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MEDICAL DEVICE GUIDANCE DOCUMENT

PRINCIPLES OF CONFORMITY ASSESSMENT FOR IN- VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;

- “should” indicates a recommendation;

- “may” indicates a permission; and

- “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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Introduction

Conformity assessment is a systematic and ongoing examination of evidence and procedures to ensure the safety, performance, benefit and risk of IVD medical devices. It is also to ensure manufacturing compliance to essential principles and requirements of the Medical Device Authority (MDA). The classification of an IVD determines the conformity assessment procedures and assists the manufacturer to choose the relevant conformity assessment procedure. Conformity assessment becomes more stringent as the risk of IVD medical devices increases.

PRINCIPLES OF CONFORMITY ASSESSMENT FOR IN- VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

1 Purpose

To describe-

a) an overview of the available conformity assessment elements to demonstrate conformity to the Essential Principles of Safety and Performance for IVD Medical Devices;

b) the conformity assessment elements that shall apply to each class of device such that the regulatory demands are proportional to the risk class of the IVD Medical Device;

c) the manufacturer's responsibilities to provide evidence that the IVD Medical Device is safe and performs as intended by the manufacturer;

d) the responsibilities of MDA or Conformity Assessment Body (CAB), to confirm that the conformity assessment elements are properly applied by the manufacturer.

2 Scope

This document applies to all products that fall within the definition of an IVD medical device. Assessment of conformity shall be according to the classification rules of IVD medical devices.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 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/N028:1999).

3.2 Authorised representative

Means any natural or legal person established within a country or jurisdiction who has received a mandate from the manufacturer to act on his behalf for

specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

3.3 Conformity assessment

The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the MDA, 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 IVD Medical Devices.

3.4 Conformity assessment body (CAB)

As specified in Act 737 (Medical Device Act 2012).

3.5 Recognised standards

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

3.6 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 IVD Medical Devices*.

3.7 Regulatory authority

Means the Medical Device Authority.

4 Conformity assessment elements

Regulatory Elements of Conformity assessment for IVD medical device are as follows-

a) quality management system (QMS);

b) a system for post-market surveillance;

c) summary technical documentation;

d) a declaration of conformity;

e) registration of manufacturers and their IVD Medical Devices by the MDA.

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 MDA or CAB. Specific guidance on the conformity assessment elements for each device class is provided in the tables in *Section 5.2*.

4.1 Quality management system (QMS)

4.1.1 The requirements for a QMS that is accepted by MDA for regulatory purposes are based on international recognised standards for medical devices, combined with conformity assessment elements, intended to ensure that IVD Medical Devices will be safe and perform as intended by the manufacturer.

4.1.2 Manufacturer should demonstrate compliance and consistently meet both customer and regulatory requirement through establishment of effective implementation of QMS.

4.1.3 The scope and complexity of the QMS that manufacturer needs to establish is influenced by varying needs, objectives, the product provided, processes employed, size, structure of the organisation, and the specific MDA requirements

4.1.4 Quality management systems 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.

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

4.1.6 For IVD medical devices of Class B, C and D devices, the MDA or CAB needs to be satisfied that the manufacturer has an effective QMS in place, appropriate for the device under assessment.

4.1.7 Medical Device Authority 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

4.1.8 Manufacturers of Class C and D devices shall have a full QMS that includes design and development.

4.1.9 Manufacturers of Class B devices shall have a QMS. However, the procedures incorporated within it may not necessarily include design and development activities.

4.1.10 Manufacturers of Class A devices are expected to have a QMS in place but need not include design and development activities.

4.1.11 The QMS for manufacturers of Class A devices is normally not subject to premarket on-site audit by the MDA or CAB.

4.2 System for post market surveillance

4.2.1 Quality Management System shall be established prior to place a product on the market and ensure the IVD medical devices are assessed throughout the lifecycle and comply to the Essential Principles of Safety and performance.

4.2.2 There are few processes that shall be implemented to monitor the IVD medical devices safety and performance such as at minimum complaint handling, vigilance reporting and corrective, and prevention action.

The MDA or CAB may confirm that such a process is in place, usually at the time of QMS audit.

4.3 Summary technical documentation

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

4.3.2 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 IVD medical device.

4.3.3 The extent of evidence in that *CSDT* is likely to increase with the class of the IVD Medical Device and its complexity.

4.3.4 A description on the subset of *Common Submission Dossier Template (CSDT) for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD* Medical Devices would be available in another separate guidance document (*Refer to MDA/GD/0004: Common Submission Dossier Template (CSDT) of IVD medical devices*).

4.3.5 Regulatory authority 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*.

4.3.6 The depth and the point in time of the review are likely to be influenced by the risk class of the IVD Medical Device and its complexity.

4.4 Declaration of conformity

IVD Medical Devices manufacturers shall 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 shall contain the following information-

a) a statement that each IVD medical device that is the subject of the declaration:

i) complies with the applicable Essential Principles for Safety and Performance; ii) has been classified according to the classification rules; iii) has met all the applicable conformity assessment elements;

b) information sufficient to identify the IVD device/s to which the Declaration of conformity applies;

c) a global medical devices code and term for the device/s;

d) the risk class allocated to the device/s after following the guidance on Principles of In Vitro Diagnostic (IVD) Medical Devices Classification;

e) which conformity assessment procedures described in Section 5.2 has been applied;

f) the date from which the DOC is valid;

g) the name and address of the device manufacturer;

h) the name, position and signature of the responsible person who has been authorised to complete the DOC upon the manufacturer's behalf. Technical documentation provides the evidence that the IVD Medical Device meets the Essential Principles.

4.5 Licensing of manufacturers and registration of their IVD medical devices by the MDA

4.5.1 Licensing of the manufacturers and registration of their IVD Medical Devices by the MDA is considered to be the most basic level of regulatory control of devices in the market.

