A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.
Draft released for comment on [release date as stated in FR Notice]

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Premarket Notifications Staff
Program Operations Staff
Office of Device Evaluation

Preface

Public Comment:

For 60 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Additional Copies

Additional copies are available from the Internet at:
http://www.fda.gov/cdrh/[specific address], or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1347 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.
Draft released for comment on [release date as stated in FR Notice]

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Premarket Notifications Staff
Program Operations Staff
Office of Device Evaluation

Preface

Public Comment:

For 60 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Additional Copies

Additional copies are available from the Internet at:
http://www.fda.gov/cdrh/[specific address], or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1347 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. Background

FDA is conducting a pilot premarket review program and is soliciting participation from the medical device industry. The pilot program is intended to assess the feasibility of a proposed internationally harmonized format and content for premarket submissions, e.g., premarket notification (510(k)) submissions and premarket approval (PMA) applications. The proposed document is entitled "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)."

This premarket pilot initiative has its origins in the recommendations of the Global Harmonization Task Force (GHTF), Study Group 1. The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The organization, goals, and procedures of the GHTF are described on the GHTF internet web site http://www.ghtf.org.

What documents are needed to implement the pilot program?

The documents generated by Study Group 1 and FDA for implementing the pilot program include the following:

- the FDA draft guidance document for the pilot (this document)

  The FDA draft guidance document is intended to assist the medical device industry in completing a premarket submission using the draft STED format and in accordance with United States requirements.

- Appendix 1: a letter of announcement to the global medical device industry

  The announcement letter summarizes the proposed pilot premarket program.

- Appendix 2: the GHTF Study Group 1 draft STED document

  The draft STED document describes an internationally harmonized format and content for premarket submissions, e.g., PMA applications and 510(k) submissions, based on conformity to "Essential Principles."

- Appendix 3: the GHTF document entitled "Essential Principles of Safety and Performance of Medical Devices"

  The Essential Principles are a GHTF-derived list of both general and specific safety and performance recommendations for medical devices.

What divisions in the Office of Device Evaluation are participating in the pilot program?

Two Office of Device Evaluation divisions will be the primary participants in the pilot program: the Division of Dental, Infection Control, and General Hospital Devices (DDIGD) and the Division of Reproductive, Abdominal, and Radiological Devices (DRARD). Because of current workload considerations, two other divisions will participate in this pilot in a more limited manner: the Division of Cardiovascular and Respiratory Devices (DCRD) and the Division of General, Restorative, and Neurological Devices (DGRND).

How will the pilot be implemented in the participating divisions?

DDIGD and DRARD will accept PMA applications and 510(k) submissions in the draft STED format instead of the customary format for certain types of devices from those manufacturers who want to participate in the pilot program. Table 1 lists the generic types of devices for DDIGD and DRARD that are candidates for the pilot program.

Manufacturers should continue to submit PMA applications and 510(k) submissions to DCRD and DGRND in the customary format described in current FDA regulations. However, these two divisions will each work with up to four manufacturers to do a parallel review of parts of these applications that will also be submitted in the draft STED format. This concurrent review of the current FDA and proposed STED formats of the same application will help these divisions assess the GHTF document without reducing review times. FDA does not expect that the submission of portions of the PMA application or 510(k) in an additional form (the draft STED format) will be burdensome because many manufacturers of these devices will be preparing submissions for other countries using the draft STED format. For the concurrent submissions, FDA is interested in evaluating how the data and information submitted in the customary format would be reformatted for a STED. A

complete concurrent submission using the draft STED format may not be necessary. Instead, only the initial volume of a submission in the draft STED format for a PMA application or complex 510(k) submission may suffice. Table 1 lists the generic types of devices that will be considered by DCRD and DGRND for the pilot program.

Table 1 Candidate Devices for the Pilot Premarket Program

Division	Device Type
Primary Division Participants, draft STED format in lieu of customary format	
DDIGD	Intravascular Catheters Administration Sets External Infusion Pumps Endosseus Dental Implants Surgical Drapes
DRARD	Hemodialyzers and Hemodialysis Catheters Plasma Cell Separators for Therapeutic Use Bone Densitometers Fluoroscopic X-ray Urological Catheters
Limited Participation, customary format concurrent with draft STED format (e.g., initial volume)	
DCRD	ECG Monitors PTCA Catheters Coronary Stents Anesthesia Catheters and Needles Pacing Leads
DGRND	Orthopedic Implants

FDA is asking persons who intend to submit PMA applications or 510(k) submissions to DDIGD, DRARD, DCRD, or DGRD to consider participating in the pilot program. The pilot program will not include premarket submissions for Special 510(k)s, product development protocols, humanitarian device exemptions, or submissions already reviewed by Third Parties.

II. Purpose

This FDA guidance document supplements the draft STED document as follows:

1. It provides administrative instructions to medical device manufacturers who are using the

draft STED document for a 510(k) submission or PMA application.

2. It describes current data and information that should be included in a 510(k) submission or PMA application, in addition to the documentation described in the draft STED document.

