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MEDICAL DEVICE GUIDANCE DOCUMENT

CONFORMITY ASSESSMENT BODY (CAB) GUIDE FOR CONDUCTING CONFORMITY ASSESSMENT BY WAY OF VERIFICATION

DRAFT FOR PUBLIC COMMENT
20/10/2026 - 12/11/2026

For initial certification assessment for new medical device registration and recertification assessment for medical device re-registration

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) as a guidance for Conformity Assessment Bodies (CAB) to conduct conformity assessment process by way of verification for initial and recertification assessment for the purpose of medical device registration in Malaysia.

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);
b) Medical Device Regulations 2012;
c) Circular Letter No. 2/2025 Conformity Assessment Procedures for Medical Device Approved by Recognised Countries

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 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 into ensuring 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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REVISION HISTORY

No	Edition no.	Section	Description of changes	Published date
	First	All	Initial release	March 2025
1	Second	4.3 Conformity Assessment Pathways	Removed 'has been marketed for at least one year in the respective agencies' jurisdictions; and' under Verification (initial certification assessment)	8 September 2025
2		Table 2 : Schemes/ programs exempt from verification pathway for medical device	Added schemes or programs not subject to verification pathways for Singapore and Thailand	
3		APPENDIX 1 (normative) RECOGNIZED REGULATORY AUTHORITIES OR NOTIFIED BODIES	Added Singapore and Thailand as recognised regulatory authorities	
4		APPENDIX 2 (informative) CONFORMITY ASSESSMENT ELEMENTS REVIEW AND VERIFICATION CRITERIA FOR CONFORMITY ASSESSMENT BY WAY OF VERIFICATION PROCESS FOR CLASS B, C AND D INITIAL CERTIFICATION AND RECERTIFICATION ASSESSMENT	Added in: evidence of pre-market clearance or approval for Singapore and Thailand under RECOGNISED REGULATORY AUTHORITY OR NOTIFIED BODY DETAILS. MDSAP under QMS certificate information in CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM Editorial changes from CER to CPR under Clinical performance for in-vitro medical devices	
5		APPENDIX 3 CONFORMITY ASSESSMENT REPORT FOR MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC DEVICES (by way of verification on evidence of conformity) FOR INITIAL	Added in evidence of pre-market clearance or approval for Singapore and Thailand under RECOGNISED REGULATORY AUTHORITY OR NOTIFIED BODY DETAILS. Removed 'to 5 years' from Post market surveillance & vigilance report for the past 3~~ to 5~~ years	

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		CERTIFICATION ASSESSMENT	under SECTION 6: CONFORMITY ASSESSMENT ON POST MARKET SYSTEM. Rephrased from 'yes or no' to 'provide summary/conclusion' under Summary/conclusion of the overall assessment on the clinical safety and efficacy, risk/benefit assessment: in SECTION 7: CONFORMITY ASSESSMENT ON TECHNICAL DOCUMENTATION	
6	**Second**	APPENDIX 5 CONFORMITY ASSESSMENT REPORT FOR MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC DEVICES (by way of verification on evidence of conformity) FOR RECERTIFICATION ASSESSMENT	Removed 'to 5 years' from Post market surveillance & vigilance report for the past 3~~ to 5~~ years under SECTION 6: CONFORMITY ASSESSMENT ON POST MARKET SYSTEM. Rephrased from 'yes or no' to 'provide summary/conclusion' under Summary/conclusion of the overall assessment on the clinical safety and efficacy, risk/benefit assessment: in SECTION 7: CONFORMITY ASSESSMENT ON TECHNICAL DOCUMENTATION	
7	**Draft public comment**	1.Introduction 2.Scope and application 3.Conformity Assessment Procedure	Updated the latest circular letter MDA Circular Letter No. 2 of 2025	20/10/2026
		APPENDIX 2 CONFORMITY ASSESSMENT ELEMENTS REVIEW AND VERIFICATION CRITERIA FOR CONFORMITY ASSESSMENT BY WAY OF VERIFICATION PROCESS FOR CLASS B, C AND D INITIAL CERTIFICATION AND RECERTIFICATION ASSESSMENT	Adding the following statement : - Pre-clinical studies should be conducted in the accredited laboratories under Section Conformity Assessment On Technical Documentation (Pre-clinical Studies) Adding the following notes : Clinical performances should be conducted in the accredited laboratories under Section Conformity Assessment On Technical Documentation (Clinical performance for in-vitro medical devices)	

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CONFORMITY ASSESSMENT BODY (CAB) GUIDE FOR CONDUCTING CONFORMITY ASSESSMENT BY WAY OF VERIFICATION

1. Introduction

Section 7 of Act 737 mandates that medical devices undergo a conformity assessment process to ensure compliance with legal requirements before registration. The process needs to be conducted by the registered conformity assessment bodies (CAB) to ensure that the medical device is safe and performs as intended by the manufacturer and further conforms to the Essential Principles of Safety and Performance. This process is time consuming.

Since most medical devices have already undergone conformity assessments and been approved for marketing in certain countries, the MDA has established a policy to simplify the conformity assessment process for devices approved in MDA-recognised countries. The policy on conformity assessment by way of verification, outlined in MDA Circular Letter No. 2 of 2025 titled Conformity Assessment Procedures for Medical Devices Approved by Recognised Countries, aims to streamline the registration process and shorten the time needed for conformity assessment.

This recognition eliminates the need to repeat the conformity assessment process and approval for a medical device, thereby simplifying the process, reducing costs, and speeding up the registration of medical devices in Malaysia.

Medical devices that have obtained approval for marketing in recognised countries may undergo a conformity assessment by way of verification to assess the compliance to the EPSP through verification of evidence provided by the manufacturer. The verification process will be carried out by a registered CAB in accordance with the procedure detailed out in this guidance document. This document aims to provide guidance to conformity assessment bodies (CAB) registered under the Act 737 to conduct conformity assessment by way of verification.

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2. Scope and application

This guidance document outlines the requirements for the verification process for class B, C, and D medical devices that have been approved by the regulatory authorities or notified bodies recognised by MDA, as written in the MDA Circular Letter No. 2 of 2025. Class A medical devices are exempt from the conformity assessment procedure conducted by a CAB, as specified in the Medical Device (Exemption) Order 2024.

This document also provides guidance on conducting the conformity assessment process for the following types of submissions:

Application type	Conformity assessment by way of verification
a) new medical device registration	Initial certification assessment
b) medical device re-registration	Recertification assessment

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations, the order

and circular letter under it and the following terms and definitions apply.

3.1 Authority

Refers to the Medical Device Authority established under the Medical Device Authority Act 2012 (Act 738).

3.2 Conformity Assessment Body

Conformity assessment body registered under section 12 of the Medical Device Act 2012 (Act 737).

3.3 conformity assessment

The technical term given to the process of evaluation and evidence generated and procedures undertaken by the manufacturer, under the requirements established by the Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to essential principles of safety and performance for medical devices [Regulation 2 - Medical Device regulations 2012].

3.4 manufacturer

As defined in Section 2 of the Medical Device Act 2012 (Act 737).

