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MEDICAL DEVICE GUIDANCE DOCUMENT

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ESTABLISHMENT GUIDE TO MEDICAL DEVICE REGISTRATION SUBMISSION IN MeDC@St THROUGH CONFORMITY ASSESSMENT BY WAY OF VERIFICATION PROCESS

- For Class A medical device submission
- For Class B, C, and D medical device submission via conformity assessment by way of verification process

Medical Device Authority
Ministry of Health Malaysia

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 the phrase 'has been marketed for at least one year in the respective agencies' jurisdictions' under Verification (initial certification assessment) as in Table 1	11 September 2025
2		Table 2 : Schemes/ programs exempt from verification pathway for medical device	Added information on schemes or programs not subject to verification pathways for Singapore (HSA) and Thailand (Thai FDA)	
3		ANNEX 1 (normative) RECOGNIZED REGULATORY AUTHORITIES OR NOTIFIED BODIES	Added Singapore (HSA) and Thailand (Thai FDA) as recognised regulatory authorities	
4		ANNEX 3 (informative) SUBMISSION GUIDE FOR CLASS A MEDICAL DEVICE REGISTRATION APPLICATION IN MeDC@St FOR NEW AND RE-REGISTRATION APPLICATION	Revised Section 9: Post-Market Surveillance and Vigilance – amended text from 'past 3 to 5 years' to 'past 3 years'.	
5		ANNEX 4 (normative) SUBMISSION GUIDE FOR CLASS B, C, AND D FOR CONFORMITY ASSESSMENT BY CAB AND SUBMISSION OF APPLICATION IN MeDC@St FOR NEW AND RE-REGISTRATION APPLICATION	• Section 6: Pre-Market Clearance / Pre-Market Approval – added evidence of pre-market clearance/approval for Singapore and Thailand • Section 9: Post-Market Surveillance and Vigilance – revised text from 'past 3 to 5 years' to 'past 3 years'.	
6	Second	ANNEX 1 (normative) RECOGNIZED REGULATORY	Editorial change to include table title *Table 4: Types of approvals eligible for conformity assessment by way of*	9 October 2025

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		AUTHORITIES OR NOTIFIED BODIES	*verification process*	
7		ANNEX 4 (normative) SUBMISSION GUIDE FOR CLASS B, C, AND D FOR CONFORMITY ASSESSMENT BY CAB AND SUBMISSION OF APPLICATION IN MeDC@St FOR NEW AND RE-REGISTRATION APPLICATION	Section 6: Pre-Market Clearance / Pre-Market Approval- Rephrase sentence for evidence of approval for Singapore (HSA) and Thailand (FDA)	
8	Draft public comment	1. Introduction 2. Scope and application 3. Terms and Definition (Note 3.8)	Updated the latest circular letter MDA Circular Letter No. 2 of 2025	20 Oktober 2026
		6.5 Table of Fees	Included application fee and registration fee for Class A medical device	
		ANNEX 3 (informative) SUBMISSION GUIDE FOR CLASS A MEDICAL DEVICE REGISTRATION APPLICATION IN MeDC@St FOR NEW AND RE-REGISTRATION APPLICATION	Rephrase the statement to: Updated copies of ISO 13485 certificates or other acceptable QMS are to be provided from the legal manufacturer – MDSAP, US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 or ISO 9001 (for a class A empty gas cylinder only) in Section 6 : Manufacturer Information (Quality management system information) Remove the statement : If the foreign legal manufacturer is not ISO 13485 certified, the ISO 13485 certificate from the OEM manufacturer can be provided, together with the Traceability of Evidence of Conformity Attestation Template for Medical Device Registration Form as a supporting document in Section 6 : Manufacturer Information (Quality management system information)	

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		Annex 4 (normative) **SUBMISSION GUIDE FOR CLASS B, C, AND D FOR CONFORMITY ASSESSMENT BY CAB AND SUBMISSION OF APPLICATION IN MeDC@St FOR NEW AND RE-REGISTRATION APPLICATION**	Adding the statement : Pre-clinical studies should be conducted in the accredited laboratories in Section 4 Common Submission Dossier Template (CSDT) (Pre-clinical Studies) Adding the notes : Clinical performances should be conducted in the accredited laboratories in Section 4 : Common Submission Dossier Template (CSDT).(Clinical performance for in-vitro medical devices)	

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PREFACE

This guidance document serves as guidance for local manufacturers and authorized representatives to apply for conformity assessment by way of verification (abridged) process to CAB for initial and re-certification assessment and to submit medical device registration submissions via the Medical Device Centralised Online System (MeDC@St) for medical device registration in Malaysia based on the Medical Device Act 2012 (Act 737) and its regulations.

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:

- Medical Device Act 2012 (Act 737); and
- Medical Device Regulations 2012

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

MDA has put much effort into ensuring 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.

