PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia

Ruj Kami : (5) dlm. MDA. 100-1/8/5
Tarikh : 22 Mei 2014

SURAT PEKELILING PIHAK BERKUASA PERANTI PERUBATAN BILANGAN 2 TAHUN 2014

DASAR PELAKSANAAN DAN PENGUATKUASAAN DI BAWAH AKTA PERANTI PERUBATAN 2012 (AKTA 737):

PENILAIAN PEMATUHAN BAGI PERANTI PERUBATAN YANG TELAH DILULUSKAN PIHAK BERKUASA NEGARA LAIN YANG DIIKTIRAF

TUJUAN

1) Surat pekeliling ini bertujuan menetapkan dasar bagi pelaksanaaan dan penguatkuasaan di bawah Akta Peranti Perubatan 2012 (Akta 737) berkaitan tatacara penilaian pematuhan bagi peranti perubatan yang telah diluluskan Pihak Berkuasa negara lain yang diiktiraf.

LATAR BELAKANG

2) Seksyen 7 Akta 737 menetapkan penilaian pematuhan oleh badan penilaian pematuhan yang berdaftar di bawah seksyen 10 Akta 737 sebagai salah satu keperluan bagi pendaftaran sesuatu peranti perubatan di bawah Akta ini.

3) Walau bagaimanapun, terdapat pelbagai peranti perubatan yang telah menjalani penilaian pematuhan dan diluluskan untuk diletakkan di pasaran negara-negara tertentu yang diiktiraf. Penilaian pematuhan yang dijalankan di negara-negara tertentu yang diiktiraf adalah setara dengan penilaian pematuhan yang dilaksanakan di bawah Akta 737.

PENETAPAN DASAR PELAKSANAAN DAN PENGUATKUASAAN

4) Pengiktirafan bermaksud menerima pakai penilaian pematuhan dan kelulusan meletakkan peranti perubatan di pasaran negara-negara tertentu. Pengiktirafan ini akan mengelakkan pengulangan proses penilaian dan kelulusan yang telah diberikan ke atas sesuatu peranti perubatan dan dengan itu ia akan memudah, mengurangkan kos dan mempercepatkan proses pendaftaran peranti perubatan di negara ini.

5) Atas alasan di atas, **Mesyuarat Pihak Berkuasa Peranti Perubatan Bilangan 2/2014 telah membuat keputusan untuk menetapkan dasar pelaksanaan dan penguatkuasaan seperti berikut:**

i) **Mengiktiraf penilaian pematuhan dan kelulusan meletakkan peranti perubatan di pasaran negara tertentu yang diiktiraf;**

ii) **Bagi peranti perubatan yang telah menjalani penilaian pematuhan dan mendapat kelulusan meletakkannya di pasaran negara yang diiktiraf, ia hanya perlu menjalani proses penilaian pematuhan yang lebih ringkas, iaitu melalui proses verifikasi bukti-bukti pematuhan yang diperolehi dari pembuat peranti perubatan tersebut;**

iii) **Proses verifikasi tersebut hendaklah dijalankan oleh badan penilaian yang berdaftar di bawah seksyen 10 Akta 737 mengikut tatacara seperti yang ditetapkan dalam Lampiran 1.**

PEMAKAIAN DAN TARIKH KUAT KUASA

6) Surat pekeliling hendaklah diguna pakai sebagai sebahagian daripada keperluan di bawah Akta 737 dan surat pekeliling ini berkuat kuasa mulai tarikh ia dikeluarkan.

PERTANYAAN

7) Sebarang pertanyaan mengenai surat pekeliling ini boleh ditujukan kepada :

Ketua Eksekutif
Pihak Berkuasa Peranti Perubatan
Kementerian Kesihatan Malaysia
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No. 26, Jalan Persiaran Perdana, Presint 3
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Emel: mdb@mdb.gov.my

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

(Y. BHG. DATUK DR. NOOR HISHAM B ABDULLAH)
Pengerusi
Pihak Berkuasa Peranti Perubatan
Kementerian Kesihatan Malaysia

Appendix 1
Revision 5
Effective Date: 25 April 2022

CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICE APPROVED BY RECOGNISED COUNTRIES

A. Introduction

(1) This appendix 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 2012 (Act 737) and the regulations under it.

