Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: **Comparison between the GHTF Summary Technical Documentation (STED) formats for Medical Devices and In Vitro Diagnostic Medical Devices and the Common Submission Dossier Template (CSDT) format**

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Preface

The document herein was produced by the Asian Harmonization Working Party.The document is intended to provide information for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Introduction

The primary way in which the AHWP achieves its goals is through the production of a series of guidance documents that together describe an internationally harmonised regulatory model for medical devices, including In Vitro Diagnostic (IVD) medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether a medical device, including IVD medical device conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Regulatory Authorities (RAs), Conformity Assessment Bodies (CABs) and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry.

The GHTF and AHWP have both identified as a priority the need to harmonize the documentation of evidence of conformity to the Essential Principles of safety and performance (hereafter referred to as Essential Principles). Each has prepared guidance on the content of summary technical documentation to be assembled and submitted to a Regulatory Authority or Conformity Assessment Body. The summary technical documentation should be prepared by the manufacturer in a format which provides different Regulatory Authorities or Conformity Assessment Bodies with the same body of documentary evidence that its medical device conforms to the Essential Principles. The use of an agreed format should reduce costs for the manufacturer and reviewer, remove barriers to trade and facilitate timely international access to medical devices.

The GHTF has prepared separate guidance documents on the STED for medical devices[1] and the STED for IVD medical devices[2].

The AHWP has established the Common Submission Dossier Template (CSDT), based on the GHTF STED for medical devices. A requirement for the CSDT has been included into the draft of the ASEAN Medical Device Directive and will become the format of premarket submissions for ASEAN once the directive is implemented. There is no CSDT specifically for IVD medical devices.

In October 2010, AHWP and GHTF did a comprehensive comparison between CSDT and the STEDs for medical devices and IVD medical devices. The result of the

1 GHTF/SG1/N011:2008: *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*
2 GHTF/SG1/N063:2011: *Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices*

comparison is given in the appendix. It is hoped that the comparison will help the reader gain more insights into both formats, before deciding which document should be adopted in premarket submissions for IVD medical devices.

Where other guidance documents within the series are referenced within this text, their titles are italicised for clarity.

Work Group 1a of the Asian Harmonisation Working Party (AHWP) has prepared this information document. Comments or questions about it should be directed to the Chair of AHWP Work Group 1a whose contact details may be found on the AHWP website[3].

Purpose

The availability of summary technical documentation in an agreed format should help eliminate differences in documentation requirements between jurisdictions, thus decreasing the cost of establishing and documenting regulatory compliance and allowing patients earlier access to new technologies and treatments.

This document is intended to provide information on the differences between the recommended content of the CSDT and the STED for IVD medical devices. Since there is no specific CSDT for IVD medical devices, the comparison includes the STED for medical devices as a more direct comparison between the two formats and allows the reader to understand the different requirements for IVD medical devices.

Comparison between CSDT and STEDs

The Appendix contains the comparison between the three documents. The core content of each document is the required content of the technical documentation to be submitted to a regulatory authority. In this respect, the CSDT is more detailed than the GHTF STED for medical devices, but the GHTF IVD STED is most detailed and very specific in setting out the requirements for IVDs.

The CSDT incorporates the requirements for labeling and instructions for use, as well as for clinical evidence. The GHTF includes these requirements as headings only, with the detailed requirements included in separate guidance documents.

[3] www.ahwp.info

Appendix

Appendix - Comparison between CSDT and STED versions

CSDT (draft 14 Sept 2006)	STED GHTF/SG1/N011:2008	STED GHTF/SG1/NO63:2011	COMMENTS
3.0 Executive Summary An executive summary shall be provided with the common submission dossier template, which shall include the following information: • an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; • 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.			No requirement for an Executive Summary in either STED.
	5.0 Preparation and Use of the STED **5.1 Preparation** Manufacturers of all classes of device are expected to demonstrate conformity of the device to the *Essential Principles of Safety and Performance of Medical Devices* (hereafter referred to as Essential Principles) through the preparation	 **5.1 Preparation** Manufacturers of all classes of IVD medical devices are expected to demonstrate conformity of the IVD medical device to the *Essential Principles of Safety and Performance of Medical Devices* through the preparation and	No explanation of the pre- and post- market purposes of the CSDT. No explanation of the relationship between the CSDT and the manufacturer's technical information.

	and holding of technical documentation that shows how each medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. This technical documentation is updated as necessary to reflect the current status, specification and configuration of the device.	holding of technical documentation that shows how each IVD medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. This technical documentation is revised to reflect the current status of the IVD medical device through normal application of the manufacturer's QMS.	No explanation in the CSDT that it reflects the status of a device at a particular moment of time (unlike the technical documentation).
	For the purpose of conformity assessment, the manufacturer creates the STED from existing technical documentation to provide evidence to the RA/CAB that the subject medical device is in conformity with the Essential Principles. 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 flow of information from the technical documentation to the STED is illustrated in Figures 1 and 2.	For the purpose of conformity assessment, the manufacturer assembles the STED from existing technical documentation to provide evidence to the RA/CAB that the subject IVD medical device is in conformity with the Essential Principles. The STED reflects the status of the IVD 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 flow of information from the technical documentation to the STED is illustrated in Figures 1 and 2. It can be seen from these figures that the content of the STED is the same for both pre and post market use but the circumstances for the use of the STED are different.	
	The STED should be in a language acceptable to the RA/CAB.	Where the STED is submitted to a RA/CAB, it should be in a language acceptable to the reviewing organisation.	No mention of language used in the CSDT.