Any inquiry on this document may be submitted to:

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GUIDE FOR MEDICAL DEVICE ESTABLISHMENT: CONFORMITY ASSESSMENT BY WAY OF VERIFICATION & SUBMISSION OF MEDICAL DEVICE REGISTRATION IN MeDC@St

1. Introduction

Section 5(1) of the Medical Device Act 2012 (Act 737) requires a medical device to be registered under the Act before it can be imported, exported, or placed in the market. For that purpose, an application for the registration of a medical device shall be made according to the requirements under Act 737 and in the manner determined by the Authority in Medical Device Regulations (MDR) 2012.

Section 7 of Act 737 mandates that a medical device shall undergo a conformity assessment process to ensure compliance with legal requirements before registration. The process needs to be conducted by a registered conformity assessment body (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.

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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-recognized 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.

Upon completing the conformity assessment and the medical device is verified to meet the EPSP requirements, the registration or re-registration application shall be made via an online system, MeDC@St. The medical device will be registered or re-registered for the period of 5 years and listed in MDAR if the Authority is satisfied that the medical device has met all regulatory requirements stipulated in Act 737 and its regulations.

2. Scope and application

This document serves as guidance for the establishment particularly manufacturer and authorized representative whose their medical device eligible for conformity assessment by way of verification,

I. to prepare the CSDT to be submitted to the registered CAB for verification process, and
II. to make an application for registration of a medical device as stipulated in Section 5 of Medical Device Act 2012 (Act 737) via an online web-based system called the Medical Device Centralised Online System (MeDC@St).

The medical device that is eligible for this pathway is the medical device that has obtained premarket approval from any recognised regulatory authorities or notified bodies, as stated in

the MDA Circular Letter No. 2/2025 and Annex 1 Recognized Regulatory Authorities and Notified Bodies.

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].

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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 Annex 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

4. Conformity Assessment Procedure

4.1 Collection of Evidence of Conformity

Part II of the Third Schedule of Medical Device Regulation 2012 addressed the requirements as follows;

I. The manufacturer shall collect and compile all evidence of conformity of a medical device to demonstrate the compliance to EPSP,
II. For an imported medical device, the AR shall provide all evidence of conformity of the medical device from the manufacturer to demonstrate the compliance to EPSP.

The evidence of conformity shall include conformity to requirements that reflect four elements of conformity as follows;

a) Quality management system (QMS),
b) Post market surveillance system (PMS),
c) Technical documentation and
d) Declaration of Conformity (DoC).

The evidence of conformity shall be compiled in accordance with the CSDT element as prescribed in Appendix 2 of Third Schedule of Medical Device Regulation and further elaborated in MDA/GD/0008 - Common Submission Dossier Template (CSDT).

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4.2 Conformity Assessment Procedure

An establishment shall appoint a Conformity Assessment Body (CAB) with expertise in the relevant Medical Device Technical Areas, to perform conformity assessment by way verification on the medical devices to be registered or re-registered based on the pathway described in clause 2.3.

4.3 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

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 ● to be marketed in Malaysia 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:

	o No reported deaths; o No reported serious deterioration in the state of health of any person; and o 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 assessment or verification pathways and registered with MDA; and ● has valid registration certificate prior to recertification assessment by CAB; and ● The medical device 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 cancelled by the MDA.

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The medical device shall undergo a full conformity assessment if the approval from a recognised regulatory authority or notified body has been cancelled 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 (FDA)	Exemptions for the manufacture or import of medical devices for non-commercial purposes, as stipulated in Section 27 of Medical Device Act.

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.

The estimated timeline for conducting the conformity assessment by way of verification by the registered CAB is detailed out in the Annex 2.

Upon completing the conformity assessment and the medical device is verified to meet the EPSP requirements, the registration or re-registration application shall be made via an online system, MeDC@St. The medical device will be registered or re-registered for the period of 5 years and listed in MDAR if the Authority is satisfied that the medical device has met all regulatory requirements stipulated in Act 737 and its regulations.

Class A medical devices are exempt from the conformity assessment procedure conducted by a CAB, as outlined in the Medical Device (Exemption) Order 2024. Therefore, this requirement does not apply to Class A medical devices.

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5. Registration Process

A manufacturer shall determine whether the product is a medical device as defined in Section 2 of Act 737 and shall appropriately classify it in accordance with the classification rules as specified in the First Schedule of MDR 2012 based on the level of risk it poses, its intended use and the vulnerability of the human body. English and/or Bahasa Malaysia are the only acceptable languages for the submission of documentation and any related correspondence.

The application for registration shall undergo the following 2 stages:

a. Stage 1: Conformity assessment procedure; and
b. Stage 2: Application for registration to MDA

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

5.1 Class A Medical Device Requirements

Stage 1 is exempted for a Class A medical device. Class A medical device new and re-registration applications can be submitted directly to MDA via MeDC@St. The submission requirements for a Class A medical device in MeDC@St are stipulated in **Annex 3** of this guideline and are based on the information requested in the MeDC@St application form. A summary of Class A medical device requirements is as **Table 3** below:

