



FINAL DOCUMENT

Global Harmonization Task Force
(Revision of GHTF/SG1/N40:2006)

Title: Principles of Conformity Assessment for Medical Devices

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

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.

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Preface

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1.0 Introduction

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

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Regulatory Authorities (RAs), Conformity Assessment Bodies (CABs) and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of RAs to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the regulated industry.

This document should be read in conjunction with the GHTF document entitled *Principles of Medical Devices Classification* that prescribes rules to separate medical devices into four groups or classes where Class A are the least hazardous and Class D the most hazardous. The link between device classification and conformity assessment is fundamental to the development of an effective global regulatory model. If both are adopted in a consistent manner, the goal of a premarket approval for a particular device being accepted globally may be achieved.

This document **supersedes** GHTF/SG1/N40:2006 which provided guidance on the same topic.

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

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 Chair or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF website¹.

2.0 Rationale, Purpose and Scope

2.1 Rationale

Conformity assessment, conducted before and after a medical device is placed on the market, and post-market 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 and risks to maintain public confidence.

¹ www.ghtf.org

Conformity assessment is primarily the responsibility of the medical device manufacturer. However, it is undertaken in the context of the regulatory requirements established in the jurisdiction where the device is sold, and both the process and conclusions may be subject to further review by the relevant Regulatory Authority (RA) and/or Conformity Assessment Body (CAB).

This document indicates conformity assessment elements that should be incorporated into a jurisdiction's medical device regulations to enable the manufacturer to demonstrate to the RA/CAB that its medical device complies with the legislation. It describes how these elements may be applied to devices with different classification such that assessment becomes more rigorous as the hazard/s presented by a particular device increases. Also, the degree of involvement of the RA or CAB in the oversight of the manufacturer's claim to comply with regulatory requirements depends on the classification of a particular device.

2.2 Purpose

To provide guidance on:

- 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.
- the conformity assessment elements that apply to each class of device such that the regulatory demands increase with the hazard presented by a particular medical device;
- the process by which a RA/CAB may confirm that such elements are properly applied by the manufacturer; and
- the manufacturer's written attestation that it has correctly applied the conformity assessment elements relevant to the classification of the device, i.e. the 'Declaration of Conformity'.

2.3 Scope

This document applies to all products that fall within the definition of the term 'medical device', other than IVD medical devices, for which separate classification and conformity assessment documents exist.

3.0 References²

GHTF/SG1/N011:2008 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*.

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

² The listed documents are subject to periodic review and may be superseded by later versions. The reader is encouraged to refer to the GHTF website to confirm whether the referenced documents remain current.

- GHTF/SG1/N55:2009 *Definition of the Terms Manufacturer, Authorised representative, Distributor and Importer.*
- GHTF/SG1/N065:2010 *Registration of Manufacturers and other Parties and Listing of Medical Devices.*
- GHTF/SG1/N068:2012 *Essential Principles of Safety and Performance of Medical Devices.*
- GHTF/SG1/N070:2011 *Label and Instructions for Use for Medical Devices.*
- GHTF/SG1/N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*
- GHTF/SG1/N077:2012 *Principles of Medical Devices Classification.*
- GHTF/SG2/N054R8:2006 *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices.*
- GHTF/SG3/N99-10:2004 (Edition 2) *Quality Management Systems - Process Validation Guidance*
- GHTF/SG3/N15R8:2005 *Implementation of Risk Management Principles and Activities Within a Quality Management System*
- GHTF/SG3/N17:2008 *Quality Management System - Medical Devices - Guidance on the Control of Products and Services Obtained from Suppliers*
- GHTF/SG3/N18:2010 *Quality Management System - Medical Devices - Guidance on corrective action and preventive action and related QMS processes*
- GHTF/SG4/N028R4:2008 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part1: General Requirements.*
- GHTF/SG5/N1R8:2007 *Clinical Evidence – Key Definitions and Concepts*
- GHTF/SG5/N2R8:2007 *Clinical Evaluation*
- GHTF/SG5/N3:2010 *Clinical Investigations*
- GHTF/SG5/N4:2010 *Post Market Clinical Follow-Up Studies*

4.0 Definitions

Audit: Systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Audit Criteria: Set of policies, procedures or requirements.

Audit Evidence: Records, statements of fact or other information, which are relevant to the audit criteria and verifiable.

NOTE: audit evidence may be qualitative and/or quantitative and is used to substantiate audit observations.

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*.

Conformity Assessment Body (CAB): A body, other than a Regulatory Authority, engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled.

Recognised Standards: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

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 (STED): A summary of technical documentation held or submitted for conformity assessment purposes.

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

Use error: Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator. Use error includes slips, lapses, mistakes and reasonably foreseeable misuse.

