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MEDICAL DEVICE GUIDANCE DOCUMENT

CONFORMITY ASSESSMENT FOR MEDICAL DEVICE

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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 incident 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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CONFORMITY ASSESSMENT ON MEDICAL DEVICE

0. Introduction

Conformity assessment is a systematic and ongoing examination of evidence and procedures to ensure the safety, performance, benefit and risk of medical devices. It is also to ensure manufacturing compliance to essential principles of safety and performance (EPSP) and requirements of the Medical Device Act 2012 (Act 737). The classification of a medical device determines the conformity assessment procedures to be undertaken. Conformity assessment becomes more stringent as the risk of medical device increases.

This guidance document provides:

- a) an overview of the conformity assessment elements to demonstrate conformity to the EPSP for 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 medical device;
- c) the manufacturer's responsibilities to provide evidence that the medical device is safe and performs as intended by the manufacturer;
- d) The responsibilities of the Authority or Conformity Assessment Body (CAB), to confirm that the conformity assessment elements are properly or adequately applied by the manufacturer.

1. Scope

This guidance document specifies requirements for conformity assessment of a medical devices for compliance with the requirements of the Act 737 and subsidiary regulations under it.

This document applies to all products that fall within the definition of a medical device, as defined under Section 2 of the Medical Device Act 2012 (Act 737).

2. Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Medical Device Act 2012 (Act 737)

Medical Device Regulation 2012

ISO 16142-1, *Medical devices - Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards.*

ISO 16142-2¹, *Medical devices - Recognized essential principles of safety and performance of medical devices - Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards*

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, Medical Device Regulations and the following 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

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 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 of the medical device.

3.4 conformity assessment body (CAB)

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

3.5 technical documentation

The documented evidence, normally an output of the quality management system, which demonstrates compliance of a device to the essential principles of safety and performance of medical devices.

3.6 Authority

The Medical Device Authority, Ministry of Health Malaysia.

4. Elements of conformity assessment

For the purpose of medical device registration, the following conformity assessment elements shall be assessed by the CAB:

- a) Quality management system (QMS);
- b) A system for post-market surveillance;

¹ Under development by ISO

- c) technical documentation; and
- d) A declaration of conformity.

The conformity assessment elements that appear in this clause describes the tasks of the manufacturer and, where appropriate, the responsibilities of the Authority or CAB to carry out conformity assessment. Specific requirements for assessment on conformity for each element are provided in Annex A.

4.1 Quality management system (QMS)

4.1.1 Manufacturers shall be certified with ISO 13485.

4.1.2 The scope of QMS certification will also depend on the risk class of the medical device. Refer Medical Device Regulation 2012 Third Schedule, Part III.

4.1.3 Table 1 shows the extend of QMS certification.

Table 1. Extend of QMS certification based on risk class

Risk Class	Scope of QMS
A	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 shall choose the one that it believes to be most suitable.
B	
C	Establish and maintain a full QMS
D	Establish and maintain a full QMS

4.1.4 Quality management systems carried out on the manufacturer's behalf by third parties shall remain the responsibility of the manufacturer and are subject to control under the manufacturer's QMS.

4.1.5 CAB will consider any relevant existing certification and, if not satisfied, may carry out an on-site audit of the manufacturer's facility.

Criteria for requirement to do on-site audit on manufacturer shall be included in the CAB documented procedure. Criteria for acceptance of existing certification shall include the following:

- a) QMS certificate issued by MDA registered CAB;
- b) QMS certificate issued by any notified body listed in New Approach Notified and Designated (NANDO);
- c) QMS certificate issued by certification bodies from recognised countries (US, Canada, Australia, Japan, EU); or

Decision to accept or not to accept QMS certification by certification bodies from other countries may be decided by the CAB with strong justification.

4.2 Post-market surveillance System (PMS)

4.2.1 To ensure continued conformity to medical device EPSP throughout the post-market stage, manufacturer shall ensure that a post-market surveillance system is in place.

4.2.2 For Class B, C and D medical device, CAB shall ensure an appropriate PMS is established, maintained and implemented by the establishment.

