

Premarket Submission Checklist for Medical Device Product Registration Submission

Note: This checklist is not applicable for applications under the Immediate route.

Instructions: Use this checklist before submitting your product registration dossier to verify that all required supporting documents have been included.

All guidance (GN) documents referenced below are available for download at: <https://www.hsa.gov.sg/medical-devices/guidance-documents>

Device name: _____

IMPORTANT NOTE

1. Please do not submit product registration application if any of the required documents are not available.

Incomplete submissions will be rejected and fees paid will not be refunded.

The following will be considered as incomplete submission (non-exhaustive):

- Premarket Submission Checklist is not submitted with the application
- Premarket Submission Checklist is submitted but not completed or only partially filled in
- Required SHARE folders are empty — no documents uploaded for applicable sections
- Annex 2 List of Configurations does not tally with information in SHARE (e.g., Identifiers, Number of Models)
- Annex 2 List of Configurations file mapping not submitted for entire implant system (including accessories)
- Document(s) uploaded to the wrong SHARE folder (e.g. Sterilisation report uploaded to the Biocompatibility folder)
- Document(s) uploaded to Section 13 (Others) when an appropriate SHARE folder exists
- Placeholder document(s) uploaded to indicate submission at a later date (e.g., a file stating "to be provided later" or blank file)
- SHARE folders corresponding to Section 8 are empty with no justification included in the Checklist

2. Section 8: For section(s) deemed not applicable, reason of non-applicability shall be provided.

Example: If no supporting document is specified for Section 8.1 (Biocompatibility), justification to explain the non-applicability (e.g. device is not patient contacting) is required

3. As a good practice, document file names should be meaningful and provide some indication of their content.

Legend:

F	Full evaluation route
A	Abridged evaluation route
E	Expedited evaluation route

SECTION 1: LETTER OF AUTHORISATION

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
1.1	Letter of Authorisation (LOA) of Registrant by the Product Owner for all products to be registered, using the latest template as per <i>GN-15 Annex 1</i> . Note: LOA should cover all models submitted for registration under Annex 2 List of Configurations (section 2.1)	F, A	F, A, E

SECTION 2: LIST OF CONFIGURATIONS

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
2.1	Annex 2 List of Configurations (<i>GN-17 / GN-18</i>), including complete list of all device configurations subject to the submission. - To use the latest version of the Excel template “Annex 2 for GN-17 and GN-18 List of Configurations” provided here - Do not include Class A devices or non-medical devices - Must be submitted as a Microsoft Excel file - For applications containing implants, please fill-up the “List of config (w File Mapping)” tab instead. The additional columns in this tab are applicable to all models, including the accessories in the List of Configurations - For devices involving software, please indicate the software version to be supplied in Singapore under the “Brief Description of Item” column. Please note that the exact software version (e.g. down to tracking of bug fixes) should be provided	F, A	F, A, E

SECTION 3: PROOF OF REFERENCE AGENCY APPROVAL(S)/ REGULATORY RELIANCE

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
3.1	Copies of approval letter(s) from each reference agency (refer to GN-15). - For CE-marked devices, the EU Declaration of Conformity by the product owner must be submitted, in addition to the EC Certificate issued by the notified bodies. - For Japan MHLW, certificates in Japanese must be accompanied by an English translation for applications leveraging on Japan approvals. - For Malaysia MDA, the medical device registration certificate from MDA and the Certificate of Conformity for full conformity assessment issued by CAB must be submitted.	A	A, E

SECTION 4: DECLARATIONS

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
4.1	<u>Template in Annex 4 of GN-15</u> Declaration from product owner on company letterhead that labelling, packaging and IFU for sale in Singapore are identical (or not identical) to that approved by the reference agency. If not identical, provide a description of the differences.	A	A, E
4.2	<u>Template in Annex 4 of GN-15</u> Summary of all reportable AEs and FSCAs since first global market introduction - To be provided in tabular format as per <i>TR-01 (GMD)</i> / <i>TR-02 (IVD)</i>. - For devices with no AEs or FSCAs to date, declaration from product owner confirming no AEs or FSCAs since commercial introduction globally.	F, A	F, A, E
4.3	Proof of marketing history, which can be supported by: - Invoice with date, - Proof of sale, or - Declaration on marketing history as per <i>Annex 2 of GN-15</i>, completed by the local Applicant	-	E (ECR1 only)