3. It includes tables that compare the differences between the draft STED document and the submission requirements in the PMA and 510(k) regulations.

III. Administrative Instructions

Persons who intend to submit a 510(k) submission or a PMA application and are interested in participating in the pilot program should:

- Ensure that the candidate medical device is subject to premarket review by FDA, i.e., it is not a Class I or a Class II exempt device.

- Verify that your medical device is a candidate for a PMA or a traditional or abbreviated 510(k). Special 510(k)s, Humanitarian Device Exemptions, 510(k)s already reviewed by a Third Party, and Product Development Protocols are not included in this pilot program. For definitions and more information on traditional, abbreviated, or special 510(k) submissions, refer to the FDA guidance document entitled, "The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" http://www.fda.gov/cdrh/ode/parad510.pdf.

- Verify that your medical device is identified in Table 1.

- Notify one of the persons identified in Part VI below of your intent to submit either a 510(k) submission or PMA application to DDIGD or DRARD using the draft STED format, or if you intend to submit a concurrent submission (e.g., initial volume) using the draft STED format to DCRD or DGRND. He/she will inform you whether or not FDA will accept and evaluate your submission or application.

- Submit your complete submission to DDIGD or DRARD in the format described in the draft STED document, or customary and concurrent submissions (e.g., initial volume) to DCRD or DGRND. Include any additional required information described in Part IV below, either in the cover letter as indicated or as additional sections of your submission using the draft STED format.

- Submit documents to the Document Mail Center HFZ-401, 9200 Corporate Blvd., Rockville, MD 20850.

- Clearly identify on the cover page, in bold large print, **Global Harmonization Pilot 510(k) or PMA**.

IV. Information required in a 510(k) or PMA compared to draft STED document recommendations

For 510(k)s:

Include the following additional information:

- Trade name and classification name of the device
- Establishment registration number, if one is available
- Device class or a statement that the device is not yet classified
- Truthful and Accurate Statement
- Indications for Use Enclosure
- SMDA Summary or Statement
- Class III Certification and Summary (for all Class III devices under 510(k) authority)
- Financial Certification or Disclosure Statement for 510(k)s including a Clinical Study.
- Name and Address of Manufacturing Facility for Class III 510(k)s

Table 2 provides a comparison between 21 CFR 807.87, Information required in a premarket notification submission, and the draft STED document.

TABLE 2: Comparison of the 510(k) Regulation to the Draft STED Document

510(k) Regulation (21 CFR 807.87)	**Corresponding STED Section**
(a) Trade or proprietary name, and common or usual name	Referred to as "cover page information" in Annex C.2. Follow 510(k) regulation.
(b) Establishment Registration Number	
(c) Class	
(d) Performance Standards	Section 7.1.2. and 7.3.1.
(e) Labels and labeling	Section 7. 4.
(f) Comparison of features	Section 7. 2.
(g) Supporting data	Section 7. 3. And 7.5
(h) 510(k) Summary	Referred to as "country-specific information" in Annex C.1. Follow 510(k) regulation.
(i) Financial Certification or Disclosure Statement	
(j) Class III Summary	
(k) Truthful and Accurate Statement	

Note: Section 7.6 of the GHTF draft STED document, which addresses manufacturing information, is ordinarily not required for a 510(k) submission.

For PMAs:

Include the following additional information:

- Applicant's name and address
- Table of contents
- Summary of Safety and Effectiveness
- Justification for a single investigator
- Samples
- Environmental assessment
- Financial certification or disclosure statement

Table 3 provides a comparison between 21 CFR 814.20, Premarket Approval Application, and the draft STED document.

TABLE 3: Comparison of the PMA Regulation to the Draft STED Document

PMA Regulation (21 CFR 814.20)(b)	Corresponding STED Section
(1) Applicant's Name & Address	Referred to as "cover page information" in Annex C.2. Follow PMA regulation.
(2) Table of Contents	
(3) Summary of Safety and Effectiveness	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(4) Device Description	Section 7.2., 7.5, 7.6.
(5) Performance or Voluntary Standard	Section 7.1.2., 7.3.1.
(6) Results of non-clinical studies and clinical investigations involving human subjects	Section 7.3.1., 7.3.2.
(7) Justification for a single investigation	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(8) Bibliography	Section 7.3.2.
(9) Samples of the device	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(10) Proposed Labeling	Section 7.4.
(11) Environmental Assessment	Referred to as "country-specific information" in Annex C.1. Follow PMA regulation.
(12) Financial Certification or Disclosure Statement	

V. Important Information about the Pilot Premarket Program

Four of the founding members of the GHTF are participating in the pilot program. They are the United States, Canada, Australia, and the European Union. Each of the participants will provide specific directions for implementing the pilot program within its jurisdiction.

The GHTF wants to assess the international utility of the draft STED document. Therefore, SG1 of the GHTF encourages manufacturers to prepare and submit, if submission is required, STEDs for the same device to as many of the four participating GHTF member countries as possible. SG1 also encourages manufacturers to try the STED format for different classes of devices that are candidates for the pilot program.