	The depth and detail of the information contained in the STED will depend on: • the classification of the subject device; • the complexity of the subject device. It also depends upon whether the device has the following characteristics: • it incorporates novel technology; • it is an already marketed device type that is now being offered for an intended use different from the original one; • it is new to the manufacturer; • the device type has been associated with a significant number of adverse events, including use errors; • it incorporates novel or potentially hazardous materials; • the device type raises specific public health concerns.	The depth and detail of the information contained in the STED will primarily depend on the classification of the subject IVD medical device. Further considerations when developing the individual sections of the STED include for instance: a) a high degree of complexity in the subject IVD medical device. b) the IVD medical device incorporates novel technology; For the purpose of STED, examples of novel technology include: 1) there has been no such IVD medical device available on any market for the relevant analyte (measurand); 2) the procedure involves analytical technology not used in connection with a given analyte (measurand) or other parameter on the market. c) the IVD medical device is an already marketed IVD medical device type that is now being offered for an intended use different from the original one; d) the IVD medical device type has been associated with a significant	IVD STED provides examples of what is 'novel'.

		number of adverse events known to the manufacturer, including use errors[4]; e) the IVD medical device incorporates novel or hazardous materials of concern; f) the IVD medical device type raises specific public health concerns (e.g. virulent influenza pandemic).	
	The STED should contain summary information on selected topics, detailed information on certain specific topics (as indicated below) and an Essential Principles checklist (EP checklist). The information provided may include, for example, abstracts, high level summaries, or existing controlled documents, as appropriate, sufficient to communicate key relevant information and allow a reviewer to understand the subject.	The STED should contain summary information on selected topics, and may contain detailed information on certain specific topics (as outlined in Part 2 of this guideline) and an Essential Principles checklist (EP checklist). The information provided may include, for example, abstracts, high level summaries, or existing controlled documents, as appropriate, sufficient to communicate key relevant information and allow a reviewer to understand the subject and assess the validity of that information.	Information on EP Checklist first appears here. Section on EP Checklist is later in the STED.
	The EP checklist is created as part of the manufacturer's technical documentation and should be a controlled document within the manufacturer's QMS. It provides a tabular overview of the Essential Principles and identifies those that are applicable to the device, the chosen method of demonstrating that the device conforms to each relevant Essential	The EP checklist is created as part of the manufacturer's technical documentation and is controlled by the manufacturer's QMS. It provides a tabular overview of the Essential Principles and identifies those that are applicable to the IVD medical device, the chosen method of demonstrating that the device conforms to each relevant Essential Principle and the	

4 See SG2/N45R8:2006 Medical Devices Post-market Surveillance : Global guidance for Adverse Reporting for Medical Devices.

	Principle and the reference of the controlled document/s that is/are relevant to a specific Essential Principle. While many controlled documents are referenced in the EP checklist, only some are contained within the STED. The cited references to the controlled documents facilitate requests from a RA/CAB to provide additional information.	reference of the controlled document that is relevant to a specific Essential Principle. While many controlled documents are referenced in the EP checklist, only some may be contained within the STED. The cited references to the controlled documents also allow easy identification of additional relevant documents and data.	
	5.2 The Use of the STED in the Premarket Phase In the premarket phase, the STED will be prepared and submitted to the RA/CAB for Class C and D devices. For Class A and B devices the STED will be prepared and submitted only at the request of a RA/CAB. (See Figure 1) NOTES: • For Class A and B devices where the STED is prepared on request, the manufacturer should be able to assemble and submit it in the timeframe indicated by the RA/CAB. This may be short. • A copy of any submitted STED should be held by the manufacturer for future reference.	**5.2 The Use of the STED in the Premarket Phase** In the premarket phase, the STED will be prepared and submitted to the RA/CAB for Class C and D IVD medical devices. For Class A and B IVD medical devices, the STED will be prepared and submitted only at the request of a RA/CAB (see Figure 1). In this case, the manufacturer should be able to assemble and submit it in the timeframe indicated by the RA/CAB. The content of any submitted STED should be traceable by the manufacturer for future reference.	No explanation of the pre- market purposes of the CSDT.
	5.3 The Use of the STED in the Post-market Phase In the post-market phase, the RA/CAB may request submission of a STED for the device in question either to	**5.3 The Use of the STED in the Post-market Phase** In the post-market phase, the RA/CAB may request submission of a STED either to investigate conformity of a	No explanation of the post- market purposes of the CSDT.

