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Guidelines for implementation of medical device regulatory system

HOW TO SUBMIT AN APPLICATION FOR REGISTRATION OF A REFURBISHED MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

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

This Guideline 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; and

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

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

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

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Introduction

This guideline is produced to assist the manufacturer and AR (authorized representative) to submit the registration on refurbished medical device. Section 5(1) of 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.

1. Scope

This guidelines specifies requirements and application process to register the refurbished medical devices. It covers all registered or unregistered medical devices that are intended to be refurbished.

In accordance with this recommendation, refurbished medical equipment must be registered via the Medical Device Centralised Online Application System (MeDC@St). The manufacturer or the authorised representative is in charge of registering a refurbished medical device.

Exclusion: This document's guidelines do not apply to the remanufacturing of medical devices.

2. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

2.1 Applicant

Manufacturer or Authorized Representative

2.2 Authority

The Medical Device Authority established under Medical Device Authority Act 2012 (Act 738).

2.3 Authorized Representative

An authorized representative appointed by a manufacturer having a principal place of business outside Malaysia, and such person and authorized representative being—

(i) a person domiciled or resident in Malaysia; or
(ii) a firm or company constituted under the laws of Malaysia,

and carrying on business or practice principally in Malaysia;

2.4 Establishment

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

2.5 Manufacturer

A person who is responsible for –

(i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a subcontractor acting on the person's behalf, who carries out these operations; and
(ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement; or

any other person who –

(i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and
(ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement

2.6 Refurbishment

To restore a used medical device or medical device to manufacturer defined safety and performance standards, which include actions such as repair, recondition, rework, software updates, replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service procedures defined by the manufacturer without changing its intended use.

2.7 Refurbished Medical Device

A medical device of which the whole or any part thereof has been rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it:
(i) stripping into component parts or subassemblies;
(ii) checking their suitability for reuse;
(iii) replacement of components/sub-assemblies not suitable for reuse;
(iv) assembly of the reclaimed and/or replacement components/sub-assemblies;
(v) testing of the assembled device against either original or revised release criteria; or
(vi) identifying an assembled medical device as a refurbished medical device.

2.8 Remanufacturing

Actions taken, such as processing, conditioning, renovating, repackaging, etc. on a used medical device or medical device, that significantly changes the device's or medical device's performance, safety specifications, or intended use.

2.9 Third party refurbisher

Any person who is authorised by the manufacturer to refurbish a medical device. If a third party refurbisher places a refurbished medical device in the market under its own name, he is considered a manufacturer as defined in Medical Device Act 2012 (Act 737).

2.10 Used medical device

A medical device that has been in use, is removed from service, and then is reactivated, typically at a different site.

2.11 Place in the market

Means to make available a medical device in return for payment or free of charge with a view to distributing, using, supplying, or putting it into service, in Malaysia, regardless of whether it is new or reprocessed, but does not include to make available for use for clinical research or for performance evaluation of a medical device.

3. Requirements for registration

3.1 An application for the registration of a refurbished medical device shall be made according to the requirements in Act 737, Medical Device Regulations 2012, medical device circular letter and guidance document.

3.2 The person responsible for registering a refurbished medical device is the manufacturer or the authorized representative. Refurbished medical device to be registered is subject to the following requirements:

Manufacturer	Authorized Representative
Shall obtain establishment license as Manufacturer	Shall obtain establishment license as Authorized Representative
Registration application shall be in accordance with the prescribed registration requirements and shall be submitted through MeDC@St	Registration application shall be in accordance with the prescribed registration requirements and shall be submitted through MeDC@St
The refurbishment activities shall be included in the scope of quality management system for the manufacture of medical device - *to include GRPMD in scope ISO 13485- clause 7.5*	Shall comply with Good Distribution Practice of Medical Device (GDPMD) - *compulsory requirement for clause 28 in GDPMD*
Refurbishment activities shall comply with Good Refurbishment Practice for Medical Devices (GRPMD)	Refurbishment activities shall comply with Good Refurbishment Practice for Medical Devices (GRPMD)
The medical device shall undergo conformity assessment by Conformity Assessment Body (CAB)	The medical device shall undergo conformity assessment by Conformity Assessment Body (CAB)
The label of a refurbished medical device shall comply with the requirements as per MDA/GD/0026 Requirements for Labelling of Medical Devices	The label of a refurbished medical device shall comply with the requirements as per MDA/GD/0026 Requirements for Labelling of Medical Devices
The medical device labelling shall include the term “Refurbished” and carry a different catalogue number with a suffix of [R]	The medical device labelling shall include the term “Refurbished” and carry a different catalogue number with a suffix of [R]

