GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT

Medical Devices Cluster

December 2018

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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) Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC).

- This document aims to provide guidance on the preparation of a product registration submission for general 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-01: Contents of a Product Registration Submission for General Medical Devices using the ASEAN CSDT.

- This document should also be read in conjunction with the ASEAN CSDT document, Product Registration E-Submission Guide for General 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 Harmonization 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) Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA 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.

- When preparing a ASEAN CSDT or IMDRF ToC-based submission to HSA via our online Medical Device Information and Communication System (MEDICS) platform, please refer to Product Registration E-Submission Guide for General Medical Devices for guidance on uploading of the relevant CSDT or ToC dossier sections to the appropriate modules in MEDICS.

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INTRODUCTION

Scope

This document applies to all general medical devices.

This document is not applicable to in-vitro diagnostic medical devices. Please refer to GN-18 Guidance on Preparation of a Product Registration Submission for In-Vitro Diagnostic Medical Devices using the ASEAN CSDT.

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INTRODUCTION

Definitions

ADVERSE EFFECT *(as set out in the Act)*: means any debilitating, harmful, toxic or detrimental effect that the medical device has been found to have or to be likely to have on the body or health of humans when such a medical device is used by or administered to humans.

ADVERSE EVENT: any event or other occurrence, that reveals any defect in any medical device or that concerns any adverse effect arising from the use thereof.

FIELD SAFETY CORRECTIVE ACTION *(as set out in the Regulations)*: any action taken to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, including

- the return of the medical device to its product owner;
- replacement or destruction of the medical device;
- any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
- the clinical management of any patient who has used the medical device;
- the modification of the medical device;
- the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;

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INTRODUCTION

Definitions

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 —

- 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.

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*.

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 E-Submission Guide for General Medical Devices for details on the data requirements for the evaluation routes.

NOTE: *Product registration applications for medical devices must be submitted online to HSA via the Medical Device Information and Communication System (MEDICS). The technical dossier and supporting documents must be submitted in softcopy in MEDICS. These documents are to be uploaded under the respective modules of the 'Dossier & Supporting Document(s)' section of the MEDICS application form. Refer to* Product Registration E-Submission Guide for General 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. continuous monitoring in critically ill patients), mode of action (e.g. absorption profile) etc.

List of regulatory approval

c) If the medical device has any unique or novel feature or characteristic (e.g. nanotechnology, incorporates animal or microbial cells or tissues), 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).

1) INTRODUCTION | **2) POINTS TO NOTE** | **3) ELEMENTS OF THE CSDT**

- 3. Executive Summary
- 4.1. Essential Principles & Evidence of Conformity
- 4.2. Device Description
- 4.3. Design Verification & Validation
- 4.3.2. Clinical Evidence
- 4.4. Device Labelling
- 4.5. Risk Analysis
- 4.6. Manufacturer Information

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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-01. 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 labeling, 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

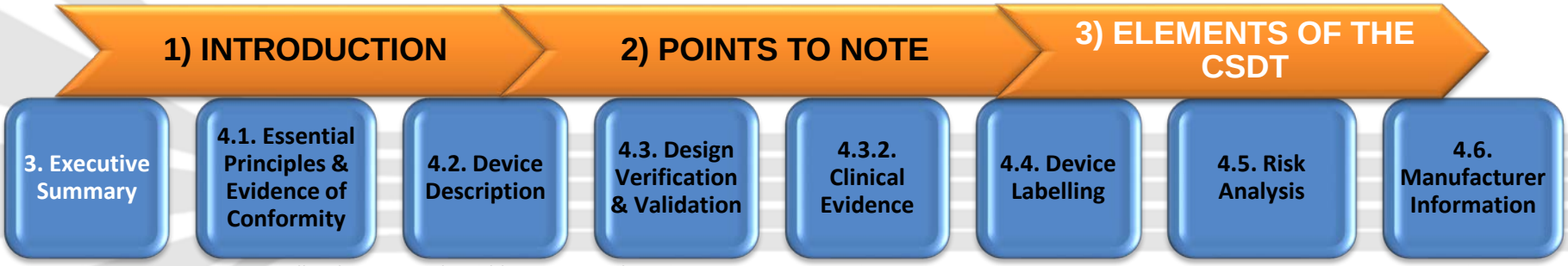
Section 3 Executive Summary

- 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-01.