Table 3: Summary of Medical Device Registration Form of Class A Medical Device

Section	Medical Device Registration Form Class A	New	Re-Reg
1	Medical device classification	√	
2	Determine if the product is a medical device	√	
3	Medical device general information	√	
4	Medical device grouping	√	
5	Additional requirements	√ if applicable	
6	Manufacturer information	√	√ updated QMS
7	Pre-market clearance / pre-market approval	√ if applicable	√ if applicable
8	Labelling	√	√ updated label
9	Post-market surveillance and vigilance	√	√ updated PMS
10	Declaration of conformity	√	√ updated DoC

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5.2 Class B, C, And D Medical Device Requirements

5.2.1 Conformity Assessment Procedure

A manufacturer shall collect and compile all evidence to demonstrate the conformity of the medical device to the requirements as determined by the Authority. Depending on the class of the medical device, the manufacturer shall appoint a registered CAB to conduct the conformity assessment. If the medical device manufacturer is not based in Malaysia, it shall:

a. Authorize an AR to act on its behalf regarding the conduct of the conformity assessment; and
b. Provide all the evidence of conformity and necessary support to the AR for the purpose of the conformity.

The CAB shall conduct the conformity assessment in accordance with the requirements prescribed by the Authority.

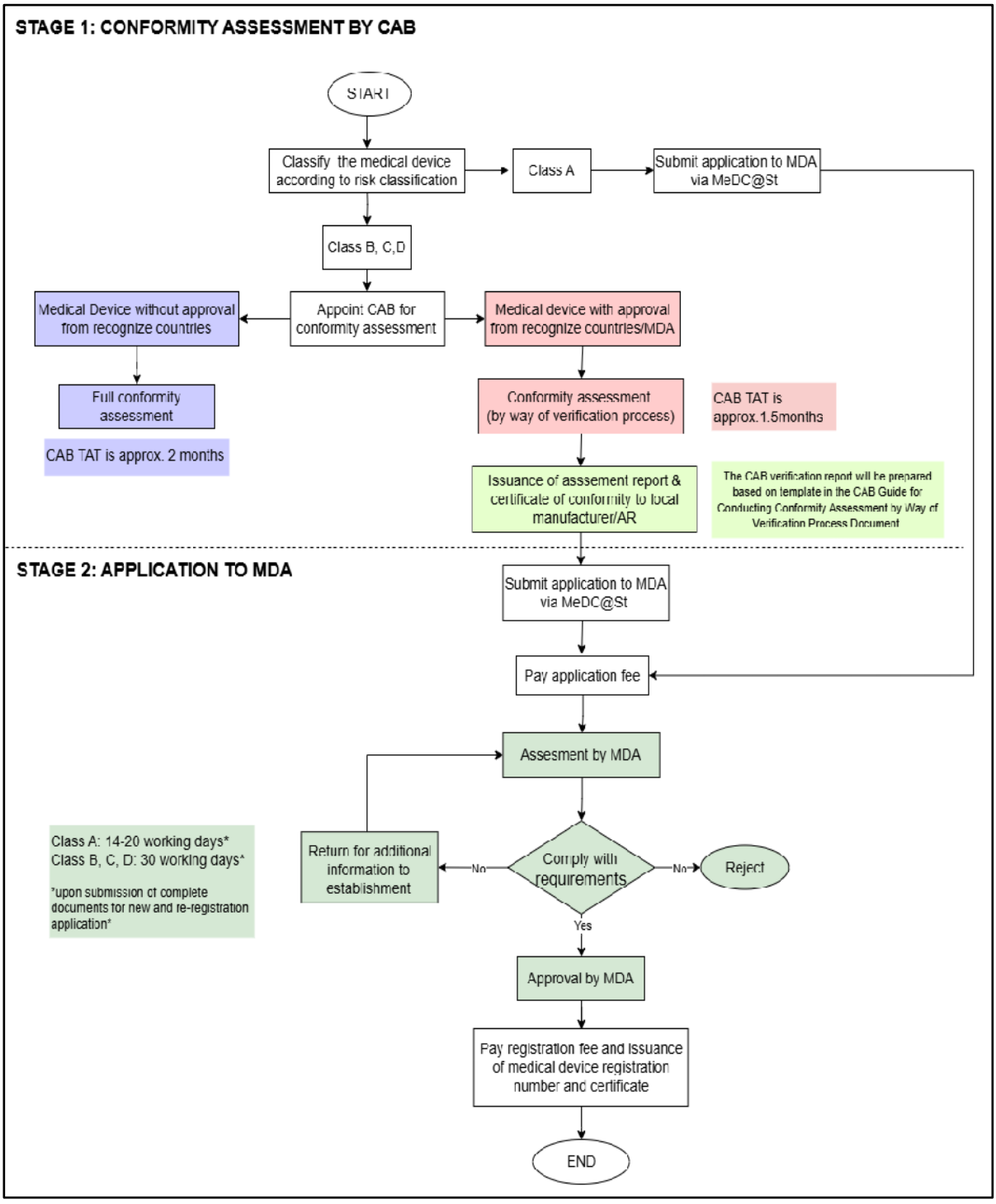


Figure 1 Overview of medical device registration process for Class A,B,C and D medical devices

5.2.3 Application to MDA

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 authorized representative. The certificate of conformity shall remain valid for a period of 5 years. The CAB report and certificate of conformity template can be referred to