4. Conducting conformity assessment

Class A medical devices are exempt from the conformity assessment process under the Exemption Order of 2016. Before submitting a registration application to the Authority, medical devices fall under Class B, C, and D must undergo a conformity assessment by an appointed Conformity Assessment Body (CAB).

A registered CAB must be appointed by the manufacturer or authorized representative to carry out the assessment. Upon completion of the conformity evaluation, the CAB will issue a certificate of conformity and the report.

While the element of conformity assessment for medical devices manufactured locally and medical devices imported from countries not recognized by MDA shall be assessed through the Full Conformity Assessment route, the element of conformity assessment shall be assessed through verification of evidence of conformity (verification process) by CAB for medical devices that have been approved by regulatory authorities or notified bodies recognized by MDA.

4.1 The parameter to be verified by CAB in its verification process shall comprise of the conformity assessment elements as stipulated in Third Schedule of MDR 2012 as follows:

i) Conformity assessment of quality management system (QMS);

ii) Conformity assessment of post market surveillance system;

iii) Conformity assessment of technical documentation; and

iv) Conformity assessment of declaration of conformity.

4.2 The CAB shall only issue the conformity assessment (verification procedure) certificate after confirming that all supporting documentation and the report have been thoroughly examined and verified independently.

4.3 Conformity assessment report and shall contain information as stated in Appendix 1.

4.4 The personnel conducting the verification process for refurbished medical devices must sign the conformity assessment report and certificate.

4.5 The certificate shall be valid for 5 years.

5. Application Procedure

The MeDC@St system, which is accessible through the MDA Portal, includes an application form for the registration of refurbished medical devices. It is an internet-accessible web-based online application form. A MeDC@St account must be set up by the applicant in order to submit an application.

The establishment shall label the medical devices in accordance with MDA/GD/0026, Requirement for Labelling of Medical Devices, with the registration number and other information.

After the medical device is registered, any changes must be reported by the establishment via a change notification in accordance with MDA/GD/0020, Change Notification for Registered Medical Device.

