

Note: Draft guidance to be proposed for consideration by AHWP TC. May require final inputs from GHTF SG1 members.

Title: Guidance on Mapping of CSDT to STED

Main Sections

Introduction:

Background of CSDT and STED.
Acknowledge contribution by GHTF SG1 members.

Purpose:

The purpose of this document is to map the sections of CSDT to STED.

.. Intended for guidance only....

To strengthen understanding of the differences between the 2 formats. To facilitate industry members who need to prepare both formats for different markets.

Scope:

... Mapping was conducted based on:
- ASEAN CSDT version x.x dated xxxx,
- STED for general devices version x.x dated xxxx,
- STED for IVD version x.x dated xxxx.

Overview of sections:

(to be modified)

CSDT

Sect.	Heading
3.0	Executive Summary
4.1	Essential Principles
4.2	Device Description
4.3	Design Verification and Validation
4.4	Risk Management
4.5	Labeling
4.6	Manufacturer's Information

STED

Sect.	Heading
6.0 - 6.3	Device Description and Product Specification
7.0	Labeling
8.0 - 8.3	Design and Manufacturing Information (design stages)
9.0	Essential Principles
10.0	Risk Analysis and Control Summary
11.0 - 11.8	Product Verification and Validation
13.0	Declaration of Conformity



CSDT		STED	
Sect.	Heading	Sect.	Heading
3.0	Executive Summary	9.0	Essential Principles
4.1	Essential Principles	6.0 - 6.3	Device Description and Product Specification
4.2	Device Description	11.0 – 11.8	Product Verification and Validation
4.3	Design Verification and Validation	10.0	Risk Analysis and Control Summary
4.4	Risk Management	7.0	Labeling
4.5	Labeling	8.0 – 8.3	Design and Manufacturing Information (design stages)
4.6	Manufacturer's Information	13.0	Declaration of Conformity

CSDT ≈ Executive summary + Re-mapped STED sections

Detailed Mapping:

(To be tidied up. To include the significant differences in the comparison table)

	CSDT (draft 14 Sept 2006)		STED GHTF/SG1/N011:2008		IVD STED GHTF/SG1/NO63
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3.0	Executive Summary <ul style="list-style-type: none"> • commercial marketing history; • intended uses and indications in labelling • list of regulatory approval or marketing clearance obtained; • status of any pending request for market clearance; and • important safety/performance related information. 		- - - - -		- - - - -
4.0	Elements of the Common Submission Dossier Template	PART 2 Page 9	CONTENTS OF THE STED	PART 2 Page 11	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	7.0	Essential Principles (EP) Checklist
4.2	Device Description (According to GHTF Classification) Description A B C D	6.0	Device Description and Product Specification, Including Variants and Accessories	6.0	Device Description including Variants (Configurations) and Accessories
4.2.1	Device description & features	6.1	Device Description	6.1	Device Description
4.2.2	Intended use	6.1a)	A general discription includeing its intntded use/purpose	6.1a)	The intended use.
4.2.3	Indications	6.1b)	...the intended patient population and medical condition to be diagnosed and/or treated and other consideration such as patient selection criteria	6.1d)	...the intended user (lay person or professional)
4.2.4	Instructions of use	7.0	Labelling	11.0	Labelling

			• instructions for use		• instructions for use
4.2.5	Contraindications		-		-
4.2.6	Warnings		-		-
4.2.7	Precautions		-		-
4.2.8	Potential adverse effects		-		-
4.2.9	Alternative therapy		-		-
4.2.10	Materials	6.1 i)	a description of the materials incorporated into key functional elements and those making either direct contact with a human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids.		
4.2.11	Other Relevant Specifications	11.3	Medicinal Substance		
4.2.12	Other Descriptive Information		-		-
4.3	Summary of Design Verification and Validation Documents	11.0 11.1 11.2 11.3 11.4 11.5 11.6	Product Verification and Validation General Biocompatibility Medicinal Substances Biological Safety Sterilisation Software Verification and Validation	10.0	Product Verification and Validation
	-		-	10.1 10.1.1 10.1.2 10.1.2.1 10.1.2.1.1 10.1.2.1.2 10.1.2.1.2.1 10.1.2.1.2.2	Analytical Studies Specimen type Analytical Performance Characteristics Accuracy of measurement Trueness of measurement Precision of measurement Repeatability Reproducibility

				10.1.2..2 10.1.2.4 10.1.2.5 10.1.2.6 10.2 10.2.1 10.2.2 10.2.3	Analytical sensitivity Metrological traceability of calibrator and control material values Measuring range of the assay Definition of Assay Cut-off Stability (excluding specimen stability) Claimed Shelf life In use stability Shipping stability
4.3.1	Pre-clinical Studies	11.7	Animal Studies		-
4.3.1.1	Software Validation Studies (if applicable)	11.6	Software Verification and Validation	10.3	Software Verification and Validation
4.3.1.2	Devices Containing Biological Material	11.4	Biological Safety		
4.3.2	Clinical Evidence	11.8	Clinical Evidence	10.4	Clinical Evidence
4.3.2.1	Use of Existing Bibliography	11.8	Clinical Evidence ... to address the elements contained in the clinical Evaluation Report described in guidance GHTF/SG5/N2	10.4	Clinical Evidence
4.4	Device Labelling	7.0	Labelling	11.0	Labelling
4.4.1	Samples of Labels on the Device and its Packaging	7.0	Labelling - labels on the device and its packaging	11.0	Labelling - labels on the device and its packaging
4.4.2	Instructions for Use, Training Materials & Instructions for Installation and Maintenance	7.0	Labelling • instructions for use; and • promotional material	11.0	Labelling instructions for use; and • promotional material
4.5	Risk Analysis	10.0	Risk Analysis and Control Summary	8.0	Risk Analysis and Control Summary
4.5.1	Results of Risk Analysis	10.0	Risk Analysis and Control Summary	8.0	Risk Analysis and Control Summary
4.6	Manufacturer Information	8.0	Design and Manufacturing Information	9.0	Design and Manufacturing Information

4.6.1	Manufacturing Process	8.2	Manufacturing Processes	9.2	Manufacturing Processes

STED PARTS NOT INCLUDED IN CSDT					
	- .	2	Product Specification The STED should contain a list of the features, dimensions and performance attributes of the medical device, its variants and accessories (if such are within the scope of the STED), that would typically appear in the product specification made available to the end user, e.g. in brochures, catalogues and the like.		
		3	Reference to similar and previous generations of the device		Reference to Previous Device Generation(s) and/or Similar Devices or Device History
	-	8.1	Device Design	9.1	Device Design
	-	12.0	Format of the STED	12.0	Format of the STED
	-	13.0	Declaration of Conformity	13.0	Declaration of Conformity

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