(2) This appendix describes the process for conducting conformity assessment by way of verification of the evidence for medical devices that have been approved by regulatory authorities or notified bodies recognized by Medical Device Authority (MDA).

(3) Irrespective of the requirements of this appendix, MDA has the right to request for information or material, or define conditions not specifically described in this appendix that is deemed necessary for the purpose of regulatory control.

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

(5) MDA reserves the right to amend any part of the appendix as necessary.

(6) This appendix has been revised from its original version and the changes as listed in Annex C. The main topics covered in this appendix are:

B. Objectives

(7) This appendix is intended to provide guidance to authorised representative (AR), manufacturer and conformity assessment body (CAB) in Malaysia on conformity assessment procedure through verification of evidence of conformity (verification process) for medical devices that have been approved by countries recognised by MDA.

(8) It identifies the requirements of verification process, eligibility of CAB to perform the verification process and the manner in which MDA approves certificate and report issued by CAB after the verification process has been completed.

(9) It also provides AR, manufacturer and CAB with suggestion on the indicative man-hour for the verification process.

C. Scope and application

(10) This appendix prescribes requirements for verification process for medical devices that have been subjected to conformity assessment and approved by regulatory authorities or notified bodies recognised by MDA.

(11) It is applicable to all medical devices that have been subjected to conformity assessment and approved by any of the recognised foreign regulatory authorities or notified bodies with respective approval type as shown in Table 1, except for those which are exempted from registration in Malaysia.

Table 1: Recognised foreign regulatory authorities and notified bodies and the respective approval types eligible for conformity assessment by way of verification process

Recognised foreign regulatory authority or notified body	Approval Type
(i) Therapeutic Goods Administration (TGA) Australia	TGA licence
(ii) Health Canada, Canada	Health Canada medical device licence
(iii) Notified bodies listed in New Approach Notified and Designated Organisations (NANDO) database of European Union (EU)	• EC Certification (CE Marking) against EU MDD, EU IVDD and EU AIMDD, as below: For general medical device: ▪ Annex II Section 3 or Annex V of MDD (for Class IIA) ▪ Annex II Section 3 or Annex III coupled with Annex V of MDD (for Class IIB) ▪ Annex II Section 3 and 4 of MDD (for Class III) ▪ Annex II Section 3 and 4 of AIMDD (for active implantable medical device)

Recognised foreign regulatory authority or notified body	Approval Type
	For IVD medical device: ▪ Annex IV (Including Section 4 and 6) of IVDD (for List A IVD) ▪ Annex IV (excluding Section 4 and 6) or Annex V coupled with Annex VII of IVDD (for List B and self-testing IVD) ▪ Annex III, EC declaration of conformity (Section 1 to 5 of Annex III). Applicable for only Class B IVD medical device in accordance with Medical Device Regulations 2012; or • EC Certification (CE Marking) against EU Medical Device Regulations and EU IVD Regulations; or • Listed in European Database on Medical Devices (EUDAMED)
(iv) Ministry of Health, Labour and Welfare (MHLW) Japan	• Pre Market Certification from a Japanese Registered Certification Body (RCB and PMDA). • Pre Market Approval from MHLW.
(v) Food and Drug Administration (FDA), United States of America (USA)	• US FDA 510(k) clearance letter • US FDA pre-market approval (PMA) letter
(vi) Medicines & Healthcare products Regulatory Agency (MHRA), United Kingdom	For Great Britain and Northern Ireland • Public Access Database for Medical Device Registration; or • UKCA Certification; or • EC (CE Marking) and UKNI Certification
(vii) Other foreign regulatory authorities or notified bodies	To be determined by MDA from time to time

(12) Medical devices which have not obtained any approval by regulatory authorities or notified bodies listed in Table 1 is required to undergo full conformity assessment by any registered CAB in accordance with the requirements stipulated in Section 7(1)(a) of Act 737.

D. Legal Basis

(13) Section 7(1)(a) of Act 737 prescribes that upon receipt of an application made under Section 6 of the Act, MDA being satisfied that the medical device has been subjected to the conformity assessment procedures to be carried out by the CAB, MDA may register the medical device for a prescribed period.