Figure 1 shows the steps to be taken to register a refurbished medical device

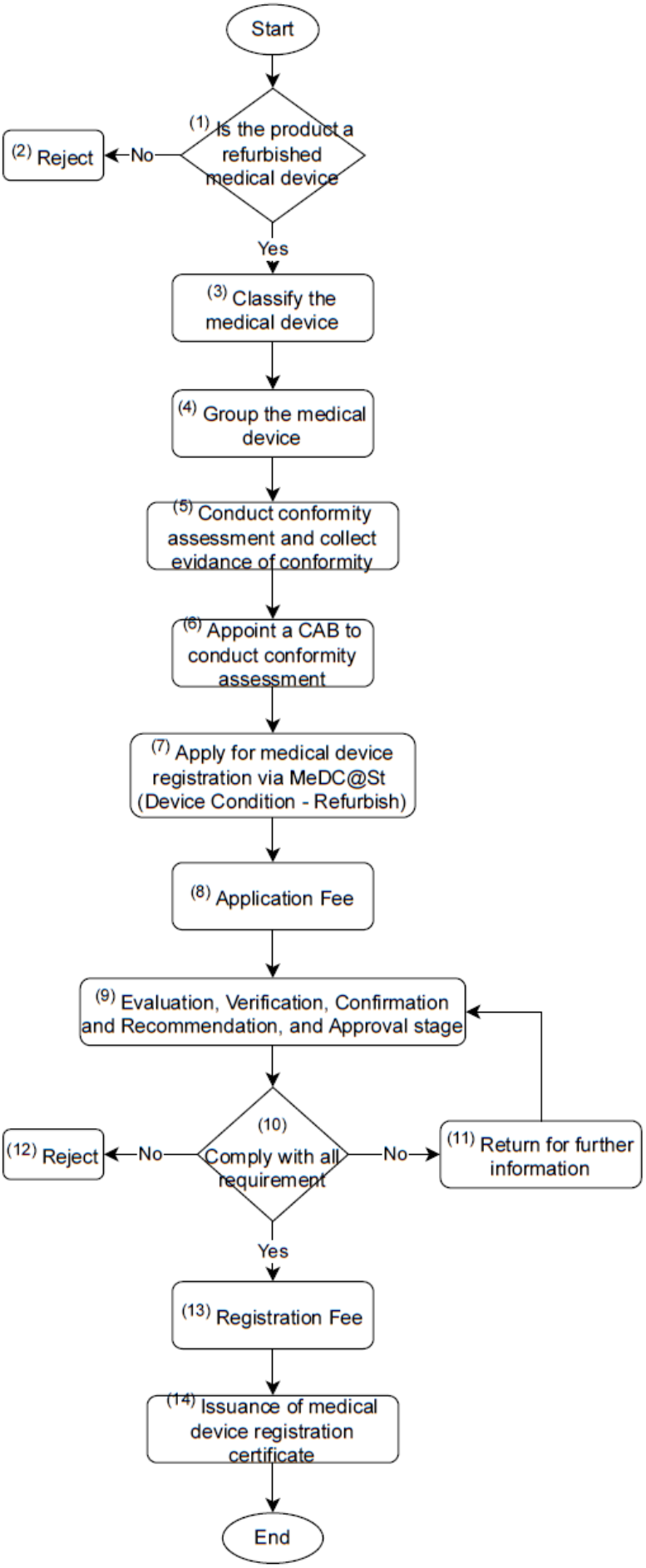

Figure 1: Flowchart of refurbished medical device registration process

Table 1: The table below provides explanation on the above flowchart

No	Step	Explanation
(1)	Determine whether the medical device is a refurbished medical device	The determination of the refurbished medical device will be based on the definition in the Guidance Document on Refurbished Medical Device (MDA/GD/0060)
(2),(12)	Reject	The application could be initially rejected due to various: i) The product is not a medical device. - The product does not meet Section 2 of Act 737's definition of a medical device. ii) The medical device is not refurbished medical device iii) Does not comply with refurbished medical device requirement iv) Misclassification of a medical device - The medical device is not classified in accordance with the First Schedule of the Medical Device Regulations of 2012.
(3)	Appropriately classify the medical device	The First Schedule of the Medical Device Regulation of 2012 specifies the rules for medical device classification, 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) elaborates these rules further.
(4)	Appropriately group the medical device	Medical device grouping should follow the guidelines outlined in the Second Schedule of the Medical Device Regulation 2012 and further clarified in the Guidance Document on Product Grouping of Medical Devices (MDA/GD/0005) or Product Grouping for In Vitro Diagnostic (IVD) Medical Devices (MDA/GD/0054).
(5)	Conduct conformity assessment and collect evidence of conformity	Conformity assessment for the purpose of registration shall comprise of the following elements: • Quality Management System (QMS) • Post-market Surveillance System (PMS) • Technical Documentation • Declaration of Conformity (DOC) Please refer to Table 2: The requirement and criteria for refurbished medical device
(6)	Appoint CAB to conduct conformity assessment	According to 3rd Schedule of Medical Device Regulation 2012 (i) the evidence of conformity has to be verified or validated by the registered CAB; (ii) the CAB has to issue certificate of conformity and the report upon completion of the conformity assessment.

