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Principles of Conformity Assessment for Medical Devices



Department of Health
The Government of the Hong Kong Special Administrative Region
of the People's Republic of China

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1. Introduction

1.1 This document is adapted from the GHTF document SG1(PD)/N040 for the conduction of conformity assessment in accordance with the requirements of the Medical Device Administrative Control System.

2. Rationale, Purpose and Scope

2.1 Rationale

2.1.1 The MDACS is 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 controlled, are based on the safety and performance of such products throughout their life cycle.

2.1.2 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 MDACS. They are intended to provide the objective evidence of safety, performance, and benefits & risks to maintain public confidence.

2.1.3 Conformity assessment is primarily the responsibility of the medical device manufacturer. However, it is done in the context of the established MDACS requirements and both the process and conclusions are subject to further review by the Conformity Assessment Body (CAB).

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

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

2.1.6 This document provides guidance on the principles of conformity assessment for medical devices. It should be read in conjunction with the *Classification Rules for Medical Devices* under GN-01 that recommends rules to assist a manufacturer to allocate its medical device to one of four risk classes. The procedures indicated in this

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document reflect the need to make conformity assessment more rigorous as the risk class of a medical device increases.

2.2 Purpose

2.2.1 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* under GN-01;
- ✧ the procedures that should apply to each class of device such that the degree of control increases with the risk class of the medical device
- ✧ the process by which a CAB recognized by the MDCO 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

2.3.1 This document applies to all products that fall within the scope of the MDACS (please refer to *Overview of the Medical Device Administrative Control System* under GN-01).

3. References

3.1 GHTF Proposed Document SG1(PD)/N040: *Principles of Conformity Assessment for Medical Devices*

3.2 *Overview of the Medical Device Administrative Control System (GN-01)*

4. Definitions and Abbreviations

Given below are the definitions and abbreviations of some of the terms which will appear in this document. Please refer to GN-01 for the definitions and abbreviations of the terms not included in the following -

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- 4.1 **Audit** means 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.
- 4.2 **Conformity Assessment** means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the MDCO, 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* under GN-01.
- 4.3 **Conformity Assessment Body (CAB)** means a body recognized by the MDCO to engage in the performance of procedures for determining whether the relevant MDACS requirements are fulfilled.
- 4.4 **Recognised Standards** means standards deemed to offer the presumption of conformity to specific essential principles of safety and performance. They are either international standards issued by IEC or ISO or equivalent or otherwise national standards in the absence of other relevant international standards.
- 4.5 **Summary Technical Documentation (STED)** means a summary of technical documentation held or submitted for conformity assessment purposes.
- 4.6 **Technical Documentation means** 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* under GN-01.
- 4.7 **Conformity Assessment Body Recognition Scheme or CAB Recognition Scheme** means the scheme under which CABs are recognized by the MDCO under the MDACS.
- 4.8 **Conformity Assessment Certificate** means the certificate issued by the CAB to the manufacturer certifying the successful completion of the conformity assessment conducted in accordance with the MDACS requirements.
- 4.9 **Subcontractors (of a CAB)** means persons or legal entities who contract with the CAB to carry out part of the CAB's conformity assessment tasks.

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4.10 **Quality Management System** means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management that complies with the standard ISO13485.

5. Conformity Assessment Elements

A medical device is subject to conformity assessment during both design and manufacture. The conformity assessment procedures in this Section describe the tasks of the manufacturer and, where appropriate, the CAB.

5.1 Quality management system

5.1.1 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.

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

5.1.3 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 MDACS requirements.

5.1.4 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 CAB's conformity assessment process, they should assess the adequacy of this control.

5.1.5 Conformity assessment of the manufacturer's quality management system is influenced by the class of the medical device. For Class II, III and IV devices, the 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 CAB will consider any

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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.

5.1.6 Manufacturers of Class III and IV devices shall have a full quality management system that includes design and development. Manufacturers of Class II devices shall have a quality management system that need not include design and development activities.

5.1.7 Although Class I devices are outside the scope of the List of Medical Devices under the MDACS, manufacturers shall include Class I devices in their quality management system if they want to apply to become Listed Local Manufacturers under the MDACS. Please refer to GN-08 for details.

5.2 System for post market surveillance

5.2.1 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* under GN-01 through the post marketing phase. This process will include complaint handling, vigilance reporting, and corrective and preventive action.