FDA intends to process premarket submissions in the GHTF harmonized format within statutory time limits and with review times comparable to other submissions for similar products. There will be no expedited review of submissions, unless the device merits such a process under current policies.

FDA plans to conduct the pilot program for one year. The pilot program will begin on the date of publication of the final FDA guidance document. FDA will assess how the pilot is proceeding during its course and may choose to decline receipt of additional submissions using the draft STED format in order to assess the initial experiences. At the end of the pilot, FDA and other GHTF participants will analyze the outcome to determine whether the draft STED document is a viable alternative to current premarket submission procedures, and if the program should be continued or expanded. FDA will post a report of the outcome of the pilot program on its Internet web site.

VI. Contacts

If you are interested in participating, or have questions regarding the pilot program, please contact one of the following individuals:

Timothy A. Ulatowski
(301) 443-8879
tau@cdrh.fda.gov

Marjorie Shulman
(301) 594-1190
mys@cdrh.fda.gov

APPENDIX 1

DATE: [DATE OF FINAL FR NOTICE]

FDA Announces Pilot Premarket Submission Review Program Utilizing the Draft Global Harmonization Task Force Summary Technical Document

FDA is announcing a pilot premarket review program and is soliciting participation from the medical device industry. The pilot program is intended to evaluate the utility of a draft document entitled "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)." The draft STED document describes an internationally harmonized format and content for premarket submissions. The Global Harmonization Task Force (GHTF), Study Group 1, developed the draft document.

The pilot premarket review program will rely on three related documents: (1) the draft STED document, (2) an FDA guidance, and (3) the GHTF document entitled "Essential Principles of Safety and Performance of Medical Devices." The FDA guidance document is intended to assist the medical device industry in completing a submission that uses the draft STED format and is consistent with United States requirements. The Essential Principles document is a key reference in the draft STED document. The draft STED document and Essential Principles document (GHTF reference numbers GHTF.SG1.N011R15 and GHTF.SG1.NO20R5) accompany this announcement.

The FDA pilot program is limited to PMA applications and 510(k) submissions for the specific types of medical devices identified in Table 1 of the FDA draft guidance. The pilot program will not include submissions for Special 510(k)s, Product Development Protocols, Humanitarian Device Exemptions, or submissions already reviewed by Third Parties. Two Office of Device Evaluation divisions will be the primary participants in the pilot. Two additional divisions will participate on a more limited basis as described in the guidance.

FDA encourages persons who intend to submit PMA applications or 510(k) submissions for the devices identified in Table 1 to consider participating in the pilot program. During the pilot program, the draft STED document, when used in conjunction with the FDA guidance, will be an alternative to the current format and content of submissions described in previous FDA guidance documents, except as described in the guidance for the two divisions participating on a more limited basis.

The objective of the GHTF is to encourage harmonization among regulatory systems in order to reduce regulatory burden for regulated industry and to help make new devices available more quickly to the international public. Those participating in the pilot program will help achieve these goals.

Four of the founding members of the GHTF are participating in the pilot program. They include the United States, Canada, Australia, and the European Union. Each of the

participants will provide specific directions for implementing the pilot program within its jurisdiction.

The GHTF wants to assess the international utility of the draft STED document. Therefore, SG1 of the GHTF encourages manufacturers to prepare and submit, if submission is required, submissions using the STED format for the same device to as many of the four participating GHTF member countries as possible. SG1 also encourages manufacturers to try the STED format for different classes of devices that are candidates for the pilot program.

FDA intends to process premarket submissions in the GHTF harmonized format within statutory time limits and with review times comparable to other submissions for similar products. There will be no expedited review of submissions, unless the device merits such a process under current policies.

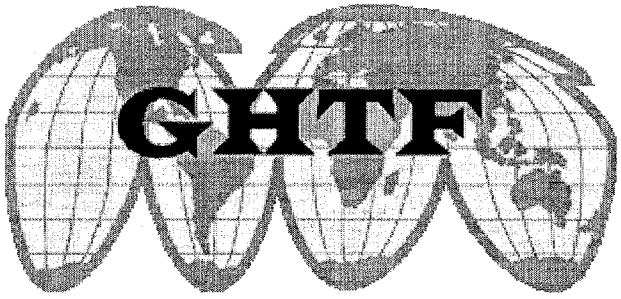
FDA plans to conduct the pilot program for one year. The pilot program will begin on the date of publication of the final FDA guidance document. FDA will assess how the pilot is proceeding during its course and may choose to decline receipt of additional submissions using the draft STED format in order to assess the initial experiences. At the end of the pilot, FDA and other GHTF participants will analyze the outcome to determine whether the draft STED document is a viable alternative to current premarket submission formats, and if the program should be continued or expanded. FDA will post in its internet web site a report of the outcome of the pilot program.

