	Examples of Analytes (non-exhaustive list)
1	Selective Therapy	(i) HER2/neu (ii) EGFR
2	Hematologic Disorder and Blood Cancer Markers	(i) Immunoglobulin Kappa chain (ii) Immunoglobulin Lambda chain
3	Other Cancer Markers	(i) Alpha fetoprotein (AFP) (ii) Cytokeratins (iii) CD117
4	Pathogen Markers	(i) Escherichia coli (ii) Candida albicans (iii) Herpes simplex virus protein VP22
5	Immune Disorders	(i) Anti-nuclear antibodies (ANAs) (ii) Anti-topoisomerase (iii) Organ-specific autoantibodies (iv) Anti-Streptococcal Hyaluronidase (v) Anti-Streptokinase (vi) Anti-Streptolysin O (vii) C-Reactive Protein
6	Other Pathology Markers	(i) P57 (ii) Growth hormone

Decision Flowchart for Grouping of Class B only or Class C only IHC IVD Grouping Category



Examples:

Product Owner is “HSA”

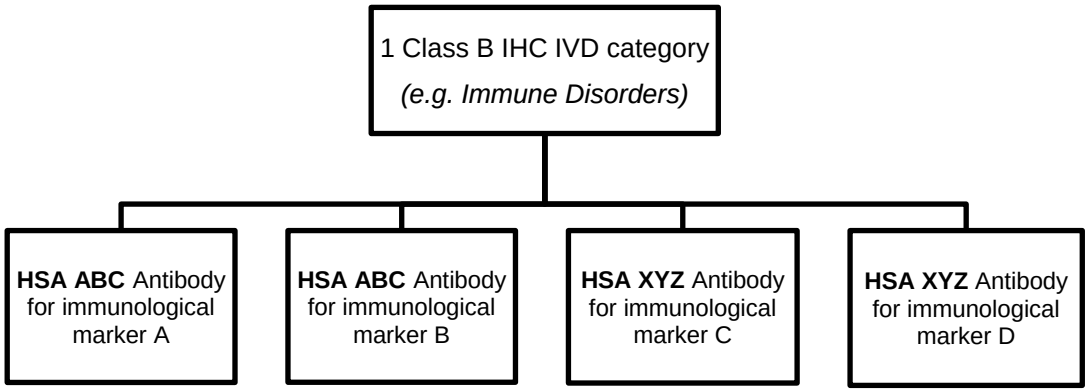


Figure 3 Example of a Class B IHC IVD grouping category with 4 products within the category

Based on the example provided in Figure 3, the 4 IHC IVD products qualify for submission as one IHC IVD grouping category of “Immune Disorders” and would be listed as 2 SMDR listings based on their proprietary names:

1. HSA ABC Immunohistochemistry Antibody (Immune Disorders)*
2. HSA XYZ Immunohistochemistry Antibody (Immune Disorders)**

* HSA ABC Antibody for immunological markers A and B are under one listing in which HSA is the product owner and ABC is the proprietary name.

** HSA XYZ Antibody for immunological markers C and D are under one listing in which HSA is the product owner and XYZ is the proprietary name.

Examples:

Product Owner is “HSA”

