

FINAL 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: February 21, 2008

A handwritten signature in black ink, appearing to read 'L. Kessler', with a long horizontal line extending to the right.

Larry Kessler, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

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Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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1.0 Introduction

The primary way in which the GHTF achieves its goals is through the production of a series of guidance documents that together describe a global regulatory model for medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether a 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 has identified as a priority the need to harmonize the documentation of evidence of conformity to the essential principles of safety and performance. This guideline provides recommendations on the content of summary technical documentation (STED) to be assembled and submitted to a Regulatory Authority or Conformity Assessment Body. It should enable a manufacturer to prepare a STED and provide 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 the STED should reduce costs for the manufacturer and reviewer, remove barriers to trade and facilitate timely international access to medical devices.

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

The regulatory requirements of some countries do not, at this time, align fully with this guidance.

Study Group 1 of the Global Harmonization Task Force (GHTF) has prepared this guidance document. Comments or questions should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page¹.

2.0 Rationale, Purpose and Scope

2.1 Rationale

Manufacturers are expected to prepare, and either hold or provide timely access to, technical documentation that shows how each medical device was developed, designed and manufactured. This technical documentation, typically controlled in the manufacturer's

¹ www.ghtf.org

quality management system (QMS), is often extensive and sections of it may be held in different locations. The documentation is updated to reflect any changes made during the lifecycle of the device.

It is advantageous to both RAs/CABs and the regulated industry if a subset of this technical documentation is used for selected premarket and postmarket conformity assessment activities. This documentation subset is intended to be in a consistent, summarised or abridged form, with sufficient detail to allow the RA/CAB to fulfil its obligations. In the main, the documents contained within this subset are derived from the technical documentation held by the manufacturer and allow the manufacturer to demonstrate that the medical device to which it applies conforms to the *Essential Principles of Safety and Performance of Medical Devices*.

The availability of such Summary Technical Documentation (STED) should help eliminate differences in documentation requirements between jurisdictions, thus decreasing the cost of gaining regulatory compliance and allowing patients earlier access to new technologies and treatments.

2.2 Purpose

This document is intended to provide guidance on the content of the STED to be assembled and submitted to a RA or CAB for premarket review, and for use post-market to assess continuing conformity to the Essential Principles of Safety and Performance.

2.3 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Document Concerning the Definition of the Term "Medical Device"*, excluding those used for the in vitro diagnostic examination of specimens derived from the human body.

3.0 References

GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices*.

GHTF/SG1/N15:2006 *Principles of Medical Devices Classification*.

GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term 'Medical Device'*.

GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices*.

GHTF/SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*.

GHTF/SG1/N43:2005 *Labelling for Medical Devices*.

4.0 Definitions

- 4.1 **Recognised standard:** standard deemed to offer the presumption of conformity to specific Essential Principles of Safety and Performance.
- 4.2 **Technical documentation:** the documented evidence, normally an output of the quality management system that demonstrates conformity of a device to the *Essential Principles of Safety and Performance of Medical Devices*.

PART 1 – PURPOSE OF THE 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 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.

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.

The STED should be in a language acceptable to the RA/CAB.

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 errors²;
- it incorporates novel or potentially hazardous materials;
- the device type raises specific public health concerns.

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 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 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.

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.

² See GHTF/SG2 guidance documents.

