PROPOSED REVISED 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

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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.

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, Conformity Assessment Bodies 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 regulatory requirements. This guideline should enable a manufacturer to prepare a STED and provide, if requested, different Regulatory Authorities or Conformity Assessment Bodies with the same body of documentary evidence that its medical device conforms to regulatory requirements, thus reducing costs for the manufacturer and reviewer, as well as removing barriers to trade.

This guidance document is one of a series that together describe a global regulatory model for medical devices. It provides guidance on the content and format of summary technical documentation to be assembled, held and, if required, submitted to a Regulatory Authority or Conformity Assessment Body. The technical documentation is controlled by the manufacturer's quality management system. GHTF Study Group 3 has provided guidance on quality system subjects, including guidance on design control. GHTF Study Group 4 guidance addresses auditing of the manufacturer's 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.

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 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[1].

1 www.ghtf.org

2.0 Rationale, Purpose and Scope

2.1 Rationale

Manufacturers are expected to record and hold documents that show how each medical device was developed, designed and manufactured. This technical documentation is often extensive and sections of it may be held in different locations. The documentation will be updated to reflect any changes made during the lifecycle of the device.

It is advantageous to both Regulatory Authorities (RAs)/Conformity Assessment Bodies (CABs) and the regulated industry if a subset of this documentation is available in a consistent, summarised form while providing sufficient detail to allow the RA/CAB to fulfil its obligations. The availability of this Summary Technical Documentation (STED) with consistent content will help eliminate differences between jurisdictions, thus decreasing the cost of gaining regulatory compliance and allowing patients earlier access to new technologies and treatments.

2.2 Purpose

To provide guidance on the content of the STED to be assembled, held and, if required, submitted to a Regulatory Authority or Conformity Assessment Body. Such STED is derived from the technical documentation held by the manufacturer and allows the manufacturer to demonstrate that the medical device to which it applies conforms to the *Essential Principles of Safety and Performance of Medical Devices*[2].

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"*[3], excluding those used for the *in vitro* examination of specimens derived from the human body.

3.0 References

GHTF/SG1/N012:2000 *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'.*

2 SG1/N041:2005 Essential Principles of Safety & Performance of Medical Devices
3 SG1/N029:2005 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

Recognised Standards: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance. (Source – GHTF/SG1/N012:2000)

Summary Technical Documentation (STED): a summary of technical documentation held or submitted for conformity assessment purposes.

Technical Documentation: the documented evidence, normally an output of the quality management system, that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices*.[4]

5.0 Intended use of the STED and its preparation

The manufacturer creates the STED from its existing technical documentation to demonstrate to a Regulatory Authority or a Conformity Assessment Body that the subject medical device is in conformity with the Essential Principles for Safety and Performance[5]. Figure 1 below illustrates the flow of technical documentation resulting from the manufacturer's quality management system into the STED.

The STED will be held by the manufacturer for audit and inspection purposes. The class of the device, its complexity and its novelty will affect the depth and detail of the information in the STED and whether the STED needs to be submitted to a Regulatory Authority or Conformity Assessment Body for review, before placing the device on the market[6].

The STED includes summary information on select topics as described below, as well as the Essential Principles (EP) checklist. The EP checklist is created as part of the manufacturer's technical documentation and it provides a tabular overview of the EP, its applicability to the device, the chosen method of conformity and identified specific controlled documents relevant to demonstrating conformity with Essential Principles for the device. While many controlled documents are referenced in the EP checklist, only those controlled documents specifically recommended in this guidance for inclusion (see below) will be incorporated within the STED. The cited references to the controlled documents in the manufacturer's QMS system within the checklist facilitate requests from the RA/CAB for any additional information.

