



FINAL DOCUMENT

Title: Principles of Conformity Assessment for Medical Devices

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A handwritten signature in black ink, appearing to read 'Georgette Lalis'.

Georgette Lalis, GHTF Chair

The document herein was produced by the Global Harmonization Task Force, which is comprised of representatives from medical device regulatory agencies 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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Preface

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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 those regulatory means considered the 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.

¹ www.ghtf.org

2.0 Rationale, Purpose and Scope

2.1 Rationale

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-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.

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 (RA) and/or Conformity Assessment Body (CAB) in the countries and regions where the device is sold.

In general, the degree of involvement of the RA or CAB in such reviews is proportional to the risks associated with a particular category of devices.

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 conformity assessment elements 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 conformity assessment elements 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 RA, or CAB appointed by or acting on behalf of the RA, 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 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, and to the activities of the medical device manufacturer.

3.0 References

GHTF final documents

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

GHTF/SG1/N015:2006 *Principles of Medical Devices Classification.*

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

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

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

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

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

GHTF/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)*

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

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 – GHTF/SG4/N28:1999).

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*.

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 Regulatory Authority 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 – GHTF/SG1/N012:2000)

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. (Source – GHTF/SG1(PD)/N11 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*.

5.0 Conformity Assessment Elements

The conformity assessment elements that the RA may make available to the manufacturer will include: a quality management system, a system for post-market surveillance, summary technical documentation, a declaration of conformity and the registration of manufacturers and their medical devices by the RA. All five elements are required for each of the device classes. Where there are alternatives within a conformity assessment element, the manufacturer may choose the one that it believes to be the most suitable.

The conformity assessment elements that appear in this Section describe the tasks of the manufacturer and, where appropriate, the responsibilities of the RA or CAB. Specific guidance on the conformity assessment elements for each device class is provided in the tables in Section 6.2.

5.1 Conformity assessment of the quality management system

5.1.1 Quality management system

The requirements for a quality management system that is accepted by RAs for regulatory purposes and based on international recognised standards², combined 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 both customer and regulatory requirements. 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 organisation, 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.

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 system³ that includes design and development. Manufacturers of Class B devices should have a quality management system also; however, the procedures incorporated within it may not include design and development activities. Manufacturers of Class A devices are expected to have the basic elements of a QMS in place but 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.

² See definition in Section 4.0.

³ See GHTF/SG3 guidance documents

In some jurisdictions, regulatory requirements permit exclusion of design and development activities 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.

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 this will be indicated as such in the technical documentation and/or STED.

The use of type examination does not replace the need to establish and maintain a production QMS.

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

5.1.2 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, post-market vigilance reporting and corrective & preventive actions⁵.

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

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 to confirm compliance.

⁵ See GHTF/SG2 guidance documents.

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

5.2 Conformity assessment of device safety and performance

5.2.1 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 to a RA or CAB, as required by the class of the device. A description of that subset is provided in the proposed GHF 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 risk 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 attestation of conformity to the essential principles of safety and performance 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.

5.2.2 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:

- An attestation that each device that is subject to the declaration:
 - complies with the applicable *Essential Principles for Safety and Performance*,
 - has been classified according to the classification rules, and
 - 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 device⁷.
- The risk class allocated to the device/s after following the guidance found in *Principles of Medical Devices Classification*⁸.
- Which of the conformity assessment elements described in Section 5 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.

⁷ www.gmdnagency.com

⁸ See SG1/N15:2006 *Principles of Medical Devices Classification*.

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.

5.3 Registration

5.3.1 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. This registration system will identify the device/s and the party responsible for the device/s within the particular jurisdiction, thereby facilitating any regulatory activity.

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.

The RA will 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 risk 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 elements become more robust and demanding as the risk class of the device increases.

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 a conformity assessment element, 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 full QMS or a QMS without design and development controls. | Regulatory audit normally not required except in special cases, e.g. assurance of sterility & of measuring function/s. | 5.1.1 |
| | 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. | 5.1.2 |
| Conformity assessment of device safety & performance | Technical Documentation | Prepare STED and have available for review by RA upon request. | Premarket submission of STED normally not requested. | 5.2.1 |
| | Declaration of Conformity | Prepare, sign and maintain. | Submission normally not requested. | 5.2.2 |
| Registration | Registration of manufacturers and their devices | Perform according to regulatory requirements. | Maintain and verify as appropriate. | 5.3.1 |

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 full QMS or a QMS without design and development controls. | Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization. | 5.1.1 |
| | 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. | 5.1.2 |
| 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 premarket review of the STED sufficient to determine conformity to Essential Principles. | 5.2.1 |
| | Declaration of Conformity | Prepare, sign and make available for review. | Review and verify compliance with requirements. | 5.2.2 |
| Registration | Registration of manufacturers and their devices | Perform according to regulatory requirements. | Maintain and verify as appropriate. | 5.3.1 |

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 full QMS. | Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization. | 5.1.1 |
| | 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. | 5.1.2 |
| 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. | 5.2.1 |
| | Declaration of Conformity | Prepare, sign and submit. | Review and verify compliance with requirements. | 5.2.2 |
| Registration | Registration of manufacturers and their devices | Perform according to regulatory requirements. | Maintain and verify as appropriate. | 5.3.1 |

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 full QMS. | Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization. | 5.1.1 |
| | 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. | 5.1.2 |
| Conformity assessment of device safety & performance | Technical Documentation | Prepare and submit a STED for review. | Receive and conduct an in-depth premarket review of the STED to determine conformity to Essential Principles. | 5.2.1 |
| | Declaration of Conformity | Prepare, sign and submit. | Review and verify compliance with requirements. | 5.2.2 |
| Registration | Registration of manufacturers and their devices | Perform according to regulatory requirements. | Maintain and verify as appropriate. | 5.3.1 |

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. 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 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 standards⁹ 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 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 errors¹⁰;
- 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.

⁹ See definition in Section 4.0.

¹⁰ See GHTF/SG2 guidance documents.