



## **PROPOSED DOCUMENT**

### **Global Harmonization Task Force**

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

**Authoring Group:** Study Group 1 of the Global Harmonization Task Force

**Date:** October 25, 2002

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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.

There are no restrictions on the reproduction, distribution, translation or use of this document however, incorporation of this document, in part or in whole, into any other document does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.

## 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*<sup>1</sup> (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 device<sup>2</sup> 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",

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<sup>1</sup> Refer to SG1/NO20 *the Essential Principles of Safety and Performance of Medical Devices*

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

“quality system record“, “design history file“, or “design dossier” (for definitions see Section 4.0).

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 document<sup>3</sup>.

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**

#### **Final documents**

SG1/N009 *Labeling for Medical Devices*

#### **Final documents that have been or are likely to be superseded**

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

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

#### **Documents available for public comment at 5 October 2002**

SG1/N015 *Medical Devices Classification.*

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

SG1/N029 *Information Document Concerning the Definition of the Term 'Medical Device'.*

SG1/N041 *Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices).*

SG1/N043 *Labeling for Medical Devices (including In Vitro Diagnostic Devices).*

## **Documents being prepared for public comment**

SG1/N040 *Premarket Conformity Assessment for Medical Devices.*

## **4.0 Definitions**

**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 Devices<sup>4</sup>, or
- b) active implantable medical devices with requirements specified in Annex II of the European Directive Concerning Active Implantable Medical Devices<sup>5</sup>.

**Design History File (DHF):** a compilation of records which describes the design history of a finished device. (Source - US Code of Federal Regulations #21 Part 820.3(e))

**Device History Record (DHR):** a compilation of records containing the complete production history of a finished device. (Source - US Code of Federal Regulations #21 Part 820(h))

**Device Master Record (DMR):** a compilation of records containing the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, and labelling of a finished device (Source - US Code of Federal Regulations #21 Part 820(j))

**Product File:** under EN46001 and EN46002, the European....etc.

**Quality System Record:** under 21 CFR Part 820....etc.

**Summary Technical Documentation:** a summary of technical documentation held for conformity assessment purposes.

**Technical File/Technical Documentation:** documentation required to assess conformity of the medical device with the regulations.

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

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<sup>4</sup> ref. 93/42/EEC of 14 June 1993.

<sup>5</sup> ref. 90/385/EEC of 20 June 1990.

## 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 a real or virtual set of documents, 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 (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 device<sup>6</sup>. It is also proposing harmonized guidance on the link between device classification and conformity assessment to the Essential Principles<sup>7</sup>.

**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.

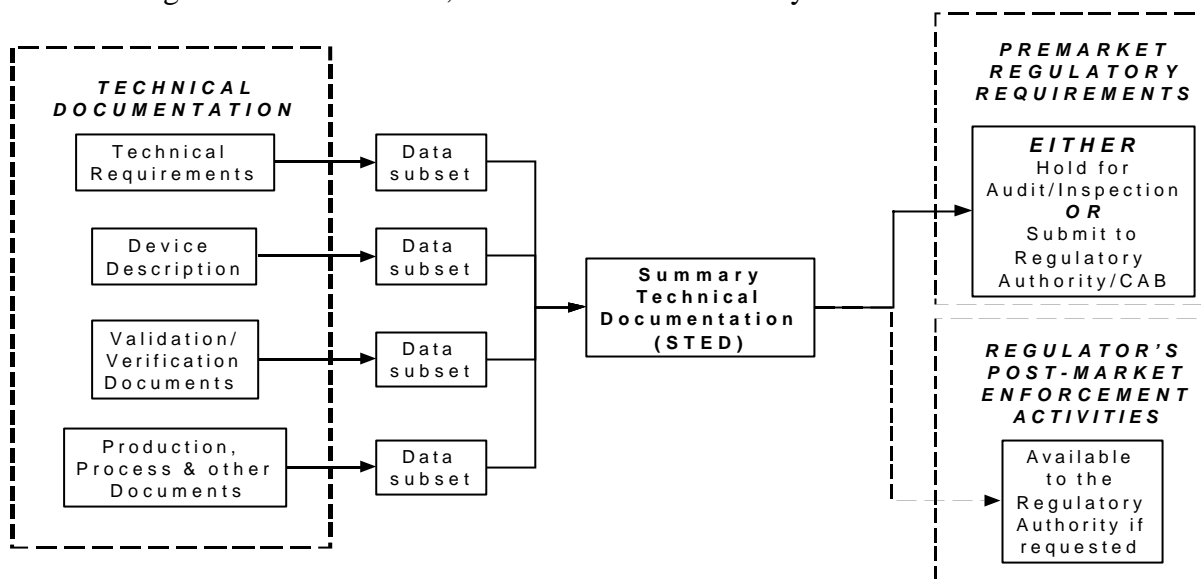
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<sup>6</sup> Refer to SG1/N015 *Medical Devices Classification* (a draft document awaiting public comment)

<sup>7</sup> Document in work and not available for comment at the present time.