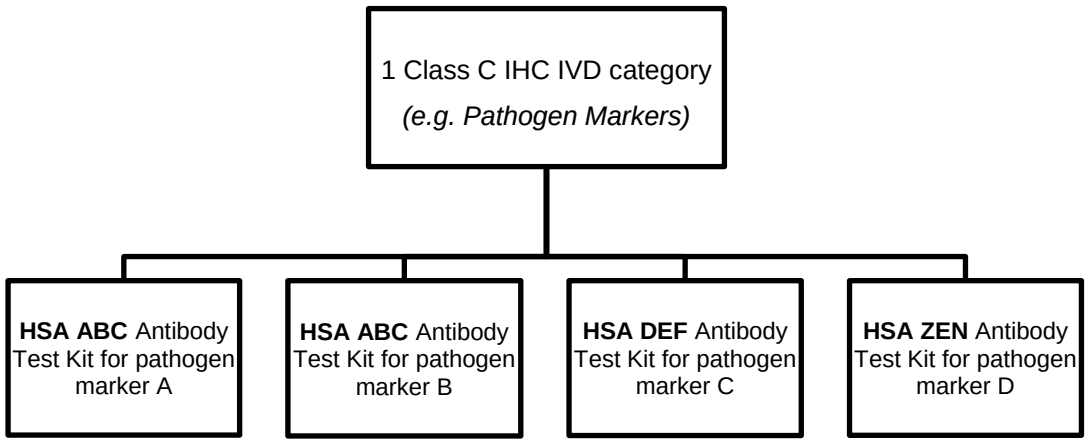


Figure 4 Example of a Class C IHC IVD grouping category with 4 products within the category

Based on the example provided in Figure 4, the four IHC IVD products qualify for submission as one IHC IVD grouping category of “Pathogen Markers” and would be listed as 3 SMDR listings based on their proprietary names:

1. HSA ABC Immunohistochemistry Antibody Test Kit (Pathogen Markers)*
2. HSA DEF Immunohistochemistry Antibody Test Kit (Pathogen Markers)**
3. HSA ZEN Immunohistochemistry Antibody Test Kit (Pathogen Markers)***

* HSA ABC Antibody Test Kit for pathogen markers A and B are under one listing in which HSA is the product owner and ABC is the proprietary name.

** HSA DEF Antibody Test Kit for pathogen marker C is under one listing in which HSA is the product owner and DEF is the proprietary name.

*** HSA ZEN Antibody Test Kit for pathogen marker D is under one listing in which HSA is the product owner and ZEN is the proprietary name.

Addition of New Models to an IHC IVD Grouping Category Listing on the SMDR

The addition of new IHC IVD products to an existing SMDR IHC IVD device listing through a Change Notification is only permissible if the new models being added fulfill the device specific grouping criteria (i.e. from the same product owner, of the same risk class and within the same IHC IVD grouping category) and have the same device proprietary name as the SMDR-listed medical devices. Although, the new medical devices may satisfy the criteria to be grouped as a FAMILY with the registered medical devices, a new product registration application has to be submitted for the registration of these new medical devices that have different proprietary names from those registered on the SMDR. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

6. DEVICE SPECIFIC GROUPING OF FLUORESCENCE IN SITU HYBRIDISATION PROBES IN VITRO DIAGNOSTIC REAGENTS

Fluorescence in situ hybridization (FISH) probes are *in vitro* diagnostic (IVD) products that allow for the detection and localisation of the presence or absence of specific DNA sequences on chromosomes, whereby the hybridisation of the probes with the DNA site will be visible using fluorescence microscopy.

A device specific grouping of FISH probes IVD grouping category comprises of a collection of IVD reagents and their accessories that are:

- from the same product owner;
- is of the same risk classification (either Class B only or Class C only);
- based on FISH methodology; and
- within the same FISH probes IVD Grouping Category as listed below.

When FISH Probes IVD reagents and their accessories satisfy the criteria to be grouped in one of the prescribed FISH Probes IVD grouping categories, they can be grouped together and submitted in one product registration application. In cases where the FISH probes IVD reagents have different device proprietary names, they may be grouped together during the product registration submission. However, the products will be listed separately on the SMDR based on their proprietary names.

The device name listed on the SMDR upon approval will be based on the proprietary name and the FISH Probes IVD grouping category used during product registration. The individual models will be listed on the SMDR as per product name (device label) under the section “Model Info”. Alternatively, product owners and applicants may choose to group these devices using the general grouping criteria described in GN-12-1 guidance document.

If any reagent and its accessories are intended for multiple usage categories such that it can be grouped in more than one FISH probes IVD grouping