4.2.3 For the purpose of 4.2.2, the following processes shall be documented, maintained and implemented by the establishment:

- a) complaint handling;
- b) distribution records;
- c) mandatory problem/adverse event reporting;
- d) field corrective action; and
- e) recall.

For the purposes of 4.2.3 (a), (b), (c), (d) and (e), refer related MDA guidance documents.

4.3 Technical documentation

4.3.1 The technical documentation provides the evidence that the medical device meets the essential principles for safety and performance (EPSP). The manufacturer shall collect and examine evidences of conformity and compile these evidences in a technical documentation.

4.3.2 The manufacturer shall also establish a summary of the technical documentation in the form of a common submission dossier template (CSDT), which is to be held or submitted, as required depending on the class of the medical device.

4.3.3 CAB determines the adequacy of the documented evidence in support of the manufacturer's declaration of conformity to the EPSP through a review of the CSDT and technical documentation.

4.3.4 CAB shall refer to ISO 16142-1 and ISO 16142-2² for selection of standards in support of EPSP. CAB shall also identify relevant established standards applicable for the medical devices within the technical area(s) they are registered for. Use of established standards to demonstrate the compliance with EPSP shall be according to the following priority:

- 1) Malaysian Standards (MS) and/ or International Standards (i.e. ISO/IEC/ITU);
- 2) Recognised Countries Standards, i.e. US, EU, Canada, Australia and Japan; and
- 3) Industry Standards/ Company standards.

In the case the manufacturer opts to diverse from the above hierarchy, the manufacturer shall provide strong justification for its deviation.

² Under development by ISO

4.3.5 For the purpose of 4.3.3, CAB shall refer to the guidance document on the Common Submission Dossier Template (CSDT) (refer MDA/GD-03, *Common Submission Dossier Template*).

4.3.6 For review of CSDT refer Annex A.

4.4 Declaration of conformity

4.4.1 Medical Devices manufacturers shall attest that its medical device complies fully with all applicable Essential Principles for Safety and Performance and other requirements of Act 737 and the subsidiary regulations under it, documented in a written 'Declaration of Conformity' (DOC).

4.4.2 Guidance Document MDA/GD/0025 specifies requirements on Declaration of Conformity and shall be used for this purpose.

4.4.3 The CAB shall ensure that all elements are clearly stated and/or listed and the DoC has been signed by a person from the top management of the manufacturer or a person authorised to sign on his/her behalf.

5. Summary of conformity assessment

Tables 2, 3 and 4 below summarise conformity assessment elements that apply to Class A, B, C and D devices. According to Medical Device (Exemption) Order 2016, Class A medical devices are exempted from conformity assessment procedures by a CAB under Section 7 of the Act.

Table 2. Conformity assessment on Class A medical devices

Conformity assessment element	Manufacturer responsibility	Conformity assessment requirement	Clause
Quality Management System (QMS)	a) Establish and maintain a full QMS or may exclude design and development controls, process control and inspection and testing; and /or b) Keeping evidence on the aspect of manufacture concerned with: <ul style="list-style-type: none"> i. Securing and maintaining sterile condition if the medical device is to be supplied sterile: Validation report and/ or; ii. Conformity of the medical device with the metrological requirements if the medical device has a measuring function: Calibration report/certificate. 	Premarket and regulatory audit not required.	4.1.
Post-market surveillance system	a) Establish and maintain PMS system b) Record and evaluate reports of adverse events. c) document, maintain and implement: <ul style="list-style-type: none"> i. complaint handling; 	Premarket and regulatory audit not required. Regulatory audits may be conducted on	4.2.

	<ul style="list-style-type: none"> ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall. 	establishment as deemed necessary by the Authority.	
Technical Documentation	Prepare summary of technical documentations in the format of CSDT (refer to MDA/GD-03: CSDT) and have available for review upon request.	Premarket submission of CSDT not required. May be requested by the Authority for the purpose of investigating specific safety or regulatory concerns.	4.3.
Declaration of Conformity (DoC)	Prepare DoC as per specified in MDA/GD/0025.	Manufacturer/ AR to submit to Authority during registration process and to keep in file and present upon request by the Authority.	4.4.