3.5 Authorized Representative (AR)

As defined in Section 2 of the Medical Device Act 2012 (Act 737).

3.6 initial certification assessment

The process to verify the conformity assessment and approval granted to a medical device applying for new registration meets the requirements outlined in Act 737 and its associated regulations.

3.7 recertification assessment

The process to verify the conformity assessment and approval granted to a medical device applying for medical device re-registration meets the requirements outlined in Act 737 and its associated regulations.

3.8 recognised regulatory authorities or notified bodies

Competent regulatory authorities or notified bodies recognised by MDA as listed in the Appendix 1 that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and can take legal action to ensure that medical devices marketed within its jurisdiction comply with legal requirements.

Note: Refer Circular Letter No. 2/2025: Conformity Assessment Procedures for Medical Device Approved by Recognised Countries

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4. Conformity assessment procedure

Part II of the Third Schedule of Medical Device Regulation 2012 addresses the requirements of conformity assessment procedure as follows;

I. For locally made medical devices, the manufacturer shall collect and compile all evidence of conformity of the medical devices to demonstrate the compliance to registration requirements,
II. For imported medical devices, the AR shall provide all evidence of conformity of the medical devices collected from the manufacturer to demonstrate the compliance to registration requirements.

Note: Evidence of conformity shall include conformity to requirements on QMS, PMS, technical documentation and DoC and shall be compiled based on CSDT elements.

An establishment shall appoint a Conformity Assessment Body (CAB) with expertise in the relevant Medical Device Technical Areas, to perform conformity assessment of the medical devices. For medical devices that have obtained premarket approval from any recognised regulatory authorities or notified bodies, as stated in the MDA Circular Letter No. 2 of 2025, conformity assessment by way of verification shall be conducted by the CAB in accordance with the requirements detailed out in this guideline.

4.1 Conformity assessment pathways

The conformity assessment pathways and eligibility criteria for class B, C and D medical devices to undergo the assessment pathway are outlined in Table 1 below:

Table 1: Conformity assessment evaluation pathways for class B, C and D medical devices

Conformity assessment pathway	Medical device eligibility
Full	The medical device has not obtained approval from any recognised regulatory authorities or notified bodies.
Verification (Initial certification assessment)	The medical device; ● has obtained an approval from at least one of recognised regulatory authorities or notified bodies; and ● has the same design, intended purpose with the medical device approved by the recognised regulatory authorities or notified bodies, and ● has no safety issues globally associated the use of medical device when used as intended by the manufacturer, in the last one year, defined as: ○ No reported deaths; ○ No reported serious deterioration in the state of health of any person; and ○ No open field safety corrective actions (including recalls) at the point of submission; and Note: All incident reporting and corrective and preventive actions have been closed. ● has not been rejected or withdrawn by any recognised regulatory authorities or notified bodies
Verification (recertification assessment)	The medical device; ● has been assessed its conformity via full conformity

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	assessment or verification pathways and registered with MDA; and ● has valid registration certificate prior to recertification assessment by CAB; and ● has not undergone any changes in design, specifications, features, or registration-related information, unless it is notified to MDA; and ● has not had its registration rejected or canceled by the MDA.

The medical device shall undergo a full conformity assessment if the approval from a recognised regulatory authority or notified body has been canceled or invalidated.

The verification pathway does not apply to medical devices that receive special authorization to access the market under the following scheme/program, including but not limited to those listed below:

Table 2: Schemes/ programs do not apply to verification pathway for medical device

Countries/Regulatory Authority	Scheme/program
US/Food and Drug Administration (FDA)	● Emergency Use Authorization (EUA) ● Expanded Access (Emergency /Compassionate Use) ● Humanitarian Device Exemption (HDE)
European Union/National Competent Authorities	Exceptional Use Authorization
United Kingdom/Medicines and Healthcare products Regulatory Agency (MHRA)	Exceptional Use Authorizations
Canada/Health Canada	● Special Access Program (SAP) ● *Interim Order (IO)
Japan/Pharmaceuticals and Medical Devices Agency (PMDA)	● Compassionate Use System ● *Emergency Regulatory Pathway
Australia/Therapeutic Goods Administration (TGA)	● Special Access Scheme (SAS) ● Authorised Prescriber Scheme ● *Emergency Exemptions
Singapore/Health Science Authority (HSA)	Special Access Routes
Thailand/Food and Drug Administration (Thai FDA)	Exemptions for the manufacture or import of medical devices for non-commercial purposes, as stipulated in Section 27 of Medical Device Act.

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Notes:
1) These schemes/programs provide temporary authorization for unapproved medical devices to enter the market for emergency use, ensuring patients could access essential medical devices in critical or urgent situations.
2) *Special approval/permission given to access the market during COVID-19 pandemic.

4.1.1 Conformity assessment process flow chart

An overview of the conformity assessment process is described in the following **Figure 1**.

