GN-18: Guidance on Preparation of a Product Registration Submission for In-Vitro Diagnostic Medical Devices using the ASEAN CSDT

Medical Devices Cluster

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Revision 5

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Revision History

Guidance Version (Effective Date) [3 latest revisions]	Revision
R3► GN-18: Revision 3 (01 March 2024)	R3
R4► GN-18: Revision 4 (21 Oct 2025)	R4
R5► GN-18: Revision 5 (01 Oct 2026)	R5

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

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INTRODUCTION

Objective

- Product registration applications for medical devices submitted to HSA may be prepared in the format set out in the ASEAN Common Submission Dossier Template (CSDT) or the International Medical Device Regulators Forum (IMDRF) R5► In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC). ◄

- This document aims to provide guidance on the preparation of a product registration submission for IVD medical devices using the ASEAN CSDT. In particular, this document serves to provide a summary of the information to be submitted under each section of the ASEAN CSDT. For detailed technical information to be provided under each section of the dossier, please refer to TR-02: Contents of a Product Registration Submission for In Vitro Diagnostic Medical Devices using the ASEAN CSDT.

- This document should also be read in conjunction with the ASEAN CSDT document, Product Registration Submission Guide for In Vitro Diagnostic Medical Devices, GN-15: Guidance to Medical Device Product Registration and other relevant guidance documents as specified in this document.

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INTRODUCTION

Background

- The ASEAN CSDT document contains elements of the Global Harmonisation Task Force (GHTF) guidance document titled “Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)” (Document number: SG1/N011R17), and the International Medical Device Regulators Forum (IMDRF) R5► In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC). ◄

- The ASEAN CSDT document is intended to provide a common template for the submission of medical device information to medical device regulatory authorities of ASEAN member countries.

- R4► When preparing a ASEAN CSDT or IMDRF ToC-based submission to HSA via our online Singapore Health Product Access and Regulatory E-System (SHARE) platform, please refer to Product Registration Submission Guide for In Vitro Diagnostic Medical Devices for guidance on uploading of the relevant CSDT or ToC dossier sections to the appropriate folders in SHARE. ◄
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INTRODUCTION

Scope

This document applies to all in-vitro diagnostic medical devices.

This document is not applicable to general medical devices. Please refer to GN-17 Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT.

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INTRODUCTION

Definitions

CALIBRATOR: Any substance, material or article intended by its product owner to be used in the calibration of a measuring instrument or measuring system.

CONTROL MATERIAL: Any substance, material or article intended by its product owner to verify the performance of an IVD medical device.

INSTRUMENT: Equipment or apparatus intended by the product owner to be used as IVD Medical Device.

IN VITRO DIAGNOSTIC (IVD) PRODUCT (as set out in the Regulations): means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information —

- concerning a physiological or pathological state or a congenital abnormality;
- to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or
- to monitor therapeutic measures; and includes a specimen receptacle.

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INTRODUCTION

Definitions

LAY PERSON: Any individual who does not have formal training in a relevant field or discipline.

MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP): Medical Device Single Audit Program administered by the International Medical Device Regulators Forum (IMDRF)

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

NEAR PATIENT TESTING: Any testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient. Also known as Point-of-Care (POC).

PERFORMANCE EVALUATION: A review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

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

- 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
- 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.

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INTRODUCTION

Definitions

REAGENT: Any chemical, biological or immunological components, solutions or preparations intended by the product owner to be used as IVD medical devices.

REGISTRANT (as set out in the Act): in relation to a registered health product, means the person who applied for and obtained the registration of the health product under the Act.

SELF-TESTING: Testing performed by lay persons.

SPECIMEN RECEPTACLE (as set out in the Regulations): An IVD medical device, whether vacuum-type or not, specifically intended by their product owner for the primary containment of specimens derived from the human body.

NOTE:

Definitions that do not indicate they are set out in the Health Products Act (Act) and Health Products (Medical Devices) Regulations 2010 (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.

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POINTS TO NOTE WHEN PREPARING A PRODUCT REGISTRATION SUBMISSION

- The registrant shall take note of the following pointers when preparing a CSDT dossier for submission to HSA:
  - the prepared dossier must be in English and must contain all sections. For sections which are not applicable to the medical device, the reason for the non-applicability should be provided under the section heading;
  - copies of labelling, certificates and reports that are referenced within the submission shall be submitted as annexes to the dossier. All supporting documents submitted must be legible, submitted in full (i.e. all the pages of a document must be submitted), and certificates must be within its validity period;
  - all reports submitted as part of the dossier should be signed-off and dated by the person issuing the report. This person should be authorised to issue such documents;
- The level of detail of information to be provided under each section will depend on the evaluation route, i.e. immediate, expedited, abridged or full evaluation. Please refer to Product Registration Submission Guide for In Vitro Diagnostic Medical Devices for details on the data requirements for the evaluation routes.

