MDA/GD/0031
October 2017
First Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

CONFORMITY ASSESSMENT FOR MEDICAL DEVICE

Contents Page

Preface iii

1 Introduction 1

2 Scope 1

3 Normative references 1

4 Term and definitions 2

5 Elements of conformity assessment 3

5.1 Quality management system (QMS) 3

5.2 Post-market surveillance System (PMS) 4

5.3 Technical documentation 4

5.4 Declaration of conformity 5

6 Summary of conformity assessment 5

ANNEX A: Checklist for medical device conformity assessment by CAB 8

ANNEX B: Full conformity assessment report template 23

ANNEX C: Certificate of Conformity Template 24

Table 1: Extend of QMS certification based on risk class 3

Table 2: Conformity assessment on Class A medical devices 5

Table 3: Conformity assessment on Class B medical devices 6

Table 4: Conformity assessment on Class C and D medical devices 7

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.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
Fax: (03) 8230 0200
Email: mdb@mdb.gov.my
Website: http://www.mdb.gov.my

CONFORMITY ASSESSMENT ON MEDICAL DEVICE

1. 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.

2. Scope

This guidance document specifies requirements for conformity assessment of a medical devices for the purpose of medical device registration by the manufacturer or authorised representative, to demonstrate 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), which require full conformity assessment.

3. 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 16142-2[1], *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*

4. Terms and definitions

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

4.1 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).

4.2 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.

4.3 Authority

The Medical Device Authority, Ministry of Health Malaysia.

4.4 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.

4.5 conformity assessment body (CAB)

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

4.6 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.

4.7 third parties

[1] Under development by ISO

For the purpose of 5.1.4, third parties are manufacturing facilities that undertake manufacturing of medical device on behalf of a manufacturer.

5. 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;

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.

5.1 Quality management system (QMS)

5.1.1 Manufacturers shall be certified with ISO 13485.

5.1.2 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.

5.1.3 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

5.1.4 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.

5.1.5 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 valid justification.

5.2 Post-market surveillance System (PMS)

5.2.1 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.

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

5.2.3 For the purpose of 5.2.2, 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 5.2.3 (a), (b), (c), (d) and (e), refer related MDA guidance documents.

5.3 Technical documentation

5.3.1 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.

5.3.2 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.

5.3.3 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.

5.3.4 CAB shall refer to ISO 16142-1 and ISO 16142-2[2] 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:

a) Malaysian Standards (MS) and/ or International Standards (i.e. ISO/IEC/ITU);

b) Recognised Countries Standards, i.e. US, EU, Canada, Australia and Japan; and

c) Industry Standards/ Company standards.

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

5.3.5 For the purpose of 5.3.3, CAB shall refer to the guidance document on the Common Submission Dossier Template (CSDT) (refer MDA/GD/0008, *Common Submission Dossier Template*).

5.3.6 For review of CSDT refer Annex A.

5.4 Declaration of conformity

5.4.1 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).

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

5.4.3 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.

6. 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/AR responsibility	Conformity assessment requirement	Clause
Quality Management System	a) Establish and maintain a full QMS or may exclude design and development	Premarket and regulatory audit not required.	5.1.

[2] Under development by ISO

(QMS)	controls, process control and inspection and testing; and /or b) Keeping evidence on the aspect of manufacture concerned with: 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.		
Post-market surveillance system	a) Establish and maintain PMS system b) Record and evaluate reports of adverse events. c) document, maintain and implement: i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall.	Premarket and regulatory audit not required. Regulatory audits may be conducted on establishment as deemed necessary by the Authority.	5.2.
Technical Documentation	Prepare summary of technical documentations in the format of CSDT (refer to MDA/GD/0008: 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.	5.3.
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.	5.4.