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.



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ELEMENTS OF THE CSDT

Section 4.1 Essential Principles & Evidence of Conformity

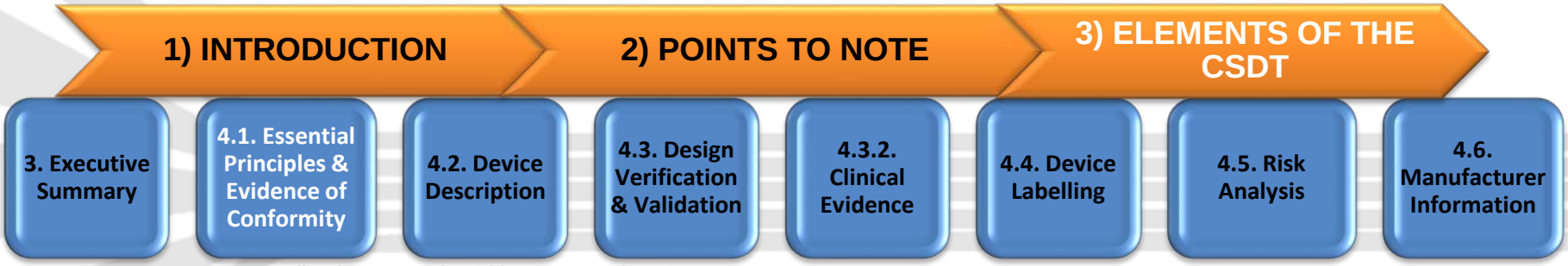
Essential Principles & Declaration of Conformity

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 sterilization) 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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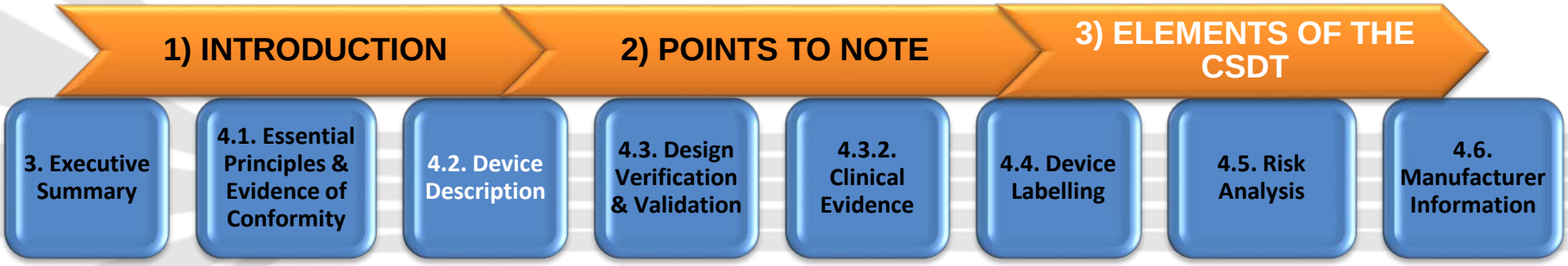
ELEMENTS OF THE CSDT

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 GN17 and GN18 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 and features. 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.

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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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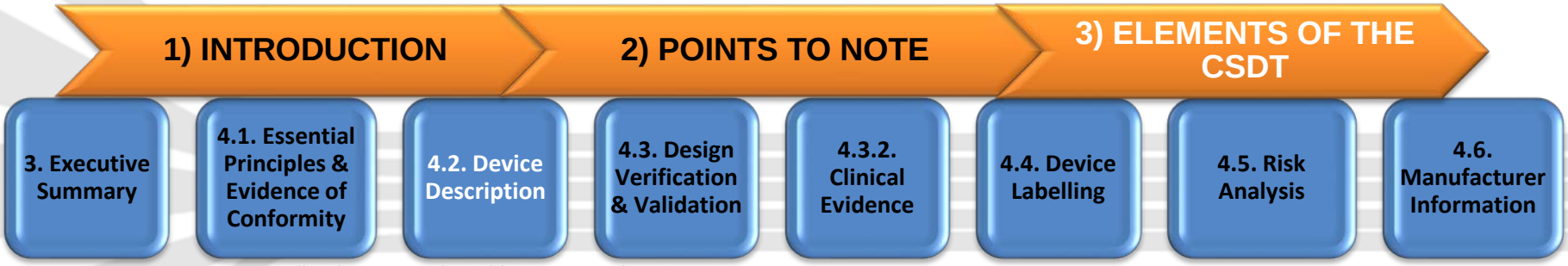
ELEMENTS OF THE CSDT