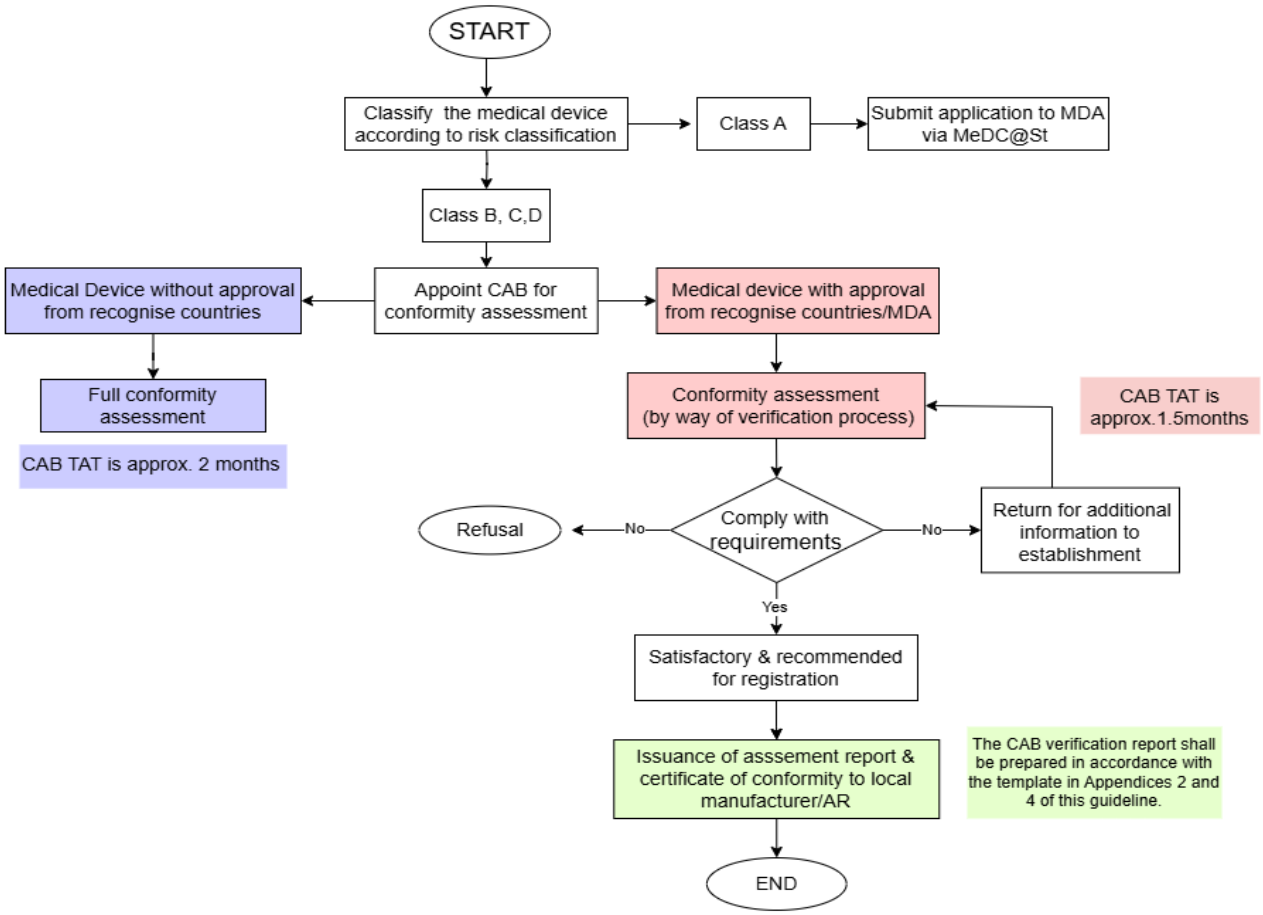


Figure 1: Process flow of conformity assessment procedure by CAB

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4.2 Criteria and roles of CAB in conformity assessment by way of verification

Section 10 of Act 737 prescribes that conformity assessment of medical devices shall be carried out by CAB. Hence, it is pertinent that the CAB shall carry out the conformity assessment with due diligence and adhere to all regulatory requirements as stipulated in Act 737 and its subsidiary legislations.

The CAB shall be independent and impartial with regard to the performance of its conformity assessment duties as stipulated in Section 10(3)(a) of Act 737 and paragraphs 9(2) and 9(7) of the Fourth Schedule of MDR 2012. The following criteria shall apply for the eligibility of CAB for performing a conformity assessment of a medical device by way of a verification process:

a. The CAB shall be registered under the Medical Device Act 2012 (Act 737);
b. For medical devices that have been subjected to conformity assessment by recognised regulatory authorities or notified bodies, the verification process of the said medical device shall be carried out by CAB registered under Act 737;

c. Where a medical device has its conformity assessment already carried out by any other regulatory authorities recognised by MDA from time to time, then the criteria in (b) shall apply;
d. The CABs which are eligible to conduct conformity assessment by way of a verification process shall be registered with at least one scope under the Medical Device Technical Area as specified in Appendix 1 of the Fourth Schedule of MDR2012.

Example: A CAB with registered scope of MD 0203 may conduct verification process on a medical device under any Medical Device Technical Areas

e. There is no longer any restriction preventing a subsidiary of a recognised regulatory authorities or notified body registered as a CAB in Malaysia from conducting the verification on the same device assessed by the foreign notified bodies. As such, while the restriction has been lifted, CAB will still need to ensure they have robust mechanisms in place to maintain impartiality. This includes, but is not limited to –

    i. The CAB must have clear policies and procedures to ensure that no conflict of interest exists when performing assessments and verifications. These policies must be documented and communicated to relevant personnel, with periodic reviews to ensure ongoing compliance; and
    ii. It is important that the CAB demonstrates a clear separation of personnel and activities between those involved in the recognised regulatory authorities or notified bodies' initial assessment and those performing the verification process locally. This ensures that no undue influence or bias affects the outcomes; and
    iii. Personnel involved in the verification process should sign impartiality declarations, affirming that they have no conflict of interest regarding the devices under assessment. This should be standard practice for all assessments and verifications conducted by the CAB.

4.3 Conformity assessment elements review criteria

The following conformity assessment elements shall be verified by the CAB conducting the conformity assessment by way of the verification process:

a. Conformity assessment of quality management system; and
b. Conformity assessment of post-market surveillance system; and
c. Conformity assessment of technical documentation; and
d. Declaration of conformity.

The verification criteria for the initial and recertification assessments are as stipulated in **Appendix 2** of this guideline.

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5.Timeline for conducting conformity assessment

The recommended man-hours for a CAB to perform the initial and recertification assessment, including report writing and issuance of the certificate of conformity for Class B, C, and D medical devices, is **4 hours** per medical device application.

The full timeline for Turnaround Time (TAT) for CAB to conduct conformity assessment are as outlined in Table 3 below. This timeline excludes the establishment timeline for any response during the submission.

Table 3: Turnaround time (TAT) for initial and recertification process

Category	Process stage	Initial/ Recertification
		TAT
Initial CAB-Establishment Engagement	Establishment engagement	3 working days
	Initial application submission	3 working days
	Contract review	3 working days (Finalization within 2 weeks)
Pre-Audit Preparation	Pre-audit document preparation	Establishment's TAT
	Documentation submission	Establishment's TAT
	Scheduling	3 working days
Document Submission for Review	Initial document review	4 hours per medical device application
Certification Decision	Final review & certification decision	Review and decision in 2 weeks from the final submission of report
	Certification decision communication	5 working days
Post-Certification Actions	Payment for Certification	Establishment's TAT (as per agreed terms)
	Certificate issuance	2 working days after payment clearance
Overall TAT (month)		**Approx. 1.5 month**

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6.Issuance of report and certificate

Upon completion of the conformity assessment, and if it is determined that all requirements have been fulfilled, a report and certificate of conformity shall be issued by the CAB to the manufacturer or the authorized representative.

CAB shall use the assessment report template and may use the certification of conformity template provided in this guideline.

Table 4: Reference appendix for initial and recertification assessment.

Submission type	Reference appendix
Initial certification assessment	● **Appendix 2**: Conformity assessment report template for medical devices, including in-vitro diagnostic medical devices ● **Appendix 3**: Certificate of conformity template
Recertification assessment	● **Appendix 4:** Conformity assessment report template for medical devices, including in-vitro diagnostic medical devices ● **Appendix 5:** Certificate of conformity template

Each certificate shall refer to only one conformity assessment procedure.

Certificates shall only be issued to one manufacturer or authorized representative. The name and address of the manufacturer or authorized representative included in the certificate shall be the same as the establishment license.

The conformity assessment report and certificate shall be signed by the technical personnel conducting the verification assessments.

The certificate of conformity shall remain valid for a period of **5 years**.