Table 3. Conformity assessment on Class B medical devices

Conformity assessment element	Manufacturer responsibility	Conformity assessment requirement	Clause
Quality Management System (QMS)	<ul style="list-style-type: none"> a) Establish and maintain a full QMS or may exclude design and development controls, process control and inspection and testing; and b) Appoint CAB to review and conduct on-site audit if necessary, to verify evidence of conformity to QMS requirements. 	CAB shall be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit on manufacturer prior to certification.	4.1.
Post Market Surveillance	<ul style="list-style-type: none"> a) Establish and maintain PMS system. b) Record and evaluate reports of adverse events. c) document, maintain and implement: <ul style="list-style-type: none"> i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall. 	CAB shall ensure an appropriate post-market surveillance system is established, maintained and implemented by manufacturer/ AR.	4.2
Technical Documentation	<ul style="list-style-type: none"> a) Collect and examine evidence and undertake procedures to determine conformity of medical device to EPSP; b) Prepare summary of technical documentations in the format of CSDT (refer to MDA/GD-03: CSDT). 	CAB to conduct a review of the CSDT to verify evidence of compliance with EPSP requirements.	4.3.
Declaration of Conformity (DoC)	Prepare DoC as per specified in MDA/GD/0025.	CAB to review and verify adequacy of the DoC.	4.4.

Table 4. Conformity assessment on Class C and D medical devices

Conformity assessment element	Manufacturer responsibility	Conformity assessment requirement	Clause
Quality Management System (QMS)	Establish and maintain a full QMS and appoint CAB to review and assess QMS compliance.	Be satisfied that a current and appropriate QMS is in place or otherwise conduct a QMS audit on manufacturer prior to certification.	4.1.
Post Market Surveillance	<ul style="list-style-type: none"> a) Establish and maintain PMS system. b) Record and evaluate reports of adverse events. c) document, maintain and implement: <ul style="list-style-type: none"> i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall. 	CAB shall ensure an appropriate post-market surveillance system is established, maintained and implemented by manufacturer/AR	4.2.
Technical Documentation	<ul style="list-style-type: none"> a) Collect and examine evidence and undertake procedures to determine conformity of medical device to EPSP; b) Prepare summary of technical documentations in the format of CSDT (refer to MDA/GD-03: CSDT). 	CAB to conduct a review of the CSDT to verify evidence of compliance with EPSP requirements	4.3.
Declaration of Conformity (DoC)	Prepare DoC as per specified in MDA/GD/0025.	CAB to review and verify adequacy of the DoC.	4.4.

ANNEX A
(normative)

Checklist for medical device conformity assessment by CAB

A.1 The checklist for Medical Device Conformity Assessment by CAB is as per the table below. This checklist is non exhaustive and as a minimum to be adopted by the CAB and included in their audit report.

NO.	INFORMATION	COMPLIANCE			EVIDENCE /FINDING
		YES	NO	N/A	
A. CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM					
1	Conformity assessment on Class B medical devices				
(a)	Establish and maintain a full QMS <u>or may exclude design and development controls</u> , process control and inspection and testing; and appoint CAB to review and conduct on-site audit if necessary, to verify evidence of conformity to QMS requirements				
(i)	Validity and authenticity of the certificate				
(ii)	Scope of certification is sufficient for the medical device.				
(iii)	Audit report for ISO 13485				
2	Conformity assessment on Class B, C and D medical devices				
(a)	Establish, maintain and implement a <u>full QMS</u> and appoint CAB to review and conduct on-site audit to verify evidence of conformity to QMS requirements				
(i)	Validity and authenticity of the certificate				
(ii)	Scope of certification is sufficient for the medical device.				
(iii)	Audit report for ISO 13485				
	<i>Note: For establishment that do not already have ISO 13485 certificate, CAB may conduct the certification process and a separate ISO 13485 checklist shall be used.</i>				
B. CONFORMITY ASSESSMENT OF POST-MARKET SURVEILLANCE SYSTEM					
3	Conformity assessment on Class B, C & D medical devices				
(a)	Establish, maintain and implement				