Further information is given in Appendix A2 and Appendix C.

As Figure 1 further illustrates, the assessment of conformity to the Essential



**FIGURE 1: SOURCE AND APPLICATION OF THE STED**

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/approval<sup>8</sup>. 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

<sup>8</sup> 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.



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.

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 standards<sup>9</sup>, 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.

#### **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

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

- 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.

### **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 manufacturer<sup>10</sup>; and/or
- summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance<sup>11</sup>.

**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.

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 experience<sup>12</sup>.

### 7.4 Labelling

The STED should summarize or reference or contain (as determined by need for a

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

<sup>11</sup> See Appendix **C4** for a **recommended** format **and content** of a test report.

<sup>12</sup> 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).

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 maintenance<sup>13</sup>;
- 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.

## **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.

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<sup>13</sup> Refer to SG1/N009 *Labelling for Medical Devices*

## **Appendices**

## **Appendix A1: The Relationship of the STED to the Work of GHTF Study Groups 2, 3 & 4**

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The GHTF Study Group 3 guidance on quality systems provides harmonized information and recommendations on quality systems subjects, including guidance on design control requirements. Harmonization of quality systems requirements is a building block for harmonization of documentation held by the manufacturer for conformity assessment purposes. The STED provides information related principally to the format of documentation for demonstrating conformity to the Essential Principles by Regulatory Authorities. GHTF Study Group 4 addresses auditing of manufacturer quality systems. Such audits may include the examination of the STED and source documents.

GHTF Study Group 2 work covers activities by manufacturers and regulators in response to a post-market adverse event. Such activities may include the examination of the STED and source documents.

## Appendix A2: Decision Process to Determine Whether to Use the STED

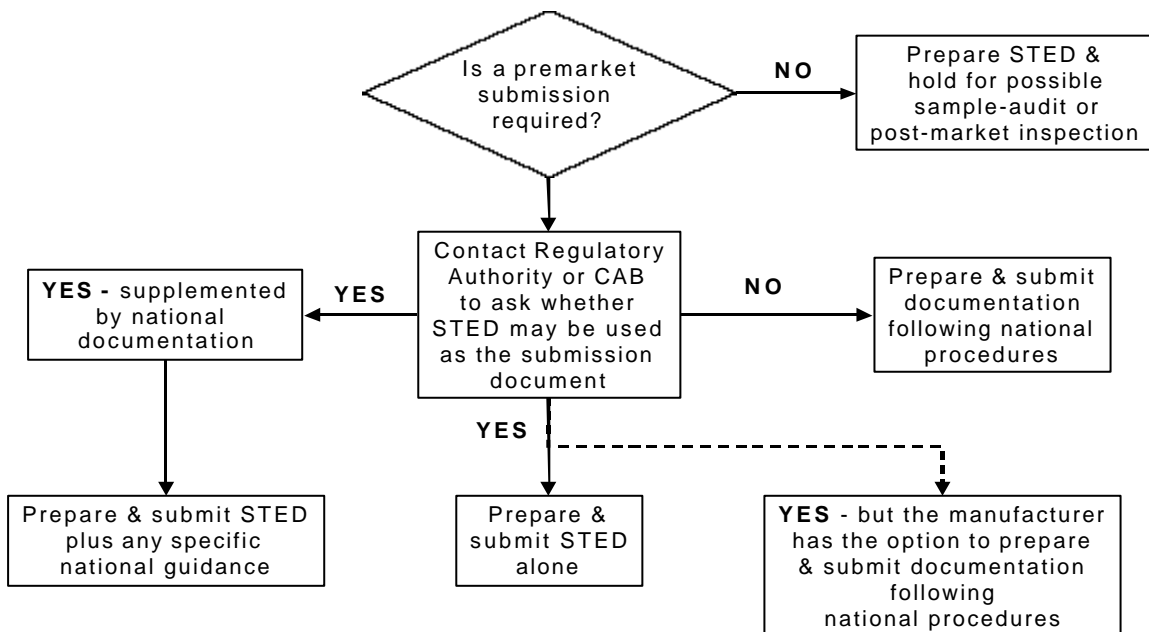
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A person intending to introduce a new device should first determine if documentation must be provided for regulatory conformity assessment purposes before placing on the market. If so, then the person should contact the Regulatory Authority for the country/ies in which marketing is planned, to determine first whether the globally harmonized approach described in this document may be used for the proposed device and then, if there are any country-specific device guidance or regulations that should be used as supplementary guidance to this GHTF STED document.

