

WORKING DRAFT DOCUMENT

Global Harmonization Task Force

Title: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

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Preface

This document was produced by the Global Harmonization Task Force, a voluntary consortium of representatives from medical device Regulatory Authorities and Trade Associations from around the world. The document is intended to provide non-binding guidance to Regulatory Authorities for use in the regulation of medical devices and has been subject to consultation throughout its development and endorsement by the current Chair. Endorsement by the Chair signifies acceptance by consensus amongst members of the GHTF Steering Committee, as a document to be promoted by all members of the GHTF.

The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities or by nations with developing regulatory programmes.

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1.0 Introduction

The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable. This is achieved by identifying and developing areas of international co-operation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices.

The GHTF has identified as a priority the need to harmonize the documentation of evidence of conformity to regulatory requirements. Differences in documentation requirements necessitate additional work for the same device in different jurisdictions, increase costs and between countries pose barriers to the timely international access to medical devices. The barriers also have economic impact.

This guidance document has been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). Comments or questions about it should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page.

2.0 Scope

This guidance document provides guidance on Summary Technical Documentation (hereafter abbreviated to STED) for demonstrating conformity to the *Essential Principles of Safety and Performance of Medical Devices*¹ (hereafter abbreviated to 'Essential Principles'). It describes the format for a globally harmonized STED (see Section 6.0 below) and provides general recommendation on the content of the formatted elements (see section 7.0 below). This document applies to all products that fall within the definition of a medical device² and to active implantable medical devices. In-vitro diagnostic medical devices are outside the scope of this document.

Annexes provide important supplementary information including a sample conformity checklist, and additional recommendations for STEDs that must be submitted to either a Regulatory Authority or to a Conformity Assessment Body for review/validation/approval, such as for a cover page, an executive summary, a sample test report format, and a sample table of contents.

This document does not recommend any new or additional technical documents above and beyond what should be created by the manufacturer to comply with existing requirements to demonstrate conformity to the Essential Principles, and to address any country-specific requirements. Notwithstanding this, the STED is not any one of those documents referred to variously in different jurisdictions as "device master record", "device history record",

¹ Refer to SG1/N020 *the Essential Principles of Safety and Performance of Medical Devices*

² Refer to SG1/N029 *Information Concerning the Definition of the Term "Medical Device"*

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“quality system record“, “design history file“, or “design dossier” (see documents from GHTF, Study Group 3 and related regulations for definitions).

The format of the STED recommended herein is based upon the goal of both regulators and manufacturers to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

As an interim measure until full global harmonization of documentation requirements is achieved, the precise content of the STED under each of the headings in Section 6.0 will need to be augmented by documentation required by country-specific regulations and regulatory guidance.

Requirements for post-market vigilance or adverse event reporting are outside the scope of this document³.

This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices Regulatory Authorities, Conformity Assessment Bodies and the regulated 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. Regulatory Authorities that are developing new regulatory systems or amending existing ones are encouraged to consider the adoption of this guidance, as this will help to reduce the diversity of systems world-wide and facilitate the process of harmonization.

NOTE: The regulatory requirements of some countries may not, at present, reflect the contents of this document. Regulatory Authorities with existing systems are also encouraged to consider adopting this system. It is the goal of the GHTF that country-specific divergences will ultimately be reduced to a minimum.

3.0 References

SG1/N009 *Labelling for Medical Devices.*

SG1/N012 *Role of Standards in the Assessment of Medical Devices.*

SG1/N020 *Essential Principles of Safety and Performance of Medical Devices.*

SG1/N029 *Information Concerning the Definition of the Term “Medical Device”.*

4.0 Definitions

Clinical investigations: any specific study in human subjects undertaken to verify the safety

³ Guidance on these subjects is provided by Study Group 2 of the Global Harmonization Task Force.

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and performance of a specific medical device under normal conditions of use.

Conformity assessment: the systematic examination to determine the extent to which a medical device fulfils specified requirements.

Conformity Assessment Body (CAB): a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorized to undertake specified conformity assessment activities by a regulatory authority that will ensure performance of the CAB is monitored and, if necessary, withdrawal of designation.