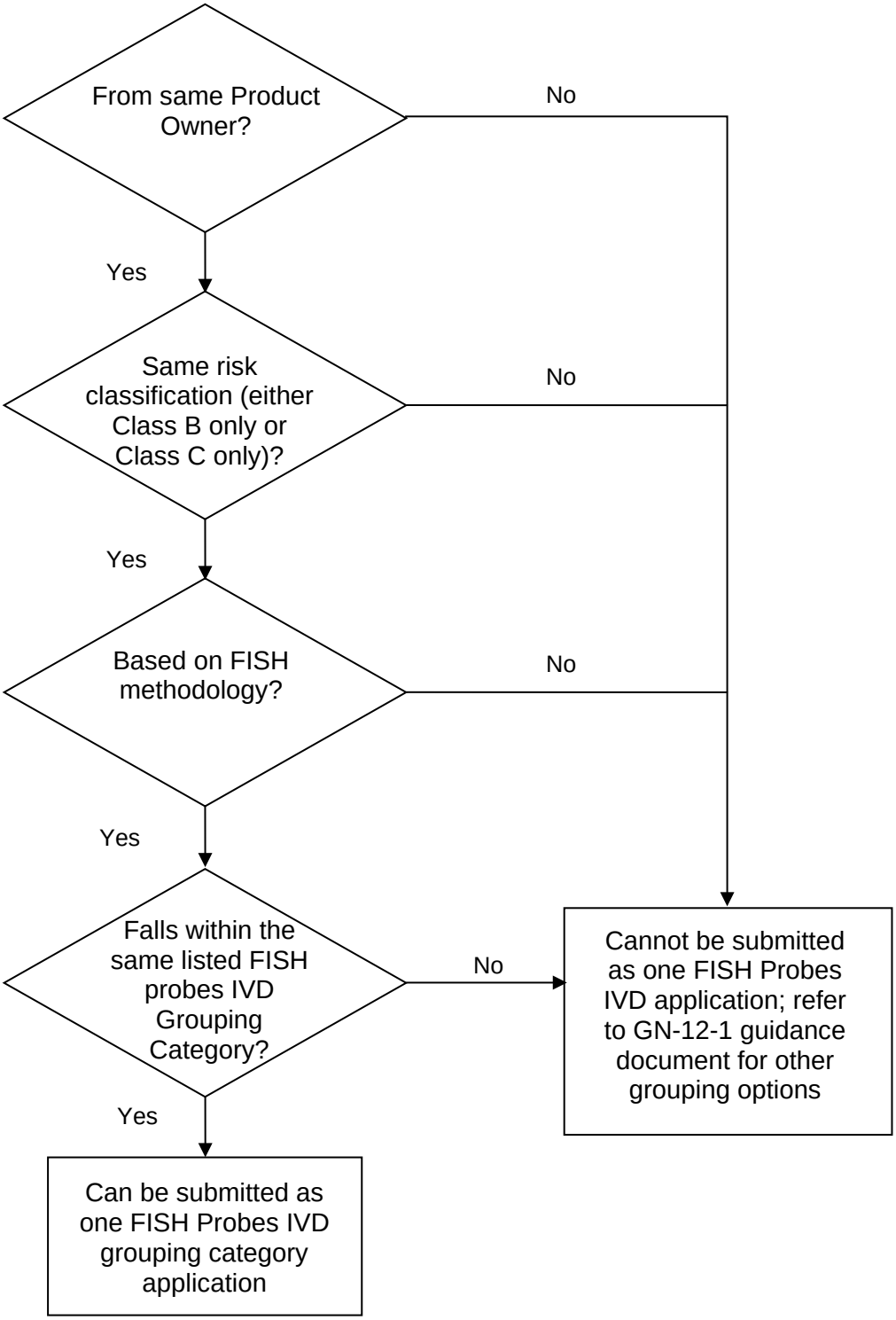
categories, the applicant can choose to group the reagent and their accessories as part of any one of the FISH probe IVD categories it qualifies. Information to support the intended purposes of all the reagents and their accessories must be submitted as part of the product registration application.

LIST OF FISH PROBES IVD GROUPING CATEGORIES

The list of FISH probes IVD grouping categories for the device specific grouping of Class B only and Class C only FISH probes IVD reagents and their accessories is a closed and positive list.

