	CSDT (draft 14 Sept 2006)		STED GHTF/SG1/N011:2008		IVD STED GHTF/SG1/NO63
3.0	**Executive Summary** • 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 description including its intended 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)

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4.2.4	**Instructions of use**	**7.0**	**Labelling** • instructions for use	**11.0**	**Labelling** • 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 extracorporial circulation of body fluids.		
4.2.11	**Other Relevant Specifications**	**11.3**	**Medicinal Substance**		
4.2.12	**Other Descriptive Information**		-		-

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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** **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 Studies** **Specimen type** **Analytical Performance Characteristics** **Accuracy of measurement** **Trueness of measurement** **Precision of measurement** **Repeatability** **Reproducibility** **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**

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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					
	- .	**6.2**	**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.		
		6.3	**Reference to similar and previous generations of the device**	**6.2**	**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**