R4► ***NOTE:*** *Product registration applications for medical devices must be submitted online to HSA via the Singapore Health Product Access and Regulatory E-System (SHARE). The technical dossier and supporting documents must be submitted in softcopy in SHARE. These documents are to be uploaded under the respective folders of the 'Supporting Document(s)' section of the SHARE application form. Refer to* Product Registration Submission Guide for In Vitro Diagnostic Medical Devices *for more information.* ◄

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ELEMENTS OF THE CSDT

Section 3 Executive Summary

Overview

a) Introductory descriptive information on the medical device, the intended use and indications for use of the device.

Commercial marketing history

b) Information on the use of the device, if any, such as targeted patient population, user profile (e.g. specific trained users), specific disease status or clinical condition (e.g. monitoring of a disease), assay principle (e.g. immunoassay) etc.

List of regulatory approval

c) If the medical device has any unique or novel feature or characteristic (e.g. nanotechnology), a description must be provided.

Important safety & performance related information

d) Any high-level background information or details that the product owner wishes to highlight in relation to the device, its history or relation to other approved devices (e.g. predicate devices) or previous submissions (provides context to submission).

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ELEMENTS OF THE CSDT

Section 3 Executive Summary

- Overview
- Commercial marketing history
- List of regulatory approval
- Important safety & performance related information

a) List of countries from HSA's reference regulatory agency jurisdictions where the medical device is marketed.

b) Date (accurate to MMYYYY) and country where the device was first introduced for commercial distribution*, globally.

**refers to supply for clinical purpose*

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ELEMENTS OF THE CSDT

Section 3 Executive Summary

- Overview
- Commercial marketing history
- List of regulatory approval
- Important safety & performance related information

a) Registration status (i.e. submitted, not submitted, pending approval, rejected or withdrawn) and approved intended use and indications of the medical device in HSA's recognised reference agencies, in a tabular format as per TR-02. If device is withdrawn/ rejected by any reference agencies, reason for rejection or withdrawal is to be provided.

b) Copies* of approval letter(s) from each reference agency. 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.

**scanned copies are acceptable*

c) Declaration from product owner that labelling, packaging and IFU of the device for sale in Singapore are identical or not identical to that approved by reference agency being used as the basis for evaluation route. If not identical, please provide a description of the differences.

d) If the subject device is different in any way (e.g. design, commercial name, specifications, intended use and indications for use) from those approved by the reference agencies, the differences should be described.

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ELEMENTS OF THE CSDT

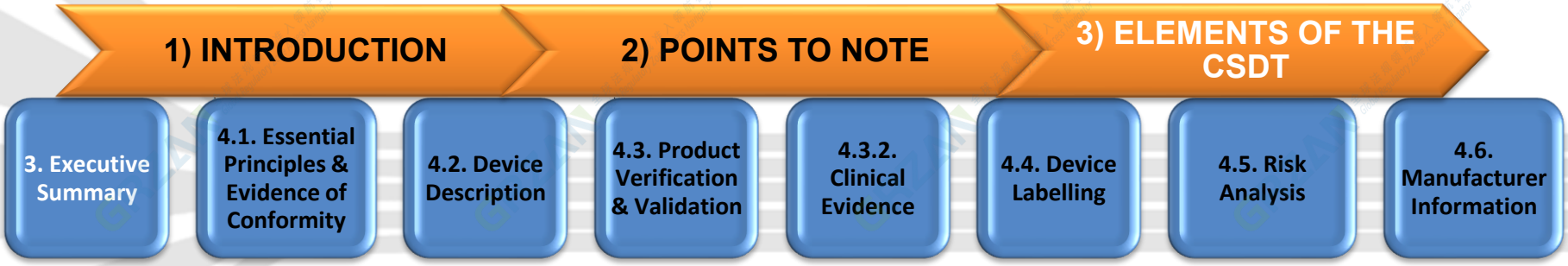
Section 3 Executive Summary

- Overview
- Commercial marketing history
- List of regulatory approval
- Important safety & performance related information

a) To include a summary of reportable adverse events (AEs) and field safety corrective actions (FSCAs) for the medical device since its first introduction on the global market, in a tabular format as per TR-02.

b) For FSCAs that are 'open', provide a description of any analysis and/or corrective and preventive actions undertaken by the product owner.

c) If there have been no adverse events or FSCAs to date, provide an attestation from product owner on company letterhead, that there have been no adverse events or FSCAs since commercial introduction of the device globally. This attestation is not restricted to usage only as intended by the product owner.