	investigate conformity of a Class A or B medical device or the continued conformity of a Class C or D medical device (see Figure 2). The STED would not typically be used to aid the postmarket investigation of adverse events, or the reporting of data from postmarket registries or studies, where different types of information are likely to be called for. NOTES: • The manufacturer should be able to prepare and submit the STED in the timeframe indicated by the RA/CAB. This may be short. • A copy of any submitted STED should be held by the manufacturer for future reference.	Class A or B IVD medical device or the continued conformity of a Class C or D IVD medical device (see Figure 2). The manufacturer should be able to prepare and submit the STED in the timeframe indicated by the RA/CAB. The content of any submitted STED should be traceable by the manufacturer for future reference. The STED would not typically be used to aid the post-market investigation of adverse events, or the reporting of data from post-market registries or studies, where different types of information are likely to be called for.	
	5.4 The Use of the STED to Notify Changes to the RA/CAB Where prior approval of a proposed change to a medical device is required, the STED may be used in support of this process. Guidance on this case will be provided in the future	**5.4 The Use of the STED to Notify Changes to the RA/CAB** Where prior approval of a proposed change to an IVD medical device is required, the STED may be used in support of this process. Guidance on this case will be provided in the future.	No explanation of the purpose of resubmitting the CSDT.
4.0 Elements of the Common Submission Dossier Template	**6.0 Device Description and Product Specification, Including Variants and Accessories**	**6.0 Device Description including Variants (Configurations) and Accessories**	

4.1 Relevant Essential Principles and Method Used to Demonstrate Conformity *The CSDT should identify the Essential Principles of Safety and Performance of Medical Devices that are applicable to the device.* The CSDT *should identify the general method used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc.* The CSDT should *identify the specific documents related to the method used to demonstrate conformity to the Essential Principles.* **4.1.1 Essential Principles and Evidence of Conformity** The *evidence of conformity can be provided in tabular form with supporting documentation available for review as required.* A sample of the essential principles conformity checklist is included in Appendix A. Draft: Version 1 AHWP Technical Committee Common Submission Dossier Template 14 Sep 2006 Page 4 of 14 For example, a completed Essential Principles	**9.0 Essential Principles (EP) Checklist** The STED should contain an EP 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. Methods used to demonstrate conformity may include one or more of the following: a) conformity with recognised or other standards; b) conformity with a commonly accepted industry test method(s); c) conformity with an in-house test method(s); d) the evaluation of pre-clinical and clinical evidence. e) comparison to a similar device already available on the market. The EP checklist should incorporate a cross-reference to the location of such evidence both within the full technical documentation held by	**7.0 Essential Principles (EP) Checklist** The STED should include an EP checklist that identifies: a) the Essential Principles; b) whether each Essential Principle applies to the IVD medical device and if not, why not; c) the method used to demonstrate conformity with each Essential Principle that applies; and d) the reference to the actual technical documentation that offers evidence of conformity with each method used. The method used to demonstrate conformity may include one or more of the following: a) conformity with recognized or other standards; b) conformity with a commonly accepted industry test method (reference method); c) conformity with appropriate in-house test methods that have been validated and verified; d) comparison to an IVD medical device already available on the market. The EP checklist should include a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer	All 3 documents have their Sections arranged in a different order.

conformity checklist can be used to demonstrate that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. As such, CSDT would then include a declaration of conformity to the standard, or other certification permitted by the Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements. When the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the CSDT should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the manufacturer uses other means, such as internal standards, the CSDT should describe the means. Not all the essential principles will apply to all devices and it is for the manufacturer of the device to assess which are appropriate for his particular device product. In determining this, account must be taken of the intended purpose of the device.	the manufacturer and within the STED (when such documentation is specifically required for inclusion in the Summary Technical Documentation as outlined in this guidance).	and within the STED (when such documentation is specifically required for inclusion in the Summary Technical Documentation as outlined in this guidance).	
4.2 *Device Description* **(According to GHTF Classification)** **Description A B C D**	**6.1 Device Description** The STED should contain the	**6.1 Device Description** The STED should include the	

Device Description *Intended Use/Indications for Use* *Product Drawing/Product Brochure* Material/Component List Statement on Shelf Life (Sterile Product only) (The aforementioned matrix is in its draft form; it describes the type and amount of information to be submitted for the various classes of devices. The draft matrix is to be discussed further, pending consensus on adoption of a 4-class risk based classification system.) **4.2.1 *Device description* & features** Besides a general description of the device, a more detailed description of the device attributes is necessary to explain how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging. A complete description of each functional component, material or ingredient of the device should be provided, with *labelled pictorial representation of the device* in the form of *diagrams, photographs or drawings*, as appropriate.	following descriptive information for the device: a) a general description including its intended use/purpose; b) the intended patient population and medical condition to be diagnosed and/or treated and other considerations such as patient selection criteria; c) principles of operation; d) risk class and the applicable classification rule according to *Principles of Medical Devices Classification*; e) an explanation of any novel features; f) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it; g) a description or complete list of the various configurations/variants of the device that will be made available; h) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this will include: labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams. 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.,	following device descriptive information: a) the intended use of the IVD medical device. This may include: 1) what is detected 2) its function (for example screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease); 3) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate; 4) whether it is automated or not; 5) whether it is qualitative or quantitative; 6) the type of specimen(s) required (eg. serum, plasma, whole blood, tissue biopsy, urine); 7) testing population; b) the intended user (lay person or professional); c) a general description of the principle of the assay method or instrument principles of operation; d) the Class of the device and the applicable classification rule according to *Principles of In Vitro Diagnostic Medical Devices Classification;* e) a description of the components (e.g. reagents, assay controls and calibrators) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers) and where applicable:	