Design Dossier: documentation the manufacturer is required to submit to a Conformity Assessment Body to demonstrate conformity of:

- a) certain high risk medical devices with requirements specified in Annex II of the European Directive Concerning Medical Devices⁴, or
- b) active implantable medical devices with requirements specified in Annex II of the European Directive Concerning Active Implantable Medical Devices⁵.

It is also a general term applied to device design records.

Regulatory Authority: a government agency or other entity, that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and to take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Summary Technical Documentation: an abstract of the complete technical records. It is held for conformity assessment purposes.

Technical File/Technical Documentation: documentation required by the European Directives to assess conformity of the medical device with the regulations. Also, general terms describing premarket records.

NOTE: Other terms used in this Summary Technical Document Guidance are derived from *ISO 8402 – Vocabulary*.

5.0 Intended use of the STED and its preparation

The STED is intended for conformity assessment purposes. The manufacturer creates the STED to demonstrate to a Regulatory Authority that the subject medical device is in conformity with the Essential Principles. The STED can be (1) a tangible set of documents all centrally located, or a “virtual” set of documents, i.e., an STED with a summary document centrally located but with sections at various locations within the company, at the discretion of the manufacturer.

For all devices, the manufacturer is required to conduct conformity assessment according to the Essential Principles before placing the device on the market. In certain cases

⁴ ref. 93/42/EEC of 14 June 1993.

⁵ ref. 90/385/EEC of 20 June 1990.

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(mostly determined by the risk class of the device), the STED may need to be reviewed/ approved by the Regulatory Authority or a Conformity Assessment Body before the applicable device is placed on the market.

Study Group 1 of the Global Harmonization Task Force is proposing a set of rules to establish the "class" of a device⁶. It is also proposing harmonized guidance on the link between device classification and conformity assessment to the Essential Principles⁷.

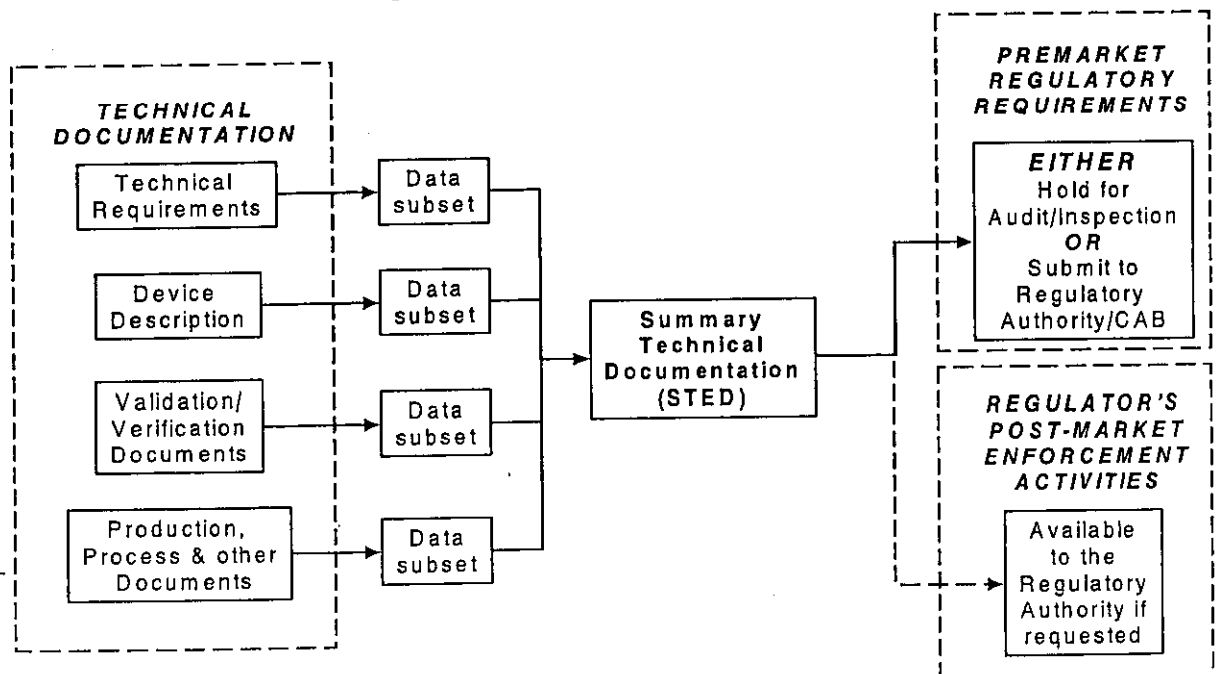
Examples: In the European Community a manufacturer determines the class of a generic type of device from a set of classification rules. Those in the highest risk class (i.e. Class III devices) require pre-market conformity assessment by a Conformity Assessment Body. In the United States a regulation establishes the class for a generic type of device. Class I and II, nonexempt and Class III devices require pre-market conformity assessment by the Regulatory Authority.