(14) Section 10(1) of Act 737 prescribes that a CAB shall be a body registered under this Act to carry out conformity assessment of a medical device to be registered.

(15) For the purpose of product registration, it is further required that all medical devices shall be subjected to conformity assessment to demonstrate its conformity to the requirements as specified in Third Schedule of Medical Device Regulation (MDR) 2012.

E. Eligibility of CABs to conduct verification process

(16) Section 10 of Act 737 prescribes that conformity assessment of medical device shall be carried out by CAB. Hence, it is pertinent that the CABs shall carry out the conformity assessment with due diligence and adhering to all the regulatory requirements as stipulated in Act 737 and its subsidiary legislations. The CABs shall be independent and impartial with regards to the performance of its conformity assessment duties as stipulated in Section 10(3)(a) of Act 737 and paragraphs 9(2) and 9(7) of Fourth Schedule of MDR 2012.

(17) The following criteria shall apply for the eligibility of CABs for performing conformity assessment of a medical device by way of verification process—

(i) For medical devices which have been subjected to conformity assessment by recognised foreign regulatory authorities in Table 1, the verification process of the said medical device may be carried out by any CABs registered under Act 737;

(ii) Where a medical device has its conformity assessment already carried out by a recognised foreign notified body in Table 1, then the subsidiary of the foreign notified body registered as CAB under Act 737 shall not be allowed to do verification on the same medical device. However, it may be carried out by any other CABs registered under Act 737;

(iii) Where a medical device has its conformity assessment already carried out by any other regulatory authorities recognised by MDA from time to time, then the criteria in (ii) shall apply; and

(iv) The CABs which are eligible to conduct verification process shall have been registered with at least one scope under Medical Device Technical Area (Appendix 1 of Fourth Schedule MDR 2012). Example: A CAB with registered scope of MD 0203 may conduct verification process on a medical device under any Medical Device Technical Areas.

F. Conformity assessment elements and parameters to be verified by CAB

(18) The parameters 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;

(ii) Conformity assessment of post market surveillance system;

(iii) Conformity assessment of technical documentation; and

(iv) Conformity assessment of declaration of conformity.

(19) The extent of verification activities will depend on the class of the medical device.

G. Verification steps for a Class B, C or D medical device

(20) Verification steps and parameters to be verified by CAB for a Class B, C or D medical device are described in Figure A and Table 2 respectively.

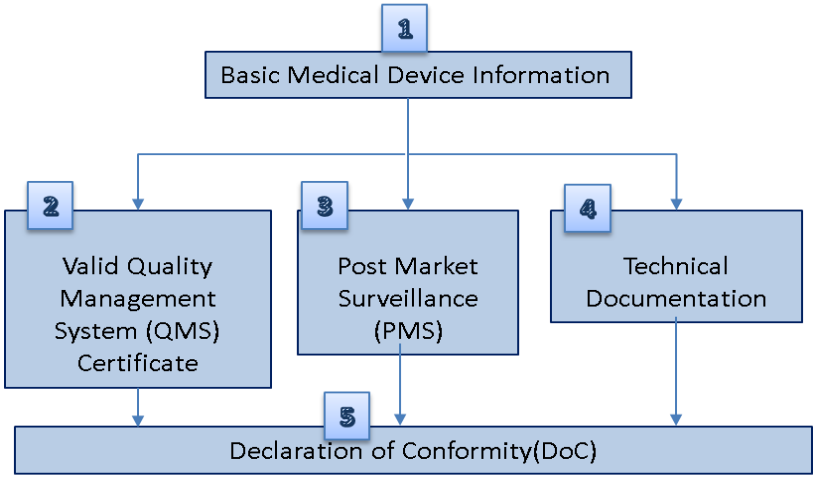

Figure A: Verification steps for a Class B, C or D medical device

Table 2: Verification steps and parameters to be verified for a Class B, C or D medical device