If you are interested in participating, or have questions regarding the pilot program, please contact one of the following individuals:

Timothy A. Ulatowski
(301)443-8879
tau@cdrh.fda.gov

Margie Shulman
(301)594-1190
mgs@cdrh.fda.gov

SG1/N011R16



WORKING DRAFT DOCUMENT

Global Harmonization Task Force

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

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

Date: December 18, 2000

Table of Contents

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.

1.0 Introduction

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

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

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

2.0 Scope

This guidance document provides guidance on Summary Technical Documentation (hereafter abbreviated to STED) for demonstrating conformity to the *Essential Principles of Safety and Performance of Medical Devices*[1] (hereafter abbreviated to 'Essential Principles'). It describes the format for a globally harmonized STED (see Section 6.0 below) and provides general recommendation on the content of the formatted elements (see section 7.0 below). This document applies to all products that fall within the definition of a medical device[2] and to active implantable medical devices. In-vitro diagnostic medical devices are outside the scope of this document.

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

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

[1] Refer to SG1/NO20 *the Essential Principles of Safety and Performance of Medical Devices*
2 Refer to SG1/N029 *Information Concerning the Definition of the Term "Medical Device*

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

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

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

Requirements for post-market vigilance or adverse event reporting are outside the scope of this document[3].

This document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. Regulatory Authorities that are developing new regulatory systems or amending existing ones are encouraged to consider the adoption of this guidance, as this will help to reduce the diversity of systems world-wide and facilitate the process of harmonization.

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

3.0 References

SG1/N009 *Labelling for Medical Devices.*

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

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

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

4.0 Definitions

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

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

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

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

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

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

a) certain high risk medical devices with requirements specified in Annex II of the European Directive Concerning Medical Devices[4], or

b) active implantable medical devices with requirements specified in Annex II of the European Directive Concerning Active Implantable Medical Devices[5].

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

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

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

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

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

5.0 Intended use of the STED and its preparation

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

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

[4] ref. 93/42/EEC of 14 June 1993.
5 ref. 90/385/EEC of 20 June 1990.

(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[6]. It is also proposing harmonized guidance on the link between device classification and conformity assessment to the Essential Principles[7].

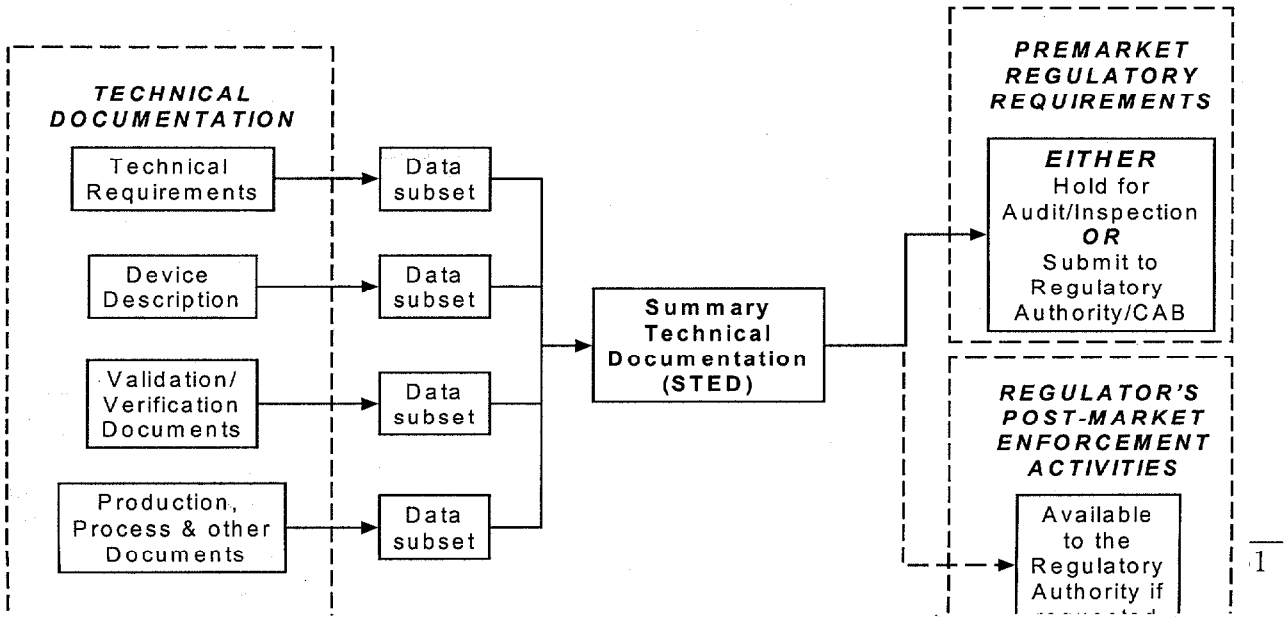
> **Examples:** In the European Community a manufacturer determines the class of a generic type of device from a set of classification rules. Those in the highest risk class (i.e. Class III devices) require pre-market conformity assessment by a Conformity Assessment Body. In the United States a regulation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

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

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

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

Further information is given in Appendix A2 and Appendix C.



