

# Principles of Conformity Assessment for IVD Medical Devices

## 1.0 Purpose

To describe:

- an overview of the available conformity assessment elements to demonstrate conformity 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 are proportional to the risk class of the IVD Medical Device;
- the manufacturer's responsibilities to provide evidence that the IVD Medical Device is safe and performs as intended by the manufacturer;
- the responsibilities of MDB, or Conformity Assessment Body (CAB) appointed by or acting on behalf of MDB, to confirm that the conformity assessment elements are properly applied by the manufacturer.

## 2.0 Conformity Assessment Elements

The conformity assessment elements that MDB may include in a conformity assessment system are:

- a quality management system
- a system for post-market surveillance
- summary technical documentation
- a declaration of conformity
- the registration of manufacturers and their IVD Medical Devices by the MDB.

All five elements are applicable to 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 most suitable.

The conformity assessment elements that appear in this Section describe the tasks of the manufacturer and, where appropriate, the responsibilities of the MDB or CAB. Specific guidance on the conformity assessment elements for each device class is provided in the tables in Section 3.2.

## 2.1 Quality management system (QMS)

The requirements for a quality management system that is accepted by MDB for regulatory purposes and based on international recognised standards<sup>1</sup> for medical devices, combined with the other conformity assessment elements are intended to ensure that IVD Medical Devices will be safe and perform as intended by the manufacturer.

A manufacturer needs to demonstrate its ability to provide IVD 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. The MDB/CAB should assess the adequacy of this control as part of the conformity assessment process.

The extent of the MDB/CAB assessment of the manufacturer's quality management system is influenced by the class of the IVD Medical Device.

For Class B, C and D devices, **the MDB 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 system<sup>2</sup> 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 necessarily 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 MDB or CAB.

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<sup>1</sup> SG1/N012 *Role of Standards in the Assessment of Medical Devices*

<sup>2</sup> See GHTE/SG3 guidance documents

## 2.2 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* throughout the IVD Medical Device lifecycle. This process will include complaint handling, vigilance reporting, and corrective and preventive action<sup>3</sup>.

**The MDB or CAB will confirm** that such a process is in place, usually at the time of the quality management system audit<sup>4</sup>.

## 2.3 Technical documentation

The technical documentation provides the evidence that the IVD Medical Device meets the Essential Principles.

For the purposes of conformity assessment, the manufacturer will establish a subset of technical documentation (Common Submission Dossier Template (CSDT)) to be held or submitted, as required by the class of the device. A description of that subset will be provided in the GHTF guidance document: *Common Submission Dossier Template (CSDT) for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices*. The extent of evidence in that CSDT is likely to increase with the class of the IVD Medical Device and its complexity.

**The MDB or CAB determines** the adequacy of the documented evidence in support of the manufacturer's Declaration of Conformity to the Essential Principles through a review of the CSDT. The depth and the point in time of the review is likely to be influenced by the risk class of the IVD Medical Device and its complexity.

## 2.4 Declaration of conformity

One element of the GHTF regulatory model for IVD Medical Devices requires that the manufacturer attest that its IVD Medical Device complies fully with all applicable *Essential Principles for Safety and Performance* as documented in a written 'Declaration of Conformity' (DOC).

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

- A statement that each device that is the subject of the declaration:
  - complies with the applicable *Essential Principles for Safety and Performance*,
  - has been classified according to the classification rules<sup>5</sup>, and
  - has met all the applicable conformity assessment elements.

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<sup>3</sup> See GHTF/SG2 guidance documents

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

<sup>5</sup> See SG1(PD)/N045 *Principles of IVD Medical Devices Classification*.

- Information sufficient to identify the device(s) to which the Declaration of Conformity applies.
- A Global Medical Device code and term for the device.
- The risk class allocated to the device/s after following the guidance found in *Principles of IVD Medical Devices Classification*<sup>6</sup>.
- Which of the conformity assessment procedures described in Section 3.2 have been applied.
- The date from which the Declaration of Conformity is valid.
- The name and address of the device manufacturer.
- The name, position and signature of the responsible person who has been authorised to complete the Declaration of Conformity upon the manufacturer's behalf.

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

## **2.5 Registration of manufacturers and their IVD Medical Devices by the Regulatory Authority**

Registration of both the manufacturers and their IVD 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 IVD Medical Device/s and the party responsible for the IVD Medical Device/s within the particular jurisdiction, thereby facilitating any regulatory activity.