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ELEMENTS OF THE CSDT

Section 4.1 Essential Principles & Evidence of Conformity

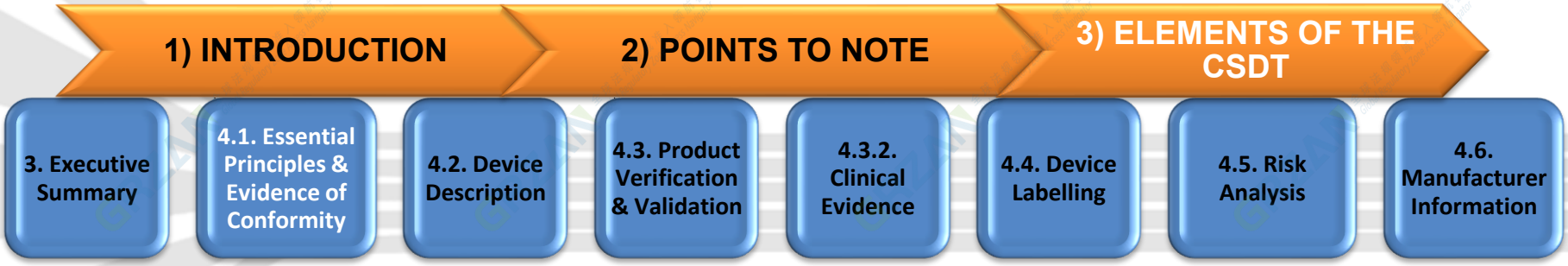
Essential Principles & Declaration of Conformity

a) Essential Principles conformity checklist (EP checklist). The checklist of conformity to the Singapore Essential Principles is to be submitted. Alternatively, the checklist to EU or Australian Essential Requirements can be submitted.

b) GN-11 Declaration of Conformity (DOC). Alternatively, the EC or AU DOC can be submitted.

c) List the standards that have been complied with in the design and manufacture (including sterilisation) of the device, if this has not been provided in the EP checklist or DOC.

NOTE: *Refer to GN-16 Guidance on Essential Principles for Safety and Performance of Medical Devices for more details*.



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ELEMENTS OF THE CSDT

Section 4.2 Device Description

- Annex 2 List of Configurations
- Comprehensive Device description and principle of operation
- Reference and comparison to similar and/or previous generations of the device
- Materials

a) A copy of Annex 2 for GN-17 and GN-18 List of Configurations, including the complete list of configurations of medical devices subject to the submission. This is to be submitted in a Microsoft Excel file. This form will provide information on the range of products included in this application and clarify the product grouping.

NOTE: *Devices shall fulfil the grouping requirements in GN-12-1 / GN-12-2 Guidance on Grouping of Medical Devices for Product Registration, which specify the conditions for devices to be grouped in a single application.*

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ELEMENTS OF THE CSDT

Section 4.2 Device Description

- Annex 2 List of Configurations
- Comprehensive Device description and principle of operation
- Reference and comparison to similar and/or previous generations of the device
- Materials

a) A comprehensive description of the device including technology, functionalities, features and connectivity capabilities (e.g. wireless enabled, Bluetooth enabled, internet-connected and network-connected devices) if applicable. To include labelled pictorial representation (diagrams, photos, drawings) if applicable.

b) Risk class and applicable classification rule for the medical device according to the Regulations.

c) Product specifications including the version number of the software if applicable.

d) List of medical device accessories intended to be used in combination with the devices. Accessories that can be sold separately should be identified and listed in the Annex 2 list of configurations if intended to be supplied in Singapore.

e) R3► Summary of software development life cycle process including processes in place to manage the various life cycle activities. Software Requirements Specification documenting functional, performance, interface, design, developmental, and other requirements for the software. ◄

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ELEMENTS OF THE CSDT

Section 4.2 Device Description

- Annex 2 List of Configurations
- Comprehensive Device description and principle of operation
- Reference and comparison to similar and/or previous generations of the device
- Materials

a) Where safety and effectiveness data of similar or previous generation devices are used in the current submission, the following information is to be provided:

i. A list of such devices and specific information on the registration status of these devices with HSA are to be included (e.g. Device registration number).

ii. A comparison, preferably in a table, of the design, specifications and intended use/indications for use between the subject device in the current submission and the comparator devices (similar and/or previous generation). To include labelled pictorial representation (diagrams, photos, drawings) where necessary.

