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MEDICAL DEVICES BRANCH
MEDICAL DEVICES CLUSTER
GROUPING ENQUIRY FORM ON MEDICAL DEVICES

E-Form ID: **MDG** Version No: 5 Effective Date: 19 Nov 2019

Notes:

a. Please download the latest version of the form at: https://www.hsa.gov.sg/medical-devices/registration/grouping

b. Please ensure that all mandatory fields (indicated by red boxes) are completed including the declaration in Section E. **Incomplete forms will not be processed and will be rejected.**

c. After completion of the form, click on the "Save" button on the first page or last page of the form to validate (check that all mandatory fields are completed) and save the form.#

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Save

SECTION A – PARTICULARS OF ENQUIRER	
Salutation	
Name	
Designation	
Email Address	
Contact Number	

SECTION B – COMPANY INFORMATION			
Company Name			
Block No			
Street Name			
Level		Unit	
Building			
City		State	
Country		Postal Code	

SECTION C - PRODUCT DETAILS			
Product Name			
Name of Manufacturer		Country of Manufacturer	
Proposed Grouping			
Intended Use			
Indications for Use			

SECTION D – REMARKS	
Remarks	

SECTION E - DECLARATION

☐ I declare that the particulars given in this application are true and that the supporting documents enclosed are authentic or true copies.

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Please read through **Annex 1** and submit this form, together with all required product information to: https://crm.hsa.gov.sg/event/feedback

Annex 1
List of Required Product Information

1. **Product Instructions for Use (IFU) or Operator's Manual or Package Insert** that should elucidate the following (if information is not present in these documents, please provide the following details):

   - ✓ Primary mode of action of product (i.e. how the product achieves its intended use)
   - ✓ Accessories for use with this medical device
   - ✓ Method of operation/directions for use (i.e. procedure for use of the product)
   - ✓ Technical specifications of the product (e.g. power/frequency of ultrasonic emission)
   - ✓ Physical/chemical composition of product (e.g. concentration of chemical/biological ingredients if any)
   - ✓ Animal or biological tissue that has been incorporated. If none, please state so.

2. **Product Catalogue or Product Labels** that represent **all product codes**

3. **List of Configurations for the Grouping Enquiry**, with the following information provided:

   - ✓ Product codes of all members of the proposed grouping:
     - For general grouping (GN-12-1): collection of devices in a FAMILY, devices and/ or accessories under a SYSTEM, IVD reagents or devices of an IVD TEST KIT or IVD CLUSTER, or collection of devices in a GROUP
     - For device-specific grouping (GN-12-2): dental devices and accessories under a DENTAL GROUPING TERM (DGT), HEARING AIDs and their corresponding accessories, IVD reagents and accessories under a IMMUNOHISTOCHEMISTRY (IHC) grouping category, IVD reagents and accessories under a FLUORESCENCE IN SITU HYBRIDIZATION (FISH) grouping category, collection of IVF media under a IVD MEDIA grouping category, IVD analysers and their corresponding accessories under an IVD ANALYSERS FAMILY.

   - ✓ A tabular comparison on the design and manufacturing processes (e.g. additive manufacturing, sterilisation method etc.), composition, specifications/ features (e.g. materials, physical dimensions etc.), intended use/indications for use between each product code. Labelled pictorial representation (diagrams, photos, drawings) may be provided where necessary.

   - ✓ General grouping (GN-12-1): The common intended purpose for proposed FAMILY, IVD TEST KIT or SYSTEM. For IVD CLUSTER grouping, please specify the cluster category and testing methodology.
   - ✓ Device-specific grouping (GN-12-2): The risk class for the models within the proposed DGT, IHC or FISH grouping. For hearing aids, please specify the design type (BTE/ITE), sound amplification technology (analogue/ digital), and communication technology (wireless/ non-wireless). For IVD analysers, please specify the methodology/ principle of operation.
   - ✓ Justification for proposed grouping based on the grouping criteria and list of permissible variants (e.g. for proposed FAMILY, justify why the variations between members should be considered to be permissible variant).

Important Information

1. Please ensure all the product information listed in **Annex 1** is provided. Failure to provide any of the required information would render the grouping enquiry incomplete. This Branch would not be able to provide advice on enquiries that are deemed incomplete.

2. Please read through **GN-12-1: Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria and GN-12-2: Guidance on Grouping of Medical Devices for Product Registration – Device Specific Grouping Criteria** prior to submission of the grouping enquiry for medical devices. The guidance documents are accessible via: https://www.hsa.gov.sg/medical-devices/guidance-documents

3. The List of Configurations of Medical Devices for Grouping Enquiry is accessible through the following link: https://www.hsa.gov.sg/medical-devices/registration/grouping

4. For other medical device related enquiries, please submit them via https://crm.hsa.gov.sg/event/feedback . Health products classification enquiries shall be submitted via https://crm.hsa.gov.sg/Webform/HPRG . Product enquiries submitted using Grouping Enquiry Form will not be accepted for review by this Branch.