**NOTE:** As an interim measure until full global harmonization of documentation requirements is achieved, a Regulatory Authority may permit use of an STED for only a few specified devices.

Even when provision to a Regulatory Authority is not required for conformity assessment purposes prior to the marketing of the device, the STED can be used for conformity assessment post-market.

See Figure 2 below for a flow chart of this process.



**FIGURE 2: DECISION MAKING PROCESS**



## Appendix B: Example of an Essential Principles Conformity Checklist

**COMPLETE THE TABLE TWICE: FOR A LOW CLASS AND A HIGH CLASS DEVICE**

Essential Principle	Applicable to the device?	Method of Conformity <sup>14</sup>	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes		
2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: <ul style="list-style-type: none"> <li>• identify hazards and the associated risks arising from the intended use and foreseeable misuse,</li> <li>• eliminate or reduce risks as far as possible (inherently safe design and construction),</li> <li>• where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,</li> <li>• inform users of the residual risks due to any shortcomings of the protection measures adopted.</li> </ul>	Yes		
3. Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.	Yes		
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	Yes		

<sup>14</sup> Select from: recognised standard/other international standard/national standard/company standard/validated test/ etc.

<p>5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.</p>	<p>Yes</p>		
<p>6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.</p>	<p>Yes</p>		
<p>7.1. The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I of the 'General Requirements'. Particular attention should be paid to:</p> <ul style="list-style-type: none"> <li>• the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,</li> <li>• the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.</li> <li>• the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.</li> </ul>			
<p>7.2. The devices should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.</p>			
<p>7.3. Etc.</p>			
<p>8. Etc.</p>			
<p>9. Etc.</p>			

## **Appendix C: Additional Recommendations for STEDs provided to regulatory authorities for review/approval**

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### **C.1 General**

If a manufacturer must provide a STED for review/approval by a Regulatory Authority, the STED must address the Authority's country-specific requirements, which – as an interim measure until full global harmonization of documentation requirements is achieved - may be in addition to the recommendations given in this guidance document.

For example, if national regulations require specific forms or legal statements, then these must be included in the STED

When conformity assessment by a Regulatory Authority to the Essential Principles is required before a device is marketed (“pre-market”), then the manufacturer should provide the STED in the format described in Section 6.0 (see also Annex A2 for deciding when to use the STED).

Even when conformity assessment by a Regulatory Authority to the Essential Principles is not required before a device is marketed, the Regulatory Authority may still request that the manufacturer demonstrate conformity after it is marketed (“post-market”). Post-market assessment may be carried out by means of providing the STED to the Regulatory Authority or by audit of the STED by a Regulatory Authority at the manufacturer's facilities. Special circumstances may necessitate the examination of documentation supporting the STED.

**EXAMPLE:** For a Class I device in Europe and Canada, and a Class I nonexempt device in the United States, as currently defined by country-specific classification regulations, the Regulatory Authority may request that the manufacturer provide documentation demonstrating conformity to the Essential Principles after the device is marketed. The manufacturer may provide documentation in any one of the four forms described as Options 1 – 4 in Section 6.0 unless the Regulatory Authority stipulates the need for a specific form or documents.

### **C.2 Cover Page**

A covering letter should be at the beginning of a STED provided to Regulatory Authorities for review/approval. The covering letter will explain the purpose of the STED. Country-specific requirements may detail information to include in the Cover Page.

### **C.3 The Executive Summary**

An executive summary provides an overview of the medical device and helps to orient the reviewer. Where the STED is provided to regulatory authorities for review/approval, the executive summary may be included in a cover page or it may be a separate section of the STED.

Country-specific requirements or guidance may indicate what the complete summary should include.

The GHTF recommends that the executive summary include at least the following information:

- an overview of the STED, 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 STED; and
- a commercial marketing history of the device including, for example, the countries in which the device is sold, the intended uses and indications in labelling, status of any pending requests for market clearance, important safety or performance related information such as recalls and adverse effects encountered.

#### **C.4 Recommended Test Report Format**

A test report should include, as applicable:

- i) Report title and other identifying information.
- ii) Name and address of facility performing the test.
- iii) Name of the responsible person involved.
- iv) Dates that testing was initiated and completed.
- v) Study plan, results, and conclusions, including, for example:
  - the study objective and test hypothesis;
  - a description of the test system used including relevant specifications (a diagram may be helpful);
  - a description of the differences between the test samples and final specifications, if any;
  - deviations from test plan, if any;
  - a comprehensive summary of the data in the form and manner specified by the Regulatory Authorities which will allow an independent assessment;
  - statistical evaluation of the test results, where appropriate;
  - bibliography of all references pertinent to the report.