(7)	Apply to register medical device using MeDC@St	(i) The manufacturer or authorized representative shall be responsible for registration of the refurbished medical device through MeDC@St.; (ii) Applicant must create an account before making application via MeDC@St. (iii) The selection of medical device condition is refurbished medical device
(8),(13)	Application fee / Registration fee	i) The application fee is as per Fifth Schedule (Table of Fees) in Medical Device Regulations 2012. ii) The payment shall be made through bank draft, online banking and credit card.
(9)	Evaluation, Verification, Confirmation & Recommendation, and Approval Stage	All application will go through Evaluation, Verification, Confirmation & Recommendation, and Approval stage by MDA
(10)	Comply with all requirement	Comply with the requirements and the information and supporting documents to support the requirement are available.
(11)	Return for further information	The applicant may receive the application back in the event of: i) Insufficient or unsatisfactory information is provided ii) Supporting document is not attached iii) Wrong supporting document is attached and etc. Note: • Any additional information requested by the Authority need to be furnished and submitted to the Authority via MeDC@St within 90 days from the request date. •The application will be removed from MeDC@St if any additional information requested by the Authority is not provided by the applicant within 90 days or any other extension period allowed by the Authority. However, this will not affect the applicant's right to submit a new application.
(14)	Issuance of medical device registration certificate	The certificate will be issued once the application has been approved and completed.

Table 2: The requirement and criteria for refurbishment of medical device:

No	Requirement	Document to be submitted	Criteria
1.	Description of medical device	IFU/Brochure/ Product Catalogue	The description of medical device should be done according to labelling (catalogue/ brochure/ IFU).
2.	Intended use of medical device	IFU/Brochure/ Product Catalogue	The intended use of medical device shall be remained with no change.
3.	CSDT	CSDT	The CSDT shall be submitted in accordance with Appendix 2 of the Medical Device Regulations 2012 or the Guidance Document on Common Submission Dossier Template (CSDT) (MDA/GD/0008) or the Guidance Document Common Submission Dossier Template (CSDT) of In-Vitro Diagnostic (IVD) Medical Device (MDA/GD/004), as applicable.
	Pre-clinical	Pre-clinical report	Preclinical report shall be provided in compliance with Medical Device Regulations 2012 Appendix 2.
	Clinical evidence	Clinical evaluation report	The clinical evaluation report shall be submitted in accordance with Appendix 2 of Medical Device Regulations 2012.
	Risk analysis	Risk analysis report	The risk analysis report shall be submitted in accordance with Appendix 2 of Medical Device Regulations 2012.
	Labelling	IFU/Brochure/ Product Catalogue	• The IFU/ brochure/ product catalogue/ labelling shall be submitted • The labelling of medical device should be done according to the labelling requirement as specified in First Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on Requirements for Labelling of Medical Devices (MDA/GD/0026). • The medical device labelling shall include the term “Refurbished” and carry a different catalogue number with a suffix of [R].

4.	Manufacturer information	Valid QMS certificate SOP on refurbishment activities	• Valid QMS certificate of the manufacturer shall be submitted. • The refurbishment activities shall be included in the scope of QMS for the manufacture of medical device • Refurbishment activities shall comply with Good Refurbishment Practice for Medical Devices (GRPMD) in accordance with Medical Device Guidance Document (MDA/GD/0029)
5.	Pre-market clearance/ approval**	Valid pre-market approval certificate	Valid pre-market approval certificate shall be submitted.
6.	Conformity assessment	Valid conformity assessment certificate and report	Valid conformity assessment certificate and report shall be submitted.
7.	Post-market surveillance and vigilance	Declaration on no ongoing post market issue: • List of reported ongoing incidents globally (if applicable); • List of incidents that have been resolved for the past 3 years (if applicable); and • Date of last audit	Shall be submitted declaration on no ongoing post market issue: • List of reported ongoing incidents globally (if applicable); • List of incidents that have been resolved for the past 3 years (if applicable); and • Date of last audit
8.	Declaration of Conformity (DoC)	Updated DoC	The updated DoC shall be submitted. The template shall be in accordance with Appendix 1A of Medical Device Regulations 2012.

6. Evaluation Timeline

The following table specifies the evaluation timeline (counted in working days upon receipt of complete application) for the refurbishment of medical device application via Medc@st.