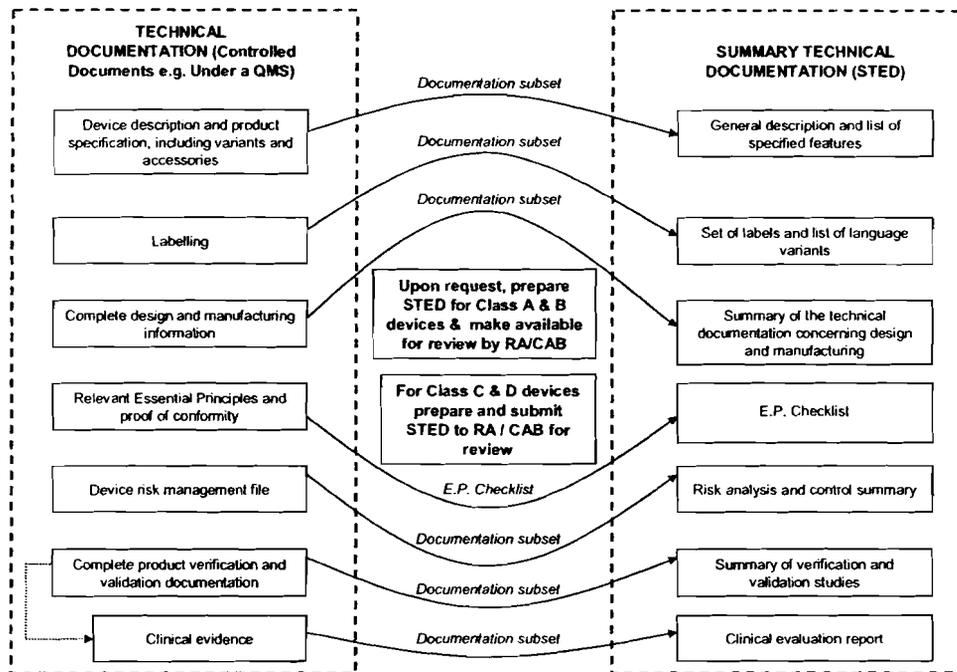


FIGURE 1: PREMARKET USE OF THE STED

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 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.

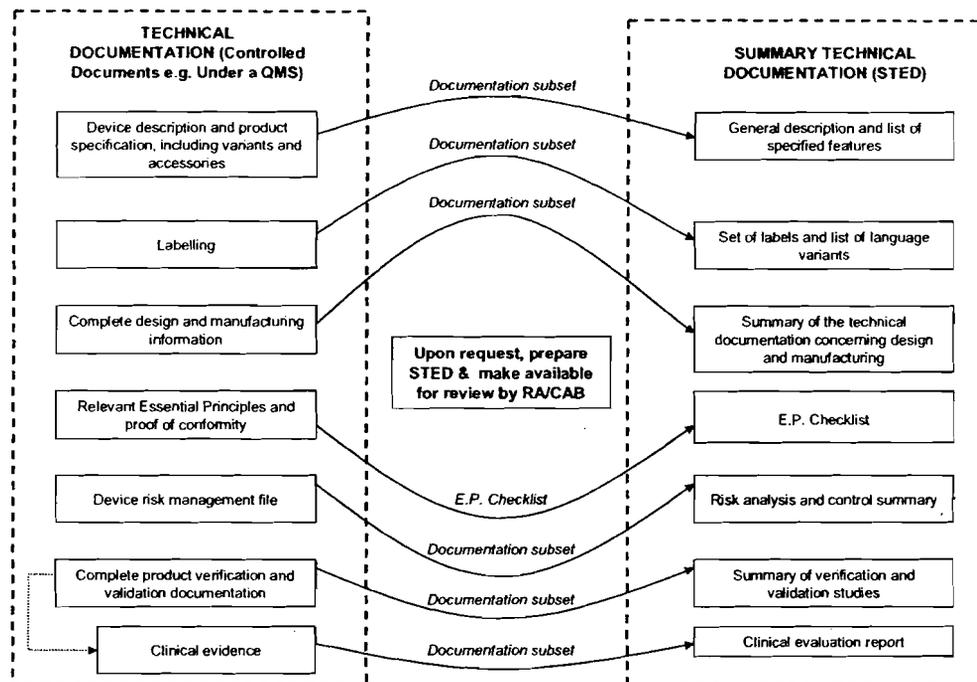


FIGURE 2: POST-MARKET USE OF THE STED

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.

PART 2 – CONTENTS OF THE STED

6.0 Device Description and Product Specification, Including Variants and Accessories

6.1 Device Description

The STED should contain the 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., 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.

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 international markets.

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;
- instructions for use; and
- promotional material.

The labelling set should be in a language acceptable to the reviewing RA or CAB.

8.0 Design and Manufacturing Information

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 information may take the form of a flow chart.

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.

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.

9.0 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 standards³;
- 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 evidence⁴.
- e) comparison to a similar device already available on the market.