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) A list of all materials in direct or indirect contact with the patient or user is to be provided. Where there are specific concerns related to the material safety (e.g. impurities or residue levels), additional information on the quality and safety of such materials may be required (e.g. conformity to relevant material standards, Certificate of Analysis).



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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

- Physical and Mechanical Testing
- Electrical Safety & Electromagnetic Compatibility
- Software Verification & Validation Studies
- Biocompatibility
- Devices Containing Biological Material
- Sterilisation Validation
- Stability studies
- Animal studies
- Cybersecurity

a) Evidence supporting the physical or mechanical properties of the subject device.

NOTE: If the device tested differs from the subject device that is to be registered, justification on the applicability of the test results to the subject device must be provided.

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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

- Physical and Mechanical Testing
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- Animal studies
- Cybersecurity

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.

NOTE: If the device tested differs from the subject device that is to be registered, justification on the applicability of the test results to the subject device must be provided.

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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

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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.

c) All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and effectiveness, and any plans for correction of the problems).

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 Design Verification & Validation

- Physical and Mechanical Testing
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- Cybersecurity

a) Studies supporting biocompatibility and assessing toxicology. If biocompatibility tests that are recommended by ISO 10993 were not performed, adequate justification must be provided.

NOTE: If the device tested differs from the subject device that is to be registered, justification on the applicability of the test results to the subject device must be provided.

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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

- Physical and Mechanical Testing
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- Animal studies
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a) Description and purpose of the biological material or derivate used in the medical device and in the manufacturing process of the medical device.

b) Risk assessment pertaining to the biological materials, which should include information on the process validation to substantiate that manufacturing and screening procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents.

c) Certificate of Suitability (CEP) for biological material that bears TSE (Transmissible Spongiform Encephalopathy) risk. If CEP is not available or not applicable, to include additional information on the evidence of proper sourcing and processing of the biological material or derivate, such as certificates that support the safety of materials of biological origin (e.g. certificate of abattoir inspection, Certificates of Analysis).

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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

- Physical and Mechanical Testing
- Electrical Safety & Electromagnetic Compatibility
- Software Verification & Validation Studies
- Biocompatibility
- Devices Containing Biological Material
- Sterilisation Validation
- Stability studies
- Animal studies
- Cybersecurity

a) Sterilisation validation report and EO residuals report (if applicable), and evidence of on-going sterilisation validation.

NOTE: If the device tested differs from the subject device that is to be registered, justification on the applicability of the test results to the subject device must be provided.

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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

- Physical and Mechanical Testing
- Electrical Safety & Electromagnetic Compatibility
- Software Verification & Validation Studies
- Biocompatibility
- Devices Containing Biological Material
- Sterilisation Validation
- Stability studies
- Animal studies
- Cybersecurity

a) Specify the claimed shelf life or projected useful life of the device.

b) Evidence that support the product stability and package integrity over the claimed shelf-life. If available, 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.

NOTE: If the device tested differs from the subject device that is to be registered, justification on the applicability of the test results to the subject device must be provided.

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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

- Physical and Mechanical Testing
- Electrical Safety & Electromagnetic Compatibility
- Software Verification & Validation Studies
- Biocompatibility
- Devices Containing Biological Material
- Sterilisation Validation
- Stability studies
- Animal studies
- Cybersecurity

a) Pre-clinical animal studies (e.g. implantation) as applicable to the device.

NOTE: If the device tested differs from the subject device that is to be registered, justification on the applicability of the test results to the subject device must be provided.