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

Medical devices that typically have a high degree of risk are those that require pre-market conformity assessment in all jurisdictions. In such cases, documentation is frequently required to be provided to either a Regulatory Authority or Conformity Assessment Body for review/approval[8]. It is intended that the STED be such documentation. For further information on STEDs provided to Regulatory Authorities for review/approval, see Annex C.

6.0 Format for Summary Technical Documentation

6.1 Basic Format

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

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

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

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

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

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

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

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[9], state of the art or internal industry methods, comparisons to other similar marketed devices, etc.

The STED should identify the specific documents related to the method used to demonstrate conformity to the Essential Principles. For example, when the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the STED should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the manufacturer uses other means, such as internal standards, the STED should describe the means.

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

7.1.2 Essential Principles and Evidence of Conformity

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

7.2 Device Description

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

7.2.1 General Information

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

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

7.2.2 Materials

- a description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles.

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[10]; and/or
- summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance[11].

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

EXAMPLE: The completed Table of Conformity to the Essential Principles that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. Section 7.0 of the STED would then include a declaration of conformity to the standard, or other certification permitted by the Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements.

[10] Refer to SG1/N012 *Role of Standards in the Assessment of Medical Devices*.
[11] See Appendix **C4** for a **recommended** format **and content** of a test report.

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[12].

7.4 Labelling

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

- labels on the device and its packaging;
- instructions for use;
- other literature or training materials;
- instructions for installation and maintenance[13];
- Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform.

7.5 Risk Analysis

The STED should summarize or reference or contain (as determined by need for a submission and the option selected by the manufacturer in Section 6.2) the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.

[12] Refer to SG1/N036 *Global Approach to Premarket Conformity Assessment for Medical Devices (document in work and not available for public comment at the present time).*
[13] Refer to SG1/N009 *Labelling for Medical Devices*

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.

Appendices

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

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. G HTF 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

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.

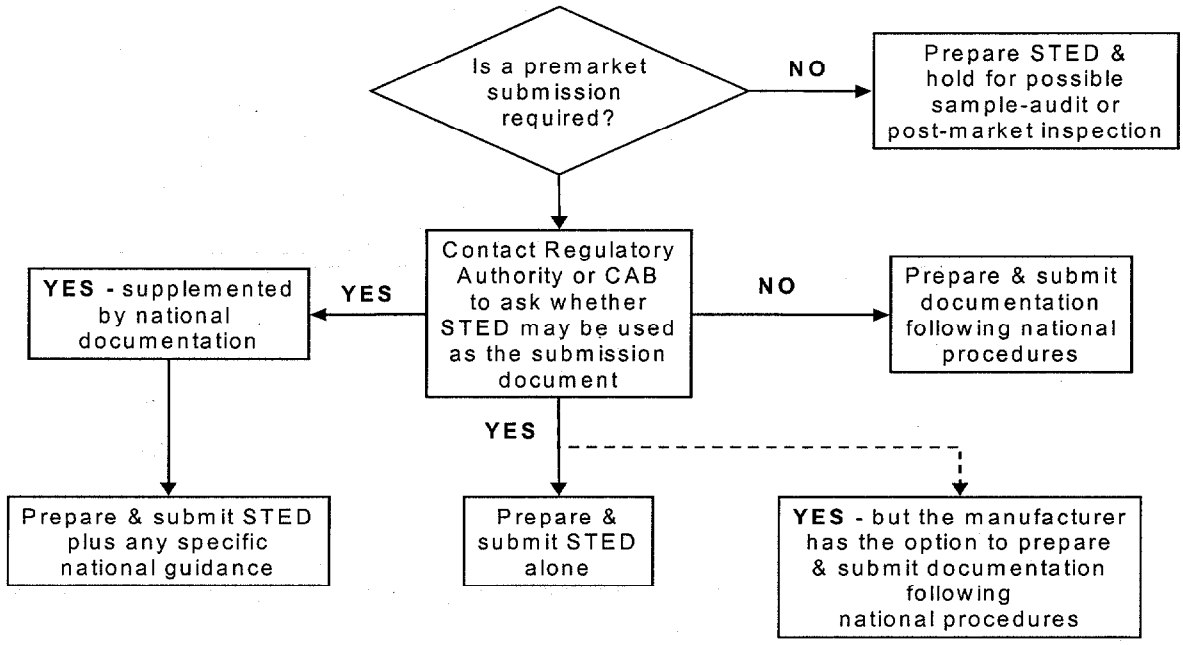


FIGURE 2: DECISION MAKING PROCESS

Appendix B: Essential Principles Conformity Checklist

Essential Principle	Applicable to the device?	Method of Conformity[14]	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: • identify hazards and the associated risks arising from the intended use and foreseeable misuse, • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted.	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		

[14] Select from: recognised standard/other international standard/national standard/company standard/validated test/ etc.

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.	Yes		
6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.	Yes		
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: • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, 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.			
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.			
7.3. Etc.			
8. Etc.			
9. Etc.			