The class of the device will affect the necessary format and content of the STED and also whether or not the STED needs to be submitted to a Regulatory Authority or Conformity Assessment Body for review and approval or validation before placing the device on the market. The extent of that conformity assessment and the required resulting documentation vary according to device class, increasing with higher class.

The manufacturer determines the type and detail of the total technical documentation they believe are needed to demonstrate conformity to the Essential Principles, and to any relevant country-specific requirements. The manufacturer holds this documentation.

As Figure 1 illustrates, the manufacturer derives the content of an STED from the total technical documentation which it has already prepared and is holding to confirm and record that the medical device is in conformity with the Essential Principles. As an interim measure until full global harmonization of documentation requirements is achieved, the manufacturer must also consider any country-specific requirements, such as product specific guidance, or legal forms, or legal statements. These country-specific requirements will have a bearing on the type and amount of total documentation that a manufacturer should compile.

Further information is given in Appendix A2 and Appendix C.



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As Figure 1 further illustrates, the assessment of conformity to the Essential Principles by a Regulatory Authority may be required before a medical device is marketed (“pre-market”), or conformity may be audited after the medical device has been marketed (“post-market”).

Medical devices that typically have a high degree of risk are those that require pre-market conformity assessment in all jurisdictions. In such cases, documentation is frequently required to be provided to either a Regulatory Authority or Conformity Assessment Body for review/approval⁸. It is intended that the STED be such documentation. For further information on STEDs provided to Regulatory Authorities for review/approval, see Annex C.

6.0 Format for Summary Technical Documentation

6.1 Basic Format

For ease of use in a global situation, it is recommended that the STED be formatted as shown in the left-hand column of the table below. The right hand column indicates where expanded guidance on each recommended section can be found elsewhere in this document.

Summary Technical Documentation	Location in this document of expanded guidance
Essential Principles and evidence of conformity	Section 7.1
Device description	Section 7.2
Summary documents of pre-clinical design verification and validation	Section 7.3
Labelling	Section 7.4
Risk analysis	Section 7.5
Manufacturing information	Section 7.6

6.2 How to Apply the Basic Format when a Pre-market Submission is not Required

The respective sections of the STED may be in any of the forms shown below, at the discretion of the manufacturer.

In consideration of the least burdensome means to demonstrate post-market conformity, the manufacturer has the following options for the STED:

Option 1: STED based on total documentation. When the total technical documentation is held in a central location and it is contained in a concise file or volume of a relatively few number of pages, then the manufacturer may choose to designate this record as also the STED for post-market assessment purposes. Ideally, this file or volume should be in the harmonized format as described in Section 6.0.

⁸ The documentation provided may be called a “dossier”, “application”, or “notification” depending on the Regulatory Authority or Conformity Assessment Body receiving it, and the regulatory class of the device.

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Option 2: STED based on summary documentation. The manufacturer may choose to create the STED as a summary of source documents and formatted as described in Section 6.0.

Option 3: Abbreviated STED. The manufacturer may choose to use the Table of Conformity to the Essential Principles (see Appendix B) as the primary method to document conformity for post-market assessment purposes. When completed, this table will point to or reference the identity of the documents used to demonstrate conformity of each relevant Essential Principle. This method may be useful if the source documents consist of many pages and if they are held in more than one location.

Option 4: Combination STED. The manufacturer may choose to create the STED containing a combination of the above options, i.e. (1) some complete source documents, (2) summaries of some source documents, and/or (3) references to source documents.