4 SG1/N041:2005 Essential Principles of Safety & Performance of Medical Devices
5 SG1/N041:2005 Essential Principles of Safety & Performance of Medical Devices
6 See GHTF/N40:2006 *Principles of Conformity Assessment for Medical Devices*

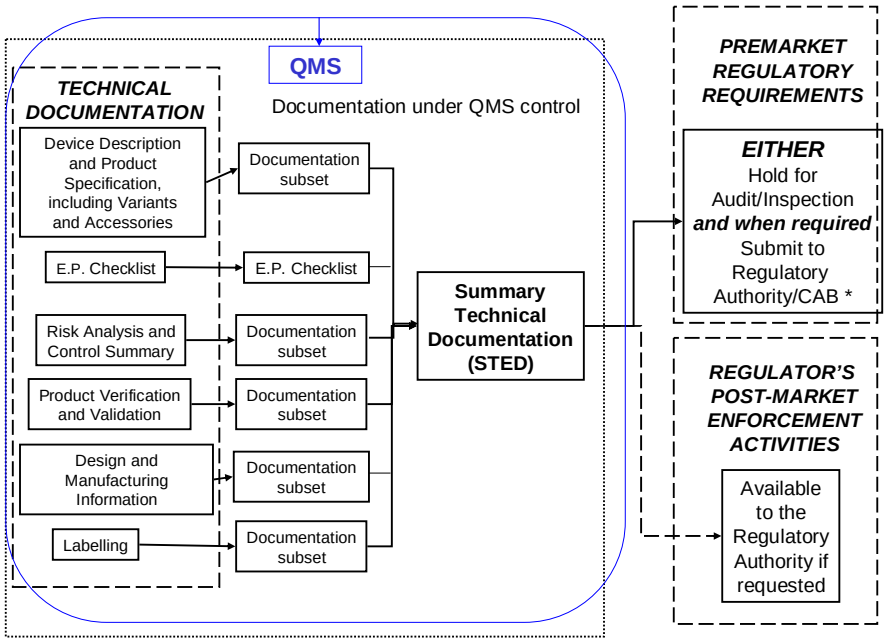

FIGURE 1: SOURCE AND APPLICATION OF THE STED [7] *

At the manufacturer's location, the STED may be a real (physical) set of documents or a virtual set of documents (system that allows for retrieval of a set of documents consisting of either electronic or physical copies of documents).

6.0 Device Description and Product Specification, Including Variants and Accessories

6.1 Device Description

The STED should include the following device descriptive information:

- a general description of the device including its intended use/purpose;
- the intended patient population and medical condition to be diagnosed and/or treated by the device and other considerations such as patient selection criteria;
- the principles of operation of the device;
- the Class of the device and the applicable classification rule according to GHTF/SG1/N15:2006 *Principles of Medical Devices Classification* etc
- an explanation of any novel features;
- a description of the accessories, other medical devices and other products that

7 * See GHTF/N40:2006 *Principles of Conformity Assessment for Medical Devices*

are not medical devices, which are intended to be used in combination with the device;
- a description or complete list of the various configurations/variants of the device that will be made available;
- a general description of the key functional elements of the device, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this will include: labelled pictorial representations of the device (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.
- a description of the materials incorporated into key functional elements of the device and those making either direct or indirect contact with a human body.

6.2 Product Specification

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 appear typically in the product specification made available to the end user.

6.3 Reference to previous generation(s) or similar devices

Where relevant to demonstrating conformity to the Essential Principles, and to provide general background information, the STED should provide an overview of:
- the manufacturer's previous generation(s) of the device, if such exist; and
- similar devices available on the market.

7.0 Essential Principles (EP) Checklist

The STED should include an EP checklist that identifies:-
- the Essential Principles of Safety and Performance;
- whether each Essential Principle applies to the device and if not, why not;
- the method used to demonstrate compliance with each Essential Principle that applies; and
- the precise identity of the controlled document/s that offers evidence of compliance with each method used.

The method used to demonstrate compliance may be:
- compliance with recognized or other standards[8];
- compliance with a commonly accepted industry test method;
- compliance with in-house test methods;
- comparison to a similar 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 and within the STED (when such documentation is specifically required for inclusion in the Summary TEchnical Documentation as outlined in this guidance).

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

A sample checklist is included in Appendix A.

8.0 Risk analysis and control summary

The STED should summarise the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. This risk analysis should be based upon international or other recognized standards, and be appropriate to the class of the device , its complexity and its novelty.