S/N	FISH Probes IVD Grouping Category (closed list)	Examples of Gene Targets (non-exhaustive list)
1	Selective Therapy	(i) ALK gene (ii) HER2
2	Pre-natal Testing	(i) Chromosomes 13, 21, 18, X and Y
3	Genetic Testing of Inheritable Disease	(i) ELN gene
4	Pathogen Identification	(i) Mycobacterium tuberculosis complex (MTC) (ii) Escherichia coli
5	Hematologic Disorder and Blood Cancer Markers	(i) Chromosomes 3, 7, 9 and 11
6	Other Cancer Markers	(i) LAMP2 gene (ii) Topoisomerase 2A gene

Decision Flowchart for Grouping of Class B and Class C FISH Probes IVD Grouping Category



Example:

Product Owner is “HSA”

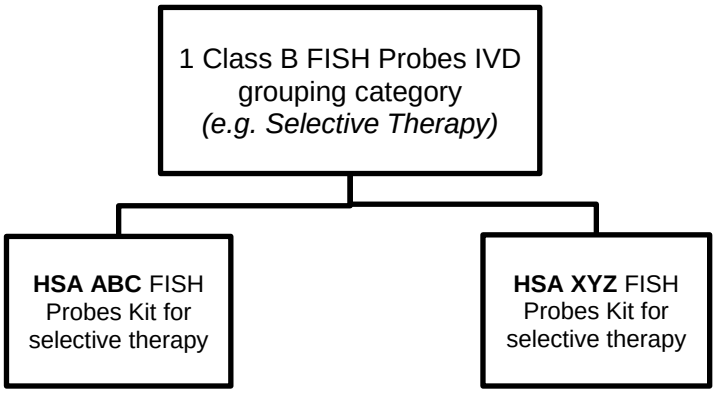


Figure 5 Example of a Class B FISH Probes IVD grouping category with 2 products within the category

Based on the example provided in Figure 5, the 2 FISH Probes IVD kits qualify for submission as one FISH Probes IVD grouping category of “Selective Therapy” and would be listed as 2 SMDR listings based on their proprietary names:

1. HSA ABC FISH Probes Kit (Selective Therapy)*
2. HSA XYZ FISH Probes Kit (Selective Therapy)**

* HSA ABC FISH Probes kit as one listing in which HSA is the product owner and ABC is the proprietary name.

** HSA XYZ FISH Probes kit as one listing in which HSA is the product owner and XYZ is the proprietary name.

Addition of New Models to a FISH Probes IVD Grouping Category Listing on the SMDR

The addition of new FISH Probes to an existing SMDR FISH Probes IVD device listing through a Change Notification is only permissible if the new models being added fulfill the device specific grouping criteria (i.e. from the same product owner, of the same risk class and within the same FISH Probes IVD grouping category) and have the same device proprietary name as the SMDR-listed medical devices. Although, the new medical devices may satisfy the criteria to be grouped as a FAMILY with the registered medical devices, a new product registration application has to be submitted for the registration of these new medical devices that have different proprietary names from those registered on the SMDR. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

7. DEVICE SPECIFIC GROUPING OF IN VITRO FERTILISATION MEDIA

In vitro fertilization (IVF) is a procedure in which eggs (ova) from a woman's ovary are removed. They are fertilised with sperm in a laboratory procedure, and then the fertilised egg (embryo) is returned to the woman's uterus.

IVF is a medical procedure where an egg is fertilised by a sperm outside the body: *in vitro*. IVF instruments and media are necessary to ensure this medical procedure is performed successfully. IVF media products are used in a wide range of *in vitro* procedures, involving processing, manipulation and conditioning of sperm, oocytes, blastocysts and embryos. The intended use of IVF media may range from maintenance of the physiological homeostasis required to support and promote fertilisation *in vitro*, to the maintenance of the physiological homeostasis of the cells during the cryopreservation process and the minimisation of cellular damage during the freezing process. IVF media products may be comprised of a cocktail of physiological inorganic salts, energy sources, amino acids and proteins, and are available in a range of different formulations.

A device specific grouping of IVF media comprises of a collection of IVF media that are:

- from the same product owner;
- R2 ► indicated for the same cell type(s) e.g. all models for oocyte handling, or all models for both oocytes and sperms handling◄

R2 ► When IVF media products satisfy the above criteria, they can be grouped together and submitted in one application for registration. Certain IVF media products e.g. oil overlay for culture medium, do not indicate usage on any specific cell type. Such IVF media products can be grouped with IVF media products indicated for specific cell type(s) provided they are compatible with each other.