Step	Parameters to be verified
1) Basic Medical Device Information	(i) It shall be a medical device, based on intended use as described in technical documentation; (ii) The intended use/indication for use shall be the same as what has been approved by the recognized country; (iii) Classification and application of risk classification rule shall be in accordance with Appendix 1of First Schedule MDR 2012; and (iv) Grouping of medical device shall be in accordance with Rule of Grouping in Second Schedule MDR 2012.
2) Valid QMS Certificate	(i) Authenticity of the manufacturer's QMS certificate, eg ISO 13485 or other equivalent QMS certificate, issued by foreign recognised 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
2) Post-market surveillance (PMS)	(i) List of reported ongoing incident globally (if applicable); (ii) List of incidents that have been resolved for the past 3 years (if applicable); and (iii) Date of last audit.
3) Technical documentation	(i) Authenticity and validity of CE mark certificate and/or evidence of approval by recognised foreign regulatory authority; (ii) Common Submission Dossier Template (CSDT);

Step	Parameters to be verified
	(iii) Any claims of intended use on labels and labelling shall be consistent with information on intended use provided in step 1; and (iv) Labelling shall be in accordance with Sixth Schedule MDR 2012.
4) Declaration of Conformity (DoC)	DoC including supporting documents prepared according to Appendix 3 Third Schedule MDR 2012.

H. Recommended man-hours for issuance of certificate

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

I. Conformity assessment (by way of verification on evidence of conformity) report and certificate

(22) CAB shall only issue the conformity assessment (verification) certificate upon completion of verification of all evidence of conformity and the report has been reviewed and checked independently.

(23) Conformity assessment report by way of verification shall contain the following—

(i) Details of CAB that include the name, address and registration number of the CAB and the name of personnel conducting the verification process;

(ii) Details of AR or manufacturer applying for verification process that include the name, address, establishment license number and contact number of the AR or manufacturer;

(iii) Details of medical device that include the name, classification and manufacturer of the medical device;

(iv) Verification review result against Table 2 and 3;

(v) The report shall be signed by the personnel conducting the verification process; and

(vi) The CAB may use report template as shown in Annex A.

(24) The elements of certificate of conformity by way of verification shall be as per the template in Annex B.

(25) The certificate shall be valid for 5 years.

Annex A

(normative)

Conformity Assessment Report Template

CAB Letterhead

Conformity Assessment Report

(By way of verification of evidence of conformity)

Details of CAB	
Name of CAB	
Address	
CAB Registration No.	
Medical Device Technical Areas (Code)	
Details of establishment applying for verification process	
Manufacturer/AR Name:	
Manufacturer/AR address:	
Establishment license No:	
Details of medical device	
Name of medical device	
Classification and classification rules	
Manufacturer of medical device	
Grouping of medical device (single, family, system, set or IVD cluster)	

No	Verification Review items	Review result		Remarks
		Evidence to be examined	Result (comply/no)	
1)	**Conformity assessment of QMS**			
(i)	Authenticity of the manufacturer's QMS certificate, eg ISO 13485 or other equivalent QMS certificate, issued by foreign recognised notified body or regulatory authority granting the certificate	Name of RA or NB:		
(ii)	Scope of QMS of the manufacturer of medical device as required by Third Schedule of MDR 2012	Scope of certificate: Certificate no:		
(iii)	All certificates submitted shall be within validity period	Date of issue:		
(iv)	Notified body shall be a valid notified body	Expiry date:		
(v)	Notified bodies listed in New Approach Notified and Designated Organisations (NANDO) database of European Union (EU)	Register No:		
2)	**Conformity assessment of PMS**			
(i)	List of reported ongoing incident globally (if applicable)	List of ongoing incidents:		
(ii)	List of incidents that have been resolved for the past 3 years (if applicable)	List of incidents resolved:		
(iii)	Date of last audit	Date of last audit:		
3)	**Conformity assessment of technical documentation**			
(i)	Authenticity and validity of CE mark certificate and/or evidence of approval by recognised foreign regulatory authority	(i) CE mark (including Annex, certificate) or letter/certificate issued by foreign regulatory authority (ii) Certificate no: (iii) Annex: (iv) Date of issue: (v) Date of expiry: (vi) Scope of certificate: (vii) Manufacturing site:		
(ii)	Common Submission Dossier Template (CSDT): The CSDT shall be submitted in accordance with Appendix 2 of Medical Device Regulation 2012 or	(i) All relevant elements of CSDT (ii) Conform to template? (Yes/No)		