EXAMPLE 1: A Class B infusion set intended to be used with an infusion pump to deliver fluids to the body. It is a non-active, single use device that is provided sterile to the user.

Essential Principle	Applicable to the device?	Method of Conformity[15]	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	Manufacturer's QA system complies with recognised and international standards. Verified through independent audit of the Manufacturer's internal systems by a Conformity Assessment Body.	ISO 9001:1994 – *Quality Systems. Model for Quality Assurance in Design, Development, Production, Installation and Servicing.* ISO 13485:1999 - *Specification for the application of ISO 9001 to Medical Devices* ISO 14969:1999 – *Guidance on the Application of ISO 13485 and ISO 13488 to medical devices*
		Sub-contract Assembler has a QA system that complies with recognised and international standards. Verified through independent audit by a Conformity Assessment Body. And by Manufacturer	ISO 9002:1994 - *Quality Systems. Model for Quality Assurance in Production, Installation and Servicing.* ISO 13488:1999 - *Specification for the application of ISO 9002 to the Manufacture of Medical Devices*
		Risk analysis prepared according to Manufacturer's QA system to comply with	ISO 14971 – *Application of Risk Management to Medical Devices*

[15] Select from: recognised standard/other international standard/national standard/company standard/validated test/ etc.

		recognised standard.	
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: • identify hazards and the associated risks arising from the intended use and foreseeable misuse, • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted.	Yes	Design and manufacture complies with Manufacturer's internal documented systems since there is no recognised standard for this particular product. Risk analysis complies with recognised standard. No alarms required (Non-active device). Labelling complies with recognised standard. Labelling and instructions provide warnings.	Refer to Manufacturer's quality system documentation. ISO 14971 – *Application of Risk Management to Medical Devices* EN 1041:1998 – *Information Supplied by the Manufacturer with Medical Devices*
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	Design and manufacture complies with Manufacturer's internal documented systems. Performance claims consistent with verification documents. Packaging meets international standard.	Refer to Manufacturer's quality system documentation. Refer to GHTF document SG1/N029 *Information Concerning the Definition of the Term "Medical Device".* Refer to Manufacturer's product brochures and specification. EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be	Yes	Manufacturer has a	Refer to GHTF document SG2/N21R8

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.		documented post-market surveillance procedure that is verified through independent audit. Management Review provides scrutiny of any product problems.	*Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative*
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.	Yes	Packaging complies with international standard.	EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report.
6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.	Yes	Risk analysis complies with recognised standard. Benefits identified and documented through review of clinical performance data of the product and its competition.	ISO 14971 – *Application of Risk Management to Medical Devices*
7 Chemical, physical and biological properties			
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: • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, 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.	Yes	Manufacturer's QA system complies with recognised standards. Verified through independent audit of the Manufacturer's internal systems by a Conformity Assessment Body. Flammability not a hazard for this product. Mechanical wear etc. not a feature of the product	ISO 9001:1994 – *Quality Systems. Model for Quality Assurance in Design, Development, Production, Installation and Servicing.* ISO 13485:1999 - *Specification for the application of ISO 9001 to Medical Devices* ISO 14969:1999 – *Guidance on the Application of ISO 13485 and ISO 13488 to medical devices*

		Documented biocompatibility assessment complies with recognised standard.	EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference Manufacturer's biocompatibility report.
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.	Yes	Documented biocompatibility assessment complies with recognised standard.	EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference Manufacturer's biocompatibility report.
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.	Yes	Risk analysis complies with recognised standard and covers these features. Documented biocompatibility assessment complies with recognised standard	ISO 14971 – *Application of Risk Management to Medical Devices* EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference Manufacturer's biocompatibility report.
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.	No - Medicines not incorporated into the device.		
7.5. The devices should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances that may leach from the device.	Yes	Documented biocompatibility assessment complies with recognised standard	EN ISO 10993-1:1998 – *Biological evaluation of Medical Devices Part 1. Evaluation and Testing* Cross-reference biocompatibility report.
7.6. Devices should be designed and manufactured in such a way as to reduce, as much as possible, 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	Yes	Product designed to prevent leaks etc. during normal use using Manufacturer's	Refer to Manufacturer's testing documentation and cross-reference to Test Report

intended to be used.		documented QA system. Performance verified through company testi procedure. Packaging meets international standard.	 EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
8 Infection and microbial contamination			
8.1. The devices and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and, where applicable, other persons. The design should allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.	Yes	Laboratory and clinical testing by independent Test House shows residual risks are acceptable in normal use. Packaging design complies with international standard and maintains the product in a sterile condition.	Cross-reference Manufacturer's Test Report EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
8.2.1. Tissues of non-human origin as far as considered a medical device, 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 Competent/Regulatory Authority should 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	No - no materials of this type are incorporated into the product.		

