



PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Principles of Conformity Assessment for Medical Devices

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Preface

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

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1.0 Introduction

The 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.

The primary way in which the GHTF achieves its goals is through the production of a series of guidance documents that together describe a global regulatory model for medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether a medical device conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Regulatory Authorities, Conformity Assessment Bodies and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry. Study Group 1 of the GHTF supports and encourages regulatory harmonization but recognises that some Regulatory Authorities may have to reflect different local needs when they introduce new regulations on conformity assessment. However, Regulatory Authorities that are developing conformity assessment schemes or amending existing ones are encouraged to consider the adoption of the system described in this document, as this will help to reduce the diversity of schemes world-wide and facilitate the process of harmonization.

At this time, conformity assessment requirements and other regulatory controls assigned to each risk class of a medical device by different Regulatory Authorities have yet to be harmonized and may vary from the guidance provided in this document.

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

2.0 Rationale, Purpose and Scope

2.1 Rationale

¹ www.gh tf.org

Regulatory systems are intended to ensure a high level of protection of public health and safety.

Public trust and confidence in medical devices, and in the administrative systems by which they are regulated, are based on the safety and performance of such products throughout their life cycle.

Conformity assessment, conducted before and after a medical device is placed on the market, and post-marketing surveillance of devices in actual use are complementary elements of the GHTF global regulatory model. They are intended to provide the objective evidence of safety, performance, and benefits & risks to maintain public confidence.

Conformity assessment is primarily the responsibility of the medical device manufacturer. However, it is done in the context of the established regulatory requirements and both the process and conclusions are subject to further review by the regulatory authority and/or conformity assessment body.

In general, the degree of involvement of the regulatory authority or conformity assessment body in such reviews is proportional to the risks associated with a particular category of devices.

A perceived failure of the conformity assessment process, even if related only to a small number of specific devices, jeopardizes the credibility of regulator and manufacturer alike.

The inter-relationship between device class and conformity assessment is critical in establishing a consistent approach across all countries/regions adopting GHTF principles, so that the premarket approval process and evidence requirements for a particular medical device are acceptable globally. This document provides guidance on the principles of conformity assessment for medical devices. It should be read in conjunction with the GHTF document on *Principles of Medical Devices Classification* that recommends rules to assist a manufacturer to allocate its medical device to one of four risk classes. The procedures indicated in this document reflect the need to make conformity assessment more rigorous as the risk class of a medical device increases.

2.2 Purpose

To describe:

- the evidence and procedures that may be used by the manufacturer to demonstrate that a medical device is safe and performs as intended by the manufacturer and conforms to the *Essential Principles of Safety and Performance for Medical Devices*;
- the procedures that should apply to each class of device such that the regulatory demands increase with the risk class of the medical device
- the process by which a Regulatory Authority, or Conformity Assessment Body appointed by or acting on behalf of the Regulatory Authority, may confirm that such procedures are properly applied by the manufacturer;

- the Declaration of Conformity, the manufacturer's written attestation that it has correctly applied the conformity assessment procedures relevant to the classification of the device.

2.3 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document GHTF/SG1/N029:2005 *Information Document Concerning the Definition of the Term "Medical Device"*, **other than those** used for the *in vitro* examination of specimens derived from the human body.

3.0 References

GHTF final documents

SG1/N012:2000 *Role of Standards in the Assessment of Medical Devices.*

SG1/N029:2005 *Information Document Concerning the Definition of the Term 'Medical Device'.*

SG1/N041:2005 *Essential Principles of Safety and Performance of Medical Devices.*

SG1/N043:2005 *Labelling for Medical Devices.*

SG2/N021:1999 *Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative.*

SG3/N010:2004 *Quality Management Systems – Process Validation Guidance.*

SG4/N024:2002 *Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements – Supplement No. 4 – Compilation of Audit Documentation (Clause 5.7)*

SG4/N028:1999 *Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part1: General Requirements.*