4.4	Safety declaration as per <i>Annex 3 of GN-15</i> , completed by the local Applicant .	-	E (ECR1 only)
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SECTION 5: EXECUTIVE SUMMARY

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
5.1	• Introductory description of the device, intended use and indications for use • Information on use of the device: targeted patient population, user profile, specific disease/clinical condition, mode of action, assay principle, etc. • Description of any unique or novel features (e.g. nanotechnology, animal/microbial cells or tissues). • High-level background information, history, or relation to other approved/predicate devices or previous submissions to HSA • List of countries from HSA's reference regulatory agency jurisdictions where the device is marketed, as applicable • Date (accurate to MM/YYYY) and country of first global commercial distribution • Registration status (approved / not submitted / pending / rejected / withdrawn) and approved intended use in HSA's recognised reference agencies, in tabular format as per <i>TR-01 / TR-02</i>. Reasons for any withdrawal or rejection must be provided. The registration status should not be indicated as "Not Applicable" or "NA".	F, A	F, A, E

SECTION 6: ESSENTIAL PRINCIPLES CHECKLIST AND DECLARATION OF CONFORMITY

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
6.1	Essential Principles (EP) conformity checklist, which can be supported using - Singapore EP checklist (as per template in GN-16) - EU Essential Requirements checklist - Australian Essential Requirements checklist	F, A	F, A, E
6.2	Declaration of Conformity (DoC), which can be supported using - Singapore DoC (as per template in GN-11) - EC DoC - Australian DoC	F, A	F, A, E

SECTION 7: DEVICE DESCRIPTION

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
7.1	- Comprehensive description of the device including technology, functionalities, features, and connectivity capabilities (e.g. wireless, Bluetooth, internet-connected). Include labelled pictorial representations (diagrams, photos, drawings) where applicable - Risk class and applicable classification rule based on GN-13, GN-14 or GL-07 - Product specifications - List of medical device accessories intended for use in combination with the device. - To note that accessories (except for Class A) to be supplied separately require registration and hence shall be listed in the Annex 2 LOC (<i>section 2.1</i>) - Where safety and effectiveness data from similar or previous generation devices are used: list of such devices with HSA registration status (e.g. product number), and a comparison table of design, specifications, and intended use/indications between the subject device and comparator devices, with labelled pictorial representations where necessary. - List of all materials in direct or indirect contact with the patient or user. Where there are specific material safety concerns (e.g. impurities, residue levels), provide additional information (e.g. conformity to material standards, Certificate of Analysis).	F, A	F, A, E

SECTION 8: DESIGN VERIFICATION AND VALIDATION

Please submit the supporting documents applicable to the device to be registered.

Full study reports containing complete descriptions of the objectives, protocols, methods of data analysis, results and conclusions are to be provided for Full (F) routes, while summary reports containing a brief description of the study objectives, test methods, results and conclusions are to be provided for Abridged (A) and Expedited (E).

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes	If any of the sections are not applicable, please clearly indicate so and justify why
8.1	Biocompatibility – <i>applicable for device components in direct or indirect contact with patients</i> Studies supporting biocompatibility and assessing toxicology. If biocompatibility tests that are recommended by ISO 10993 were not performed, adequate justification must be provided.	F, A	F, A, E	
8.2	Sterilisation – <i>applicable for device components that are supplied sterile</i> Sterilisation validation report, EO residuals report (if applicable), and evidence of on-going sterilisation validation.	F, A	F, A, E	
8.3	Shelf-life / projected useful life - Specify the claimed shelf life or projected useful life (reusable medical device or equipment) of the device components. - Evidence that supports the product stability and package integrity over the claimed shelf-life. If applicable, both real time and accelerated stability studies are to be submitted. If real time aging has not been performed, adequate justification must be provided. Additional requirements for IVD devices: - Evidence supporting the stability during actual routine use of the device (real or simulated), including all applicable components (e.g. reagents, reaction cartridges) as well as stability during transport.	F, A	F, A, E	
8.4	Electrical safety – <i>applicable for devices that are electrically powered</i> Evidence supporting electrical safety. For example, if a device is claimed to meet the requirements of IEC 60601-1 / IEC 61010-1, summary test reports and/or certificates are to be submitted for verification of conformance to these standards.	F, A	F, A, E	