4.2.2 *Intended use* This means the use for which the medical device is intended, for which it is suited according to the data Draft: Version 1 AHWP Technical Committee Common Submission Dossier Template 14 Sep 2006 Page 5 of 14 supplied by the manufacturer in the instructions as well as the functional capability of the device. **4.2.3 *Indications*** This is a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the device is intended.	during extracorporeal circulation of body fluids. **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.	f) a description of the specimen collection and transport materials provided with the IVD medical device or descriptions of specifications recommended for use; g) for instruments of automated assays : a description of the appropriate assay characteristics or dedicated assays; h) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation; i) a description of any software to be used with the IVD medical device; j) a description or complete list of the various configurations/variants of the IVD medical device that will be made available; k) a description of the accessories, other IVD medical devices and other products that are not IVD medical devices, which are intended to be used in combination with the IVD medical device.	
	6.3 Reference to similar and previous generations of the device Where relevant to demonstrating conformity to the Essential Principles, and to the provision of general background information, the STED should contain an overview of: a) the manufacturer's previous generation(s) of the device, if such exist; and/or b) similar devices available on the local and	**6.2 Reference to the Manufacturer's Previous Device Generation(s) and/or Similar Devices or Device History** **6.2.1 For an IVD medical device not yet available on any market** Where relevant to demonstrating conformity to the Essential Principles, and	CSDT does not call for information on previous generations of device.

	international markets.	to provide general background information, the STED may provide a summary of: a) the manufacturer's previous generation(s) of the IVD medical device, if such exist; and/or b) the manufacturer's similar IVD medical devices available on the market. **6.2.2 For an IVD medical device already available on the market in any jurisdiction** This information may include a summary of the number of adverse event reports related to the safety and performance of this IVD medical device in relation to the number of IVD medical devices placed on the market. External certificates and documents which give written evidence of conformity with the Essential Principles may be annexed to the STED.	
4.2.4 *Instructions of use* These are all necessary information from the manufacturer including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the	**7.0 Labelling** The STED should typically contain a complete set of labelling associated with the device as described in GHTF guideline *Labelling for Medical Devices* and a list of language variants for the countries where the device will be marketed. Information on labelling should include the following: • labels on the device and its packaging;	**11.0 Labelling** The STED should typically contain a complete set of labelling associated with the device as described in GHTF guideline *Labelling for Medical Devices* and a list of language variants for the countries where the device will be marketed. Information on labelling should include the following: • labels on the device and its	STED & IVD STED reference another GHTF document, specific to labels and instructions for use, rather than incorporate the details into the text (as the CSDT has). CSDT has separate sections on 'Instructions for Use' (4,2.4) and Device 'Labelling' (4.4).

device itself and/or on its packaging by other formats / forms.	• instructions for use; and • promotional material. The labelling set should be in a language acceptable to the reviewing RA or CAB.	packaging; • instructions for use; and • promotional material. The labelling set should be in a language acceptable to the reviewing RA or CAB.	
4.2.5 *Contraindications* This is a general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.			
4.2.6 Warnings This is the specific hazard alert information that a user needs to know before using the device.			
4.2.7 Precautions This alerts the user to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid			

such effects.			
4.2.8 Potential adverse effects These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions.			
4.2.9 Alternative therapy This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.			
4.2.10 *Materials* A description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device.			
4.2.11 Other Relevant *Specifications* The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic devices, reliability and other factors; and other specifications	**11.3 Medicinal Substances** Where the medical device incorporates a		CSDT has no specific requirement regarding 'medicinal substances'.

including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.	medicinal substance(s), the STED should provide detailed information concerning that medicinal substance, its identity and source, the intended reason for its presence, and its safety and performance in the intended application.		
4.2.12 Other Descriptive Information Other important descriptive characteristics not detailed above, to the extent necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished device). NOTE: For simple, low risk devices, the above information will typically be contained in already existing sales brochures, instructions for use, etc.	**11.2 Biocompatibility** The STED should contain a list of all materials in direct or indirect contact with the patient or user. Where biocompatibility testing has been undertaken to characterize the physical, chemical, toxicological and biological response of a material, detailed information should be included on the tests conducted, standards applied, test protocols, the analysis of data and the summary of results. At a minimum, tests should be conducted on samples from the finished, sterilised (when supplied sterile) device.		
4.3 Summary of Design Verification and Validation Documents This section *should summarize or reference or contain design verification and design validation data to the extent appropriate to the complexity and risk class of the device*: *Such documentation should typically include:* *• declarations/certificates of conformity to the "recognized"*	**11.0 Product Verification and Validation** **11.1 General** The STED should contain product verification and validation documentation. The level of detail will vary (see Section 5.1). As a general rule, the STED should	**10.0 Product Verification and Validation** The information provided in the product verification and validation section of the STED will vary in the level of detail as determined by the class of the device. Also other characteristics as outlined in section 5.1 will influence the level of detail of the STED. As a general rule, the STED	Title in CSDT includes the word 'design'.