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APPENDIX 1

RECOGNISED REGULATORY AUTHORITIES OR NOTIFIED BODIES

The approval types eligible for conformity assessment by way of verification process are listed in Table 5 below:

Table 5: Types of approvals eligible for conformity assessment by way of verification process

Recognised regulatory authorities or notified bodies	Recognised approvals
European Union Notified Bodies (EU NB)	For Class B via EC certificates issued according to: ● Directive 93/42/EEC Annex II section 3 or Annex V for Class IIa devices ● Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III or MDR Annex XI PART A for Class IIa ● Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs ● In Vitro Diagnostic Medical Device Regulation (IVDR) Annex IX Chapter I and Chapter III for Class B IVD For Class C and D via EC certificates issued according to: ● Directive 93/42/EEC Annex II section 3 or Annex III with Annex V for Class IIb ● Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III, including assessment of technical documentation for implantable, or MDR Annex X coupled with Annex XI PART A for Class IIb ● Directive 93/42/EEC Annex II section 3 and 4 for Class III ● Medical Device Regulation (MDR) Annex IX Chapter I and Chapter III, including assessment of the technical documentation for Class III ● Directive 90/385/EEC Annex II section 3 and 4 for Active Implantable Medical Devices (note: Directive 90/385/EEC is incorporated into MDR and active implantable medical device is Class III under MDR) ● Directive 98/79/EC Annex IV including sections 4 and 6 for List A IVDs ● IVDR Annex IX Chapter I and Chapter III, including assessment of technical documentation for Class D IVD ● Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs ● In Vitro Diagnostic Medical Device Regulation (IVDR) Annex IX Chapter I and Chapter III, including assessment of technical documentation for companion diagnostics, self-testing & near-patient testing devices, or IVDR Annex X coupled with Annex XI (except section 5) for Class C IVD
Japan Ministry of Health, Labour and Welfare	● Pre-market certification (Ninsho) from a Japanese registered certification body

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(MHLW)	● Pre-market approval (Shonin) from MHLW
Australia Therapeutic Goods Administration (TGA)	ARTG Registration Certificate
Health Canada (HC)	Health Canada License
US Food and Drug Administration (US FDA)	● 510K clearance ● Premarket approval (PMA)
Medicines & Healthcare products Regulatory Agency (MHRA)	For Great Britain ● UK Conformity Assessed (UKCA) ● EC certificates issued according to recognised approvals in listed from the above EU NB For Northern Ireland ● EC certificates issued according to recognised approvals in listed from the above EU NB ● UK Northern Island (UKNI) and EC certificates issued according to recognised approvals in listed from the above EU NB
Health Science Authority (HSA)	Registered in the Singapore Medical Device Register (SMDR)
Thailand Food and Drug Administration (FDA)	Class 2-3: Certificate of Notified Medical Device Class 4: Certificate of Licensed Medical Device

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APPENDIX 2

CONFORMITY ASSESSMENT ELEMENTS REVIEW AND VERIFICATION CRITERIA FOR CONFORMITY ASSESSMENT BY WAY OF VERIFICATION PROCESS FOR CLASS B, C AND D INITIAL CERTIFICATION AND RECERTIFICATION ASSESSMENT

The guides represent the minimum evidence that CAB shall review, verify, and include in the verification report. Additional remarks may be added. Irrespective of the requirements in the table below, MDA has the right to request information or material or define conditions not specifically described in this document that are deemed necessary for the purpose of regulatory control.

CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
CONFORMITY ASSESSMENT BODY (CAB) DETAILS			
CAB name	• A registered CAB name under Act 737	√	√
CAB technical personnel' name	• Name of CAB technical personnel who review the application	√	√
Previous CAB certification details	• Previous CAB information - who conducted the initial certification assessment. • This should include the CAB name, certificate of conformity expiry date and assessment route: full or verification assessment		√
ESTABLISHMENT DETAILS			
Establishment name, role, license number and license expiry date	• Review and verify that the establishment name on the establishment license and registration certificate (for recertification) is identical. • Review and verify that the establishment has a valid license as a local manufacturer or authorised representative (AR) with a valid license number and expiration date.	√	√

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
MEDICAL DEVICE DETAILS			
Risk classification and rule	• Review and verify the risk classification and rule in accordance with the rules of medical device classification as outlined in the First Schedule of MDR 2012 and the Guidance Document on the Rules of Classification for General Medical Devices (MDA/GD/0009) or In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001).	√	√
Generic name	• Review and verify that the name given to a medical device that is used to identify it irrespective of trademark or etc is consistent across technical documentation. • For recertification, no changes to existing information unless approved by MDA via a change notification application.	√	√
Medical device name	• Review and verify that the product meets the definition of a medical device under Section 2 of Act 737. • The name of a medical device given by its manufacturer that identifies a manufacturer's medical device distinct from those of other manufacturers, as per device label, IFU, catalogue, brochure. • For recertification, no changes to existing information unless approved by MDA via a change notification application.	√	√
Brand	• Review and verify the brand name is on the label, DoC and technical documentation. A brand name is a unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name. • For recertification, no changes to existing information unless approved by MDA via a change notification application.	√	√
Description of medical device	• Review and verify the detailed description of the medical device which includes how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging. This should include a complete description of each functional component, material or ingredient of the device. • For recertification, no changes to existing information unless approved by MDA via a change notification application.	√	√
Intended use of medical device	• Review and verify the intended use of the medical device, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device, as stated in: a. the information provided with the device, or b. the instructions for use of the device, or c. any advertising material applying to the device.	√	√

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
	• It shall be consistent with the data in technical documentation including IFU, CSDT, clinical evaluation report and approved intended use in the recognised regulatory authorities or notified bodies. • For recertification, no changes to the existing information unless approved by MDA via a change notification application.		
The device is an implantable device?	• Review and verify if the device is an implantable device.	√	
The device is delivered in sterile condition?	• Review and verify if the device is supplied sterile.	√	
The device has a measuring function?	• Review and verify if the device has a measuring function.	√	
The device is an active medical device	• Review and verify if the device is an active device.	√	
The device incorporates software?	• Review and verify if the device incorporates software.	√	
The device is a combination product?	• Review and verify if the device incorporates medicinal substance in an ancillary role. • If yes, an endorsement letter (EL) or acknowledgement receipt (AR) issued by NPRA shall be provided. • State yes or no and specify the medicinal substance name and NPRA reference number in the report. • The name of the medicinal substance in the NPRA letter and technical documentation are identical.	√	√
The device containing formulation, active ingredient, poison or drug?	• Review and verify if the device contain any formulation, active ingredient, poison or drug. • If yes, the ingredient, scientific name, ingredient function, quantity and composition percentage information shall be provided. State yes or no and indicate the document filename in the report.	√	
Grouping – list of devices	• Review and verify the listing based on grouping criteria specified in MDR 2012, and Guidance Document on General Medical Device Grouping (MDA/GD/0005) and Guidance on the Product Grouping for In vitro Diagnostic (IVD) Medical Devices (MDA/GD/0054), including identifier (e.g. bar code, catalogue, model or part number, UDI) and description of device. • For recertification, this information shall align with the device listing in the registration certificate. No changes to existing information unless approved by MDA via a change notification application.	√	√