8.5	Electromagnetic compatibility – applicable for devices that emit or are susceptible to electromagnetic interference Evidence supporting electromagnetic compatibility. For example, if a device is claimed to meet the requirements of IEC 60601-1-2 / IEC 61326-1, summary test reports and/or certificates are to be submitted for verification of conformance to these standards.	F, A	F, A, E	
8.6	Software – applicable for devices involving software - Specify the version of the software to be supplied. <i>NOTE: The exact software version that represents all software changes/iterations (e.g. graphic interface, functionality, bug fixes, etc.) should be provided. Software version numbering that is solely for testing or internal use are not required.</i> - Summary of software development life cycle process including processes in place to manage the various life cycle activities. - Include the Software Requirements Specifications documenting functional, performance, interface, design, developmental, and other requirements for the software. - An overview of all verification, validation and testing performed for the software both in-house and in a simulated or actual user environment prior to final release. Where the software has been validated together with the IVD instruments (e.g. IVD analysers), reports of such validation addressing the safety and performance considerations for the software are to be provided. <i>NOTE: The version tested must be clearly identified and should match the release version of the software, otherwise to provide justification.</i> - All unresolved anomalies in the release version of the software should be summarised, along with a justification for acceptability (i.e. the problem, impact on safety and effectiveness, and any plans for correction of the problems). - Traceability Analysis linking product design requirements, design specifications, and testing requirements. Identified hazards should be tied to implementation and testing of the mitigations.	F, A	F, A, E	

8.7	Cybersecurity – applicable for devices with connectivity features Evidence to support the cybersecurity of connected medical devices such as wireless enabled, Bluetooth enabled, internet-connected and network-connected devices. Examples include, but are not limited to: • Cybersecurity vulnerabilities and risk analysis • Cybersecurity control measures • Security test reports and/or evidence to verify the device cybersecurity and effectiveness of the implemented cybersecurity control measures • A traceability matrix between security risks, security controls, and testing to verify those controls • Operating system (OS) information: For SaMD installed on a mobile computing device, the compatible OS(es) on which the software is intended to operate. • For medical device systems with a dedicated or embedded OS, the OS used or embedded to operate the system. • On-going plan, processes or mechanisms for surveillance, timely detection and management of cybersecurity-related threats throughout the useful life of the device, including Operating System reaching end-of-support, emerging vulnerabilities, and when a breach is detected.	F, A	F, A, E	
8.8	Machine learning – applicable for devices involving machine learning Refer to <i>GL-04</i> Regulatory Guidelines for Software Medical Devices including Machine Learning-Enabled Medical Devices – A Life Cycle Approach.	F, A	F, A, E	
8.9	Bench testing • Evidence supporting the physical or mechanical properties of the subject device, where applicable. • Pre-clinical animal studies (e.g. implantation) as applicable to the device.	F, A	F, A, E	
8.10	IVD pre-clinical requirements – applicable for IVD devices Evidence supporting the analytical performance of the subject device:	F, A	F, A, E	
	• Analytical sensitivity	F, A	F, A, E	
	• Analytical specificity including cross reactivity and interference	F, A	F, A, E	

	Precision	F, A	F, A, E	
	Linearity/assay measuring range/hook effect	F, A	F, A, E	
	Traceability	F, A	F, A, E	
	Cut-off value	F, A	F, A, E	
	Trueness	F, A	F, A, E	
	Specimen stability	F, A	F, A, E	
	Specimen matrix	F, A	F, A, E	
	Performance characteristics for instrument	F, A	F, A, E	
	Flex Study/Robustness for rapid test kits only	F, A	F, A, E	
8.11	Biological Safety - Description, origin, source, donor and purpose of the biological material or derivative used in the medical device and in the manufacturing process of the medical device. - Summary description of the manufacturing process including procedures and measures in place to minimise biological risks and reduce contamination to an acceptable level e.g. process validation results to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents. This also includes inactivation of infectious organisms in the device during the manufacturing process of the device. - Where applicable, Certificate of Suitability (CEP) for biological material	F, A	F, A, E	
8.12	Others <i>If design verification and validation supporting documents do not fit any of the above categories, you may upload them under "Others". Please ensure that the filename describes the verification/validation test contained within it.</i>	-	-	