standards listed as applied by the manufacturer; and/or *• summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.* ***EXAMPLE:** The completed Table of Conformity to the Essential Principles that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle*. Section 3.0 of the CSTD would then *include a declaration of conformity to the standard, or other certification permitted by the relevant Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements.* Draft: Version 1 AHWP Technical Committee Common Submission Dossier Template 14 Sep 2006 Page 7 of 14 *The data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the device:* *• a listing of and conclusions drawn from published reports that concern the safety and*	summarise the results of verification and validation studies undertaken to demonstrate conformity of the device with the Essential Principles that apply to it. Such information would typically cover: a) engineering tests; b) laboratory tests; c) simulated use testing; d) any animal tests for demonstrating feasibility or proof of concept of the finished device; e) any published literature regarding the device or substantially similar devices. Such summary information may include: a) declaration/certificate of conformity to a recognised standard(s) and summary of the data if no acceptance criteria are specified in the standard; b) declaration/certificate of conformity to a published standard(s) that has not been recognised, supported by a rationale for its use, and summary of the data if no acceptance criteria are specified in the standard; c) declaration/certificate of conformity to a professional guideline(s), industry method(s), or in-house test method(s), supported by a rationale for its use, a description of the method used, and summary of the data in sufficient detail to allow assessment of its adequacy; d) a review of published literature regarding the device or substantially similar devices.	should summarise the results of verification and validation studies undertaken to demonstrate conformity of the IVD medical device with the Essential Principles that apply to it. Where appropriate, such information might come from literature. For the purpose of the STED document, summary and detailed information are defined as: **1. Summary Information** A summary should provide enough information to allow the RA/CAB to assess the validity of that information. This summary should contain a brief description of: a) the study protocol, b) the study results, c) the study conclusion. This summary may include: a) Where a recognized standard exists, a declaration/certificate of conformity to a recognized standard can be provided with a summary of the data if no acceptance criteria are specified in the standard; b) In the absence of a recognized standard, a declaration/certificate of conformity to a published standard that has not been recognized might be provided if	

performance of aspects of the device with reference to the Essential Principles; • *engineering tests;* • *laboratory tests;* • *biocompatibility tests;* • *animal tests;* • *simulated use;* • *software validation.*	In addition, where applicable to the device, the STED should contain detailed information on: a) biocompatibility; b) medicinal substances incorporated into the device, including compatibility of the device with the medicinal substance; c) biological safety of devices incorporating animal or human cells, tissues or their derivatives; d) sterilisation; e) software verification and validation; f) animal studies that provide direct evidence of safety and performance of the device, especially when no clinical investigation of the device was conducted; g) clinical evidence. Detailed information will describe test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions. Where no new testing has been undertaken, the STED should incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous, legally marketed version of the device. The rationale may be incorporated into the EP checklist.	it is supported by a rationale for its use, and summary of the data, and a conclusion, if no acceptance criteria are specified in the standard; c) In the absence of a recognized standard and non-recognized published standards, a professional guideline, industry method, or in-house standard may be referred to in the summarized information. However, it should be supported by a rationale for its use, a description of the method used, a summary of the data in sufficient detail and a conclusion to allow assessment of its adequacy; d) A review of relevant published literature regarding the device/analyte (measurand) or substantially similar IVD medical devices. **2 Detailed Information** Detailed information should include: a) the complete study protocol, b) the method of data analysis, c) the complete study report, d) the study conclusion. For detailed information, when a recognized standard exists that contains the protocol and the method of data analysis, this information can be substituted by a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions. For clinical performance (which is	

		part of the clinical evidence), the detailed information will typically include individual data points (formatted raw data) for a Class D IVD medical device. Where appropriate, actual test result summaries with their acceptance criteria should be provided and not just pass/fail statements.	
4.3.1 Pre-clinical Studies Details must be provided on all biocompatibility tests conducted on materials used in a device. At a minimum, tests must be conducted on samples from the finished, sterilized device. All materials that are significantly different must be characterized. Information describing the tests, the results and the analyses of data must be presented. Complete pre-clinical physical test data must be provided, as appropriate. The report must include the objectives, methodology, results and manufacturer's conclusions of all physical studies of the device and its components. Physical testing must be conducted to predict the adequacy of device response to physiological stresses, undesirable conditions and forces, long-term use and all known and possible failure modes. Pre-clinical animal studies used to support the	**11.7 Animal Studies** Where studies in an animal model have been undertaken to provide evidence of conformity with the Essential Principles related to functional safety and performance, detailed information should be contained in the STED. The STED should describe the study objectives, methodology, results, analysis and conclusions and document conformity with Good Laboratory Practices. The rationale (and limitations) of selecting the particular animal model should be discussed.	**10.1 Analytical Studies** The statements and descriptions in the following sections refer to all IVD medical devices. It must be noted however that there are applicability differences between instrumentation and reagent-based assays, and that the assays themselves may be quantitative, semi-quantitative or qualitative in nature. There may be limited applicability of some of the following subsections for qualitative or semi-quantitative assays. Where possible, comments regarding instrumentation or qualitative assays appear in the subsections. **10.1.1 Specimen type** This section should describe the different specimen types that can be used. This should include their stability and storage conditions and is typically applicable to all systems and assay types. Stability includes storage and where applicable transport conditions.	IVD STED incorporates guidance specific to IVD medical devices. IVD STED incorporates guidance specific to IVD medical devices.