	PMS system					
(b)	Review record and evaluate reports of adverse events.					
(c)	Establish, maintain and implement:					
	i. complaint handling;					
	ii. distribution records;					
	iii. mandatory problem/adverse event reporting;					
	iv. field corrective action; and					
	v. recall					
(d)	List of reported ongoing incidents globally (if applicable)					
(e)	List of incidents that have been resolved for 5 years (if applicable)					
(f)	Date of last audit					
C. CONFORMITY ASSESSMENT OF TECHNICAL DOCUMENTATION						
Elements of Commission Submission Dossier Template						
4	Executive summary					
(a)	Overview					
	i. medical device description					
	ii. Novel features					
	iii. Synopsis of the content of CSDT					
(b)	Commercial Marketing History					
	i. List of countries where the medical device is marketed, date of introduction to those countries					
(c)	Intended use in its label					
(d)	Indication in its label					
(e)	List of regulatory approval or marketing clearance from other countries with the following information/documents					
	i. registration status,					
	ii. intended use,					
	iii. indications					
	iv. copies of certificates/ approvals,					
	v. declaration on label, packaging and IFU					
(f)	Status of any pending application for regulatory approval or marketing clearance					
(g)	Important safety and performance					

	related information:					
	i. summary of reportable adverse events and field corrective actions,					
	ii. Description of medical device if contain animal, human cells, tissues and /or derivatives, thereof, rendered non-viable cells, tissues and/or derivatives of microbial or recombinant origin, irradiating components, ionising or non-ionising.					
(h)	Company stamp, signed by designated person, and dated					
5	Relevant Essential Principles and Method Used to Demonstrate Conformity					
(a)	Determine all the relevant Essential Principle that are applicable to the medical device, taking into account the intended purpose of the device.					
(b)	The specific documents shall be referenced in the element of CSDT to support the rule used to demonstrate conformity to the essential principles					
	i. Compliance with standards according to 4.3.4. Are applicable standards applied in full? (Consider that if standards are referenced on the declaration of conformity, all applicable parts of the standards must be fulfilled)					
	ii. Internal industry methods					
	iii. Comparison to other similar marketed device					
(c)	The essential principle conformity checklist is to be prepared based on the list of essential principle referred to MDR 2012 and MDA/GD-02- Essential Principle of Safety & Performance of Medical Device, First Edition March 2014					
6	Description of medical device;					
(a)	A complete description of the medical device					
(b)	Principles of operation or mode of action					
(c)	Risk class and applicable classification rule					
(d)	A description of the accessories					

(e)	A description or complete list of the various configurations (same with grouping)				
(f)	A complete description of the key functional elements				
(g)	An explanation of any novel features				
(h)	Where appropriate, this will include labelled pictorial representation				
(i)	Intended use				
(j)	Indications				
(k)	Instructions of use				
(l)	Contraindications				
(m)	Warnings				
(n)	Precautions				
(o)	Potential adverse effects				
(p)	Alternative therapy				
(q)	Materials				
(r)	Other relevant specifications and descriptive information				
7	Summary of design verification and validation documents shall include:				
(a)	Declarations/certificates of conformity to the "recognized" standards listed as applied by the manufacturer; and/or				
(b)	Summaries or reports of tests and evaluations based on other standards, manufacturer rules and tests, or alternative ways of demonstrating compliance. The data may cover:				
	i. A listing of and conclusions drawn from published reports that concern the safety and performance.				
	ii. engineering tests				
	iii. laboratory tests (e.g: sterility tests, metrology tests, etc)				
	iv. biocompatibility tests;				
	v. animal tests;				
	vi. simulated use;				
	vii. software validation				
8	Pre-clinical studies (if the device is invasive and/or in contact with patient)				

	Reports containing information on the objectives, methodology, result, discussion and conclusion of the testing and/or certification and/or declaration of:					
(a)	Biocompatibility test conducted on materials used in a medical device					
(b)	Pre-clinical physical tests conducted on the medical device					
(c)	Pre-clinical animal studies to support the probability of effectiveness in humans.					
9	Software validation studies					
a)	Documentation on software validation studies. i. Objective evidence that validates the software design and development process ii. results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, and representative data generated from both testing environments					
10	Medical devices containing biological material					
(a)	A list of all materials of animal, human, microbial and/or recombinant origin used in the medical device and in the manufacturing process of the medical device. This includes animal or human cells, tissues and/or derivatives, rendered non-viable and cells, tissues and/or derivatives of microbial or recombinant origin;					
(b)	Detailed information concerning the selection of sources/donors;					
(c)	Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;					
(d)	Process validation results to substantiate that manufacturing procedures are in place to minimise biological risk in particular, with regard to viruses and other transmissible agents					
(e)	Full description of the system for record keeping allowing traceability from sources to the finished medical					