Table 3. Conformity assessment on Class B medical devices

Conformity assessment element	Manufacturer/AR 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 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.	5.1.
Post Market Surveillance	a) Establish and maintain PMS system.	CAB shall ensure an appropriate post-market	5.2

	b) Record and evaluate reports of adverse events. c) document, maintain and implement: i. complaint handling; ii. distribution records; iii. mandatory problem/adverse event reporting; iv. field corrective action; and v. recall.	surveillance system is established, maintained and implemented by manufacturer/ AR.	
Technical Documentation	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/0008: CSDT).	CAB to conduct a review of the CSDT to verify evidence of compliance with EPSP requirements.	5.3.
Declaration of Conformity (DoC)	Prepare DoC as per specified in MDA/GD/0025.	CAB to review and verify adequacy of the DoC.	5.4.

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

Conformity assessment element	Manufacturer/AR 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.	5.1.
Post Market Surveillance	a) Establish and maintain PMS system. b) Record and evaluate reports of adverse events. c) document, maintain and implement: 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	5.2.
Technical Documentation	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/0008: CSDT).	CAB to conduct a review of the CSDT to verify evidence of compliance with EPSP requirements	5.3.
Declaration of Conformity (DoC)	Prepare DoC as per specified in MDA/GD/0025.	CAB to review and verify adequacy of the DoC.	5.4.

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 or may exclude design and development controls, 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 full QMS 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					
	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.					
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						
C.1 Elements of Commission Submission Dossier Template for General Medical Device						
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 by manufacturer, 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 5.3.4. 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/0007-Essential Principle of Safety and Performance of Medical Device					
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 *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*					
(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 *Note: Labelling complies with requirements as per MDA/GD/0026 – guidance Document on requirement for labelling of medical device.*					
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.					
C.2 Elements of Commission Submission Dossier Template for IVD Medical Device						
16	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:					
	iii. summary of reportable adverse events and field corrective actions, If there have not been adverse events of FSCAs to date, an attestation that this is the case required					
(h)	Company stamp, signed by designated person by manufacturer, and dated					
17	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 5.3.4. 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					
18	Description of medical device;					
(a)	A general description of the principle of assay method or instrument principles of operation.					
(b)	A description of all components of the IVD medical device, including but not limited to:					
	i. antibodies, antigens, nucleic acid primers;					
	ii. buffers, assay controls and calibrators;					

	iii. substrates used to detect antigen-antibody complexes; and					
	iv. reagents provided with the IVD medical device or recommended for use					
(c)	A description of the specimen collection and transport materials provided with the IVD medical device or recommended for use.					
(d)	A description or complete list of various configurations of the IVD medical device to be registered as a family/ system, if applicable. For example, a family of pregnancy rapid test can consist of device available in different configurations, such as a test strip or in a cassette.					
(e)	A description of the accessories, other IVD medical devices and other products that are not IVD medical devices, which are intended to be used in combination with the IVD medical device. For example, a lancet, which is a medical device and not an IVD medical device that is provided in the package to the user to perform a test. Note: Supporting documents, in CSDT format, must be provided for the medical device accompanying the IVD medical device.					
19	Intended Use					
	i. Type of analyte or measure and of the assay.					
	ii. Whether the test is quantitative or qualitative.					
	iii. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring.					
	iv. Disease or condition that the test is intended for					
	v. Type of specimen to be used e.g. serum, plasma etc.					
	vi. The intended users (e.g. self-testing by lay person, near-patient by trained personnel or professionals					

	vii. Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry					
	viii. The specific name of the instrument required for the assay, if any.					
	ix. For instruments, the intended use shall also include the modes of operation for instruments e.g., random access, batch, stat, open tube, closed tube, automatic, manual.					
20	Instruction of use					
21	Warnings					
22	Precautions					
23	Materials					
(a)	All components of the IVD medical device shall be listed and chemically and biologically characterised, including antibodies, antigens, assay controls, substrates used to detect antigen-antibody complexes, and test reagents. Appropriate references shall be cited.					
(b)	If synthetic peptides are used, the peptide sequence shall be provided					
(c)	If components are of biological origin or recombinant, the source must be indicated and details on production must be provided. These details would include the strain of the virus, the cell line for cultivation of the virus, sequences of relevant nucleic acids and amino acids, etc., used in the manufacturing process of viral lysate, purified proteins, recombinant and synthetic proteins.					
(d)	If applicable, process validation results to be provided to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents. This also includes inactivation of infectious organisms in reagents and the production of reagents.					
(e)	if applicable, information to be provided on irradiating components, nonionising or ionising (e.g. Iodide-131 in the Radioimmunoassay kit,					