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		Initial certification	Re certification
Medical device registration number	• For recertification, review and verify the medical device registration number against the registration certificate and labelling.		√
Summary of change notification(s) that was approved by MDA	• For recertification, review and verify the summary of change(s) for the last 5 years. If there is no change, a declaration of change shall be provided by the manufacturer.		√
RECOGNISED REGULATORY AUTHORITY OR NOTIFIED BODY DETAILS			
Therapeutic Goods Administration (TGA), Australia	• Review and verify the authenticity and validity of the TGA license, as listed in Table 1 and 5 (Appendix 1), and evidence of approval against the ARTG database. • A declaration of conformity by the manufacturer shall be submitted, in addition to the TGA license. • For re-registration, providing the pre-market information is optional but advisable to support the application.	√	√ if applicable
Ministry of Health, Labour and Welfare (MHLW) Japan	• Review and verify the authenticity and validity of the certificate as listed in Table 1 and 5 (Appendix 1) and evidence of approval. • The certificate shall be translated into English. • For re-registration, providing the pre-market information is optional but advisable to support the application.		
Health Canada	• Review and verify the authenticity and validity of the Health Canada license and evidence of approval against the Health Canada database. • For re-registration, providing the pre-market information is optional but advisable to support the application.		
Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom	• Review and verify the authenticity and validity of the certificate as listed in Table 1 and 5 (Appendix 1) . • For re-registration, providing the pre-market information is optional but advisable to support the application.		
Food and Drug Administration (FDA), USA	• Review and verify the authenticity and validity of the certificate as listed in Table 1 and 5 (Appendix 1) and evidence of approval against the US FDA database. • For re-registration, providing the pre-market information is optional but advisable to support the application.		
European Union (EU)	• Review and verify the authenticity and validity of the EC Certificate as listed in Table 1 and 5 (Appendix 1).		

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
	• A declaration of conformity by the manufacturer shall be submitted, in addition to the EC certificate issued by the notified bodies. • For re-registration, providing the pre-market information is optional but advisable to support the application.		
Health Science Authority (HSA), Singapore	• Review and verify the authenticity and validity of the medical device registration number, as listed in Table 1 and 5 (Appendix 1), against the Singapore Medical Device Register (SMDR) as evidence of approval • A declaration of conformity by the manufacturer shall be submitted. • For re-registration, providing the pre-market information is optional but advisable to support the application.	√	√ if applicable
Food and Drug Administration (Thai FDA), Thailand	• Review and verify the authenticity and validity of the certificate issued as listed in Table 1 and 5 (Appendix 1). • A declaration of conformity by the manufacturer shall be submitted. • The certificate shall be translated into English. • For re-registration, providing the pre-market information is optional but advisable to support the application.	√	√ if applicable
CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM			
Manufacturer name	• Review and verify the name of the device manufacturer against all technical documentation. • No changes to existing information unless approved by MDA via a change notification application	√	√
Manufacturer address	• Review and verify the device legal manufacturer's address against technical documentation. • No changes to existing information unless approved by MDA via a change notification application	√	√
QMS certificate information	• Review and verify the authenticity and validity of the manufacturer's QMS certificate, issued by a notified body (NB) or regulatory authority (RA) or MDA-registered conformity assessment body (CAB). • Copies of ISO 13485 certificates or MDSAP,US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 are to be provided from the legal manufacturer or other acceptable QMS. The scope of certification shall be applicable for the device to be registered and outsourcing activities shall be reviewed and addressed in the audit report. • For refurbished devices, the refurbishment process must be covered within the scope of the QMS certificate. • For recertification, an updated QMS certificate shall be provided.	√	√ updated QMS
Manufacturing site information	• Review and verify the manufacturing site's QMS certificate. The sites including contract manufacturers where design and manufacturing activities are performed shall be identified.	√	

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
	• If a listing is provided as an attachment to the report, it shall be reviewed & verified by CAB. • If the information is the same as the legal manufacturer, state the same as above or state not applicable if there is no manufacturing site information. • For recertification, no changes to existing information unless approved by MDA via a change notification application.		
CONFORMITY ASSESSMENT ON POST MARKET SYSTEM			
Post market surveillance & vigilance report for the past 3 years	• Review and verify the summary of reportable adverse events and field corrective actions (FCAs), including recalls for the past 3 years. • For recertification, FCAs that are 'open', the manufacturer shall provide a description of any analysis and/or corrective and preventive actions. • For recertification, if there is an ongoing adverse event or field safety corrective action for the medical device that has been reported to MDA, provide the MDA reference number. • If there have been no adverse events or FCAs, including recalls to date, the manufacturer shall provide an attestation letter that there have been no AEs, FCAs or recalls since the commercial introduction of the device.	√	√ updated PMS
CONFORMITY ASSESSMENT ON TECHNICAL DOCUMENTATION			
CSDT	• Review and verify CSDT elements that include an executive summary, EPSP, description of the medical device, summary of design verification and validation documents, summary of clinical evidence, labelling, risk analysis and manufacturer information as outlined in the Guidance Documents on the Common Submission Dossier Template (CSDT) for Medical Devices (MDA/GD/0008) and IVD Medical Devices (MDA/GD/0004). • Where there are elements not applicable to the medical device dealt with, the justification for the non-applicability should be provided. • Where such supporting documents are referenced within CSDT, every document must be submitted in full, e.g. all the pages of a document must be submitted. Those documents must be legible and within their validity period. • All certificates or reports submitted shall be signed off and dated by the person issuing the document. • For recertification, no changes to existing information unless approved by MDA via a change notification application.	√	
EPSP	• Review and verify the Essential Principles (EP) checklist to the Malaysian EP as stipulated in the MDR 2012 and Guidance Documents on the Essential Principles of Safety and Performance of Medical Devices (MDA/GD/0007). Alternatively, the checklist of EU or Australian Essential Requirements addressing similar elements as Malaysian EP can be submitted.	√	

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
	• An EP checklist established for the medical devices includes information about method(s) used to demonstrate conformity with each EP that applies, references for the method adopted and identification of the controlled document with evidence of conformity with each method used. • For the controlled documents indicated which are required for inclusion in the submission: a cross-reference of the location of such evidence within the submission.		
	• If any EP indicated in the checklist does not apply to the device, a documented rationale of the non-application of each EP that does not apply. • Methods used to demonstrate conformity may include one or more of the following: a. conformity with recognised or other standards; b. conformity with a commonly accepted industry test method(s); c. conformity with an in-house test method(s); d. the evaluation of preclinical and clinical evidence; e. comparison to a similar device already available on the market. • If outdated standards were applied, a gap assessment needs to be provided to demonstrate state of the art.		
Preclinical studies	• Review and verify the preclinical studies based on the device's intended use. - For general medical devices, it shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate the conformity of the device with the requirements of MDR 2012 and the applicable EPSP. It shall include a. biocompatibility tests conducted on materials used in a medical device; b. preclinical physical tests conducted on the medical device; c. preclinical animal studies to support the probability of effectiveness in humans; d. software verification and validation. - For IVD medical devices, it shall contain the information on study design, complete test or study protocols, methods of data analysis, data summaries and study conclusions. Pre-clinical studies should be conducted in the accredited laboratories. The most common characteristics that must be validated should include but are not limited to- analytical sensitivity; limit of detection/ limit of blank/ limit of quantitation, analytical specificity; cross reactivity, interference; endogenous, exogenous, linearity/ assay's measuring (reportable) range, accuracy, trueness, shelf life/ projected useful life, precision (repeatability / reproducibility), traceability and expected values, cut-off value, stability of reagent,	√	