9.0 Product Verification and Validation

For STED documentation of product verification and validation, the level of detail will vary, and be determined by:

- the class of the device
- the complexity of the device
- the novelty of the device

As a general rule, the STED should summarise the results of verification and validation studies undertaken to demonstrate compliance of the device with the Essential Principles that apply to it. Such information would typically cover:

- engineering tests;
- laboratory tests;
- simulated use testing;
- any animal tests for demonstrating feasibility or proof of concept of the finished device;
- any published literature regarding the device or substantially similar devices.

Summary information may include:

- declaration/certificate of compliance to a recognized standard and summary of the data if no acceptance criteria are specified in the standard;
- declaration/certificate of compliance to a published standard that has not been recognized, supported by a rationale for its use, and summary of the data if no acceptance criteria are specified in the standard;
- declaration/certificate of compliance to a professional guideline, industry method, or in-house standard, 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;
- a review of published literature regarding the device or substantially similar devices.

As a general rule, the STED should include detailed information on:

- sterilisation;
- biocompatibility;
- software verification and validation;
- biological safety of devices incorporating animal or human cells, tissues or their derivatives;

- medicinal substances, if any, incorporated into the device, including compatibility of the device with the medicinal substance;

- animal studies that provide direct evidence of safety and performance of the device, especially when no clinical investigation of the device was conducted;
- clinical evidence.

These topics are not applicable to all devices.

Detailed information will describe test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions.

9.1 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. Evidence of the ongoing revalidation of the process shall also be provided in the form of the most recent validation report.

Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed against the standards, and a summary of the results against the protocol.

9.2 Biocompatibility

Details should be provided on all biocompatability tests conducted on materials used in the device. At a minimum, tests should be conducted on samples from the finished, sterilized (when supplied sterile) device. All materials that are significantly different from materials known to be biocompatible should be characterized. Information describing the tests, the results and the analyses of data should be included.

9.3 Software Verification and Validation

The correctness of the software cannot be fully verified in the finished device. The manufacturer should 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 representative data generated from both testing environments.

9.4 Biological Safety

In the case of a medical device manufactured from or incorporating animal or human tissue or their derivative, detailed information should be provided substantiating the adequacy of the measures taken with regard to the risks associated with transmissible agents. This will include viral clearance results for known hazards. Donor screening concerns should be fully addressed. Methods of harvesting and long-term registries should also be fully described.

Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

9.5 Animal Studies

Reports of animal studies should be included, when these studies are conducted to support the probability of effectiveness in humans. These studies should be undertaken using good laboratory practices. The objectives, methodology, results, analysis and manufacturer's conclusions should be described. The study conclusion should address the device's interaction 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.

9.6 Medicinal Substances

As yet there is no specific advice on device-medicinal combination products but it is anticipated that the GHTF will develop recommendations in the future, at which time it will be referenced within this document.

9.7 Clinical Evidence

The STED should summarise (see Section 4.0) the results of clinical evaluation studies undertaken to demonstrate compliance of the device with the Essential Principles of Safety and Performance that apply to it and should take the form of the summary Clinical Evaluation Report described in guidance published by Study Group 5 of the GHTF.

10.0 Design and Manufacturing Information

10.1.1 Manufacturing Processes

The manufacturing processes for the finished device should be provided in the form of an overview of the activities and quality management system associated with the fabrication of the device. This would include design, production, assembly, final product testing and packaging of the finished medical device.

10.1.2 Design and Manufacturing Sites

If multiple facilities are involved in the design and manufacture of a device, the overview of activities for each facility should be included in the STED. If the information is identical for a number of sites, this should be noted. This does not include identification of sub-contractors supplying components incorporated into the device.

11.0 Labelling

The STED should contain all labelling associated with the device as described in GHTF guideline SG1/N043:2005 *Labelling for Medical Devices (revised).* Information on labelling will include the following subsets:

- labels on the device and its packaging;
- instructions for use, including an overview of any end-user training materials offered by the manufacturer and not included within them;

- promotional material.