Guidance document MDA/GD/00XX Conformity Assessment Body (CAB) Guide For Conducting Conformity Assessment By Way Of Verification Process

The report and certificate of conformity assessment shall be submitted as one of the requirements for registration of a medical device. The submission requirements for a Class B, C, and D medical device in MeDC@St are stipulated in **Annex 4** of this guidance document and are based on the information requested in the MeDC@St application form. The same technical dossier and supporting documents that were reviewed by the CAB shall be submitted in soft copy to MeDC@St. English and/or Bahasa Malaysia are the only acceptable languages for the submission of documentation and any related correspondence. A summary of Class B, C, and D medical device requirements is in **Table 4** below:

Table 4 Medical Device Registration Requirements for New Registration and Re-registration

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Section	Medical Device Registration Form Class B, C, and D	New	Re-Reg
1	Medical device classification	√	
2	Medical device general information	√	
3	Medical device grouping	√	
4	Common submission dossier template (CSDT)	√	√ updated CER/CPR, label, risk analysis
5	Manufacturer information	√	√ updated QMS
6	Pre-market clearance / pre-market approval	√	√ if applicable
7	Conformity assessment	√	√ updated CAB report & certificate
8	Post-market surveillance and vigilance	√	√ updated PMS
9	Declaration of conformity	√	√ updated DoC

6. Supplementary Information

6.1 Additional Information Before Submitting Re-Registration Application

a. The application for re-registration shall be submitted through the (MeDC@St).
b. The re-registration button will appear in the system 1 year prior to the registration certificate expiry date. If a change notification application is submitted and approved by MDA, the re-registration button can be found on the completed change notification application.
c. The re-registration button will not appear if the application is incomplete.
d. Concurrent submission for re-registration and change notification application is not permitted.

e. No changes to the existing information unless it has been approved by MDA as prescribed in the guidance document MDA/GD/0020 Change Notification for Registered Medical Device.
f. Any technical issues related to MeDC@St, such as re-registration, that do not appear shall be forwarded to MDA via the MeDC@St Helpdesk.

6.2 Submitting Response in Medc@St

To enable the identification and review of information uploaded onto MeDC@St in response to queries raised during the evaluation process, a written response to each input request query shall be provided. If additional documents are submitted to support your response, please indicate the relevant file name(s) in your response. Responses to a return form MDA (input request) may be included under Section 10: Any related information for a Class A application and Section 4: Common submission dossier template (CSDT) – Misc for Class B, C, and D applications.

Any other additional information, particulars, document on the application or sample of the medical device as required by the Authority shall be submitted by the applicant within **90 working days** from the date of request by the Authority. Failure to provide the information, particulars, document on the application within the specified time will result in the application being rejected by MDA. However, this will not affect the right of the applicant to make a new application and the application fee is not refundable.

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6.3 Refusal to Register a Medical Device

The Authority shall not register the medical device if it is not satisfied with any matter as follows:

a. The product is not classified as a medical device in accordance with the definition of a medical device as stipulated in Section 2 of the Medical Device Act 2012 (Act 737); or
b. The selected risk of classification of the medical device is inaccurate in accordance with the First Schedule of the Medical Device Regulation 2012; or
c. The mandatory information, particulars, or document, are not provided by the applicant within **30 working days** from the date of request by the Authority; or
d. The information, particulars, or document are not provided by the applicant within **90 working days** from the date of request by the Authority; or
e. The application is returned to the Authority without the mandatory information, or documents within **30 working days** from the date of request by the Authority; or
f. The information, particulars, or document on the application do not meet the requirements of the Medical Device Act 2012 (Act 737), Medical Device Regulations 2012, guidance documents, and guidelines set by the Authority; or
g. The establishment licence has been revoked by the Authority based on Section 22 of the Medical Device Act 2012 (Act 737); or
h. Others such as falsifying documents.

6.4 MDA Review Timeline

The MDA timeline review is as follows:

Class	Turn-around time
Class A	**14-20** working days upon submission of complete documents and cleared payment
Class B, C, and D	**30** working days upon submission of complete documents and cleared payment

6.5 Table of Fees

The fees stipulated in the Fifth Schedule of MDR 2012 are on a per-application basis and for a 5-year validity period.

Mode of payment: **FPX and FPX (credit card)**

Class	Application Fee (RM)	Registration Fee (RM)
A	500	750
B	250	1,000
C	500	2,000
D	700	3,000
A medical device that contains a medicinal product	700	5,000

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ANNEX 1

(normative)

RECOGNIZED REGULATORY AUTHORITIES OR NOTIFIED BODIES

Recognised regulatory authorities or notified bodies and the respective approval types of eligible for conformity assessment by way of verification process:

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

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	● 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 (MHLW)	● Pre-market certification (Ninsho) from a Japanese registered certification body ● 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
Singapore/Health Science Authority (HSA)	Registered in the Singapore Medical Device Register (SMDR)
Thailand/Food and Drug Administration (Thai FDA)	**Class 2–3**: Certificate of Notified Medical Device **Class 4**: Certificate of Licensed Medical Device

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ANNEX 2
(normative)

CAB TIMELINE FOR CONDUCTING CONFORMITY ASSESSMENT

The recommended man-days for a CAB to perform the initial and recertification assessment, including report writing and issuance of a certificate of conformity for Class B, C, and D medical devices, are as outlined in **Table 6** below. This timeline excludes the establishment timeline for any response during the submission.