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
	specimen stability, carryover, software verification and validation studies, usability testing (for self-test use), electrical safety testing report, another applicable test.		
Clinical evidence for medical devices	• Review and verify the clinical evaluation report (CER): An updated clinical evaluation report (CER) reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device. Clinical evidence for general medical device may include, a. A systematic review of existing bibliography including the search strategy with sufficient detail. This should incorporate a documented search protocol to a level of detail that allows the search to be reproduced, a selection strategy (inclusion/exclusion criteria), criteria for appraising the data (both favourable and unfavourable) to determine the contribution of each data set to support the conclusions, results of the literature search; and a documentation of the appraisal to the extent that it can be critically reviewed by others; and/or b. Clinical experience with the same or similar devices which compares the clinical, technical and biological characteristics including identifying and justifying the related clinical impact for each difference; and/or c. Clinical investigation data including all pivotal clinical study reports.	√	√ updated CER
	• Where applicable, other clinical experience data/real-world data (including device registries, post-market studies conducted in other jurisdictions) or post-market clinical follow-up (PMCF) including post-market data from all regulatory jurisdictions where the device (or a predicate or similar marketed device) has been marketed. • The clinical evaluation report shall be actively updated when the manufacturer receives new information from PMS that has the potential to change the current evaluation; if no such information is received, then at least annually if the device carries significant risks or is not yet well established or every 2 to 5 years if the device is not expected to carry significant risks and is well established, a justification should be provided. • In the absence of a CER, another CER with substantially equivalent information shall be submitted. A device is considered "substantially equivalent" if the following criteria are met: - Has the same intended use as the predicate device; and - Has the same technological characteristics as the predicate; OR - Has the same intended use as the predicate; and - Has different technological characteristics and does not raise different questions of safety and effectiveness; and - The device is demonstrated to be as safe and effective as the legally marketed device.	√	√ updated CER
Clinical performance for in-	• Review and verify the performance evaluation for the IVD medical device:	√	√

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
vitro medical devices	a. The document should list the evidence presented, its characteristics (e.g. well-controlled studies, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, literature review, post-market data from another jurisdiction or from a marketed device) and provide a discussion of how this is considered sufficient to support a request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section. b. If any of the study IVD medical devices differ from the IVD medical devices to be marketed, including competitors' IVD medical devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application for any device referenced in the application. This may include a detailed comparison of the clinical. c. Guidance on clinical performance studies is also available in ISO 20916 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice. d. A discussion of the clinical evidence considered for the IVD medical device and support for their selection (i.e. what type of evidence was considered and why they were or were not used). e. Discussion to support why the evidence presented is sufficient to support the application. f. NOTE: Human factors testing that includes patients should be included here. ● The clinical performance report (CPR) shall be actively updated when the manufacturer receives new information from PMS that has the potential to change the current evaluation; if no such information is received, then at least annually if the device carries significant risks or is not yet well established or every 2 to 5 years if the device is not expected to carry significant risks and is well established, a justification should be provided. ● In the absence of a CPR, another CPR with substantially equivalent information shall be submitted. A device is considered "substantially equivalent" if the following criteria are met: - Has the same intended use as the predicate device; and - Has the same technological characteristics as the predicate; OR - Has the same intended use as the predicate; and - Has different technological characteristics and does not raise different questions of safety and effectiveness; and - The device is demonstrated to be as safe and effective as the legally marketed device. NOTE: Clinical performances should be conducted in the accredited laboratories.		updated CPR
Labelling	● Review and verify that the label shall be updated in accordance with the Sixth Schedule of the MDR 2012, Guidance Document on the Requirements of Labelling for Medical Devices (MDA/GD/0026) and other relevant guidance documents specific to the device. ● This should include:	√	√ updated label

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
	a. sample of labels on the device and its packaging, instruction for use, other literature or training materials (such as physician's manual), instructions for installation and maintenance (if applicable), any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable). b. promotional material or brochure- - materials that contain product pictorial representation, brand and/or company name and/or logo that do not consist of any product claims or descriptions including catalogs, brochures, flyers, and etc. c. The details such as device name, identifier, brand name, name & address of the manufacturer/AR, sterile or single use symbol, an indication of lot number/serial number/expiry date/manufacturing date/proposed MDA registration number, storage conditions and shelf life information, and Bahasa Malaysia translation for home use/self-test device shall be stated on the device label.		
Risk analysis	● Review and verify the results of the risk analysis process conducted in accordance with ISO 14971:2019. ● This should include: o the latest risk management report, o a list of possible hazards of these devices, o the technique used to analyse risk, o the evaluation of these risks against the claimed benefits of the device, o the description of the method (s) used to control or reduce risk to acceptable levels and o the identification of an individual or organisation that carries out the risk analysis. ● For recertification, an updated risk analysis shall be provided.	√	√ updated risk analysis
Manufacturing process information	● Review and verify the manufacturing process for the device. This should be provided in the form of a list of resources and activities that transform inputs into the desired output. ● The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labelling, and storage of the device.	√	√
DECLARATION OF CONFORMITY			
Declaration of Conformity	● Review and verify that the DoC is prepared by the manufacturer to attest that its medical device complies fully with all essential principles for safety and performance and shall draw up a declaration of conformity in the format as specified in Appendix 3 of the Third Schedule of MDR 2012 and Guidance Document on Declaration of Conformity (MDA/GD/0025).	√	√ updated DoC

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CONFORMITY ASSESSMENT ELEMENTS	CAB REVIEW AND VERIFICATION GUIDE	Elements to be checked	
		Initial certification	Re certification
	• The DoC shall be prepared with the manufacturer's letterhead and signed by the company's top management. The QMS information shall be valid and vertical and horizontal standards shall be stated. The information in the DoC shall align with technical documentation. • For recertification, an updated DoC shall be provided.		
SUMMARY OF CAB VERIFICATION ASSESSMENT			
Summary of CAB verification assessment	• CAB shall provide a verification assessment as follows: a. If the device conforms to the relevant EPSP as outlined in Appendix 1 of the Third Schedule of the MDR 2012; and b. If the safety, quality and performance of the device are addressed; and c. If the risks associated with the medical device are acceptable, in view of the current state of the art; and d. If the medical device is recommended for registration/re-registration and issuance of CAB recertification; and e. Overall verification findings and conclusions. • The conformity assessment report and certificate shall be signed by the technical personnel conducting the verification assessment. • If verification assessment findings are not recommended and/or the conclusion is not recommended, a justification shall be provided by the CAB.	√	√

-End of Table -

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Reference Number: state CAB name/MDV/client number/device number

APPENDIX 3

CONFORMITY ASSESSMENT REPORT FOR MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC DEVICES (by way of verification on evidence of conformity)

FOR INITIAL CERTIFICATION ASSESSMENT

Date of verification: *<start date>* to *<end date>*

All 9 sections are mandatory, unless stated otherwise. For non-applicability, a justification shall be provided. The notes represent the minimum evidence that the CAB shall include in the verification report.