6.3 How to Apply the Basic Format when a Pre-market Submission is Required

Where (for a particular higher risk class) the STED is provided to the Regulatory Authority for conformity assessment before placing the device on the market, it is recommended that the above sections be preceded by a cover page and an executive summary (see Appendix C).

7.0 Guidance on the Elements of the STED

7.1 Relevant Essential Principles and Method Used to Demonstrate Conformity

7.1.1 General

The STED should identify the Essential Principles of Safety and Performance of Medical Devices that are applicable to the device.

The STED 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 standards⁹, state of the art or internal industry methods, comparisons to other similar marketed devices, etc.

The STED should identify the specific documents related to the method used to demonstrate conformity to the Essential Principles. For example, when the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the STED 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 STED should describe the means.

⁹ Refer to SG1/N012 on the Role of Standards in the Assessment of Medical Devices.

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7.1.2 Essential Principles and Evidence of Conformity

For ease of use in a global situation, it is recommended that the evidence of conformity be provided in tabular form with supporting documentation available for review as required. A sample table is included in Appendix B.

7.2 Device Description

The STED should summarize or reference or contain (according to the option selected by the manufacturer in Section 6.2) the following device description data, to the extent appropriate to the complexity and risk class of the device:

7.2.1 General Information

- the functional purpose of the device (intended use);
- the intended patient population(s) and medical condition(s) to be diagnosed and/or treated by the device (indications for use) and other considerations such as patient selection criteria;
- the reasonably foreseeable medical conditions for which the device is not to be used (contraindications);
- a general description of the device including its principles of operation, (capabilities, the inputs to the device and outputs);
- an explanation of any novel features;
- the accessories, and other devices or equipment which are intended to be used in combination with the device;
- the variants of the device to be marketed including, if the STED is to be provided for regulatory review, the parameters of the range of variants;
- a general description of each of the functional parts/components of the device with labelled pictorial representations of the device (e.g. diagrams, photograph, drawing(s)), clearly indicating each part, including sufficient explanation to understand the drawings and diagrams;
- other information as needed to provide a description of the device, e.g., for an implant, a description of the anatomical location of the device in the body; attachment mechanisms for the device, including diagrams or illustrations of the implant in situ;
- comparisons to other devices to establish conformity to the Essential Principles. This could include, for example, information on previous designs of the same type of device or comparisons to other related devices.

NOTE: For simple, low risk devices, the above information will typically be contained in already existing sales brochures, instructions for use, etc.

7.2.2 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.

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7.2.3 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;
- other specifications 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.

7.2.4 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).

7.3 Summary of Design Verification and Validation Documents

7.3.1 General

The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the manufacturer in Section 6.2) 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” standards listed as applied by the manufacturer¹⁰; and/or
- summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance¹¹.

NOTE: Regulatory Authorities presently differ on what they expect in terms of a “summary”. As an interim measure until full global harmonization of documentation requirements is achieved, the manufacturer should research available sources of information, e.g. country-specific information, to help determine the type of summary that is acceptable.

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 7.0 of the STED 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.

¹⁰ Refer to SG1/N012 *Role of Standards in the Assessment of Medical Devices*.

¹¹ See Appendix C4 for a recommended format and content of a test report.

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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 performance of aspects of the device with reference to the Essential Principles;
- engineering tests;
- laboratory tests;
- biocompatibility tests;
- animal tests;
- simulated use;
- software validation.

A recommended test report format and content is shown in Appendix C4.

7.3.2 Clinical Evidence

The STED 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 experience¹².

7.4 Labelling

The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the manufacturer in Section 6.2) the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as "labelling":

- labels on the device and its packaging;
- instructions for use;
- other literature or training materials;
- instructions for installation and maintenance¹³;
- Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform.

7.5 Risk Analysis

The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the manufacturer in Section 6.2) 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.

¹² Refer to SG1/N036 *Global Approach to Premarket Conformity Assessment for Medical Devices* (document in work and not available for public comment at the present time).

¹³ Refer to SG1/N009 *Labelling for Medical Devices*

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7.6 Manufacturer Information

The STED should summarize or reference or contain (e.g. whether submitted or according to the option selected by the manufacturer in Section 6.2) documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.