Table 6: CAB Timeline for conducting initial certification assessment or recertification assessment for Class B, C and D medical device

Process Stage	Description of Process Stage	TAT of Initial/Recertification
Initial CAB-Establishment Engagement	Establishment engagement Discussion of the scope and assessment process	3 working days
	Initial application submission	3 working days
	Contract review	3 working days (Finalization within 2 weeks)
Pre- Assessment Preparation	Pre- assessment 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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ANNEX 3
(informative)

SUBMISSION GUIDE FOR CLASS A MEDICAL DEVICE REGISTRATION APPLICATION IN MeDC@St
FOR NEW AND RE-REGISTRATION APPLICATION

The guides represent the minimum information/documentation that the manufacturer shall prepare and submit in the system. 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.

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
SECTION 1: MEDICAL DEVICE CLASSIFICATION			
Medical device risk and classification details	● The risk classification and rule in accordance with the rules of medical device classification as outlined in the First Schedule of MDR 2012 and 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).	√	
Establishment detail	● The establishment shall have a valid license as a local manufacturer or authorised representative (AR) as defined in Section 2 of Act 737 with a valid license number and expiration date. ● This information is pre-populated from the establishment license module.	√	
SECTION 2: DETERMINE IF THE PRODUCT IS A MEDICAL DEVICE			
Medical device interpretation, accessory, component	● Determine whether a product is a medical device as defined in Section 2 of Act 737, an accessory or a component. ● Accessory means an article that is intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose or to augment or extend the capabilities of that device in fulfilment of its intended use as a medical device. ● Component means one of several possibly unequal subdivisions that together constitute the whole medical device to achieve the latter's intended purpose, which may also be known as a part but not a medical device in its own right.	√	
SECTION 3: MEDICAL DEVICE GENERAL INFORMATION			
Medical device name	● The product meets the definition of a medical device under Section 2 of Act 737 and Guidance Document on the Definition of Medical Device (MDA/GD/0006). ● The name of a medical device given by its manufacturer that identifies a manufacturer's medical device as distinct from those of other manufacturers, as per device label, IFU, catalogue and brochure. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Proprietary name / brand	● 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. The brand name shall be on the label, DoC and technical documentation.	√	

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MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
	● For re-registration, no changes to existing information unless approved by MDA via a change notification.		
Medical device category	● A medical device category is a broad grouping of medical devices that share common characteristics, such as their purpose, type of use (diagnostic, therapeutic, monitoring, etc.), or the area of the body they affect.	√	
Is the medical device meant for export only?	● The importation, exportation, or placement of a medical device in the Malaysian market requires the medical device to be registered under Act 737. Medical Device (Exemption) Order 2024 states that medical devices for the purpose of export only are exempted from registration requirements and shall make an application for an exemption to the Authority as outlined in the Guidance Document on Notification on Export only Medical Device (MDA/GD/0051).	√	
Description of medical device	● 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 re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Common intended use of medical device	● 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. ● It shall be consistent with the data in technical documentation including IFU, CSDT, clinical evaluation report and approved intended use in the recognised foreign regulatory authorities or notified bodies. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
HS Code/GMDN Code /Unique device identifier/UMDNS Code	● HS Code (Harmonized System Code) means an internationally standardized system of names and numbers used to classify traded products. ● GMDN means the code to identify a medical device at generic level in a meaningful manner used by regional or national regulatory bodies. The code is an international nomenclature system provided by GMDN Agency. ● UDI stands for Unique Device Identifier. It is a globally standardized system used to identify and track medical devices throughout their lifecycle, from production to use and eventual disposal. The UDI system enhances patient safety, facilitates post-market surveillance, and improves supply chain efficiency. ● UMDNS Code stands for Universal Medical Device Nomenclature System Code. It is a coding system developed to provide a standardized way to identify and classify medical devices and equipment.	√ if applicable	

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MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
IFU / Brochure / Product Catalogue	● The IFU is also known as the product insert user or operating manual. Instructions of use including the procedures, methods, frequency, duration, quantity and preparation to be followed for the safe use of the medical device. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging in other formats/forms. ● Brochure/product catalogue is 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, etc. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
SECTION 4: MEDICAL DEVICE GROUPING			
Medical device grouping (list of devices)	● 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 re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
SECTION 5: ADDITIONAL REQUIREMENTS			
Measuring function ● Validation report & certificate (conforms to metrological requirement)	● For medical devices with a measuring function where inaccuracy could have a significant adverse effect on the patient, studies demonstrating conformity with metrological requirements shall be provided.	√ if applicable	
Supplied sterile - Sterillization validation report & certificate	● For medical devices supplied sterile, the following information is to be provided: - detailed information of the initial sterilisation validation including bio burden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. If initial sterilisation validation is not performed, adequate justification must be provided. For example, if reference to the sterilisation validation conducted for another medical device is made for the medical device in the application, the justification for the applicability of the previously conducted validation to the current medical device must be provided. In addition, the initial sterilisation validation report for the reference medical device must be provided; - evidence of the on-going revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilisation processes; - detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed in accordance with those standards, and a summary of results; - post-sterilisation functional test on the medical device;	√ if applicable	