	device.					
(f)	Selection of relevant tests, justification available for not doing certain tests, results of testing, reference standard for testing and if not current, justification and gap analysis					
(g)	Test Report /certification from accredited Laboratory; e.g. OECD, ISO 17025					
	(i) Shelf life report					
11	Clinical Evidence <i>Note: This section should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of the medical device when used as intended by the manufacturer</i>					
(a)	A systematic review of existing bibliography					
(b)	Clinical experience with the same or similar devices, or					
(c)	Detailed checklists for clinical evaluation / investigation in separate forms – refer to ISO 14155					
12	Use of existing bibliography					
(a)	Copies of all literature studies, or existing bibliography to support safety and effectiveness.					
(b)	Bibliography shall be derived from relevant publication in peer-reviewed scientific literature containing:					
	i. Objective					
	ii. methodology					
	iii. Result presented in context, clearly and meaningfully					
(c)	The conclusion on the outcome of clinical studies should be preceded by a discussion in context with published literature					
13	Medical device labelling					
(a)	Sample of labelling is provided <i>Note: Labelling complies with requirements as per MDA/GD/0026 – guidance Document on requirement for labelling of medical device.</i>					
14	Risk analysis/ Risk Management file					

(a)	Risk management report demonstrated conformance with ISO 14971					
15	Manufacturing Information					
(a)	Documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the medical device. Manufacturing process shall include resources and activities that transform input into the desired output.					
D. DECLARATION OF CONFORMITY						
16	Prepare declaration of conformity as per specified in MDA/GD/0025.					
(a)	Name and address of manufacturer and printed on company letterhead					
(b)	Name of Person Responsible/ Manufacturer					
(c)	Particular of medical device:					
	i. Generic Name					
	ii. Specified Name					
	iii. Brand / Model					
	iv. Manufacturer					
	v. Country of Origin					
	vi. Manufacturing Site					
	vii. Risk-based classification					
	viii. Classification rule					
	ix. GMDN Code					
	x. Medical Device Registration Code/ Approval number (e.g: CE marking code, USFDA approval number, etc)					
(d)	QMS certificate					
	i. Conformity Assessment Body issuing the certificate					
	ii. Certificate Number					
	iii. Issuance Date					
	iv. Expiry Date					
(e)	List of all standards (vertical and horizontal standard) applicable for the medical device.					

(f)	Name & Position i. The name and position of top management ii. Company Stamp					
(g)	Signature and date of Signatory					

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ANNEX B
(normative)

Full conformity assessment report template

B.1 CAB shall prepare a report following full assessment of a medical device as per the template below.

CAB Letterhead

Conformity Assessment Report

Details of CAB	
Name of CAB	
Address	
CAB Registration number	
Medical Device Technical Area (Code)	
Details of Establishment applying for Full Conformity Assessment Process	
Manufacturer/AR Name:	
Manufacturer/AR Address:	
Establishment License No:	
Details of Medical Device	
Name of medical device	
Classification and classification rules	
Manufacturer of medical device	
Grouping of medical device (single, family, system, set or IVD cluster)	

Prepared by:
Name and signature of technical personnel
Date:

B.2 The checklist in Annex A shall be attached as Attachment 1 to this report.

ANNEX C
(normative)

Certificate of Conformity Template

C.1 CAB shall prepare a Certificate of Conformity following successful assessment of a medical device as per the template below.

< CAB Name & Logo >

Certificate of Conformity

This is to certify that : < Name of client >
< Address of client >

Holds certificate No: < Certificate No >

Has met the requirement of

For the following medical device

< list of medical device, class, rule and manufacturer >

For and behalf of < Name of CAB >

Signed by: < Certification Manager >

Effective Date:

Expiry Date:

CAB registration number:

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