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CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
SECTION 1: CONFORMITY ASSESSMENT BODY (CAB) DETAILS	
CAB name	
CAB technical personnel' name	*Technical personnel's name who review the application*
SECTION 2: ESTABLISHMENT DETAILS	
Establishment name	
Establishment role	*e.g. Local manufacturer/authorised representative*
Establishment license number	
License expiry date	
SECTION 3: MEDICAL DEVICE DETAILS	
Risk classification and rule	*e.g. Class C Rule 1*
Generic name	
Medical device name	
Brand	
Description of medical device	
Intended use of medical device	
The device is an implantable device?	*yes or no*

CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
The device is delivered in sterile condition?	*yes or no*
The device has a measuring function?	*yes or no*
The device is an active medical device	*yes or no*
The device incorporates software?	*yes or no*
The device is a combination product?	*yes or no* If yes, medicinal substance name: *state substance name* NPRA reference number: *state EL or AR and NPRA reference number*
The device containing formulation, active ingredient, poison or drug?	*yes or no* If yes, document file name: *specify document file name*
Grouping – list of devices	Grouping: *Single/family/family of system/system/set/IVD test kit/IVD cluster* Total number of devices in the LoC: *e.g. 100 devices* The LoC is reviewed and verified by CAB: *yes or no*
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 4: RECOGNISED REGULATORY AUTHORITY OR NOTIFIED BODY DETAILS *Unrelated rows may be deleted*	
Therapeutic Goods Administration (TGA), Australia	Approval type: *e.g. TGA license* ARTG number: Issuance date:
Ministry of Health, Labour and Welfare (MHLW) Japan	Approval type: *e.g. Pre-Market Approval from MHLW* Notified body name for certificate issued by RCB: Issuance date:
Health Canada	Approval type: *e.g. Medical device license* MDALL number: Issuance date:
Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom	Approval type: *e.g. EC Certificate and UKNI Certification* Issuance Date:
Food and Drug Administration (FDA), USA	Approval type: *e.g. Pre-Market Approval* Approval number:

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CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
	Issuance date:
European Union (EU)	Notified body name and no.: Certificate no.: Expiry date: Scope of certification: *e.g. state scope of certification applicable for this device*
Health Science Authority (HSA)	Product no.:
Thailand Food and Drug Administration (FDA)	Certificate no.: Issuance date:
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 5: CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM	
Manufacturer name	
Manufacturer address	
QMS certificate information	QMS standard name: *e.g. ISO 13485* Name of CAB or RA or NB: Certificate no.: Expiry date: Scope of certification: *e.g. state scope of certification applicable for this device*
Manufacturing site information	Manufacturing site name and address: *If a listing is provided as an attachment to the report, it shall be reviewed & verified by CAB. If the information is the same as the legal manufacturer, state 'same as above' or state 'not applicable' if there is no manufacturing site.*
Other remarks	*Other remarks may be added or delete row or state NA.*
SECTION 6: CONFORMITY ASSESSMENT ON POST MARKET SYSTEM	
Post market surveillance & vigilance report for the past 3 years	*e.g. summary of reportable adverse events and field corrective actions (FCAs) for the past 3 years. If there have been no AEs, FCAs or recalls to date, the manufacturer shall provide an attestation letter that there have been no AEs, FCAs or recalls since the commercial introduction of the device.*
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 7: CONFORMITY ASSESSMENT ON TECHNICAL DOCUMENTATION	

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CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
CSDT	CSDT document file name: *specify document file name* CSDT includes all elements: *yes or no* Date signed & prepared:
EPSP	EPSP document file name: *specify document file name* EPSP includes all applicable elements: *yes or no* Is evidence of conformity acceptable and adequate? *yes or no* Is there adequate and appropriate justification provided for non-applicability of EPSP? *yes or no* Date signed & prepared:
Preclinical studies	Test/standard name: *e.g. ISO 10993-1: 2018* Document file name: *specify document file name* Summary/conclusion of the test:
Clinical evidence for medical devices / Clinical performance for in-vitro medical devices	CER/CPR document file name: *specify document file name* Method(s) to conduct clinical evaluation: *e.g. a systematic review of existing bibliography/ a clinical experience with the same or similar devices/ clinical investigation/ post market clinical follow up (PMCF)* Summary/conclusion of the overall assessment on the clinical safety and efficacy, risk/benefit assessment: *provide summary/conclusion* Date CER/CPR signed & prepared:
Labelling	The device is labelled as: *home use/self-test/professional use/home use and professional use/refurbished* The details below are stated on the device label: *yes or no* ● Device name, identifier, brand name ● Name & address of the manufacturer and AR ● Sterile or single use symbol ● An indication of lot number/serial number/expiry date/manufacturing date/proposed MDA registration number ● Storage conditions and shelf life information ● Bahasa Malaysia translation for home use/self-test device ● Others: *please specify*
Risk analysis	Risk analysis document file name: *specify document file name* Are all the known and foreseeable risks, and any undesirable side-effects identified? *yes or no*

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CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
	Are these risks and undesirable side effected minimized and deemed acceptable when weighed against the benefits of the intended use of the medical device? *yes or no* Date signed & prepared:
Manufacturing process information	Manufacturing process flow chart document file name: *specify document file name*
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 8: DECLARATION OF CONFORMITY	
Declaration of Conformity	The information in the DoC is consistent across the technical documentation: *yes or no*
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 9: SUMMARY OF CAB VERIFICATION ASSESSMENT	
The conformity assessment for the *state device name* was conducted in accordance with the requirements as prescribed in Part III of Third Schedule of MDR 2012. The conformity assessment by way of verification has been performed for the purpose of medical device registration in Malaysia.	
● The medical device conforms to the relevant EPSP as outlined in the Appendix 1 of Third Schedule of MDR 2012?	*yes or no*
● The safety, quality and performance of the device are addressed?	*yes or no*
● The risks associated with the medical device are acceptable, in view of the current state of the art?	*yes or no*
● The medical device is **recommended for registration** and issuance of report and certificate of conformity assessment	*yes or no*
CAB overall verification findings and conclusions:	

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Reviewed and verified by,

Signature:

Reviewed and approved by,

Signature:

Technical personnel's name:
Date:

Technical personnel's name:
Date:

Reference Number: state CAB name/MDV/client number/device number

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APPENDIX 4

CERTIFICATE OF CONFORMITY TEMPLATE
(INITIAL CERTIFICATION)

This template represents the minimum evidence that CAB shall include in the certificate.