Prior to placing an IVD Medical Device on the market, the manufacturer, its local distributor or its Authorized Representative should provide the Regulatory Authority with the required information.

**The MDB will maintain** the register.

## **3 Harmonized Conformity Assessment System**

### **3.1 The relationship between conformity assessment and device classification**

The GHTF recommends that each IVD Medical Device be allocated to one of four classes, using a set of rules as defined in the GHTF document *Principles of IVD Medical Devices Classification*. Class A devices are the lowest risk devices, Class 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 and evidence needed to demonstrate that the IVD Medical Device meets the *Essential Principles for Safety and Performance* and

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<sup>6</sup> See SG1(PD)/N045 Principles of IVD Medical Devices Classification

conformity assessment procedures should be proportional to the risk class of the IVD Medical Device.

This principle is illustrated in the tables that follow. The tables identify available conformity assessment elements and propose a combination of those elements that may be applied to different classes of IVD Medical Devices to construct a harmonized conformity assessment system that may be adopted as part of the GHTF regulatory model for IVD Medical Devices. Where there are alternatives within conformity assessment elements, e.g. the quality management system for a Class A or Class B 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.

### **3.2 Conformity assessment system**

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

**CLASS "A" DEVICE**

<b>Conformity Assessment Element</b>	<b>Manufacturer Responsibility</b>	<b>MDB / CAB Responsibility</b>	<b>Section</b>
Quality Management System (QMS)	Establish and maintain a full QMS  or  a QMS without design and development controls	Premarket regulatory audit not required.	2.1
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.	2.2
Technical Documentation	Prepare CSDT and have available for review upon request.	Premarket submission of CSDT not required. May be requested to investigate specific safety or regulatory concerns	2.3
Declaration of Conformity	Prepare, sign and maintain	On file with the manufacturer; available upon request	2.4
Registration of manufacturers and their devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	2.5

**CLASS “B” DEVICE**

<b>Conformity Assessment Element</b>	<b>Manufacturer Responsibility</b>	<b>MDB / CAB Responsibility</b>	<b>Section</b>
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.	2.1
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.	2.2
Technical Documentation	Prepare CSDT and have available for review upon request.	Premarket submission normally not required but if requested, receive and conduct a premarket review of the CSDT to determine conformity to Essential Principles.	2.3
Declaration of Conformity	Prepare, sign and submit	Review and verify compliance with requirements.	2.4
Registration of manufacturers and their devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	2.5

## CLASS "C" DEVICE

<b>Conformity Assessment Element</b>	<b>Manufacturer Responsibility</b>	<b>MDB / CAB Responsibility</b>	<b>Section</b>
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.	2.1
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.	2.2
Technical Documentation	Prepare and submit CSDT for review.	Receive and conduct a premarket review of the CSDT sufficient to determine conformity to Essential Principles.	2.3
Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.	2.4
Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	2.5

## CLASS “D” DEVICE

<b>Conformity Assessment Element</b>	<b>Manufacturer Responsibility</b>	<b>MDB / CAB Responsibility</b>	<b>Section</b>
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.	2.1
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.	2.2
Technical Documentation	Prepare and submit CSDT for review	Receive and conduct an in-depth premarket review of the CSDT to determine conformity to Essential Principles.	2.3
Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.	2.4
Registration of manufacturers and their devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	2.5

### **3.3 Conformity assessment considerations**

There are situations when characteristics of the device and/or its manufacturer may cause the MDB or CAB, by exception, to modify particular requirements of the elements of conformity assessment.

For example:

- This may include deferring the review of the CSDT for Class C devices until a subsequent regulatory audit.
- The MDB or CAB may exempt the manufacturer from making a complete premarket submission and/or require a less rigorous audit than would apply normally to a device of that class when:
  - the device incorporates well-established technology that is present in the market;
  - the MDB 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 MDB and/or CAB has particular experience with a comparable device;
  - internationally recognised standards<sup>7</sup> are available to cover the main aspects of the device and have been used by the manufacturer.

Similarly, the MDB or CAB may require more detailed premarket submission and/or require a more rigorous audit and/or the provision of more performance evaluation data 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 manufacturer's experience level with the type of IVD Medical Device is limited;
- the device type tends to be associated with an excessive number of adverse events, including use errors;
- the device incorporates innovative or potentially hazardous materials;
- the device type raises specific public health concerns.

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

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<sup>7</sup> SG1/N012 *Role of Standards in the Assessment of Medical Devices*