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ELEMENTS OF THE CSDT

Section 4.2 Device Description

- Annex 2 List of Configurations
- Comprehensive Device description and principle of operation
- Reference and comparison to similar and/or previous generations of the device
- Materials

a) An indication of biological material or derivative used in the medical device, its origin and source/donor.

b) 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 reagents and the production of reagents.

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ELEMENTS OF THE CSDT

Section 4.3 Product Verification & Validation

- Analytical Performance
- Stability studies
- Software V&V studies
- Electrical Safety & Electromagnetic Compatibility
- Cybersecurity
- Machine Learning
- Other Evidence

a) Evidence supporting the analytical performance of the subject device. This includes but is not limited to:

   i. Analytical sensitivity

   ii. Analytical specificity and interference

   iii. Precision

   iv. Linearity/assay's measuring range/hook effect

   v. Traceability and expected values

   vi. Cut-off value

   vii. Trueness

   viii. Specimen stability

   ix. Performance characteristics for instrument e.g. accuracy, precision/reproducibility, linearity, carry-over, interfering substances

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ELEMENTS OF THE CSDT

Section 4.3 Product Verification & Validation

- Analytical Performance
- Stability studies
- Software V&V studies
- Electrical Safety & Electromagnetic Compatibility
- Cybersecurity
- Machine Learning
- Other Evidence

a) Specify the claimed shelf life of the device components (e.g. reagents, calibrators/reference materials, control material, any other components susceptible to degradation).

b) Evidence supporting the claimed shelf-life of device components. If applicable, both real time and accelerated stability studies are to be submitted. If real time aging is not to be performed, adequate justification must be provided.

c) Evidence supporting the stability during actual routine use of the device (real or simulated), including all applicable components (e.g. reagents, reaction cartridges).

d) Information regarding and studies to support the stability of all of the sample type(s) identified in the labelling, including any and all recommended additives (e.g. anticoagulants).

e) For IVD medical device that does not have expiry dates, the projected useful life of the device.

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ELEMENTS OF THE CSDT

Section 4.3 Product Verification & Validation

- Analytical Performance
- Stability studies
- Software V&V studies
- Electrical Safety & Electromagnetic Compatibility
- Cybersecurity
- Machine Learning
- Other Evidence

a) Specify the version of the software to be supplied.

b) 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 is to be provided.

c) 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).

d) R4► Traceability Analysis linking product design requirements, design specifications, and testing requirements. Identified hazards should be tied to implementation and testing of the mitigations. ◄

NOTE:

i. Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

ii. The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided.

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ELEMENTS OF THE CSDT

Section 4.3 Product Verification & Validation

- Analytical Performance
- Stability studies
- Software V&V studies
- Electrical Safety & Electromagnetic Compatibility
- Cybersecurity
- Machine Learning
- Other Evidence

a) Evidence supporting electrical safety and electromagnetic compatibility. For example, if a device is claimed to meet the requirements of IEC 60601-1 and IEC 60601-1-2, summary test reports and/or certificates are to be submitted for verification of conformance to these standards.

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ELEMENTS OF THE CSDT

Section 4.3 Product Verification & Validation

- Analytical Performance
- Stability studies
- Software V&V studies
- Electrical Safety & Electromagnetic Compatibility
- Cybersecurity
- Machine Learning
- Other Evidence

a) Evidence to support the cybersecurity of connected medical devices such as wireless enabled, Bluetooth enabled, internet-connected and network-connected devices. For example, but not limited to:

i. Cybersecurity vulnerabilities and risks analysis

ii. Cybersecurity control measures

iii. Security test reports and/or evidence to verify the device cybersecurity and effectiveness of those implemented cybersecurity control measures (not applicable to IBR & ICR applications).

iv. On-going plans, processes or mechanisms for surveillance, timely detection and management of the cybersecurity related threats during the useful life of the device, especially when a breach has been detected.