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MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
	- if the sterilant is toxic or produces toxic residuals (e.g. ethylene oxide residues), test data and methods that demonstrate that post-process sterilant and/or residuals are within acceptable limits must be presented.		
Others: please specify - Any related document	● This section is specifically intended for tests performed to ensure the safety and/or effectiveness of the device that are not addressed in other sections. This should include a description of the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test, e.g. biological evaluation test, software validation, stability, certificate of analysis, material safety data sheet, etc.	√ if applicable)	√ if applicable
Active medical device ● Validation report / certificate	● Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be provided. This should include a summary of the non-clinical evidence, e.g. summary and electrical safety test protocols, reports, certificates (IEC 60601-1 series).	√ if applicable	
Contain animal, human, microbial, recombinant origin (IVD) ● Package insert containing information on all list of material ● Identify of immediate sources of all list material	● Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included. This should include: - 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; - detailed information concerning the selection of sources/donors; - detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances; - process validation results to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents; - full description of the system for record keeping allowing traceability from sources to the finished medical device.	√ if applicable	
SECTION 6: MANUFACTURER INFORMATION			
Legal manufacturer's name and address	● The name and address of the legal manufacturer. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Quality management system information - QMS standard(s), certificate no., issuance	● The manufacturer's QMS certificate, issued by a foreign recognised notified body (NB) or regulatory authority (RA) or MDA registered CAB granting the certificate. ● Updated copies of ISO 13485 certificates or other acceptable QMS are to be provided from the legal manufacturer – MDSAP, US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 or ISO 9001 (for a class A empty gas cylinder only).	√	√ updated QMS

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MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
date, expiry date, QMS certificate	● Copies of ISO 13485 certificates or MDSAP,US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 or ISO 9001 (for a class A empty gas cylinder only) 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. ● Outsourcing activities shall be addressed in the audit report. An audit report may be requested if deemed necessary. ● For re-registration, the QMS shall be updated.		
List of manufacturing site ● Manufacturing site's name and address, QMS information	● The sites including contract manufacturers where design and manufacturing activities are performed and/or outsourcing of manufacturing activities shall be indicated. ● The manufacturing site's QMS certificate shall be provided for the manufacturing sites of the finished devices. ● For refurbished devices, the refurbishment process must be covered within the scope of the QMS certificate. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.	√ if applicable	
SECTION 7: PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL			
● USFDA ● Australia TGA ● European Union (EU) ● Health Canada ● Japan MHLW ● Non-reference countries	● Providing the pre-market information is optional but advisable to support the application. ● MDA may also request the document if deemed necessary.	√ if applicable	√ if applicable
SECTION 8: LABELLING			
Medical device labelling	● 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: - 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). - 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/ MDA registration number, storage conditions and shelf life information, Bahasa Malaysia translation for home use/self-test device shall be stated on the device label. ● For re-registration, an updated label shall be provided, with the MDA registration number and AR information.	√	√ updated label
SECTION 9: POST-MARKET SURVEILLANCE AND VIGILANCE			

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MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
● History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies	● Include a summary of reportable adverse events and field corrective actions (FCAs), including recalls for the past 3 years. ● For FCAs, including recalls that are 'open', provide a description of any analysis and/or corrective and preventive actions undertaken by the manufacturer. ● 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, provide an attestation letter from the manufacturer on company letterhead, that there have been no adverse events or FCAs, including recalls since the commercial introduction of the device. ● For re-registration, an updated PMS shall be provided.	√	√ updated PMS
SECTION 10: DECLARATION OF CONFORMITY			
Declaration of Conformity (DoC)	● The manufacturer shall be required to attest that its medical device complies fully with all essential principles for safety and performance and shall draw up an updated DoC in the format as specified in Appendix 3 of the Third Schedule of MDR2012 and Guidance Document on Declaration of Conformity (MDA/GD/0025). The QMS information shall be valid and vertical and horizontal standards shall be stated. ● The DoC shall be prepared with the manufacturer's letterhead and signed by the company's top management. ● For re-registration, an updated DoC shall be provided.	√	√ updated DoC
Any related information	● Other information not covered under the above sections such as a change notification letter issued by MDA (if any) shall be submitted. If no changes, provide a declaration letter of no change to the device for the last 5 years for re-registration.	√ if applicable	√ if applicable

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-End of Table -

ANNEX 4
(normative)

SUBMISSION GUIDE FOR CLASS B, C, AND D FOR CONFORMITY ASSESSMENT BY CAB AND SUBMISSION OF APPLICATION IN MeDC@St

FOR NEW AND RE-REGISTRATION APPLICATION

The guides represent the minimum information/documentation that the manufacturer shall prepare and submit in the system. 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.