of elimination or viral inactivation in the course of the manufacturing process.			
8.2.2. In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, selection, 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 viral inactivation in the course of the manufacturing process.	No - no materials of this type are incorporated into the product.		
8.3. 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 storage and transport conditions laid down, until the protective packaging is damaged or opened.	Yes	Packaging design complies with international standard and maintains the product in a sterile condition.	EN 868-1:1997 *Part 1: General Requirements and Test Methods* Cross-reference Manufacturer's Test Report
8.4. Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	Yes	Sterilisation procedures validated and comply with recognised standard.	EN 556 – *Sterilization of Medical Devices. Requirements for Terminally-Sterilised Medical Devices to be Labelled "Sterile"* Cross-reference Manufacturer's Test Report
8.5. Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	Yes	Environmental conditions of manufacture controlled through Manufacturer's QA system by the QA system and controls at the sub-contract sterilisation company. All procedures/systems subject to validation and testing.	EN 556 – *Sterilization of Medical Devices. Requirements for Terminally-Sterilised Medical Devices to be Labelled "Sterile"* Refer to relevant aspects of manufacturing procedures and cross-reference Test Report/s.
8.6. Packaging systems for non-sterile devices should keep the product without	No – device is		

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.	sterile.		
8.7. The packaging and/or label of the device should distinguish between identical or similar products sold in both sterile and non-sterile condition.	Yes	Quality assurance procedures of the Manufacturer ensure clear identification of work-in-progress.	
9 Construction and environmental properties			
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 should be indicated on the label or in the instructions for use.	Yes	Luer connectors comply with international standard.	EN 1707:1997 - *Conical Fittings with a 6% [Luer] Taper for Syringes, Needles and Certain Other Medical Equipment.*
9.2. Devices should be designed and manufactured in such a way as to remove or minimise as far as is practicable: • 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 environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, • 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.	No - The product is small and light. The product is manufactured from non-magnetic materials. The device is non-active. The device is not calibrated		
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 flammable substances or to substances which could cause combustion.	No - The device is non-active and does not channel flammable materials		
10 Devices with a measuring function			
10.1. Devices with a measuring function should be designed and	No - The device		

manufactured in such a way as to provide sufficient accuracy, precision and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.	does not have a measuring function.		
10.2. The measurement, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.	No - The device does not have a measuring function.		
10.3. The measurements made by devices with a measuring function should be expressed in legal units as required by the legislation governing such expression of each jurisdiction in which the device is to be sold	No - The device does not have a measuring function.		
11 Protection against radiation			
11.1. General 11.1.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation should be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	No - The device does not emit radiation.		
11.2. Intended radiation 11.2.1 Where devices are designed to emit hazardous levels of 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 and tolerance of relevant variable parameters.	No - The device does not emit radiation.		
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.	No - The device does not emit radiation.		
11.3. Unintended radiation 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 possible.	No - The device does not emit radiation.		
11.4. Instructions for use	No - The device		

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.	does not emit radiation.		
11.5. Ionizing radiation 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.	No - The device does not emit radiation.		
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 minimizing radiation exposure of the patient and user.	No - The device does not emit radiation.		
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.	No - The device does not emit radiation.		
12 Requirements for medical devices connected to or equipped with an energy source			
12.1. Devices incorporating electronic programmable systems 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 possible consequent risks.	No - The device is non-active.		
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.	No - The device is non-active.		
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.	No - The device is non-active.		
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.	No - The device is non-active.		
12.5. Devices should be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	No - The device is non-active.		
12.6. Protection against electrical risks 12.6.1 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	No - The device is non-active.		

devices are installed correctly.			
12.7 Protection against mechanical and thermal risks 12.7.1. 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.	No – There are no hazards of this type.		
12.7.2. 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.	No - The device does not vibrate.		
12.7.3 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.	No - The device does not emit noise.		
12.7.4. 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 minimise all possible risks.	No - The device is not connected to such energy supplies.		
12.7.5. 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.	No - The device does not generate heat.		
12.8. Protection against the risks posed to the patient by energy supplies or substances. 12.8.1 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.	No - The device does not supply energy.		
12.8.2. 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.	No - The device does not supply energy.		
12.8.3. 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.	No - The device does not incorporate indicators and controls.		
13 Information supplied by the manufacturer			
13.1. Each device should be accompanied by the information needed to identify the manufacturer, to use it safely and to ensure	Yes	Labelling complies with recognised standard and with	EN 1041:1998 – *Information Supplied by the Manufacturer with Medical Devices*

the intended performance, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use, and should be easily understood. (NOTE: Detailed information on labelling requirements is the subject of a separate document)		the GHTF guidance.	Refer to GHTF guidance SG1/N009 *Labelling for Medical Devices.*
14 Clinical Evaluation			
14.1. Where conformity with these Essential Principles should be based on clinical evaluation data, such data should be established in accordance with the relevant requirements applicable in each jurisdiction. Clinical investigations on human subjects should be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in 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.	Yes	Clinical bibliography and a summary of clinical performance of the product, its predecessors and competitor devices has been documented and is available to the Regulatory Authority/CAB if required. It is sufficient in itself a further testing of the medical device is not required.	Cross-reference Manufacturer's clinical bibliography and summary of clinical experience.

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

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.