CAB Name and Logo

Certificate of Conformity

(by way of verification on evidence of conformity)

FOR INITIAL CERTIFICATION

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This is to certify that : *Name of establishment*
Address of establishment

Role of establishment : *Manufacturer / AR*

Holds certificate No : *Certificate No*

Scope:

On the basis of our verification on evidence of conformity of medical device **approved by recognised regulatory authorities or notified bodies** for the medical device below:
<name of medical device including list of medical devices in the grouping, brand, class and manufacturer>

For and on behalf of *Name of CAB*

Signed by:

(*Name of the signatory*)
(*Position of the signatory*)

Effective Date: *CAB verification report approval date*
Expiry Date: *5 years validity*
CAB Registration No: *Registered CAB registration number*

Reference Number: state CAB name/MDV/client number/device number

APPENDIX 5

CONFORMITY ASSESSMENT REPORT FOR MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTIC DEVICES (by way of verification on evidence of conformity)

FOR RECERTIFICATION ASSESSMENT

Date of verification: *<start date>* to *<end date>*

All 8 sections are mandatory, unless stated otherwise. For non-applicability, a justification shall be provided. The notes represent the minimum evidence that the CAB shall include in the verification report

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CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
SECTION 1: CONFORMITY ASSESSMENT BODY (CAB) DETAILS	
CAB name	
CAB technical personnel' name	*Technical personnel's name who review the application*
Previous CAB certification details	*CAB name, certificate of conformity expiry date and assessment route: full or verification assessment*
SECTION 2: ESTABLISHMENT DETAILS	
Establishment name	
Establishment role	*e.g. Local manufacturer/authorised representative*
Establishment license number	
License expiry date	
SECTION 3: MEDICAL DEVICE DETAILS	
Medical device registration number	*e.g. GC1234567*
Summary of change notification(s) that was approved by MDA	*e.g. addition of manufacturing sites (include name of sites), addition of medical devices (number of devices), labelling changes, removal of CE marking*
Risk classification and rule	*e.g. Class C Rule 1*
Generic name	
Medical device name	

CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
Brand	
Description of medical device	
Intended use of medical device	
The device is a combination product?	*yes or no* If yes, medicinal substance name: *state substance name* NPRA reference number: *state EL or AR and NPRA reference number*
Grouping – list of devices	Grouping: *Single/family/family of system/system/set/IVD test kit/IVD cluster* Total number of devices in the LoC: *e.g. 100 devices* The LoC is reviewed and verified by CAB: *yes or no*
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 4: CONFORMITY ASSESSMENT ON QUALITY MANAGEMENT SYSTEM	
Manufacturer name	
Manufacturer address	
Updated QMS certificate information	QMS standard name: *e.g. ISO 13485* Name of CAB or RA or NB: Certificate no.: Expiry date: Scope of certification: *e.g. state scope of certification applicable for this device*
Manufacturing site information	Manufacturing site name and address: *If a listing is provided as an attachment to the report, it shall be reviewed & verified by CAB. If the information is the same as the legal manufacturer, state 'same as above' or state 'not applicable' if there is no manufacturing site.*
Other remarks	*Other remarks may be added or delete row or state NA.*
SECTION 5: CONFORMITY ASSESSMENT ON POST MARKET SYSTEM	
Updated post market surveillance & vigilance report for the past 3 years	*e.g. summary of reportable adverse events and field corrective actions (FCAs) for the past 3 years. If there have been no AEs or FCAs to date, the manufacturer shall provide an attestation letter that there have been no AEs or*

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CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
	FCAs for the past 5 years.
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 6: CONFORMITY ASSESSMENT ON TECHNICAL DOCUMENTATION	
Updated clinical evidence for medical devices / clinical performance for in-vitro medical devices	CER/CPR document file name: *specify document file name* Method(s) to conduct clinical evaluation: *e.g. a systematic review of existing bibliography/ a clinical experience with the same or similar devices/ clinical investigation/ post market clinical follow up (PMCF)* Summary/conclusion of the overall assessment on the clinical safety and efficacy, risk/benefit assessment: *provide summary/conclusion* Date CER/CPR signed & prepared:
Updated labelling	The device is labelled as: *home use/self-test/professional use/home use and professional use/refurbished* The details below are stated on the device label: *yes or no* ● Device name, identifier, brand name ● Name & address of the manufacturer and AR ● Sterile or single use symbol ● An indication of lot number/serial number/expiry date/manufacturing date/MDA registration number ● Storage conditions and shelf life information ● Bahasa Malaysia translation for home use/self-test device ● Others: *please specify*
Updated risk analysis	Risk analysis document file name: *specify document file name* Are all the known and foreseeable risks, and any undesirable side-effects identified? *yes or no* Are these risks and undesirable side effected minimized and deemed acceptable when weighed against the benefits of the intended use of the medical device? *yes or no* Date signed & prepared:
Other remarks	*Other remarks may be added or deleted or state NA.*
SECTION 7: DECLARATION OF CONFORMITY	
Updated Declaration of Conformity	The information in the DoC is consistent across the technical documentation: *yes or no*

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CONFORMITY ASSESSMENT ELEMENTS	VERIFICATION FINDINGS/REMARKS
Other remarks	*Other remarks may be added or deleted or state NA.*

SECTION 8: SUMMARY OF CAB VERIFICATION ASSESSMENT

The conformity assessment for the *state device name* was conducted in accordance with the requirements as prescribed in Part III of Third Schedule of MDR 2012. The conformity assessment by way of verification has been performed for the purpose of medical device registration in Malaysia.

● The medical device conforms to the relevant EPSP as outlined in the Appendix 1 of Third Schedule of MDR 2012?	*yes or no*
● The safety, quality and performance of the device are addressed?	*yes or no*
● The risks associated with the medical device are acceptable, in view of the current state of the art?	*yes or no*
● The medical device is **recommended for re-registration** and issuance of report and certificate of conformity assessment	*yes or no*

CAB overall verification findings and conclusions:

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Reviewed and verified by,	**Reviewed and approved by,**
Signature: Technical personnel's name: Date:	Signature: Technical personnel's name: Date:

Reference Number: state CAB name/MDV/client number/device number

APPENDIX 6

CERTIFICATE OF CONFORMITY TEMPLATE (RECERTIFICATION)

This template represents the minimum evidence that CAB shall include in the certificate.

CAB Name and Logo

Certificate of Conformity

(by way of verification on evidence of conformity)

FOR RECERTIFICATION

This is to certify that	: *Name of establishment* *Address of establishment*
Role of establishment	: *Manufacturer / AR*
Holds certificate No	: *Certificate No*

Scope:

On the basis of our verification on evidence of conformity for **re-registration of the medical device** below:
<name of medical device including list of medical devices in the grouping, brand, class and manufacturer>

For and on behalf of *Name of CAB*

Signed by:

(*Name of the signatory*)
(*Position of the signatory*)

Effective Date: *(1) If the initial CAB certificate is still valid, the effective date continues from the previous CAB certificate validity date, or (2) If the CAB certificate has expired, the effective date is the CAB verification report approval date.*
Expiry Date: *5 years validity.*
CAB Registration No: *Registered CAB registration number.*

DRAFT FOR PUBLIC COMMENT
20/10/2026 – 2/11/2026

Acknowledgements

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MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

DRAFT FOR PUBLIC COMMENT
20/10/2026 – 2/11/2026

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