GHTF documents available for public comment

SG1(PD)/N015 *Principles of Medical Devices Classification.*

International standards

ISO 19011:2002 *Guidelines for quality and/or environmental management system auditing*

ISO 9000:2000 *Quality Management Systems – Fundamentals and vocabulary*

ISO 13485:2003 *Medical devices -- Quality management systems -- Requirements for regulatory purposes*

ISO/TR 14969:2004 *Medical devices -- Quality management systems -- Guidance on the application of ISO 13485:2003*

ISO 14971:2000 *Medical devices -- Application of risk management to medical devices.*

ISO/TR 16142:1999 *Medical devices -- Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices.*

ISO 14155-1:2003 *Clinical investigation of medical devices for human subjects – Part 1: General requirements*

ISO 14155-2:2003 *Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans*

ISO 15225:2000 *Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange and its amendment ISO 15225:2000/Amd 1:200X*

4.0 Definitions

Audit: a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. (Source - ISO 8402).

Authorized Representative: means any person explicitly designated by a manufacturer, to represent it within a country or jurisdiction where it is not itself established, in respect of matters raised by the relevant Regulatory Authority, with regard to the manufacturer's obligations under the regulations that operate within that country or jurisdiction. (Source – European Directive 98/79/EC modified)

Conformity Assessment: the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices (SG1/N041)*.

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

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

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

Summary Technical Documentation: a summary of technical documentation held or submitted for conformity assessment purposes. (Source – SG1/N011 modified)

Technical Documentation: the documented evidence, normally an output of the quality management system, that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices (SG1/N041)*.

5.0 Conformity Assessment Elements

The conformity assessment procedures that the RA may make available to the manufacturer will be selected from those described below. They relate either to the design and performance of the product, to its manufacture, or both. As a general rule, a medical device is subject to conformity assessment during both design and manufacture. Some of the procedures described in this document are alternatives to others and it is neither intended nor desirable that every listed conformity assessment procedure should be applied to every medical device.

The conformity assessment procedures that appear in this Section describe the tasks of the manufacturer and, where appropriate, the RA or CAB.

5.1 Quality management system

The requirements for a quality management system together with the other conformity assessment elements are intended to ensure that medical devices will be safe and perform as intended by the manufacturer.

A manufacturer needs to demonstrate its ability to provide medical devices that consistently meet customer requirements and regulatory requirements applicable to those medical devices. Manufacturers demonstrate compliance through an established and effectively implemented quality management system that meets the regulatory requirements.

The scope and complexity of the quality management system that a manufacturer needs to establish is influenced by varying needs, objectives, the products provided, processes employed, the size and structure of the organization, and the specific regulatory requirements.

Processes required by the quality management system but carried out on the manufacturer's behalf by third parties remain the responsibility of the manufacturer and are

subject to control under the manufacturer's quality management system. As part of the RA/CAB's conformity assessment process, they should assess the adequacy of this control.

If regulatory requirements permit exclusion of design and development controls, this can be used as a justification for their exclusion from the quality management system. Some country or regional regulations can allow for alternative arrangements that must be carried out as part of the quality management system.

Conformity assessment of the manufacturer's quality management system is influenced by the class of the medical device.

For Class B, C and D devices, the RA or CAB needs to be satisfied that the manufacturer has an effective quality management system in place, appropriate for the device under assessment. In doing this, the RA or CAB will consider any relevant existing certification and, if not satisfied e.g. with its scope or with post market performance history, may carry out an on-site audit of the manufacturer's facility.

Manufacturers of Class C and D devices should have a full quality management system² that includes design and development. Manufacturers of Class B devices should have a quality management system that need not include design and development activities. Manufacturers of Class A devices are expected to have the elements of a QMS in place that need not include design and development activities.

The QMS for manufacturers of Class A devices is normally not subject to premarket on-site audit by the RA or CAB.