5.0 Conformity Assessment Elements

Medical device regulations should specify the manner in which the manufacturer demonstrates to the RA/CAB that its medical devices comply with the legislation. The necessary conformity assessment elements are:

- i. a quality management system (QMS),
- ii. a system for post-market surveillance,
- iii. technical documentation,
- iv. a declaration of conformity, and
- v. the registration of manufacturers and their medical devices by the RA.

All five elements are required for each of the device classes but there is flexibility in the manner of their application to a particular device class e.g. whether or not the technical documentation is subject to premarket review by the RA/CAB. Where there are alternatives within a conformity assessment element, the manufacturer may choose the one that it uses.

Where a substantial change to either the device or to the manufacturer's QMS is planned that could affect one of the conformity assessment elements, it may have to be notified to, and assessed by, the RA or CAB prior to implementation.

The conformity assessment elements that appear in Sections 5.1 to 5.5 describe the tasks of the manufacturer and, where appropriate, the responsibilities of the RA or CAB. Specific guidance on how these conformity assessment elements should be applied to a particular class of device is provided in the four tables in Section 6.2.

The requirements for a QMS that is accepted by RAs for regulatory purposes and based on international recognised standards³, combined with the other four conformity assessment elements are intended to ensure that medical devices will be safe and perform as intended by the manufacturer.

5.1 Quality management system (QMS)

The manufacturer should implement, document and maintain a QMS that ensures the medical devices it designs, manufactures and supplies to the market are safe, perform as intended and comply with the relevant provisions of the regulations. The scope and complexity of the QMS are influenced by the range of different medical devices that are under QMS control, the processes employed, the size and structure of the organisation, and the specific regulatory requirements.

Processes required by the QMS 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 QMS. As part of the RA/CAB's conformity assessment process, it should assess the adequacy of this control.

Conformity assessment of the manufacturer's QMS is influenced by the class of the medical device, as follows.

Manufacturers of **Class A** devices should implement and maintain the basic elements of a QMS but have the option of excluding design and development controls from it. The QMS for manufacturers of **Class A** devices is normally not subject to premarket on-site audit by the RA or CAB. The exception is where assurance of sterility or of a measuring function is required, in which situation the associated procedures should be subject to independent premarket audit.

Manufacturers of **Class B** devices should implement and maintain an effective QMS but may have the option of excluding design and development controls from it.

³ See definition in Section 4.0.

Manufacturers of **Class C and D** devices should implement and maintain an effective QMS that includes design and development controls, and complies with GHF SG3 guidance documents.

For **Class B, C, and D** devices, the RA or CAB needs to have confidence that the manufacturer has an appropriate and effective QMS in place, suitable for the range of different medical devices that are under QMS control. To achieve this, **the RA/CAB will review** any relevant existing certification and/or regulatory audit reports, and may **undertake periodic on-site audits** of the manufacturer's facility. Provided the audit confirms the QMS meets the requirements of the relevant medical device regulations, the RA/CAB may issue a certificate listing the medical devices covered by the QMS and indicating its period of validity.

In some jurisdictions, regulatory requirements permit exclusion of design and development controls from the scope of the manufacturer's QMS. Although a full QMS is preferred, some country or regional regulations may allow the manufacturer to choose type examination⁴ as an alternative means of demonstrating conformity with the relevant Essential Principles of safety and performance. GHF discourages jurisdictions introducing medical device regulations for the first time to permit this alternative.

Full quality management systems are preferred because they implement a full cycle of design and development controls to ensure that medical devices comply with the relevant Essential Principles of safety and performance. For products that are in existence at the time of establishment of a QMS, evidence of design control and the resulting outputs would be difficult for the manufacturer to demonstrate retrospectively. In these circumstances, the manufacturer may request a CAB, in jurisdictions where such is permitted, to conduct a type examination to verify conformity with the relevant Essential Principles and to establish a baseline for entry into the design and development cycle. It is expected that for future design changes to this product, originally assessed for conformity by type examination, or for the introduction of a new product, the manufacturer would introduce the full design and development controls of the QMS.

If the manufacturer chooses to use type examination by a CAB or RA this will be indicated in the technical documentation and Summary Technical Documentation (STED).

The use of type examination does not replace the need to establish and maintain a QMS that covers all manufacturing activities.

Type examination should never be imposed on a manufacturer by a RA.

⁴ 'Type examination' is a means of demonstrating compliance with relevant *Essential Principles of Safety and Performance of Medical Devices*. One or more representative units of the device (i.e. the "type") chosen by the manufacturer (e.g. final prototypes representative of the production configuration), together with relevant technical documentation, are submitted to a comprehensive examination by a CAB or RA to confirm compliance.

5.2 System for post-marketing surveillance

Prior to placing the product on the market, the manufacturer will establish, as part of its QMS, 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, post-market vigilance reporting, and any subsequent corrective & preventive actions⁵.

The RA or CAB will confirm that such a process is in place, usually at the time of the QMS audit⁶.

Furthermore, the RA may require manufacturers to perform a specific post-marketing study of a particular type of device, and report the outcome to the RA.