³ See GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices*

⁴ See GHTF/SG5 guidance documents

The EP checklist should incorporate a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer and within the STED (when such documentation is specifically required for inclusion in the Summary Technical Documentation as outlined in this guidance).

A template for a checklist is shown in Appendix A.

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.

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 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.

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.

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.

11.3 Medicinal Substances

Where the medical device incorporates a 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.

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.

11.5 Sterilisation

Where the device is supplied 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.

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.

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.

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.

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..

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*.

Appendix A

Essential Principles (EP) Checklist

The EP checklist can be used by RAs, CABs and manufacturers to readily understand how the manufacturer demonstrates conformity to the essential principles for a particular device. The EP checklist also allows easy identification of relevant documents and data for conformity assessment purposes.

The contents of the checklist will vary from device to device. Complex devices are likely to reference a large number of standards, test reports and documents. The EP checklist in such cases may be many pages long. Very simple devices are more likely to have shorter EP checklists as many of the Essential Principles may not be applicable. In these cases, the supporting references to be incorporated into the checklist may be minimal.

The following is a recommended template for the EP checklist. Preparation of the EP checklist as outlined below will provide a useful overview of the device's conformity with the Essential Principles. The consistent use of this template will support harmonization across jurisdictions.

How to Complete the Checklist

a) Identity of the device

The manufacturer should identify the device, and where applicable the various configurations / variants covered by the checklist.

b) Applicable to the device?

Is the listed Essential Principle applicable to the device? Here the answer is either 'YES' or 'NO'. If the answer is 'NO' this should be explained briefly in the 'method used to demonstrate conformity' column.

Example: For a device that does not incorporate biological substances, the answer to Essential Principle 5.8.2 would be 'NO' and, in the 'method used to demonstrate conformity' column, would include an explanation such as 'The device does not incorporate biological substances.'

c) Method used to demonstrate conformity

In this column the manufacturer should state the type(s) of method(s) that they have chosen to use to demonstrate conformity e.g. the recognised standard(s), industry or in-house test method(s), comparison study(ies) or other method used.

d) Method reference

After having stated the method in the previous column, here the manufacturer should now name the title and reference of the recognised standard(s), industry or in-house test method(s), comparison study(ies) or other method used to demonstrate conformity. For standards, this should include the date of the standard and where appropriate, the clause(s) that demonstrates conformity with the relevant EP.

e) Reference to supporting controlled documents

This column should contain the reference to the actual technical documentation that demonstrates conformity to the essential principle, i.e. the certificates, test reports, validation

reports, study reports or other documents that resulted from the method used to demonstrate conformity and its location within the STED.

NOTE: the Table that follows is for illustrative purposes only. The Essential Principles listed in the first column should be extracted from the latest version of GHTF's guidance document *Essential Principles of Safety and Performance of Medical Devices*. Those incorporated into this document are extracted from GHTF/SG1/N41:2005.

Essential Principle Checklist	
Device:	

Essential Principle	Applicable to the Device?	Method Used to Demonstrate Conformity	Method Reference	Reference to Supporting Controlled Documents
General Requirements				
5.1 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.				
5.2 The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: <ul style="list-style-type: none"> ▪ identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse. ▪ eliminate risks as far as reasonably practicable through inherently safe design and manufacture, ▪ reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, ▪ inform users of any residual risks. 				

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Essential Principle	Applicable to the Device?	Method Used to Demonstrate Conformity	Method Reference	Reference to Supporting Controlled Documents
5.3 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.				
5.4 The characteristics and performances referred to in Clauses 5.1, 5.2 and 5.3 should not be adversely affected to such a degree that the health or safety of the patient or the user 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.				
5.5 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 under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.				
5.6 The benefits must be determined to outweigh any undesirable side effects for the performances intended.				

Design and Manufacturing Requirements				
5.7 Chemical, physical and biological properties				
<p>5.7.1 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 5.1 to 5.6 of the 'General Requirements'. Particular attention should be paid to:</p> <ul style="list-style-type: none"> ▪ the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, ▪ the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device, ▪ the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength. 				
<p>5.7.2 The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.</p>				
5.7.3 ----- etc. -----				
5.7.4 ----- etc. -----				