5.2 System for post market surveillance

Prior to placing the product on the market, the manufacturer will put in place, as part of its quality management system, a process to assess the continued conformity of the device to the *Essential Principles of Safety and Performance* through the post marketing phase. This process will include complaint handling, vigilance reporting, and corrective and preventive action³.

The RA or CAB will confirm that such a process is in place, usually at the time of the quality management system audit⁴.

5.3 Summary technical documentation

The technical documentation provides the evidence used in the conformity assessment process.

For the purposes of conformity assessment, the manufacturer will establish a subset of technical documentation to be held or submitted, as required by the class of the device. A

² See GHTF/SG3 guidance documents

³ See GHTF/SG2 guidance documents

⁴ Further details are provided in the GHTF guidance documents issued by Study Groups 3 and 4

description of that subset is provided in the GHTF guidance document: *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*. The extent of evidence in that STED is likely to increase with the class of the medical device, its complexity and the extent to which it incorporates new technology.

The RA or CAB determines the adequacy of the documented evidence in support of the manufacturer's Declaration of Conformity to the Essential Principles through a review of the STED. The depth and timing of the review is likely to be influenced by the risk class of the medical device, its complexity and the extent to which it incorporates new technology.

5.4 Declaration of conformity

One element of a global regulatory model for medical devices is that the manufacturer attests that its medical device complies fully with all applicable *Essential Principles for Safety and Performance* and draws up a written 'Declaration of Conformity'.

As a minimum, this declaration should contain the following information:

- A statement that each device that is subject to the declaration:
 - Ø complies with the applicable *Essential Principles for Safety and Performance*,
 - Ø has been classified according to the classification rules⁵, and
 - Ø has met all the applicable conformity assessment elements.
- Information sufficient to identify the device(s) to which the Declaration of Conformity applies.
- The Global Medical Device Nomenclature (GMDN) code and term for the device.
- The risk class allocated to the device/s after following the guidance found in *Principles of Medical Devices Classification*⁶.
- Which of the conformity assessment procedures described in Section 6.2 have been applied.
- The date from which the Declaration of Conformity is valid.
- The name and address of the device manufacturer.
- The name, position and signature of the responsible person who has been authorised to complete the Declaration of Conformity upon the manufacturer's behalf.

The RA or CAB may review and confirm the adequacy of the Declaration of Conformity, if required, by examining the supporting documents or other evidence.

5.5 Registration of manufacturers and their medical devices by the Regulatory Authority

Registration of manufacturers and their medical devices is considered to be the most basic level of regulatory control of devices in the market. This registration system will identify the devices, the responsible party and will facilitate any regulatory activity. GHTF

⁵ See SG1(PD)/N015 *Principles of Medical Devices Classification*.

⁶ See SG1(PD)/N015 *Principles of Medical Devices Classification*.

guidance regarding the establishment by Regulatory Authorities of a harmonized approach to a registration system will be forthcoming.

Prior to placing a medical device on the market, the manufacturer, its local distributor or its Authorized Representative should provide the Regulatory Authority with the required information.

6.0 Harmonized Conformity Assessment System

6.1 The relationship between conformity assessment and device classification

The GHTF recommends that each medical device be allocated to one of four groups, or classes, using a set of rules. Class A devices are the lowest risk devices, Classes B are moderate to low risk, Class C are moderate to high risk and Class D devices present the highest risk. The level of scrutiny, evidence requirements that the device meets the *Essential Principles for Safety and Performance* and conformity assessment procedures become more robust and demanding for higher risk classes of devices.

This principle is illustrated in the guidance that follows. It identifies available conformity assessment elements and proposes a combination of those elements that may be applied to different classes of medical devices to construct a harmonized conformity assessment system that may be adopted as part of a global regulatory model for medical devices. Where there are alternatives within conformity assessment elements, e.g. the quality management system for a Class A device may be either a full quality management system or one without design and development control, the manufacturer may choose the one that it believes to be most suitable.