GHTF.SG1.N020R5

FINAL DOCUMENT

Title: Essential Principles Of Safety & Performance of Medical Devices

Authoring Group: SG1

Endorsed by: The Global Harmonization Task Force

Date: June 30, 1999

Elizabeth D. Jacobson, Ph.D., GHTF Chair

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 regulators, 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. The document will be of value to countries developing or amending regulations. The regulatory requirements of some countries may not, at present, reflect the contents of this document.

FOREWORD

"Essential Principles of Safety and Performance of Medical Devices on a Global Basis"

Study Group 1 recognizes that to further the processes of global harmonization of regulatory requirements, it is necessary to have common guidelines to indicate the Essential Principles of safety and performance of medical devices in the interests of public health.

Existing regulations and draft regulations of participating members of the Task Force have already included, in many cases, such statements of principles and it has been the conclusion of the Study Group that, although presented in different ways, the features of such principles are common to all such regulations.

For these reasons, Study Group 1 proposes that the following set of principles should be considered in the development or amendment of regulatory systems.

The Study Group recommends that Regulatory Authorities consider accepting, for placing on the market, medical devices where compliance with relevant Essential Principles has been demonstrated.

NOTE: (1) There may be further safety and performance principles for devices incorporating substances derived from tissues of human or animal origin and in vitro diagnostic devices. This may suggest the need for additional review of this Essential Principles document in the future.

(2) It is understood that the operation of a quality system, the use of standards, post-market vigilance, the pre-market review of a technical file, type testing and final product testing, are all important means, which may individually or jointly be utilized, to achieve compliance with the Essential Principles. These matters are not addressed within this document.

(3) Information on labelling requirements is the subject of a separate document.

GLOBAL HARMONIZATION TASK FORCE
STUDY GROUP 1

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

GENERAL REQUIREMENTS

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.

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:

   - identify hazards and the associated risks arising from the intended use and foreseeable misuse,
   - eliminate or reduce risks as far as possible (inherently safe design and construction),
   - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
   - inform users of the residual risks due to any shortcomings of the protection measures adopted.

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.

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.

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.

6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.

REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

Chemical, physical and biological properties

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:

- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
- the compatibility between the materials used and biological tissues, cells and body fluids, 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.

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.

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.

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.

7.5 The devices should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances that may leach from the device.

7.6 Devices should be designed and manufactured in such a way as to reduce, as much as possible, 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.

Infection and microbial contamination

8.1 The devices and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and, where applicable, other persons. The design should allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.

8.2.1 Tissues of non-human origin as far as considered a medical device, 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 Competent/Regulatory Authority should 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 viral inactivation in the course of the manufacturing process.

8.2.2 In some jurisdictions products incorporating human tissues, cells and substances may be considered medical devices. In this case, selection, 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 viral inactivation in the course of the manufacturing process.

8.3 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 storage and transport conditions laid down, until the protective packaging is damaged or opened.

8.4 Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.

8.5 Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

8.6 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.

8.7 The packaging and/or label of the device should distinguish between identical or similar products sold in both sterile and non-sterile condition.

Construction and environmental properties

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 should be indicated on the label or in the instructions for use.

9.2 Devices should be designed and manufactured in such a way as to remove or minimise as far as is practicable:

- 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 environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
- 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.

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 flammable substances or to substances which could cause combustion.

Devices with a measuring function

10.1 Devices with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.

10.2 The measurement, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3 The measurements made by devices with a measuring function should be expressed in legal units as required by the legislation governing such expression of each jurisdiction in which the device is to be sold

Protection against radiation

11.1 General

11.1.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation should be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

11.2 Intended radiation

11.2.1 Where devices are designed to emit hazardous levels of 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 and tolerance of relevant variable parameters.

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.

11.3 Unintended radiation

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 possible.

11.4 Instructions for use

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.

11.5 Ionizing radiation

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.

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 minimizing radiation exposure of the patient and user.

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.

Requirements for medical devices connected to or equipped with an energy source

12.1 Devices incorporating electronic programmable systems 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 possible consequent risks.

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.

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.

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

12.5 Devices should be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.

12.6 Protection against electrical risks

12.6.1 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 correctly.

12.7 Protection against mechanical and thermal risks

12.7.1 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.

12.7.2 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.

12.7.3 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.

12.7.4 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 minimise all possible risks.

12.7.5 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.

12.8 Protection against the risks posed to the patient by energy supplies or substances.

12.8.1 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.

12.8.2 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.

12.8.3 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.

Information supplied by the manufacturer

13.1 Each device should be accompanied by the information needed to identify the manufacturer, to use it safely and to ensure the intended performance, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use, and should be easily understood.

(NOTE: Detailed information on labelling requirements is the subject of a separate document)

Clinical Evaluation

14.1 Where conformity with these Essential Principles should be based on clinical evaluation data, such data should be established in accordance with the relevant requirements applicable in each jurisdiction.

Clinical investigations on human subjects should be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in 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.

(NOTE: Specific guidance on clinical evaluation may be developed in the future)