probability of effectiveness in humans must be reported. These studies must be undertaken using good laboratory practices. The objectives, methodology, results, analysis and manufacture's conclusions must be presented. The study conclusion should address the device's interactions with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.		Storage includes elements such as duration, temperature limits and freeze/thaw cycles. This section should include summary information for each matrix and anticoagulant when applicable, including a description of the measurement procedure for comparison or determination of measurement accuracy. This includes information such as specimen type tested, number of samples, sample range (using spiked samples as appropriate) or target concentrations tested, calculations and statistical methods, results and conclusions. Typically for a class D IVD medical device, detailed information would be provided. **1.1.1 10 .1.2 Analytical Performance Characteristics** **10.1.2.1 10.1.2.1 Accuracy of measurement** This section should describe both trueness and precision studies. <u>Note:</u> The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness.	IVD STED incorporates guidance specific to IVD medical devices.

		While measurement **trueness**, affected by systematic error, is normally expressed in terms of bias, measurement **precision**, affected by random error, is naturally expressed in terms of standard deviation, Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement. **10.1.2.1.1 Trueness of measurement** This section should provide information on the trueness of the measurement procedure and summarize the data in sufficient detail to allow assessment of the adequacy of the selected means. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. Typically for Class C and D IVD medical devices, detailed information would be provided. **10.1.2.1.2 Precision of measurement** This section should describe repeatability and reproducibility studies. **10.1.2.1.2.1 Repeatability**	IVD STED incorporates guidance specific to IVD medical devices. IVD STED incorporates guidance specific to IVD medical devices. IVD STED incorporates guidance specific to

		This section should include repeatability estimates and information about the studies used to estimate, as appropriate, within-run variability. Repeatability data is obtained for instrumentation in conjunction with an appropriate assay. Typically for Class C and D IVD medical devices, detailed information would be provided. Note 1: Such studies should include the use of samples that represent the full range of expected analyte (measurand) concentrations that can be measured by the test as claimed by the manufacturer. Note 2: If a recognized standard is used, a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions should be provided. **10.1.2.1.2.2 Reproducibility** This section should include reproducibility estimates and information about the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators and instruments. Such variability is also known as **"Intermediate Precision".** Reproducibility data is obtained for instrumentation in conjunction with an appropriate assay.	IVD medical devices. IVD STED incorporates guidance specific to IVD medical devices.

		Typically for Class C and D IVD medical devices, detailed information would be provided. Note 1: Such studies should include the use of samples that represent the full range of expected analyte (measurand) that can be measured by the test as claimed by the manufacturer. Note 2: If a recognized standard is used, a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions should be provided. **10.1.2..2 Analytical sensitivity** This section should include information about the study design and results. It should provide a description of specimen type and preparation including matrix, analyte (measurand) levels, and how levels were established. The number of replicates tested at each concentration should also be provided as well as a description of the calculation used to determine assay sensitivity. For example: a) Number of standard deviations above the mean value of the sample without analyte (measurand), commonly referred to as limit of blank (LoB). b) Lowest concentration distinguishable from zero, based on measurements of samples containing analyte	IVD STED incorporates guidance specific to IVD medical devices.

		(measurand), commonly referred to as limit of detection (LoD). c) Lowest concentration at which precision and/or trueness are within specified criteria, commonly referred to as limit of quantitation (LoQ). Typically for a Class C and D IVD medical devices, detailed information would be provided. **10.1.2.3 Analytical specificity** This section should describe interference and cross reactivity studies to determine the analytical specificity, defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the sample. Provide information on the evaluation of potentially interfering and cross reacting substances/agents on the assay. Information should be provided on the substance/agent type and concentration tested, sample type, analyte (measurand) test concentration, and results. Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as: a) substances used for patient	IVD STED incorporates guidance specific to IVD medical devices. IVD STED incorporates guidance specific to IVD medical devices.

		treatment (e.g. therapeutic drugs, anticoagulants, etc.); b) substances ingested by the patient (e.g. over the counter medications, alcohol, vitamins, foods, etc.); c) substances added during sample preparation (e.g. preservatives, stabilizers); d) substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins); e) analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition (e.g. for a hepatitis A assay: test specimens negative for hepatitis A virus, but positive for hepatitis B virus). Typically, interference studies involve adding the potential interferent to the sample and determining any bias of the test parameter relative to the control sample to which no interferent has been added. Typically for Class C and D IVD medical devices, detailed information would be provided. **10.1.2.4 Metrological traceability of calibrator and control material values**	IVD STED incorporates guidance specific to IVD medical devices.

		Where applicable, summarize the information about metrological traceability of values assigned to calibrators and trueness control materials. Include, for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation. Precision control materials, used when establishing the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method. Typically for a class D IVD medical device, detailed information would be provided. **10.1.2.5 Measuring range of the assay** This section should include a summary of studies which define the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. This summary should include a description of specimen type, number of samples, number of replicates, and preparation including information on matrix, analyte (measurand) levels and how levels were established. If applicable, add a description of high dose hook effect and	IVD STED incorporates guidance specific to IVD medical devices.

		the data supporting the mitigation (e.g. dilution) steps. Typically for Class C and D IVD medical devices, detailed information would be provided. **10.1.2.6 Definition of Assay Cut-off** This section should provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including: a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included); b) method or mode of characterization of specimens; and c) statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define gray-zone/equivocal zone. Typically for Class C and D IVD medical devices, detailed information would be provided. **10.2 Stability (excluding specimen stability)** This section should describe claimed shelf life, in use stability and shipping studies.	IVD STED incorporates guidance specific to IVD medical devices. IVD STED incorporates guidance specific to IVD medical devices.