IVF media products with different device proprietary names will be listed separately on the SMDR based on their proprietary names. The device name listed on the SMDR will follow the following format: “<Product owner name> <Proprietary name><(IVF media for <cell type)>”. E.g. “*HSA XYZ (IVF media for oocytes)”*, in which “HSA" is the product owner name and “XYZ” is the proprietary name. IVF media not indicated for specific cell type will be listed together with the compatible IVF media. ◄

Alternatively, product owners and their applicants may choose to group these devices using the general grouping criteria in GN-12-1 guidance document.

R2 ► **Examples of Device Specific Grouping of In Vitro Fertilisation Media**

"HSA" is the product owner. "ABC", "DEF" and "XYZ" are proprietary names.

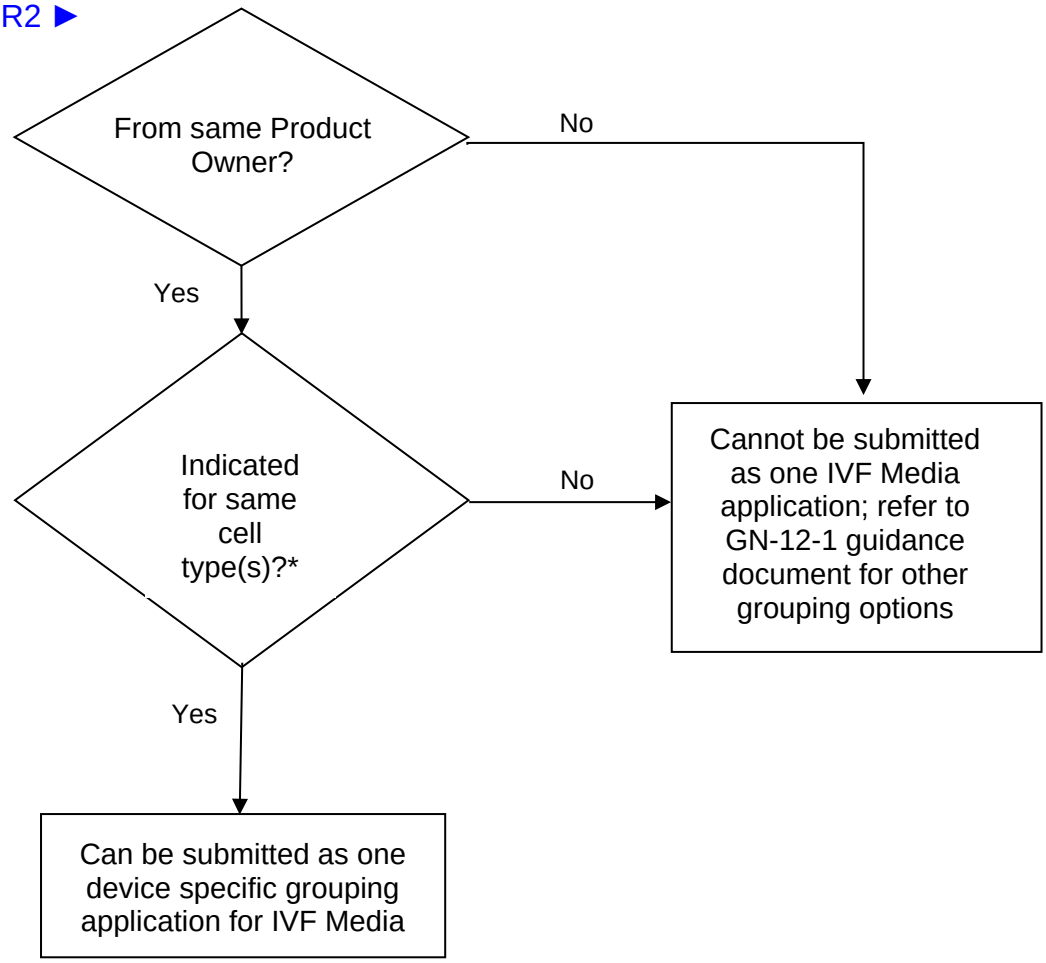
Example	Models for premarket submission	Grouping for premarket submission
1.	1. HSA ABC IVF media for use as culture medium for oocytes 2. HSA ABC IVF media for use as culture medium for oocytes and sperms 3. HSA XYZ IVF media for use as culture medium for oocytes 4. HSA XYZ IVF media for use as culture medium for oocytes and sperms 5. HSA DEF IVF media for freezing oocytes 6. HSA DEF IVF media for thawing oocytes	Submit as two premarket applications. These four models indicated for **oocytes** only to be grouped in one application 1. HSA ABC IVF media for use as culture medium for **oocytes** 2. HSA XYZ IVF media for use as culture medium for **oocytes** 3. HSA DEF IVF media for freezing **oocytes** 4. HSA DEF IVF media for thawing **oocytes** These two other models indicated for **oocytes and sperms** to be grouped in another application **1.** HSA ABC IVF media for use as culture medium for **oocytes and sperms** 2. HSA XYZ IVF media for use as culture medium for **oocytes and sperms**
2.	1. HSA ABC IVF media for use as culture medium for oocytes 2. HSA ABC IVF media for use as culture medium for oocytes and sperms 3. HSA XYZ IVF media; Oil overlay for culture medium	Submit as minimum two applications. This model indicated for **oocytes** to be submitted in one application **1.** HSA ABC IVF media for use as culture medium for **oocytes**

