Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

REFERENCE DOCUMENT

Title: Guidance on Mapping of STED to CSDT

Authoring Group: Working Group 1, Pre-Market Submission and CSDT

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Preface

The document herein was developed with participation from AHWP regulatory and industry representatives and Study Group 1 of the Global Harmonisation Task Force (GHTF). The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

1. Introduction:

The Global Harmonisation Task Force (GHTF) has recommended the summary technical documentation (STED) as a harmonized template for the documentation of evidence of conformity to the Essential Principles of safety and performance (hereafter referred to as Essential Principles).

The Common Submission Dossier Template (CSDT) has been endorsed by the medical device regulatory authorities of ASEAN Member States as the common template for the submission of device information. It contains elements of the GHTF STED.

2. Purpose:

The purpose of this document is to map the sections of STED to CSDT and provide a brief comparison of the requirements in the two dossier templates. The mapping and comparison information serves to strengthen understanding of the similarities and differences between the two templates and to facilitate the bi-lateral transposition of STED and CSDT product dossiers.

This document is intended for general guidance only.

3. Scope:

The mapping and comparison information presented in this guidance document are based on the following documents and should be read in conjunction with these documents:
- Guidance on ASEAN Common Submission Dossier Template (CSDT) (final) dated 10 October 2011,
- Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of General Medical Devices GHTF/SG1/N011:2008 dated Nov 2008 and
- Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices, GHTF/SG1/NO63 dated 26 March 2010.

4. Overview of CSDT and STED:

The STED is primarily intended to be created from existing technical documentation to provide evidence to the RA/CAB that the subject medical device is in conformity with the Essential Principles. It builds on the GHTF regulatory model and is supported by the GHTF principles including the risk classification system, conformity assessment, Essential Principles and recognition of standards. The STED reflects the status of the medical device at a particular moment in time (e.g. at the moment of premarket submission or when requested by a RA for post-market purposes) and is prepared in order to meet regulatory requirements.

The purpose of the CSDT is to provide one common template acceptable by the medical device regulatory authorities of ASEAN Member States for submission of device information. Although

not explicitly stated, it is based on regulatory principles that are similar to that recommended by the GHTF (e.g. risk-based classification system and Essential Principles). Currently, the CSDT is mainly intended for the pre-market registration of medical devices but there is flexibility to extend the submission template to the post- market phase.

The key sections of the 2 template formats are listed in Figure 1. Both template formats share similar heading sections and requirements. More importantly, they are both built on the GHTF regulatory model and cater for flexibility of implementation to particular risk classes of devices.

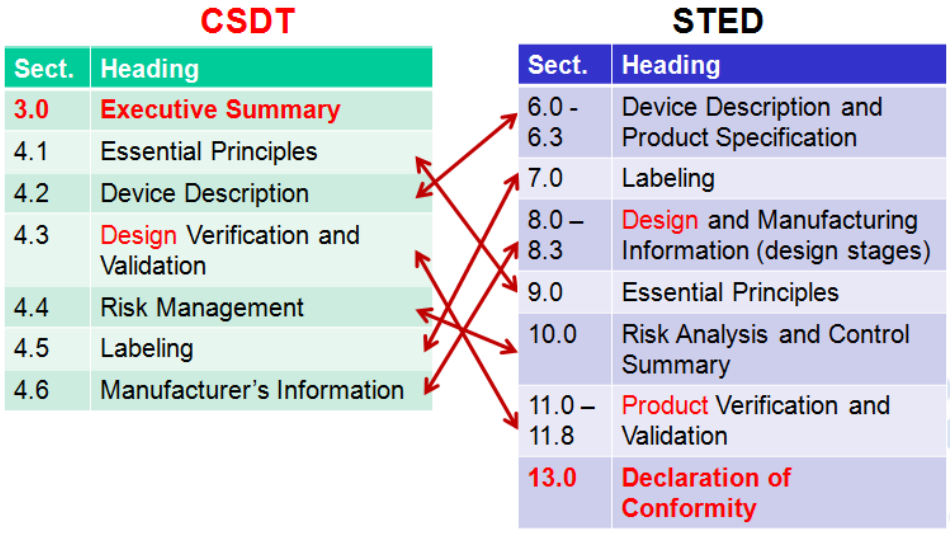

Figure 1: Key sections of the CSDT and STED.

Mapping of Sections of STED to CSDT:

CSDT Section	CSDT Section Heading	Corresponding STED Section	Corresponding Section Heading in STED	Remarks
3.0	Executive Summary	Nil	Nil	STED does not contain the Executive Summary. The Executive Summary provides an overview of the device and facilitates the pre-market registration process.
4.0	Elements of the Common Submission Dossier Template	2.0	Contents of the STED	
4.1 4.1.1	Relevant Essential Principles and Method Used to Demonstrate Conformity Essential Principles and Evidence of Conformity .	9.0	Essential Principles (EP) Checklist	The requirements are the same. Both template formats require an Essential Principles checklist that identifies:- a) the Essential Principles; b) whether each Essential Principle applies to the device and if not, why not; c) the method(s) used to demonstrate conformity with each Essential Principle that applies; d) a reference for the method(s) employed (e.g., standard), and e) the precise identity of the controlled document(s) that offers evidence of conformity with each method used.
4.2	Device Description	6.0	Device Description and Product Specification, Including Variants and Accessories	The IVD STED outlines the characteristics of the IVD that have to be described in this section. The CSDT is not as specific. The CSDT does not call for information on previous generations of device (STED section 6.2).
4.3	Summary of Design Verification and	11.0 or 10.0 (IVD	Product Verification and Validation	The verification and validation information required in CSDT includes design aspects. Verification of the

CSDT Section	CSDT Section Heading	Corresponding STED Section	Corresponding Section Heading in STED	Remarks
	Validation Documents	STED)		design may be required for novel products, e.g. the design rationale for incorporating nanomaterials into a medical device. IVD STED incorporates guidance specific to IVD medical devices, e.g. accuracy of measurements and analytical sensitivity. The requirements on pre-clinical studies, clinical evidence and use of existing bibliography are similar.
4.4	Device Labelling	7.0	Labelling	The requirements with regards to labeling are the same.
4.5	Risk Analysis	10.0 or 8.0 (IVD STED)	Risk Analysis and Control Summary	The risk analysis requirements are the same. IVD STED incorporates risk analysis guidance specific to IVD medical devices.
4.6	Manufacturer Information	8.0 and 9.0 (IVD STED)	Design and Manufacturing Information	The requirements are similar.
4.6.1	Manufacturing Process .	8.2 and 9.2 (IVD STED)	Manufacturing Processes	The requirements are similar.

Acknowledgement:

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