

**GUIDELINE FOR:
CONFORMITY ASSESSMENT PROCEDURE FOR RE-REGISTRATION OF REGISTERED MEDICAL
DEVICE BY CONFORMITY ASSESSMENT BODY (CAB)**



Introduction

- (1) This document was prepared by the MDA to guide CAB to conduct conformity assessment procedure for registered medical device (re-registration applications).
- (2) This document describes the process for conducting conformity assessment by way of verification of the evidence for medical devices that have been registered with MDA for the first 5 years and their registration certificate are near expiry or expired.
- (3) Irrespective of the requirements of this 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.
- (4) MDA reserves the right to amend any part of the document as necessary.

Objective

- (5) This document is intended to provide guidance to CAB in Malaysia on conformity assessment procedure for re-registration of registered medical device.

Scope

- (6) This document prescribes verification process requirements for re-registration of registered medical devices for near expiry or expired medical device registration applications only for Class B, C and D.

Note :

This document is only valid for an interim period before further notification by MDA on the re-registration policy.

Eligibility of CAB

- (7) The eligibility of CAB to conduct verification process for re-registration of registered medical device are as follows:
 - i) The CAB shall be registered under Medical Device Act 2012 (Act 737); and
 - ii) The auditor or technical personnel shall be registered for verification scope under Medical Device Act 2012 (Act 737).

Process flow of conformity assessment procedure by CAB for re-registration of registered medical device

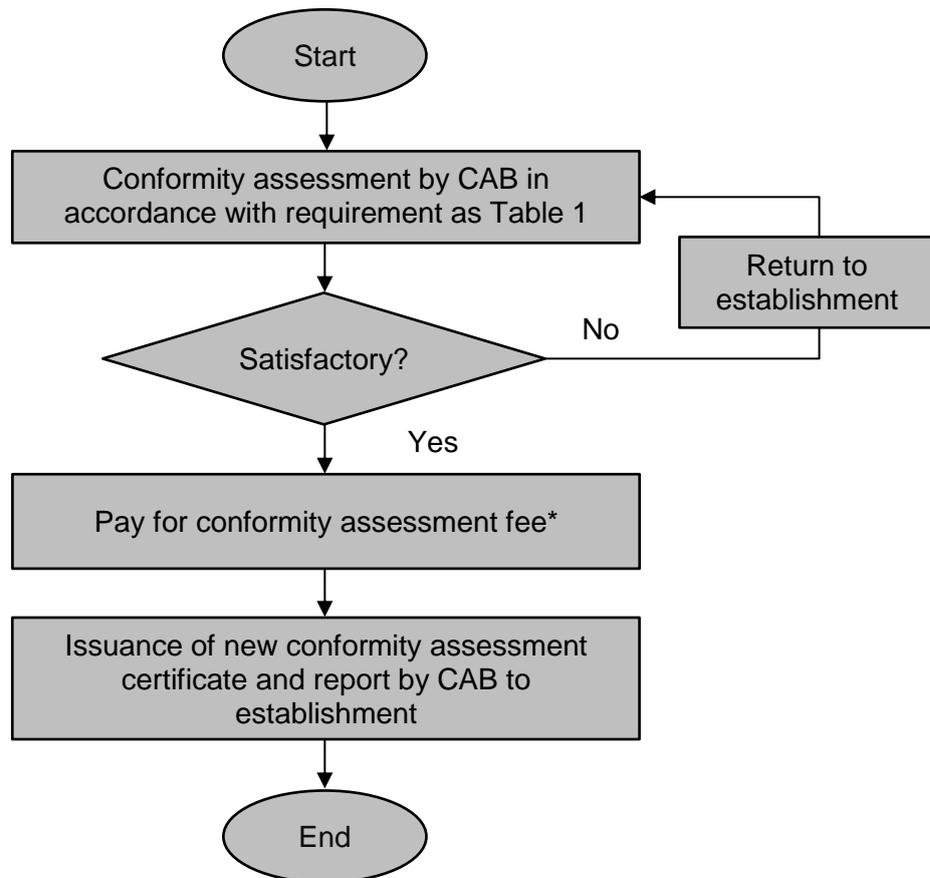


Figure 1: Flowchart of conformity assessment procedure by CAB for re-registration of registered medical device.

Note :

*The recommended man-hours is 2 hours per application. Please refer paragraph 9 below.

Conformity assessment element to be verified by CAB

(8) 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.

(9) Requirement for conformity assessment procedure for re-registration of registered

medical device.