12.0 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 Principal (EP) Checklist

The EP checklist can be used by Regulatory Authorities, CABs and even manufacturers themselves to readily understand how the manufacturer demonstrates compliance to the essential principals 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. Very simple devices will have EP checklists of a few pages as many of the essential principals may not be applicable. In these cases, the supporting references to be included in the checklist will be minimal. More complex devices are more likely to reference a larger number of standards, test reports and documents. The EP checklist in those cases might be many pages long.

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 manufacturer's conformity to the essential principles. The consistent use of this template will support harmonization across jurisdictions.

How to fill in the checklist

Device

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

Applicable to device?

Here the answer is either 'Yes' or 'No'. If the answer is 'No' this should be briefly explained.

> Example: For a device that does not incorporate biological substances, the answer to Essential Principal 5.8.2 would be 'No – The device does not incorporate biological substances.'

Method of Conformity

The manufacturer should name the title and reference of the standard(s), industry or in-house test method(s), comparison study(ies) or other method used to demonstrate compliance. For standards, this should include the date of the standard and where appropriate, the clause(s) that demonstrates conformity with the relevant EP. Where a standard is referred to more than once in the checklist, simply the reference number and date can be repeated.

Identity of Specific Documents

This column should contain the reference to the actual technical documentation that demonstrates compliance to the essential principal, i.e. the certificates, test reports, study reports or other documents that resulted from the method used to demonstrate compliance.

Essential Principal Checklist	
Device:	

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific 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: ▪ 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.			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific 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			
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: ▪ 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.			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
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.			
5.7.3 The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.			
5.7.4 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.			
5.7.5 The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.			
5.7.6 Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.			
5.8 Infection and microbial contamination			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.8.1 The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: ▪ allow easy handling, and, where necessary: ▪ reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use, ▪ prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.			
5.8.2 Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.			
5.8.3 In some jurisdictions products incorporating tissues, cells and substances of non-human origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.8.4 In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
5.8.5 Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.			
5.8.6 Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.			
5.8.7 Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			
5.8.8 Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			
5.8.9 Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.			
5.8.10 The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
5.9 Manufacturing and environmental properties			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.			
5.9.2 Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: ▪ the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; ▪ risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; ▪ the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; ▪ the risks of accidental penetration of substances into the device; ▪ the risk of incorrect identification of specimens; ▪ the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; ▪ risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
5.9.3 Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
5.9.4 Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.10 Devices with a diagnostic or measuring function			
5.10.1 Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.			
5.10.2 Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.			
5.10.3 Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.			
5.10.4 Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
5.10.5 Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device. **Note:** While SG1 generally supports convergence on the global use of internationally standardised measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement units.			
5.11 Protection against radiation			
5.11.1 General			
5.11.1.1 Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			
5.11.2 Intended radiation			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.11.2.1 Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
5.11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.			
5.11.3 Unintended radiation			
5.11.3.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.			
5.11.4 Instructions for use			
5.11.4.1 The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.			
5.11.5 Ionizing radiation			
5.11.5.1 Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.			
5.11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.			
5.11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.12 Requirements for medical devices connected to or equipped with an energy source			
5.12.1 Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
5.12.2 Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.			
5.12.3 Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			
5.12.4 Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health			
5.12.5 Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.			
5.12.6 Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			
5.12.7 Protection against electrical risks Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.			
5.13 Protection against mechanical risks			
5.13.1 Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.13.2 Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			
5.13.3 Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.			
5.13.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.			
5.13.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.			
5.14 Protection against the risks posed to the patient by supplied energy or substances			
5.14.1 Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
5.14.2 Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			
5.14.3 The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.			
5.15 Protection against the risks posed to the patient for devices for self-testing or self-administration			

Essential Principal	Applicable to the device?	**Method of Conformity**	Identity of Specific Documents
5.15.1 Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.			
5.15.2 Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
5.15.3 Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the manufacturer.			
5.16 Information supplied by the manufacturer			
5.16.1 Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood. **Note:** Further information is provided in *SG1/N009 Labelling for Medical Devices* and in SG1/N043 *Labelling for Medical Devices (revised).*			
5.17 Performance evaluation including, where appropriate, clinical evaluation			
5.17.1 All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.			
5.17.2 Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.			