	4. HSA XYZ IVF media; human albumin as protein supplement in culture medium	This model indicated for **<u>oocytes and sperms</u>** to be submitted in another application **1.** HSA ABC IVF media for use as culture medium for **oocytes and sperms** Models #3 and #4 may be added to either of the applications or to both applications since they are not specific to any cell type. This is provided they are compatible with the models in the application.

◀

Decision Flowchart for Grouping of IVF Media Products

R2 ►



* Certain IVF media products do not indicate for any specific cell type can be grouped with IVF media products that are indicated for specific cell type(s) provided they are compatible with each other.

◄

Addition of New Models to an IVF Media Listing on the SMDR

The addition of new IVF media products to an existing SMDR IVF Media device listing through a Change Notification is only permissible if the new models being added fulfill the device specific grouping criteria and carry the same device proprietary name as the SMDR-listed medical devices. Although, the new medical devices may satisfy the criteria to be grouped as a device specific group with the registered medical devices, a new product registration application has to be submitted for the registration of new medical devices that have different proprietary names from those registered on the SMDR. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

R1.1 ►

8. DEVICE SPECIFIC GROUPING OF IVD ANALYSERS

IVD analysers are equipment intended to be used with IVD reagents so as to allow the IVD reagents to achieve their intended use. IVD analysers are typically instruments that analyse the reaction and yield a result of positive, negative, amount of analyte detected, etc.

An IVD analyser FAMILY is a collection of IVD analysers. Each analyser in the FAMILY fulfills the following criteria:

- Same product owner;
- Same proprietary name;
- Same risk classification;
- Same methodology / principles of operation; and
- Differences among analysers fall within a list of permissible variants.

The IVD analyser FAMILY may contain accessories of the same or lower risk class if these accessories are specifically intended to be used with the analysers in the FAMILY.