R4► **NOTE**: For more details, please refer to GL-04 Regulatory Guidelines for Software Medical Devices including Machine Learning-Enabled Medical Devices – A Life Cycle ◄

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ELEMENTS OF THE CSDT

Section 4.3 Product Verification & Validation

- Analytical Performance
- Stability studies
- Software V&V studies
- Electrical Safety & Electromagnetic Compatibility
- Cybersecurity
- Machine Learning
- Other Evidence

R4►

a) Description of the Machine Learning (ML) features and how its output relates to the clinical condition being assessed.

b) Information to be provided to users about the device's ML capabilities, clinical workflow integration, risks and limitations associated with ML function, etc.

c) Model's inputs and outputs

d) Clinical workflow during deployment

e) Model training details including source and size of dataset and data annotation protocols

f) Performance validation of the Machine Learning model

g) Machine Learning vulnerabilities and risk analysis

NOTE: For more details, please refer to GL-04 Regulatory Guidelines for Software Medical Devices including Machine Learning-Enabled Medical Devices – A Life Cycle ◄

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ELEMENTS OF THE CSDT

Section 4.3 Product Verification & Validation

- Analytical Performance
- Stability studies
- Software V&V studies
- Electrical Safety & Electromagnetic Compatibility
- Cybersecurity
- Machine Learning
- Other Evidence

a) For non-IVD medical device accessories to be registered with the IVD medical device e.g. a lancet that is provided in the package to the user to perform a test, information on preclinical studies necessary to establish the safety and performance of these medical devices shall be provided e.g. biocompatibility and sterilisation validation studies.

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ELEMENTS OF THE CSDT

Section 4.3.2 Clinical Evidence

Clinical Evidence

a) 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. Clinical evidence should include the following:

i. Clinical (Diagnostic) Sensitivity

ii. Clinical (Diagnostic) Specificity

iii. Method Comparison

iv. Matrix Comparison

v. Clinical Cut-off

vi. Reference Interval (Expected values)

vii. Additional requirements for IVD medical device for self-testing and near patient testing (if applicable)

b) For IVD medical device undergoing full evaluation, clinical evaluation conducted by independent third parties (e.g. accredited clinical laboratories) may be required.

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ELEMENTS OF THE CSDT

Section 4.4 Device Labelling

Samples of Labels on the Device and its Packaging

Instructions for Use (IFU)

a) Primary and secondary labels in their original colour for the device and its accessories as applicable.

b) If representative labels are provided, variable fields on the artwork must be highlighted, and ranges of values for the variable fields should be indicated.

NOTE: *Refer to GN-23 Guidance on Labelling for Medical Devices for more details on labelling requirements.*

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ELEMENTS OF THE CSDT

Section 4.4 Device Labelling

Samples of Labels on the Device and its Packaging

a) Copy of the IFU to be supplied in Singapore for the device and its accessories as applicable.

Instructions for Use (IFU)

b) Indicate format of the IFU to be supplied with every medical device e.g. paper or electronic.

NOTE: *Refer to GN-23 Guidance on Labelling for Medical Devices for more details on labelling requirements.*

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ELEMENTS OF THE CSDT

Section 4.5 Risk Analysis

Risk Analysis & Risk Management Report

a) 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, including cybersecurity risks if applicable, have been reasonably mitigated and the residual risks have been reduced or controlled to an acceptable level is to be submitted.

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ELEMENTS OF THE CSDT

Section 4.6 Manufacturer Information

Manufacturing Information and Manufacturing Process

a) Name and address for all manufacturing and sterilisation sites (including contract manufacturers and contract sterilisers).

b) ISO 13485 or MDSAP certificates for all the physical manufacturing and sterilisation sites of finished devices. Certification bodies for ISO 13485 must be either accredited by R5► Global ACI ◄ recognised accreditation bodies or are EU MDR/IVDR Notified Bodies.

c) For sites without ISO 13485 or MDSAP certification, comparable audit reports for the actual site e.g. US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 can be submitted.

d) Manufacturing process flow diagram.

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ANNEX 2 - List of Configurations of Medical Devices to be Registered

Name of Medical Device FAMILY/GROUP/IVD TEST KIT/SYSTEM:				
Proposed Grouping for Medical Device (FAMILY/GROUP/IVD TEST KIT/SYSTEM):				
Name as per Device Label	Identifier	UDI-DI(s)	DM-DI(s)	Brief Description of Item (e.g. the key distinguishing attributes, specifications of each item (including Volume, Length, Gauge, Diameter) and/or SaMD Version number/ software version number)

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