Class of Medical Device	Timeline
Class A	30 days
Class B	60 days
Class C	60 days
Class D	60 days

Table 3: Evaluation timeline of refurbishment of medical device

7. Table of Fee

As per the Fifth Schedule of the Medical Device Regulations 2012, the descriptions of fees are as below:

Class of Medical Device	Application Fee (RM)
Class A	100
Class B	250
Class C	500
Class D	750

Table 4: Application fee

Class of Medical Device	Application Fee (RM)
Class A	-
Class B	1000
Class C	2000
Class D	3000

Table 5: Registration fee

APPENDIX 1

REPORT ON CONFORMITY ASSESSMENT FOR REFURBISHED MEDICAL DEVICE TEMPLATE

[To be printed on CAB Letterhead]

Conformity Assessment Report for Refurbished Medical Device

Details of CAB	
Name of CAB	
Address	
CAB registration no.	
Medical Device Technical Areas (Code)	
Details of establishment applying for conformity assessment for refurbished medical device	
Manufacturer/ AR name	
Manufacturer/ AR address	
Establishment license no.	
Details of medical device	
Name of medical device	
Classification and classification rules	
Manufacturer of medical device	
Grouping of medical device (single, family, system. Set or IVD cluster)	

Conformity assessment checklist by CAB for refurbished medical device				
No	**Verification Review Items**	**Review result**		**Remark/ Justification**
		Evidence to be examined	**Comply/ Not comply**	
Basic medical device information				
1.	Medical device classification: The classification of medical device should be done according to the rules of medical device classification as specified in First Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on The Rules of Classification for General Medical Devices	The classification of medical device done according to the rules of medical device classification as specified in First Schedule of Medical Device Regulation 2012? ☐ Correct ☐ Incorrect		

	(MDA/GD/0009) or In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001).			
2.	Intended use of medical device: i) The intended use/ indication for use shall be the same as what has been approved by the recognized country. ii) The intended use/ indication for use of medical device shall be remained with no change with existing registered medical device.	i) The intended use/ indication for use shall be the same as what has been approved by the recognized country? ☐ Yes ☐ No ii) The intended use/ indication for use of medical device shall be remained with no change with existing registered medical device. ☐ Yes ☐ No iii) Intended use/ indication for use in accordance with instruction for use (IFU)? ☐ Yes ☐ No		
3.	Medical device grouping: i) The grouping of medical device should be done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on Product Grouping of Medical Device (MDA/GD/0005);	i) The grouping of medical device done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012? ☐ Yes ☐ No		
Conformity assessment of quality management system (QMS)				
4.	Manufacturer information i) Authenticity of the manufacturer's QMS certificate, e.g. ISO 13485 or other equivalent QMS certificate issued by	i) Authenticity of the manufacturer's QMS certificate, ISO 13485 other equivalent QMS certificate issued by foreign recognized notified body or		

	foreign recognized notified body or regulatory authority granting the certificate; ii) Scope of QMS of the manufacturer of medical device as required by Third Schedule of MDR 2012; and iii) All certificates submitted shall be within validity period. iv) The refurbishment activities shall be included in the scope of QMS for the manufacture of medical device v) Refurbishment activities shall comply with Good Refurbishment Practice for Medical Devices (GRPMD) in accordance with Medical Device Guidance Document (MDA/GD/0029)	regulatory authority granting the certificate has been reviewed and verified? ☐ Yes ☐ No Name of RA or NB: ii) Scope of QMS of the manufacturer of medical device as required by Third Schedule of MDR 2012 has been reviewed and verified? ☐ Yes ☐ No Scope of certificate: iii) A certificate submitted is within validity period? ☐ Yes ☐ No Certificate no.: Date of issue: Expiry date: Register no.: iv) Scope of QMS for refurbishment activities has been reviewed and verified? ☐ Yes ☐ No Scope of certificate: v) Refurbishment activities comply with Good Refurbishment Practice for Medical Devices (GRPMD) ☐ Yes ☐ No vi) SOP on refurbishment activities ☐ Yes ☐ No		
Conformity assessment of post market surveillance system				
5.	Post-market surveillance and vigilance:	i) List of reported ongoing incidents globally has been		