6.2 Conformity assessment system

The four tables below summarise conformity assessment elements that apply to Class A, B, C and D devices.

CLASS “A” DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	RA / CAB Responsibility	Section
Conformity assessment of the QMS	Quality Management System (QMS)	Establish and maintain a QMS or a QMS without design and development	Regulatory audit normally not required except in special cases, e.g. assurance of sterility & of measuring function/s.	5.1
	Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	May audit post-market to investigate specific safety or regulatory concerns.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Prepare STED and have available for review by RA upon request.	Pre-market submission of STED normally not requested.	5.3
	Declaration of Conformity	Prepare, sign and maintain	Normally not requested	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	5.5

CLASS “B” DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	RA / CAB Responsibility	Sub-Clause
Conformity assessment of the QMS	Quality Management System (QMS)	Establish and maintain a QMS or a QMS without design and development.	Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.	5.1
	Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Prepare STED and have available for review upon request.	Not normally reviewed premarket. If submission is requested, receive and conduct a pre-market review of the STED sufficient to determine conformity to Essential Principles.	5.3
	Declaration of Conformity	Prepare, sign and make available for review.	Review and verify compliance with requirements.	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	5.5

CLASS “C” DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	RA / CAB Responsibility	Sub-Clause
Conformity assessment of the QMS	Quality Management System (QMS)	Establish and maintain a QMS.	Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.	5.1
	Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Prepare and submit a STED for review.	Conduct a review, normally premarket, of the STED sufficient to determine conformity to Essential Principles.	5.3
	Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

Note: At the option of the manufacturer, the manufacturer of Class C devices may ask the RA or CAB, in jurisdictions where such is permitted, to conduct a type examination to verify compliance to some of the relevant Essential Principles. The use of type examination does not replace the need to establish and maintain a QMS.

SG1 recognises that some Founding Members have permitted the use of type examination. In an effort to support harmonization, to discourage the inclusion of mandatory type examination in future regulations and to support other GHTF guidance documents, SG1 anticipates that type examination may not be offered as an option in future revisions of this guidance document.

CLASS “D” DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	RA / CAB Responsibility	Sub-Clause
Conformity assessment of the QMS	Quality Management System (QMS)	Establish and maintain a QMS	Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.	5.1
	Post Market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Prepare and submit a STED for review	Receive and conduct an in-depth pre-market review of the STED to determine conformity to Essential Principles.	5.3
	Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	5.5

6.3 Conformity assessment considerations

There are situations when characteristics of the device and/or its manufacturer may cause the RA or CAB, by exception, to modify its requirements relating to conformity assessment. This may include deferring the review of the STED for Class C devices until a subsequent regulatory audit.

For example, the RA or CAB may exempt the manufacturer from making a complete premarket submission and/or require a less rigorous audit than would apply normally to a device of that class when:

- the device incorporates well-established technology that is present in the market;
- the RA and/or CAB is familiar with the manufacturer’s capabilities and its products;
- the device is an updated version of a compliant device from the same manufacturer that contains little substantive change;
- the RA and/or CAB has particular experience with a comparable device;

- internationally recognised standards⁷ are available to cover the main aspects of the device and have been used by the manufacturer.

Similarly, the RA or CAB may require more detailed pre-market submission and/or require a more rigorous audit and/or the provision of more clinical evidence than would apply normally to a device of that risk class when:

- the device incorporates innovative technology;
- an existing compliant device is being used for a new intended use;
- the device is new to the manufacturer;
- the device type tends to be associated with an excessive number of adverse events, including use errors;
- the device incorporates innovative or potentially hazardous materials;
- the device type raises specific public health concerns.

It should be emphasised that there must be a fully justified and documented case before the RA or CAB modifies in any way the relationship between device class and the associated conformity assessment procedure. Where there is justification for variation to the conformity assessment procedures normally applicable to a particular device class, a statement in this regard should be included in the STED.

⁷ See GHTF document: *Role of Standards SG1/N044*