		10.2.1 Claimed Shelf life This section should provide information on stability testing studies to support the claimed shelf life. Testing should be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. Typically for Class C and D IVD medical devices, detailed information would be provided. Such detailed information should describe: a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals) b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies c) conclusions and claimed shelf life <u>Note:</u> Shelf life can be derived from the lot with the longest real time stability data as long as accelerated or extrapolated data from all three lots are comparable.	IVD STED incorporates guidance specific to IVD medical devices.

		10.2.2 In use stability This section should provide information on in use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability. In the case of automated instrumentation if calibration stability is claimed, supporting data should be included. Such detailed information should describe: a) the study report (including the protocol, acceptance criteria and testing intervals) b) conclusions and claimed in use stability Typically for Class C and D IVD medical devices, detailed information would be provided. **10.2.3 Shipping stability** This section should provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions. Shipping studies can be done	IVD STED incorporates guidance specific to IVD medical devices. IVD STED incorporates guidance specific to IVD medical devices.

		under real and/or simulated conditions and should include variable shipping conditions such as extreme heat and/or cold. Such information should describe: a) the study report (including the protocol, acceptance criteria) b) method used for simulated conditions c) conclusion and recommended shipping conditions Typically for a Class C and D IVD medical device, detailed information would be provided.	
4.3.1.1 Software Validation Studies (if applicable) The correctness of a software product is another critical product characteristic that cannot be fully verified in a finished product. The manufacturer and/or device sponsor must provide evidence that validates the software design and development process. This information should include the results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, as well as Draft: Version 1 AHWP Technical Committee Common Submission Dossier Template 14 Sep 2006 Page 8 of	**11.6 Software Verification and Validation** The STED should contain information on the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.	**10.3 Software Verification and Validation** The STED should contain evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. Typically for a class D IVD medical device, detailed information would be provided.	

14 representative data generated from both testing environments.			
4.3.1.2 Devices Containing Biological Material Results of studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents must be provided. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.	**11.4 Biological Safety** The STED should contain a list of all materials of animal or human origin used in the device. For these materials, detailed information should be provided concerning the selection of sources/donors; the harvesting, processing, preservation, testing and handling of tissues, cells and substances of such origin should also be provided. Process validation results should be included to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. The system for record-keeping to allow traceability from sources to the finished device should be fully described.		Text in CSDT seems to focus on 'transmissible agents.
4.3.2 *Clinical Evidence* This section *should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar devices, or by clinical investigation. Clinical investigation is most likely to be needed for higher risk class devices, or for devices where there is little or no clinical experience.*	**11.8 Clinical Evidence** The STED should contain the clinical evidence that demonstrates conformity of the device with the Essential Principles that apply to it. It needs to address the elements contained in the Clinical Evaluation Report described in guidance GHTF/SG5/N2.	**10.4 Clinical Evidence** The STED should contain the Clinical Evidence Evaluation report that demonstrates conformity of the IVD medical device to the Essential Principles that apply to it. More detailed recommendations regarding this element of the STED will be provided in guidance developed in cooperation with SG5.	STED & IVD STED reference another GHTF guidance document.

4.3.2.1 Use of Existing Bibliography Copies are required of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness. These will be a subset of the bibliography of references. General bibliographic references should be device-specific as supplied in chronological order. Care should be taken to ensure that the references are timely and relevant to the current application. Clinical evidence of effectiveness may comprise device-related investigations conducted domestically or other countries. It may be derived from relevant publications in a peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.			Information on what is to be incorporated into the STED and IVD STED provided in GHTF SG5 documents.
4.4 Device *Labelling* This is the descriptive and informational product literature that accompanies the device any time while it is held for sale or			For STED see Section 7.0 For IVD STED see Section 11.0

shipped, such as any physician's manuals, pack labeling, promotional material and product brochures etc. This section *should summarize or reference or contain the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as "labelling"*: • Sample of labels on the device and its packaging Draft: Version 1 AHWP Technical Committee Common Submission Dossier Template 14 Sep 2006 Page 9 of 14 • Instructions for use • Other literature or training materials • Instructions for installation and maintenance (if applicable). • Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable).			
4.4.1 Samples of Labels on the Device and its Packaging This is the printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. Any pack labelling, which is not			

provided on the outer packaging must be easily legible through this outer packaging. If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.			
4.4.2 Instructions for Use, Training Materials & Instructions for Installation and Maintenance The instructions for use is commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. This should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the device. Where applicable, this section should include instructions for training of the end-users for			

competent use of the device for its intended purpose, as well as installation and maintenance of the device.			
4.5 *Risk Analysis* This section *should summarize or reference or contain the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.*	**10.0 Risk Analysis and Control Summary** The STED should contain a summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. Preferably, this risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan.	**8.0 Risk Analysis and Control Summary** The STED should contain a summary of the risks identified during the risk analysis process and a description of how these risks have been controlled to an acceptable level. Preferably, this risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan. The summary should address possible hazards for the IVD medical device such as the risk from false positive or false negative results, indirect risks which may result from IVD medical device-associated hazards, such as instability, which could lead to erroneous results, or from user-related hazards, such as reagents containing infectious agents. The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits. Typically for a class D IVD medical device a detailed report would be provided.	
4.5.1 Results of Risk Analysis A list of possible hazards for these devices must be prepared.			

Indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from Draft: Version 1 AHWP Technical Committee Common Submission Dossier Template 14 Sep 2006 Page 10 of 14 user-related hazards, such as ionizing radiation from an X-ray machine. The evaluation of these risks against the claimed benefits of the device and the method(s) used to reduce risk to acceptable levels must be described. The individual or organization that carries out the risk analysis must be clearly identified. The technique used to analyze risk must be specified, to ensure that it is appropriate for the device and the risk involved.			
4.6 *Manufacturer Information* This section *should summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.*	**8.1 Device Design** The STED should contain information to allow a reviewer to obtain a general understanding of the design stages applied to the device. It is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. The	**9.0 Design and Manufacturing Information** **9.1 Device Design** The STED should contain information to allow a reviewer to obtain a general understanding of the design applied to the IVD medical device. It should include a description of	STED and IVD STED both ask for information on the stages of design.

	information may take the form of a flow chart.	the critical ingredients of an assay such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the IVD medical device, For instruments this would include a description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software. For instruments and software, an overview of the entire system would be required, including an Architecture Design Chart which is typically a flowchart of the relationships among the major functional units in the software, including relationships to hardware and to data flows such as networking. For standalone software, this would typically include a description of the data interpretation methodology (i.e. algorithms). For self-testing devices the design should include a description of the design aspects that make it suitable for lay person use. Typically for a class D IVD medical device detailed information on material specifications would be provided. This section is not intended to take the place of the more detailed information required for a QMS audit or	

		other conformity assessment activity. If design takes place at multiple sites, a controlling site must be identified.	
	8.3 Design and Manufacturing Sites For the activities in 8.1 and 8.2, the STED should identify the sites where these activities are performed. If QMS certificates, or the equivalent, exist for these sites, they should be annexed to the STED.	**9.3 Manufacturing Sites** For the activities in 9.2, the STED should identify the sites where these activities are performed (this does not include the sites of all suppliers of raw materials but only the sites that are involved in critical manufacturing activities). If QMS certificates, or the equivalent, exist for these sites, they may be annexed to the STED.	No requirement to identify different manufacturing sites in CSDT
4.6.1 Manufacturing Process Manufacturing process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output. **EXAMPLE:** The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labeling, storage of the device. Sufficient detail must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. A brief summary of the sterilization	**8.2 Manufacturing Processes** The STED should contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. It is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. The information may take the form of a process flow chart showing, for example, an overview of production, assembly, any final product testing, and packaging of the finished medical device. **11.5 Sterilisation** Where the device is supplied	**9.2 Manufacturing Processes** Only for Class D, the STED should contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. It is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. The information may take the form of a process flow chart showing, for example, an overview of production including the technologies used, assembly, any in-process and final product testing, and packaging of the finished IVD medical device.	Should the CSDT be modified to incorporate the text from the EXAMPLE into 4.6.1? Certainly it needs editing for clarity No requirement for a 'process flow chart' in the CSDT No requirement in IVD STED for information on sterilisation.

method and processing should be included, if any. If multiple facilities are involved in the manufacture of device, the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted. Firms that manufacture or process the device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file. The manufacturer should inform these contractors of the need to supply detailed information on the device. However, it is not the intent of this section to capture information relating to the supply of sub-components (i.e.unfinished medical device) that contributes towards the manufacture of the finished device itself.	sterile, the STED should contain the detailed information of the initial sterilisation validation including bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed in accordance with those standards, and a summary of results. Evidence of the ongoing revalidation of the process should also be provided. Typically this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilisation processes.		
	12.0 Format of the STED While this guidance document makes no specific recommendation for the format of the STED, it would be helpful to both manufacturers and reviewers if the STED was organized such that it incorporates the same sections as described in this guidance document e.g. device	**12.0 Format of the STED** While this guidance document makes no specific recommendation for the format of the STED, it would be helpful to both manufacturers and reviewers if the STED was organized such that it incorporates the same sections as described in this guidance document e.g. Device	

	description, product specification etc..	Description, Reference to Previous Device Generation(s) and/or Similar Devices or Device History, Essential Principles Checklist, etc.	
	13.0 Declaration of Conformity The Declaration of Conformity is not part of the STED. However, it may be annexed to the STED once the conformity assessment process has been completed. The content of the Declaration of Conformity is described in GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*.	**13.0 Declaration of Conformity** The Declaration of Conformity is not part of the STED. However, it may be annexed to the STED once the conformity assessment process has been completed. The content of the Declaration of Conformity is described in GHTF/SG1/N46:2007 *Principles of Conformity Assessment for In Vitro Diagnostic Medical Devices*.	