No	Element	Criteria/ Parameters to be verified
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 (MDA/GD/0009) or In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001).
2.	Intended use of medical device	<ul style="list-style-type: none"> 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.
3.	Medical device grouping	<ul style="list-style-type: none"> 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); ii) The list of configurations shall be same with existing registered medical device; and iii) The medical device list in grouping shall be in accordance with Medical device registration certificate and change notification approval letter issued by MDA (if applicable).
Conformity assessment of quality management system (QMS)		
4.	Manufacturer information	<ul style="list-style-type: none"> i) Authenticity of the manufacturer's QMS certificate, e.g. ISO 13485 or other equivalent QMS certificate issued by 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.
Conformity assessment of post market surveillance system		
5.	Post-market surveillance and vigilance	<ul style="list-style-type: none"> 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
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.
7.	CSDT	The updated CSDT shall be in accordance with

CONFORMITY ASSESSMENT PROCEDURE FOR RE-REGISTRATION BY CAB

		Appendix 2 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).
8.	Labelling	The labelling of medical device shall be in accordance with 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).
9.	Combination Product (Device-drug) (Class D Rule 13)	Endorsement letter issued by National Pharmaceutical Regulatory Agency (NPRA) for combination product in accordance with Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products Third Edition.
10.	Declaration on change of notification	Change notification letter issued by MDA (if applicable) shall be submitted.
11.	Medical device registration certificate	A copy of medical device registration certificate shall be submitted.
Conformity assessment of Declaration of Conformity (DoC)		
12.	Declaration of Conformity (DoC)	The updated DoC shall be submitted. The template shall be in accordance with Appendix 1A of Medical Device Regulations 2012.

Table 1: Requirement for conformity assessment procedure for re-registration of registered medical device.

Recommended man-hours for issuance of certificate

- (10) The recommended man-hours for a CAB to perform the verification process for re-registration of registered medical device including report writing and issuance of certificates for all classes of medical devices is 2 hours per application.

Conformity assessment for re-registration of registered medical device report and certificate

- (11) CAB shall only issue the conformity assessment (verification process for re-registration of registered medical device) certificate upon completion of verification of all evidence of conformity and report has been reviewed and checked independently.
- (12) Conformity assessment report and certificate for re-registration of registered medical device shall contain information as stated in Appendix 1.
- (13) The conformity assessment report and certificate shall be signed by the personnel conducting the verification process for re-registration of registered medical device.
- (14) The certificate shall be valid for 5 years.

APPENDIX 1

CONFORMITY ASSESSMENT REPORT FOR RE-REGISTRATION OF REGISTERED
MEDICAL DEVICE TEMPLATE

[To be printed on CAB Letterhead]

Conformity Assessment Report For Re-Registration of Registered 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 re-registration of registered 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 re-registration of registered medical device				
No	Verification Review Items	Review result		Remark/ Justification
		Evidence to be examined	Comply/ Not comply	
Basic medical device information				
1.	<p>Medical device classification:</p> <p>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 (MDA/GD/0009) or In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001).</p>	<p>The classification of medical device done according to the rules of medical device classification as specified in First Schedule of Medical Device Regulation 2012?</p> <p><input type="checkbox"/> Correct</p> <p><input type="checkbox"/> Incorrect</p>		
2.	<p>Intended use of medical device:</p> <p>i) The intended use/ indication for use shall be the same as what has been approved by the recognized country.</p> <p>ii) The intended use/ indication for use of medical device shall be remained with no change with existing registered medical device.</p>	<p>i) The intended use/ indication for use shall be the same as what has been approved by the recognized country?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>ii) The intended use/ indication for use of medical device shall be remained with no change with existing registered medical device.</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>iii) Intended use/ indication for use in accordance with instruction for use (IFU)?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>		
3.	<p>Medical device grouping:</p> <p>i) The grouping of medical device should be done</p>	<p>i) The grouping of medical device done according to the rules of medical device</p>		

CONFORMITY ASSESSMENT PROCEDURE FOR RE-REGISTRATION BY CAB

	<p>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);</p> <p>ii) The list of configurations shall be same with existing registered medical device; and</p> <p>iii) The medical device list in grouping shall be in accordance with Medical device registration certificate and change notification approval letter issued by MDA (if applicable).</p>	<p>grouping as specified in Second Schedule of Medical Device Regulation 2012?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>ii) The list of configurations is same with existing registered medical device?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>iii) The medical device list in grouping is in accordance with Medical device registration certificate and change notification approval letter issued by MDA?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>		
Conformity assessment of quality management system (QMS)				
4.	<p>Manufacturer information</p> <p>i) Authenticity of the manufacturer's QMS certificate, e.g. ISO 13485 or other equivalent QMS certificate issued by foreign recognized notified body or regulatory authority granting the certificate;</p> <p>ii) Scope of QMS of the manufacturer of medical device as required by Third Schedule of MDR 2012; and</p> <p>iii) All certificates submitted shall be within validity period.</p>	<p>i) Authenticity of the manufacturer's QMS certificate, ISO 13485 other equivalent QMS certificate issued by foreign recognized notified body or regulatory authority granting the certificate has been reviewed and verified?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Name of RA or NB:</p> <p>ii) Scope of QMS of the manufacturer of medical device as required by Third Schedule of MDR 2012 has been reviewed and verified?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Scope of certificate:</p>		