SECTION 9: CLINICAL EVALUATION REPORT

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
9.1	A clinical evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device. Refer to <i>GN-20</i> for further guidance on clinical evaluation. For GMD: Clinical evidence may include clinical literature review, clinical experience (e.g. registries and post market surveillance reports), and clinical investigation. For IVD: Clinical evidence should include the following: • Clinical (Diagnostic) Sensitivity • Clinical (Diagnostic) Specificity • Method Comparison • Matrix Comparison • Clinical Cut-off • Reference Interval (Expected values) • Additional requirements for IVD medical device for self-testing and near patient testing (if applicable) (e.g. lay user performance study, usability studies) Where specific indications are claimed, e.g. asymptomatic patients, evidence to support safety and performance of the IVD in the specific indicated population should be submitted. For IVD undergoing full evaluation, clinical evaluation conducted by independent third parties (e.g. accredited clinical laboratories) may be required.	F, A (if applicable) Applicable for medical devices with labelled use beyond the inherent performance of the device.	F, A, E

SECTION 10: DEVICE LABELLING

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
10.1	Primary and secondary labels in their original colour for all models in the Annex 2 LOC, as applicable. Refer to GN-23 for labelling requirements. - If representative labels are provided, variable fields on the artwork must be highlighted, and ranges of values for the variable fields should be indicated. - Should there be only one set of labelling (i.e. secondary label), packaging / labelling configuration of device should be described. Labels with “-Free” claim (e.g. DEHP-free, pyrogen-free, BPA-free, latex-free): evidence should be provided to support the claim.	F, A	F, A, E
10.2	IFU to be supplied in Singapore for the devices (as applicable) in this application. Format of the IFU to be supplied with every medical device e.g. paper or electronic should be specified. Refer to GN-23 for labelling requirements. Note: - For Software as a Medical Device or devices not sold to the general public, IFU may be supplied in non-paper format (refer to GN-23 for details). - For information downloadable from the internet, please confirm that the IFU will be accessible through the weblink indicated on the physical label prior to supply of the device in Singapore, and is identical to the IFU submitted for registration.	F, A	F, A, E

SECTION 11: RISK MANAGEMENT

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
11.1	Risk analysis describing the risks identified, severity of harm and probability of occurrence including the mitigation measures. A risk management report to substantiate that all known and foreseeable risks have been reasonably mitigated and the residual risks have been reduced or controlled to an acceptable level.	F, A	F, A, E

SECTION 12: MANUFACTURING INFORMATION

No.	Supporting Document / Information	Applicability for Class B routes	Applicability for Class C & D routes
12.1	Names and addresses for all manufacturing and sterilisation sites (including contract manufacturers and contract sterilisers) of the finished device.	F, A	F, A, E
12.2	ISO 13485 or MDSAP certificates for all manufacturing and sterilisation sites identified in 12.1. - For ISO 13485, certification bodies must be either accredited by Global ACI recognised accreditation bodies or are EU MDR/IVDR Notified Bodies. - For sites without ISO 13485 or MDSAP certification, audit reports of comparable QMS (e.g. US FDA Quality Systems Regulations or Japan MHLW Ordinance 169) for the site shall be submitted.	F, A	F, A, E
12.3	Manufacturing process flow diagram	F	F, A, E

SECTION 13: OTHERS

Should there be additional relevant supporting documents that are deemed essential to supporting the registration and do not fit under any of the sections above, please upload under section 13 in SHARE and provide the information below.

Please do not submit irrelevant documents. Please ensure that only one file is inserted per row.

No.	Filename	Brief Description of File (purpose of document in relation to device under review)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

☐ I hereby attest that the information provided on this application and in any attached documentation in SHARE is accurate, correct and complete.