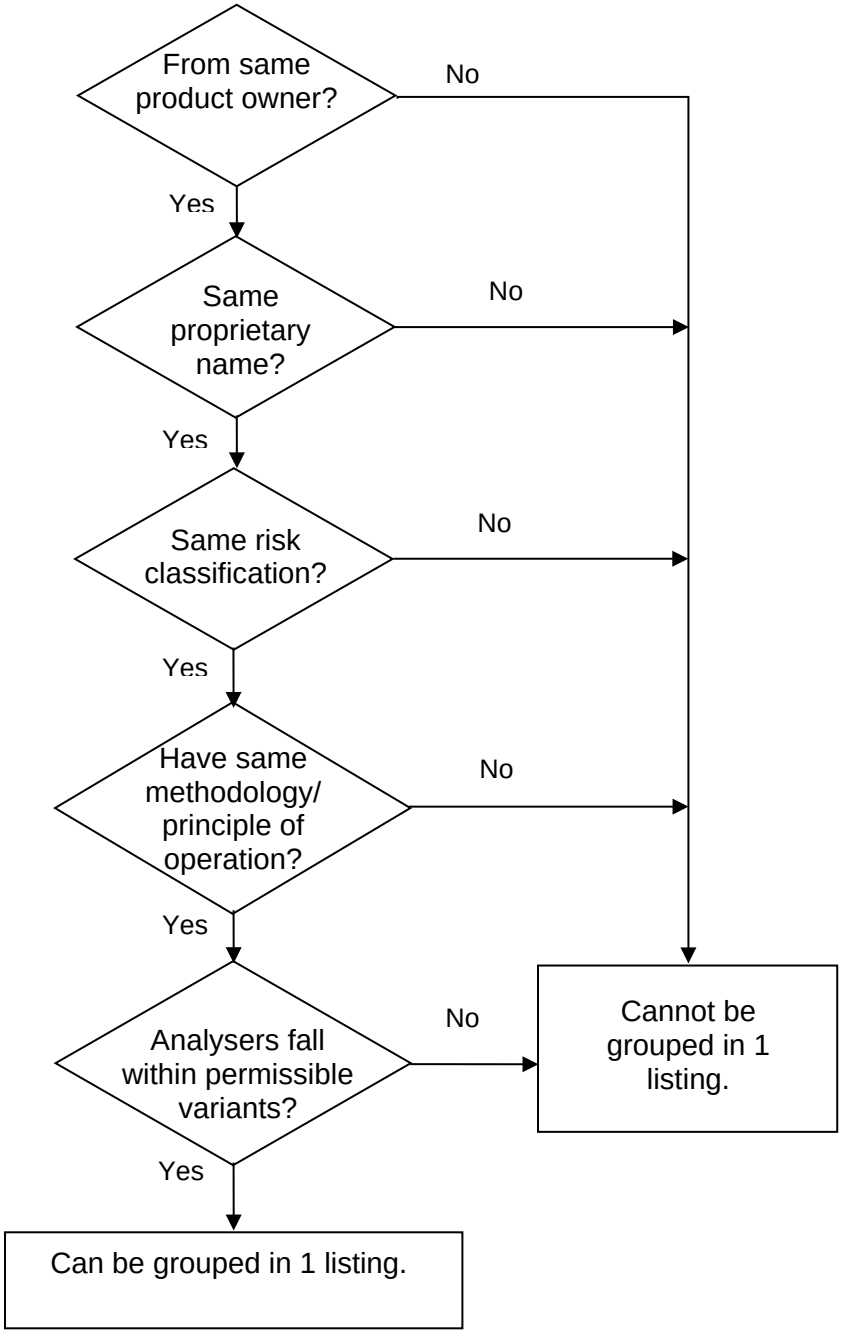
Applicants may choose to list IVD analysers with their respective IVD TEST KITS using the IVD SYSTEM grouping criteria described in GN-12-1 Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria or to list IVD analysers separately as part of an IVD analyser FAMILY in a SPLIT listing. Please refer to GN-34 Guidance Document for IVD Analysers for more information on IVD analyser listing options.

LIST OF PERMISSIBLE VARIANTS FOR IVD ANALYSER FAMILY

Kindly refer to the table below for permissible and non-permissible variants for the IVD analyser FAMILY.

Permissible Variants	Non-Permissible Variants
1. Features that do not impact the diagnostic function • throughput • differences in user interface • printing function • wireless capability • software • sample volume • onboard stability • calibration frequency	1. Features that impact the diagnostic function or lead to different performance characteristics for their compatible reagent kits for example but not limited to: • sensitivity • specificity • linearity • measuring range 2. Methodology/ principles of operation

Decision flowchart for grouping of IVD analysers as a FAMILY



Addition of New Models to an IVD ANALYSER FAMILY Listing on the SMDR.

The addition of new IVD analysers to an existing SMDR IVD analyser FAMILY listing through a Change Notification is only permissible if the new IVD analysers fulfil the IVD analyser FAMILY specific grouping criteria.

If a new IVD analyser has a different proprietary name from the existing IVD analysers in the FAMILY, a new product registration application must be submitted for the IVD analyser even though the new analyser fulfils the other FAMILY criteria. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information. ◄

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

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HSA
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