4.5.2 This registration system will identify the IVD Medical Device/s and the party responsible for the IVD Medical Device/s within Malaysia, thereby facilitating any regulatory activity.

4.5.3 Prior to placing an IVD Medical Device on the market, the manufacturer, Authorized representative (AR) shall provide the MDA with the required information.

5 Harmonized conformity assessment system

5.1 The relationship between conformity assessment and device classification

The IVD medical devices are allocated to one of four classes, using a set of rules as defined in the guidance documents of Principles of in Vitro Diagnostic (IVD) Medical Devices Classification.

Table 1. IVD medical devices risk and conformity assessment elements

IVD medical device classification	Risk	Conformity assessment elements
Class A	lowest risk devices	the quality management system for a Class A or Class B device shall be either a full quality management system or one without design and development control, the manufacturer must choose the one that it believes to be most suitable.
Class B	moderate to low risk	
Class C	moderate to high risk	Establish and maintain a full QMS
Class D	highest risk	Establish and maintain a full QMS
The level of scrutiny and evidence needed to demonstrate that the IVD Medical Device meets the *Essential Principles for Safety and Performance* and conformity assessment procedures shall be proportional to the risk class of the IVD Medical Device.		

5.2 Conformity assessment system

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

Table 2. Conformity assessment system for Class A (IVD medical devices)

CLASS "A" DEVICE **Conformity Assessment Element**	**Manufacturer Responsibility**	**MDA / CAB Responsibility**	**Section**

Quality Management System (QMS)	Establish and maintain a full QMS or a QMS without design and development controls	Premarket regulatory audit not required.	4.1.
Post Market Surveillance	Establish and maintain an adverse event reporting procedure.	May audit postmarket to investigate specific safety or regulatory concerns.	4.2.
Technical Documentation	Prepare summary of technical documentations in the format of CSDT (refer to MDA/GD/0004: CSDT) and have available for review upon request.	Premarket submission of CSDT not required. May be requested to investigate specific safety or regulatory concerns	4.3.
Declaration of Conformity	Prepare, sign and maintain	On file with the manufacturer; available upon request	4.4.
Licensing of manufacturers and registration of their IVD medical devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	4.5.

Table 3. Conformity assessment system for Class B (IVD medical devices)

CLASS "B" DEVICE **Conformity Assessment Element**	**Manufacturer Responsibility**	**MDA / CAB Responsibility**	**Section**

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.	4.1.
Post Market Surveillance	Establish and maintain an adverse event reporting procedure	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	4.2
Technical Documentation	Prepare and submit CSDT for review.	Premarket submission normally not required but if requested, receive and conduct a premarket review of the CSDT to determine conformity to Essential Principles.	4.3.
Declaration of Conformity	Prepare, sign and submit	Review and verify compliance with requirements.	4.4.
Licensing of manufacturers and registration of their IVD medical devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	4.5.

Table 4. Conformity assessment system for Class C (IVD medical devices)

CLASS "C" DEVICE **Conformity Assessment Element**	**Manufacturer Responsibility**	**MDA / CAB Responsibility**	**Section**

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.	4.1.
Post Market Surveillance	Establish and maintain an adverse event reporting procedure	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	4.2
Technical Documentation	Prepare and submit CSDT for review.	Receive and conduct a premarket review of the CSDT sufficient to determine conformity to Essential Principles.	4.3.
Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.	4.4.
Licensing of manufacturers and registration of their IVD medical devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	4.5.

Table 5. Conformity assessment system for Class D (IVD medical devices)

CLASS "D" DEVICE **Conformity Assessment Element**	**Manufacturer Responsibility**	**MDA / CAB Responsibility**	**Section**

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.	4.1.
Post Market Surveillance	Establish and maintain an adverse event reporting procedure	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	4.2
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.	4.3.
Declaration of Conformity	Prepare, sign and submit.	Review and verify compliance with requirements.	4.4.
Registration of manufacturers and their devices	Perform according to regulatory requirements	Maintain and verify as appropriate.	4.5.

Note :

CSDT of higher class medical devices shall contain more elaborated information than lower class.

The main difference for higher class is that the CSDT would be in the level of details in the clinical/performance data and details of the manufacturer's QC release program.

During the review process MDA / CAB may not require more elaborate information for lower class device. However, this does not preclude that MDA / CAB from requesting such information in specific cases.

5.3 Other conformity assessment considerations

There may be situation when MDA or CAB may modify the elements of conformity assessment based on the change in characteristic of the device and / or manufacturer.

5.3.1 This may include deferring the review of the CSDT for Class C devices until a subsequent regulatory audit.

5.3.2 Manufacturer may be exempted from making complete premarket submission and / or require a less rigorous audit that would normally apply to a device of that class when:

a) the device incorporates well-established technology that is present in the market

b) Regulatory authority and / or CAB is familiar with the manufacturer's capabilities and its products

c) the device is an updated version of a compliant device from the same manufacturer that contains little substantive change

d) Regulatory authority and / or CAB have particular experience with a comparable device;

e) Internationally recognised standards are available to cover the main aspects of the device and have been used by the manufacturer.

5.3.3 Similarly, the MDA 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-

a) the device incorporates innovative technology;

b) an existing compliant device is being used for a new intended use;

c) the manufacturer's experience level with the type of IVD Medical Device is limited;

d) the device type tends to be associated with an excessive number of adverse events, including use errors;

e) the device incorporates innovative or potentially hazardous materials;

f) the device type raises specific public health concerns.

5.3.4 It should be emphasised that there must be a fully justified and documented case before the MDA or CAB modifies in any way the relationship between device class and the associated conformity assessment procedure.

5.3.5 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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