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

5.3 Summary technical documentation

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

5.3.2 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 description of that subset is provided in the TR-001: *Summary Technical Document for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices* (STED). The extent of evidence in that STED shall increase with the class of the medical device, its complexity and the extent to which it incorporates new technology.

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5.3.3 The 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 shall 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

5.4.1 The manufacturer attests that its medical device complies fully with all applicable *Essential Principles of Safety and Performance of Medical Devices* in GN-01 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:
 - complies with the applicable *Essential Principles of Safety and Performance of Medical Devices* under GN-01,
 - has been classified according to the classification rules for Medical Devices under GN-01, and
 - Has met all the applicable conformity assessment elements.
- ✧ Information sufficient to identify the device 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 *Classification Rules for Medical Devices* in GN-01.
- ✧ The conformity assessment procedures described in this document have been applied.
- ✧ The date from which the Declaration of Conformity is valid.
- ✧ The name and address of the device manufacturer.

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- ✧ The name, position and signature of the responsible person who has been authorised to complete the Declaration of Conformity upon the manufacturer's behalf.
- ✧ Any international and/or national standards the device complies with

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

6. Conformity Assessment System

6.1 The relationship between conformity assessment and device classification

6.1.1 Each medical device shall be allocated to one of four classes in accordance with *Classification Rules for Medical Devices* under GN-01. Class I devices are the lowest risk devices, Classes II are moderate to low risk, Class III are moderate to high risk and Class IV devices present the highest risk. The level of scrutiny, evidence requirements that the device meets the *Essential Principles for Safety and Performance* under GN-01 and conformity assessment procedures become more robust and demanding for higher risk classes of devices.

6.1.2 Where there are alternatives within the conformity assessment elements, e.g. the quality management system for a Class I 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 three tables at Appendix 1 summarise conformity assessment elements that apply to Class II, III and IV devices.

7. Conformity Assessment Considerations

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

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- 7.2 The 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 only when all the following conditions are applicable:
- ✧ the device incorporates well-established technology that is present in the market;
 - ✧ the 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 CAB has particular experience with a comparable device; and
 - ✧ recognised standards are available to cover the main aspects of the device and have been used by the manufacturer.
- 7.3 Similarly, the 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 either one of the following conditions is applicable:
- ✧ 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 incidents, including use errors;
 - ✧ the device incorporates innovative or potentially hazardous materials;
 - ✧ the device type raises specific public health concerns.
- 7.4 It should be emphasised that there must be a fully justified and documented case before the CAB modifies in any way the relationship between device class and the associated conformity assessment procedure.
- 7.5 Where there is justification for variation to the conformity assessment procedures normally applicable to a particular device class, the CAB shall confirm in writing of its decision and a statement in this regard should be included in the STED.

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8. Enquiries

Enquiries concerning this booklet and the MDACS should be directed to:

Medical Device Control Office,

Department of Health,

18/F, Wu Chung House,

213 Queen's Road East,

Wanchai, Hong Kong

Facsimile number: 3157 1286

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Appendix 1

Conformity assessment elements apply to Class II devices

	Conformity Assessment Element	Manufacturer Responsibility	CAB Responsibility	Section/ Document
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 incident reporting procedure to support LRP to comply with GN-03.	Be satisfied that a current and appropriate adverse incident 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
Device Listing	Listing of Medical Devices	Perform according to MDACS requirements	Verify as appropriate. (Listing is within the purview of MDCO)	GN-05

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Conformity assessment elements apply to Class III devices

	Conformity Assessment Element	Manufacturer Responsibility	CAB Responsibility	Section/ Document
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 incident reporting procedure to support LRP to comply with GN-03.	Be satisfied that a current and appropriate adverse incident 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
Device Listing	Listing of Medical Devices	Perform according to MDACS requirements	Verify as appropriate. (Listing is within the purview of MDCO)	GN-05

Note: At the option of the manufacturer, the manufacturer of Class III devices may ask the CAB 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.

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Conformity assessment elements apply to Class IV devices

	Conformity Assessment Element	Manufacturer Responsibility	CAB Responsibility	Section/ Document
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 incident reporting procedure to support LRP to comply with GN-03.	Be satisfied that a current and appropriate adverse incident 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
Device Listing	Listing of Medical Devices	Perform according to MDACS requirements	Verify as appropriate. (Listing is within the purview of MDCO)	GN-02