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MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
SECTION 1: MEDICAL DEVICE CLASSIFICATION			
Establishment detail	• The establishment shall have a valid license as a local manufacturer or authorised representative (AR) as defined in Section 2 of Act 737 with a valid license number and expiration date. • This information is pre-populated from the establishment license module.	√	
SECTION 2: MEDICAL DEVICE GENERAL INFORMATION			
Role of establishment to the medical device	• Role of establishment to the medical device – local manufacturer or authorised representative	√	
Medical device name	• The product meets the definition of a medical device under Section 2 of Act 737 and Guidance Document on the Definition of Medical Device (MDA/GD/0006). • The name of a medical device given by its manufacturer that identifies a manufacturer's medical device as distinct from those of other manufacturers, as per device label, IFU, catalogue, brochure. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Proprietary name / brand	• 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. The brand name shall be on the label, DoC and technical documentation. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Medical device category	• A medical device category is a broad grouping of medical devices that share common characteristics, such as their purpose, type of use (diagnostic, therapeutic, monitoring, etc.), or the area of the body they affect.	√	
Device meant for export only	• The importation, exportation, or placement of a medical device in the Malaysian market requires the medical device to be registered under Act 737. Medical Device (Exemption) Order 2024 states that medical devices for the purpose of export only are exempted from registration requirements and shall make an application for an exemption to the Authority as outlined in the Guidance Document on Notification on Export only Medical Device (MDA/GD/0051).	√	
Combination product	• The medical device incorporates medicinal substance in an ancillary role as defined in the Guideline for Drug-Medical Device and Medical Device-Drug Combination Products 5th Edition. • If yes, provide an endorsement letter (EL) / acknowledgement receipt (AR) issued by NPRA. If AR is submitted, an EL shall be submitted to MDA within a year from the AR issuance date.	√	
Medical device contains any active ingredient, poison or drug	• Indicate whether the medical device contains any formulation, active ingredient, poison or drug. The ingredient, scientific name, ingredient function, quantity and composition percentage information shall be provided. • The template is downlodable from MeDC@St system.	√	

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	● MDA may seek confirmation from NPRA to confirm that the components does not achieve its primary mode of action by pharmacological, immunological or metabolic action in/on the body.		
Description of medical device	● 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 re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Intended use of medical device	● 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. ● It shall be consistent with the data in technical documentation including IFU, CSDT, clinical evaluation report and approved intended use in the recognised foreign regulatory authorities or notified bodies. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
● HS Code ● GMDN Code ● Unique device identifier ● UMDNS Code	● HS Code (Harmonized System Code) means an internationally standardized system of names and numbers used to classify traded products. ● GMDN means the code to identify a medical device at generic level in a meaningful manner used by regional or national regulatory bodies. The code is an international nomenclature system provided by GMDN Agency. ● UDI stands for Unique Device Identifier. It is a globally standardized system used to identify and track medical devices throughout their lifecycle, from production to use and eventual disposal. The UDI system enhances patient safety, facilitates post-market surveillance, and improves supply chain efficiency. ● UMDNS Code stands for Universal Medical Device Nomenclature System Code. It is a coding system developed to provide a standardized way to identify and classify medical devices and equipment.	√	
SECTION 3: MEDICAL DEVICE GROUPING			
Medical device grouping (list of devices)	● The listing is 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 re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
SECTION 4: COMMENT SUBMISSION DOSSIER TEMPLATE (CSDT)			

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CSDT	● CSDT elements 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 re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Executive summary	● An executive summary shall be provided with the CSDT, which shall include the following information: a. an overview which covers an introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features (e.g. nanotechnology) and a synopsis of the content of the CSDT; b. commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries; c. intended uses and indications in its label; d. list of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in all reference agencies; copies of certificates or approval letters from each reference agency and declaration on labelling, packaging and instructions for use (IFU); e. The IFU is also known as the products insert user or operating manual. Instructions of use including the procedures, methods, frequency, duration, quantity and preparation to be followed for the safe use of the medical device. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging in other formats/forms.	√	
EPSP	● 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) shall be submitted. Alternatively, the checklist of EU or Australian Essential Requirements addressing similar elements as Malaysian EP can be submitted. ● An EP checklist established for the medical devices includes information about the 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.	√	

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	● 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.		
Description of medical device	● 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.	√	
Summary of design verification and validation documents	● This section should summarize or reference or contain design verification and design validation data to the extent appropriate to the complexity and risk class of the device. Such documentation should typically include: a. declarations/certificates of conformity to the "recognised" standards listed as applied by the manufacturer; and/or b. summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.	√	
Pre-clinical studies	● The preclinical studies are 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 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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	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	● An updated clinical evaluation report (CER) reviewed and signed by an expert in the relevant field contains an objective critical evaluation of all of the clinical data submitted about the device. Clinical evidence for general medical device may include: - A systematic review of the 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 documentation of the appraisal to the extent that it can be critically reviewed by others; and/or - 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 - Clinical investigation data including all pivotal clinical study reports; ● 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-vitro medical devices	● Performance evaluation for IVD medical devices shall include the following: -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 a marketed device)) and provide a	√	√ updated CPR