The RA will monitor any post-marketing study and consider whether any additional regulatory action is required after analysing the outcome.

5.3 Technical documentation

Manufacturers of all classes of device are expected to demonstrate conformity of the device to the *Essential Principles of Safety and Performance of Medical Devices* through the preparation and holding of technical documentation that shows how each medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. This technical documentation is updated as necessary to reflect the current status, specification and configuration of the device.

As part of its task to demonstrate conformity of a device to the medical device regulations, the manufacturer creates the *Summary Technical Documentation for demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices* (STED) from existing technical documentation to provide evidence to the RA/CAB that the subject medical device is in conformity with the essential principles of safety and performance, labelling, risk analysis and other regulatory requirements. The STED reflects the status of the medical device at a particular moment in time (e.g. at the moment of premarket submission or when requested by a RA for post-marketing purposes) and is prepared in order to meet regulatory requirements. 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.

Where the STED is submitted to a RA or CAB, it should incorporate an attestation that the contents is truthful and accurate, and indicate the name, position and signature of the responsible person who has been authorised to submit it on the manufacturer's behalf.

The RA or CAB determines the adequacy of the documented evidence in support of the manufacturer's attestation of conformity to the essential principles of safety and performance, and other regulatory requirements, through a review of the STED. The depth

⁵ See GHTF/SG2 guidance documents.

⁶ Further details are provided in the GHTF guidance documents issued by Study Groups 3 and 4.

and timing of the review is likely to be influenced by the 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 regulatory requirements and draws up a written 'Declaration of Conformity'.

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

- An attestation that each device that is subject to the declaration complies with the applicable *Essential Principles for Safety and Performance* and the applicable requirements of *Label and Instructions for Use for Medical Devices*,
- Information sufficient to identify the device/s to which the Declaration of Conformity applies.
- The Global Medical Device Nomenclature (GMDN) code for the device⁷.
- The classification of the device/s after following the guidance found in *Principles of Medical Devices Classification*.
- The date on which the Declaration of Conformity is issued.
- 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 and, if required, examine 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 by the RA is considered to be the most basic level of regulatory control of devices in the market. The collection and retention of information on manufacturers, authorised representatives, importers and distributors and the medical devices supplied to the market by those parties are fundamental elements of regulatory control. Guidance on the information to be provided may be found in the document entitled *Registration of Manufacturers and other Parties and Listing of Medical Devices*.

Prior to placing a medical device on the market, the manufacturer, or distributor, or importer, or authorised representative should provide the RA with the information it needs in respect of registration and medical device listing requirements.

⁷ www.gmdnagency.com

The RA will implement and maintain the register.

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 derived from the potential of a medical device to cause harm to a patient or user (i.e. the hazard it presents). Class A devices offer the lowest hazard, Class B low to moderate hazard, Class C moderate to high hazard, and Class D the highest hazard. The level of regulatory oversight, the evidence requirements that the device meets the *Essential Principles for Safety and Performance*, and the conformity assessment elements, becomes more robust and demanding as the classification of the device increases from A to D.

This principle is illustrated in Section 6.2 below. 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 a conformity assessment element, e.g. the QMS for a Class A device may be either a full QMS 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	Establish and maintain a full QMS or a QMS without design and development controls.	Regulatory audit normally not required except where assurance of sterility or of a measuring function is required.	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	Establish and keep up to date, technical documentation, and prepare and submit STED only at the request of a RA/CAB.	Premarket submission of STED normally not requested.	5.3
	Declaration of Conformity	Prepare, sign, and maintain.	Submission 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	Establish and maintain a full QMS or a QMS without design and development controls.	Have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorisation.	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	Establish and keep up to date, technical documentation, and prepare and submit STED only at the request of a RA/CAB.	Not normally reviewed premarket. If submission is requested, receive and conduct a premarket 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	Establish and maintain a full QMS.	Have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorisation.	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	Establish and keep up to date, technical documentation, and prepare and submit a STED for review.	Undertake a review of the STED sufficient to determine conformity to Essential Principles, prior to the device being placed on the market.	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

CLASS D DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	RA / CAB Responsibility	Sub-Clause
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS.	Have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorisation.	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	Establish and keep up to date, technical documentation, and prepare and submit a STED for review.	Undertake an in-depth review of the STED to determine conformity to Essential Principles, prior to the device being placed on the market.	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 requirements relating to its conformity assessment.

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 already;
- 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 standards⁸ 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 premarket 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 class when:

- the device incorporates innovative technology;
- an existing compliant device is being used for a new intended use;
- the device type is new to the manufacturer;
- the device type tends to be associated with an excessive number of adverse events, including use errors⁹;
- 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 element. Where there is justification for variation to the conformity assessment elements normally applicable to a particular device class, a statement in this regard should be included in the STED.

⁸ See definition in Section 4.0.

⁹ See GHTF/SG2 guidance documents.