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ELEMENTS OF THE CSDT

Section 4.3 Design Verification & Validation

- Physical and Mechanical Testing
- Electrical Safety & Electromagnetic Compatibility
- Software Verification & Validation Studies
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- Devices Containing Biological Material
- Sterilisation Validation
- Stability studies
- Animal studies
- Cybersecurity

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

i. Cybersecurity vulnerabilities and risks analysis

ii. Cybersecurity control measures

iii. 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.

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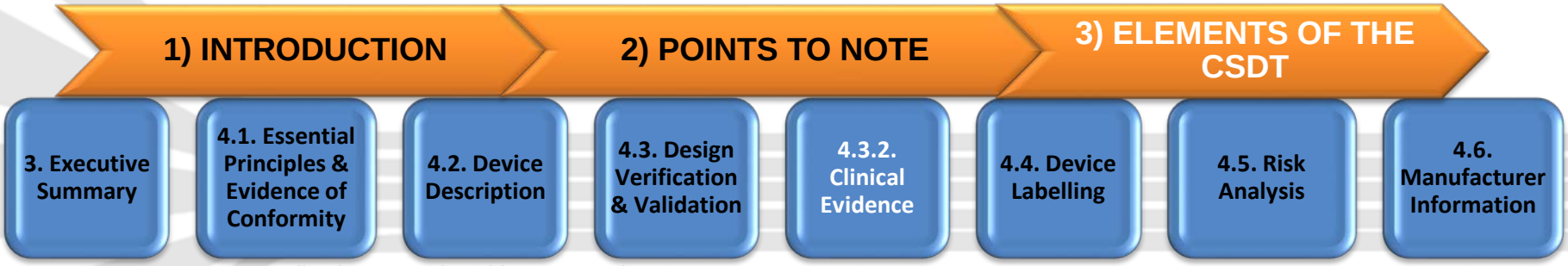
ELEMENTS OF THE CSDT

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 may include clinical literature review, clinical experience (e.g. registries and post market surveillance reports), and clinical investigation.

NOTE: *Refer to GN-20 Guidance on Clinical Evaluation for more details.*



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ELEMENTS OF THE CSDT

Section 4.4 Device Labelling

Samples of Labels on the Device and its Packaging

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

Instructions for Use (IFU)

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 Labeling 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 Labeling for Medical Devices for more details on labelling requirements.*

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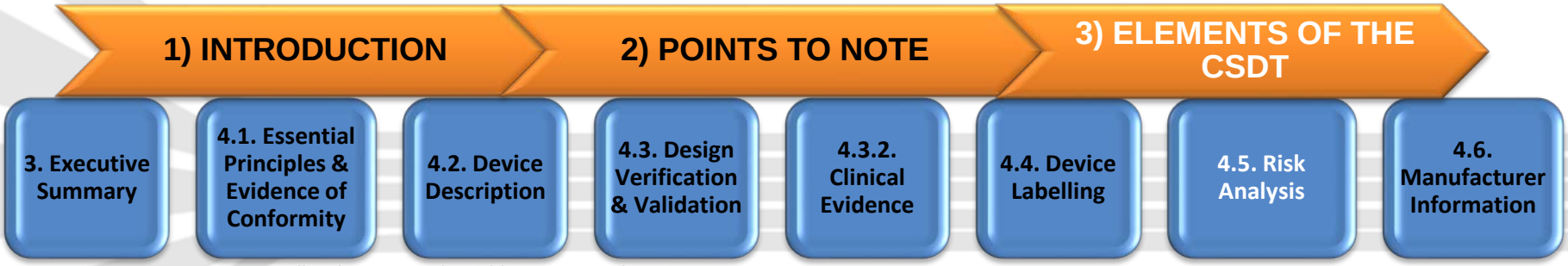
ELEMENTS OF THE CSDT

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 have been reasonably mitigated and the residual risks have been reduced or controlled to an acceptable level.



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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) ISO13485 certificates for all the physical manufacturing and sterilisation sites of finished devices.

c) For sites without ISO 13485 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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CONTACT INFORMATION

Medical Devices Branch Medical

Devices Cluster

Health Products Regulation Group

Health Sciences Authority

11 Biopolis Way, #11-03 Helios

Singapore 138667

www.hsa.gov.sg

https://crm.hsa.gov.sg/event/feedback

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