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	discussion of how this is considered sufficient to support the request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section; -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. NOTE: Clinical performances should be conducted in the accredited laboratories.		
	-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; -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); -Discussion to support why the evidence presented is sufficient to support the application. 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.		
Medical device labelling	● 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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	- 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); - 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/ MDA registration number, storage conditions and shelf life information, Bahasa Malaysia translation for home use/self-test device shall be stated on the device label. ● This shall include brochure/product catalogue - 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. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.		
Risk analysis	● Results of the risk analysis process conducted in accordance with ISO 14971:2019 ● This should include: - the latest risk management report; - a list of possible hazards of these devices; - the technique used to analyse risk; - the evaluation of these risks against the claimed benefits of the device; - the description on the method (s) used to control or reduce risk to acceptable levels; - 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
Manufacturer information	● The manufacturing process for the device 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. ● For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Use of existing bibliography	● If clinical evaluation is done by conducting a systematic review of the existing bibliography, copies of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness are required.	√	

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Misc	• This section is specifically intended for tests performed to ensure the safety and/or effectiveness of the device that are not addressed in other sections. This should include a description of the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test.	√	
SECTION 5: MANUFACTURER INFORMATION			
Legal manufacturer's name and address	• The name and address of the legal manufacturer. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Quality management system information - QMS standard(s), certificate no., issuance date, expiry date, QMS certificate	• The manufacturer's QMS certificate, issued by a foreign recognised notified body (NB) or regulatory authority (RA) or MDA registered conformity assessment body (CAB) granting the certificate. • Updated copies of ISO 13485 certificates are to be provided from the legal manufacturer or other acceptable QMS – MDSAP, US FDA Quality Systems Regulations or Japan MHLW Ordinance 169. • The scope of certification shall be applicable for the device to be registered. • Outsourcing activities shall be addressed in the audit report. An audit report may be requested if deemed necessary. • For re-registration, the QMS shall be updated.	√	√ updated QMS
List of manufacturing site • Manufacturing site's name, address, QMS information	• The sites including contract manufacturers where design and manufacturing activities are performed and/or outsourcing of manufacturing activities shall be indicated. • The manufacturing site's QMS certificate shall be provided for the manufacturing sites of the finished devices. • For refurbished devices, the refurbishment process must be covered within the scope of the QMS certificate. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√ if applicable	
SECTION 6: PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL			
Therapeutic Goods Administration (TGA), Australia	• As listed in Table 1 and Annex 1 of this guidance document. • A declaration of conformity by the manufacturer shall be submitted, in addition to the TGA license.	√	√ If applicable
Ministry of Health, Labour and Welfare (MHLW) Japan	• As listed in 1 and Annex 1 of this guidance document. • The certificate shall be translated into English language.		
Health Canada	• As listed in Table 1 and Annex 1 of this guidance document..		
Medicines & Healthcare Products Regulatory	• As listed in Table 1 and Annex 1 of this guidance document.		

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Agency (MHRA), United Kingdom			
Food and Drug Administration (FDA), USA	• As listed in Table 1 and Annex 1 of this guidance document..		
European Union (EU)	• As listed in Table 1 and Annex 1 of this guidance document. • A declaration of conformity by the manufacturer shall be submitted, in addition to the EC certificate issued by the notified bodies.		
Health Science Authority (HSA), Singapore	• As listed in Table 1 and Annex 1 of this guidance document..		
Food and Drug Administration (Thai FDA), Thailand	• As listed in 1 and Annex 1 of this guidance document. • The certificate shall be translated into English language.		
SECTION 7: CONFORMITY ASSESSMENT			
Name of CAB	• A registered CAB name under Act 737	√	√ updated CAB report and certificate
CAB registration no.	• Registered CAB registration number		
CA certificate: valid from	• State CAB certificate validity date		
CA certificate: valid to	• State CAB certificate validity date		
CAB certificate and CAB report	• Certificate and report issued by a registered conformity assessment body (CAB)		
SECTION 8: POST-MARKET SURVEILLANCE AND VIGILANCE			
• History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies • Application/registration has been rejected /	• Include a summary of reportable adverse events and field corrective actions (FCAs) for the past 3 years. • For FCAs, including recalls that are 'open', provide a description of any analysis and/or corrective and preventive actions undertaken by the manufacturer. • 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, provide an attestation letter from the manufacturer on company letterhead, that there have been no adverse events or FCAs, including recalls since the commercial introduction of the device.	√	√ updated PMS

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suspended in other country (-ies)? ● Ongoing Post-Market Issues?			
SECTION 9: DECLARATION OF CONFORMITY			
Declaration of Conformity	● The manufacturer shall be required 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). ● The updated 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. ● For reregistration, an updated DoC shall be provided. ● Other information not covered under the above sections such as a change notification letter issued by MDA (if any) shall be submitted. If no changes, provide a declaration letter of no change to the device for the last 5 years for re-registration.	√	√ updated DoC

-End of Table -

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MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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