	radio-labelled Phosphorus-32 DNA probes in Southern blots)					
(f)	if applicable, information to be provided on the poison or controlled substance (e.g. Buprenorphine in drug assay kit).					
24	Other relevant Specifications					
(a)	The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.					
25	Other descriptive Information					
(a)	The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles					
26	Product verification and Validation					
(a)	Pre-clinical Studies The pre-clinical studies provided should include information on study design, complete test or study protocols, methods of data analysis, data summaries and study conclusions. The most common characteristics that must be validated should include but are not limited to:					
	i. Analytical Sensitivity					
	ii. Analytical Specificity and Interference					

	iii. Precision (Repeatability /Reproducibility)					
	iv. Linearity/Assay's Measuring (Reportable) Range					
	v. Traceability, & Expected Values					
	vi. Cut-off Value					
	vii. Trueness					
	viii. Stability of reagent					
	ix. Specimen stability					
	x. Performance Characteristics for Instrument (if applicable):					
	xi. Accuracy					
	xii. Precision/Reproducibility					
	xiii. Linearity					
	xiv. Carryover					
	xv. Interfering Substances					
	xvi. Projected useful life					
	xvii. Software Verification and Validation Studies					
(b)	Clinical Evidence The clinical evidence to be provided shall include the information mentioned in this section. For any IVD medical device, if discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, using one or more of the following approaches:-					
	i. evaluation of the discrepant sample in further test systems,					
	ii. use of an alternative method or marker,					
	iii. a review of the clinical status and diagnosis of the patient,					
	iv. the testing of follow-up-samples.					
	v. Clinical (Diagnostic) Sensitivity					
	vi. Clinical (Diagnostic) Specificity					
	vii. Comparison Studies Using Clinical Specimens (Method comparison: All performance evaluations shall be carried out					

	in direct comparison with an established state of the art IVD medical device. The established product for comparison must have obtained marketing clearance from the reference agencies, namely Australia TGA, Canada TPP, Europe, Japan MHLW, and US FDA.					
(c)	Result shall include:-					
	i. Description on the overall results and/or results from specific sites and patient groups, as appropriate					
	ii. For quantitative tests, information such as slope and intercept (with confidence intervals), correlation coefficient, measure of scatter around the regression line, measure of bias at medical decision levels					
	iii. In some cases, a graph (x-y graph or bias plot) can be included, and					
	iv. For qualitative or semi-quantitative tests, per cent agreement with comparator for positive/negative samples, confidence intervals.					
(d)	Matrix comparison:					
	i. for each matrix in the intended use, the method for comparison or determination of accuracy, and					
	ii. sample types tested, number of samples, sample range or target concentrations tested and calculations/statistical methods					
	iii. Results/Acceptance criteria shall include: the accuracy of the new matrix or results of the matrix comparison					
(e)	Clinical Cut-off					
	i. The established cut-off and its validation for the new IVD medical device; and					
	ii. If applicable, the “equivocal zone” is to be defined, and include a description of how results within this zone are reportable to the user					

(f)	Reference Interval (Expected Values)					
	i. The reference interval for this measured and the method used to determine it;					
	ii. Additional requirements for IVD medical device for self-testing and near patient testing (if applicable)					
(g)	USE of Existing Bibliography					
27	Device labelling					
(a)	Sample of labelling is provided Note: Labelling complies with requirements as per MDA/GD/0026 – guidance Document on requirement for labelling of medical device.					
	i. Labels on the device and its packaging;					
	ii. Instructions for use;					
28	Risk analysis/ Risk Management file					
(a)	Risk management report demonstrated conformance with ISO 14971					
29	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					

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

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website: http://www.mdb.gov.my