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醫療儀器的規管



Regulation of
Medical Devices

**Principles of Conformity Assessment for
Medical Devices**

Technical Reference: TR-001



中華人民共和國

香港特別行政區政府衛生署

Department of Health

The Government of the Hong Kong Special Administrative Region
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1. Introduction

1.1 This document is adapted from the GHTF document GHTF/SG1/N40:2006 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-market 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 and 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 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 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

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 of Medical Devices* under GN-01;
- ✧ the conformity assessment elements 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 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

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

3. References

- 3.1 GHTF Final Document GHTF/SG1/N40:2006: *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 -

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

4.11 **Essential Principles** means the Essential Principles of Safety and Performance of Medical Devices under GN-01.

5. **Conformity Assessment Elements**

The conformity assessment elements include: a quality management system, a system for post-market surveillance, summary technical documentation, a declaration of conformity and the listing of medical devices by MDCO. All five elements are required for classes II, III and IV devices. 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 MDCO or CAB. Specific guidance on the conformity assessment elements for each device class is provided in the tables in Section 6.2.

5.1 Quality management system

5.1.1 The requirements for a quality management system that is accepted by MDCO under MDACS and based on recognized standards, combined 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 organisation, 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 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 also; however, the procedures incorporated within it may 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.
- 5.1.8 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. 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 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.

- 5.1.9 If the manufacturer chooses to use type examination by a CAB, this will be indicated as such in the technical documentation and/or STED.
- 5.1.10 The use of type examination does not replace the need to establish and maintain a production QMS.
- 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 of Medical Devices* under GN-01 through the post-marketing phase. This process will include complaint handling, vigilance reporting, and corrective & preventive actions.
 - 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-002: *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 shall increase with the risk class of the medical device, its complexity and the extent to which it incorporates new technology.
 - 5.3.3 The CAB determines the adequacy of the documented evidence in support of the manufacturer's attestation 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:

- ✧ An attestation 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.
- ✧ Which of the conformity assessment elements 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.
- ✧ 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.

5.5 Listing of medical devices by MDCO

5.5.1 Listing of classes II, III and IV devices by the MDCO through the MDACS is the current administrative control of medical devices in the market. The manufacturer shall designate or (if the manufacturer meets the requirements for becoming a Local Responsible Person) act as the Local Responsible Person itself to apply to MDCO for the listing of a medical device.

5.5.2 If the manufacturer has designated a Local Responsible Person for a device, the manufacturer shall have established a communication channel with the Local Responsible Person such that complaints, recalls and safety information regarding the device could be communicated effectively.

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 of Medical Devices* under GN-01 and conformity assessment elements become more robust and demanding as the risk classes of device increases.

6.1.2 Where there are alternatives within a conformity assessment element, e.g. the quality management system for a Class II 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 requirements relating to its conformity assessment. This may include deferring the review of the STED for Class III devices until a subsequent audit by the CAB.
- 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 already;
 - ✧ 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 element. Where there is justification for variation to the conformity assessment elements 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.

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~~ Rm 3101, 31/F, Hopewell Centre,
~~213 Queen's Road East~~ 183 Queen's Road East,
Wanchai, Hong Kong
Facsimile number: 3157 1286
Telephone number: ~~2961-8788~~ 3107 8484
E-mail address: mdco@dh.gov.hk

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 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 |
| | 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 | Maintain and verify as appropriate. (Listing is within the purview of MDCO) | GN-05 |

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 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 |
| | 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 | Maintain and verify as appropriate. (Listing is within the purview of MDCO) | GN-05 |

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 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 |
| | 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 | Maintain and verify as appropriate. (Listing is within the purview of MDCO) | GN-02 |