CONFORMITY ASSESSMENT PROCEDURE FOR RE-REGISTRATION BY CAB

		<p>iii) A certificate submitted is within validity period?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Certificate no.:</p> <p>Date of issue:</p> <p>Expiry date:</p> <p>Register no.:</p>		
Conformity assessment of post market surveillance system				
5.	<p>Post-market surveillance and vigilance:</p> <p>i) List of reported ongoing incidents globally (if applicable);</p> <p>ii) List of incidents that have been resolved for the past 3 years (if applicable); and</p> <p>iii) Date of last audit</p>	<p>i) List of reported ongoing incidents globally has been reviewed and verified?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>List of reported ongoing incidents:</p> <p>ii) List of incidents that have been resolved for the past 3 years has been reviewed and verified?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>List of incidents that have been resolved:</p> <p>iii) Date of last audit has been reviewed and verified?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Date of last audit:</p>		
Conformity assessment of technical documentation				
6.	<p>Pre-market clearance/ approval:</p> <p>Authenticity and validity of CE mark certificate and/ evidence of approval by recognized foreign regulatory authority.</p>	<p>Authenticity and validity of CE mark certificate and/ evidence of approval by recognized foreign regulatory authority has been reviewed and verified?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>Certificate no.:</p> <p>Date of issue:</p> <p>Expiry date:</p> <p>Scope of certificate:</p> <p>Manufacturing site:</p>		
7.	<p>CSDT:</p> <p>The updated CSDT shall be submitted in accordance with Appendix 2 of Medical Device Regulations 2012 or Guidance Document</p>	<p>i) The updated CSDT in accordance with Appendix 2 of Medical Device Regulations 2012 authority has been reviewed and verified?</p>		

CONFORMITY ASSESSMENT PROCEDURE FOR RE-REGISTRATION BY CAB

	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).	<input type="checkbox"/> Yes <input type="checkbox"/> No ii) All the element of CSDT in accordance with Appendix 2 of Medical Device Regulations 2012 authority has been reviewed and verified? <input type="checkbox"/> Yes <input type="checkbox"/> 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).	i) The labelling of medical device done according to the labelling requirement as specified in First Schedule of Medical Device Regulation 2012? <input type="checkbox"/> Yes <input type="checkbox"/> No ii) The labelling of medical device done according to Guidance Document on Requirements for Labelling of Medical Devices (MDA/GD/0026)? <input type="checkbox"/> Yes <input type="checkbox"/> No Manufacturer/ AR information: Malaysia Medical Device Registration No:		
9.	Combination Product (Device-drug) (Class D Rule 13)	Endorsement letter issued by National Pharmaceutical Regulatory Agency (NPRA) on combination product has been reviewed and verified? <input type="checkbox"/> Yes <input type="checkbox"/> No		
10.	Declaration on change of notification: Change notification letter issued by MDA (if applicable) shall be submitted.	Change notification letter issued by MDA has been reviewed and verified? <input type="checkbox"/> Yes <input type="checkbox"/> No		
11.	Medical device registration certificate: A copy of medical device registration certificate shall be submitted.	The current Medical device registration certificate has been reviewed and verified? <input type="checkbox"/> Yes <input type="checkbox"/> No		

Conformity assessment of Declaration of Conformity (DoC)				
11.	<p>Declaration of Conformity (DoC): The updated DoC shall be submitted. The template shall be in accordance with Appendix 1A of Medical Device Regulations 2012.</p>	<p>i) The updated DoC done in accordance with Appendix 1A of Medical Device Regulations 2012? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>ii) All the information specified in DoC has been reviewed and verified in accordance with relevant supporting document? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>iii) Supporting document available? List of medical device: <input type="checkbox"/> Yes <input type="checkbox"/> No List of standard: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>iv) DoC is valid? <input type="checkbox"/> Yes <input type="checkbox"/> No Date of issued:</p> <p>v) DoC signed by manufacturer? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>		

Prepared by:

Name and signature of technical personnel:

Date:

Approved by:

Name and signature of certification manager:

Date:

Certificate of Conformity Template

<CAB Name and Logo>

Certificate of Conformity

(by way of verification on evidence of conformity)
FOR RE-REGISTRATION OF REGISTERED MEDICAL DEVICE

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

Holds certificate No : <Certificate No>

Scope:

On the basis of our verification on evidence of conformity of medical device **for re-registration of registered medical device** for the medical device below.

<List of medical device, class and manufacturer>

For and on behalf of <Name of CAB>

Signed by: <Certification Manager>

Effective Date:

Expiry Date:

CAB Registration No:

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

Registration, Licensing and Enforcement Division
Medical Device Authority Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor
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