	i) List of reported ongoing incidents globally (if applicable); ii) List of incidents that have been resolved for the past 3 years (if applicable); and iii) Date of last audit	reviewed and verified? ☐ Yes ☐ No List of reported ongoing incidents: ii) List of incidents that have been resolved for the past 3 years has been reviewed and verified? ☐ Yes ☐ No List of incidents that have been resolved: iii) Date of last audit has been reviewed and verified? ☐ Yes ☐ No Date of last audit:		
Conformity assessment of technical documentation				
6.	Pre-market clearance/ approval: Authenticity and validity of CE mark certificate and/ evidence of approval by recognized foreign regulatory authority.	Authenticity and validity of CE mark certificate and/ evidence of approval by recognized foreign regulatory authority has been reviewed and verified? ☐ Yes ☐ No Certificate no.: Date of issue: Expiry date: Scope of certificate: Manufacturing site:		
7.	CSDT: The CSDT shall be submitted in accordance with Appendix 2 Third Schedule of Medical Device Regulations 2012 or Guidance Document on Common Submission Dossier Template (CSDT) (MDA/GD/0008) or Guidance Document Common Submission Dossier Template (CSDT) of In- Vitro Diagnostic (IVD) Medical Device (MDA/GD/004).	i) The CSDT in accordance with Appendix 2 Third Schedule of Medical Device Regulations 2012 authority has been reviewed and verified? ☐ Yes ☐ No ii) All the element of CSDT in accordance with Appendix 2 Third Schedule of Medical Device Regulations 2012 authority has been reviewed and verified? ☐ Yes ☐ No		

	Preclinical report shall be provided in compliance with Appendix 2 Third Schedule of the Medical Device Regulations 2012	Preclinical report is provided in compliance with Appendix 2 Third Schedule of the Medical Device Regulations 2012 ☐ Yes ☐ No		
	The clinical evaluation report shall be submitted in accordance with Appendix 2 Third Schedule of Medical Device Regulations 2012	The clinical evaluation report is submitted in accordance with Appendix 2 Third Schedule of the Medical Device Regulations 2012 ☐ Yes ☐ No		
	The risk analysis report shall be submitted in accordance with Appendix 2 of the Medical Device Regulations 2012	The risk analysis report is submitted in accordance with Appendix 2 of the Medical Device Regulations 2012 ☐ Yes ☐ No		
8.	Labelling: The labelling of medical device should be done according to the labelling requirement as specified in First Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on Requirements for Labelling of Medical Devices (MDA/GD/0026). The medical device labelling shall include the term “Refurbished” and carry a different catalogue number with a suffix of [R].	i) The labelling of medical device done according to the labelling requirement as specified in First Schedule of Medical Device Regulation 2012? ☐ Yes ☐ No ii) The labelling of medical device done according to Guidance Document on Requirements for Labelling of Medical Devices (MDA/GD/0026)? ☐ Yes ☐ No Manufacturer/ AR information: Malaysia Medical Device Registration No: iii) The medical device labelling shall include the term “Refurbished” and carry a different catalogue number with a suffix of [R]. ☐ Yes ☐ No		

Conformity assessment of Declaration of Conformity (DoC)				
9.	Declaration of Conformity (DoC): The updated DoC shall be submitted. The template shall be in accordance with Appendix 1A of Medical Device Regulations 2012.	i) The updated DoC done in accordance with Appendix 1A of Medical Device Regulations 2012? ☐ Yes ☐ No ii) All the information specified in DoC has been reviewed and verified in accordance with relevant supporting document? ☐ Yes ☐ No iii) Supporting document available? List of medical device: ☐ Yes ☐ No List of standard: ☐ Yes ☐ No vii) DoC is valid? ☐ Yes ☐ No Date of issued: viii) DoC signed by manufacturer? ☐ Yes ☐ No		

Prepared by:
Name and signature of technical personnel:
Date:

Approved by:
Name and signature of certification manager:
Date:

References

[1] Medical Device Act 2012 (ACT 737)

[2] Medical Device Regulation 2012

[3] Circular Letter No. 1/2016 Refurbishment of Medical Device

[4] Circular Letter No. 3/2022 Refurbishment of Medical Device

[5] Guidance Document MDA/GD/0029 Good Refurbishment Practice of Medical Device (GRPMD)

[6] Guidance Document MDA/GD/0060 Refurbished Medical Device – Requirements

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