No	Verification Review items	Review result		Remarks
		Evidence to be examined	Result (comply/no)	
	Guidance Document on Common Submission Dossier Template (CSDT) (MDA/GD/0008) or Guidance Document on Common Submission Dossier Template (CSDT) of In-Vitro Diagnistic (IVD) Medical Device (MDA/GD/0004)	(iii) All headers included? (Yes/No) (iv) CSDT prepared by manufacturer includes all relevant elements? (Yes/No) (v)Evidence has been reviewed and verified? e.g. review on relevant test reports, sterilization reports, calibration certificate, software validation report.		
(iii)	Any claims of intended use on labels and labelling shall be consistent with information on intended use provided in step 1	(i) Label? (Yes/No) (ii) MD name: (iii) Intended use: (iv) Legal manufacturer:		
(iv)	Labelling shall be in accordance with Sixth Schedule MDR 2012	Labelling according to Sixth Schedule MDR 2012?		
4)	**Conformity assessment of declaration of conformity** Declaration of conformity including supporting documents prepared according to Appendix 3 Third Schedule MDR 2012	(i) Is DoC available? (Yes/No) (ii) Is DoC conform to template? (Yes/No) (iii) Supporting documents available? a) List of device? b) List of standards? (iv) Validity of DoC a) Date issued (v) DoC signed by manufacturer? (Yes/No)		

No	Verification Review items	Review result		Remarks
		Evidence to be examined	**Result (comply/no)**	
5)	**Conclusion of verification** Conclusion and recommendation	(i) Satisfactory/Not satisfactory (ii) Recommended for issuance of certificate (iii) Pending for outstanding documents (iv) Remarks are rectified		

Prepared by:

Name and signature of technical personnel:

Date:

Annex B

(normative)

Certificate of Conformity Template

< CAB Name & Logo>

Certificate of Conformity

(by way of verification on evidence of conformity)

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 approved by **recognised foreign regulatory authorities and/or notified bodies** 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:

Annex C

(informative)

List of changes

Revision	Description of Amendment	Effective Date
Revision 1	Title: **Original:** Directive on Conformity Assessment for the purpose of registration of medical device under Medical Device Act 2012 (Act 737): Verification of Evidence of Conformity of Imported Medical Device **Revised:** Conformity Assessment Procedures For Medical Device Approved By Recognised Countries Scope: **Original version** covers conformity assessment to be conducted by CAB on the evidence of conformity collected by the local ARs of the imported medical device **Revised version** covers conformity assessment to be conducted by CAB on the evidence of conformity collected by manufacturer or ARs of the medical devices whether imported or locally manufactured. Eligibility of CABs to conduct verification process: **Additional requirement:** The CABs which are eligible to conduct verification process shall have been registered with at least one scope under Medical Device Technical Area (Appendix 1 of Fourth Schedule MDR 2012). Conformity assessment elements and parameters to be verified by CAB: Table 2 **replaced** with: • new Table 2: Verification steps and parameters to be verified for Class A (active, sterile or measuring function) medical device • new Table 3: Verification steps and parameters to be verified for a Class B, C or D medical device Recommended man-hours for issuance of certificates: **Original:** Explained in Table 3, Man-hours vs medical device class	4th Jan 2016

Revision	Description of Amendment	Effective Date
	Revised: 2 man-hours per application for all classes of medical devices <u>Templates for verification Report and template for Certificate of Conformity:</u> **Introduced** in Annex A and B	
Revision 2	<u>Table 1: Recognised foreign regulatory authorities and notified bodies</u> **Addition** of Annex III, EC declaration of conformity (Section 1 to 5 of Annex III). Applicable for only Class B IVD medical device in accordance with Medical Device Regulation 2012, in approval type from EU notified bodies in Table 1 <u>Annex A. Conformity Assessment Report Template</u> 1. **Addition** of Medical Device Technical Areas Code in Conformity Assessment Report Template. 2. **Addition** of register number of Notified bodies listed in New Approach Notified and Designated Organisations (NANDO) database of European Union (EU) as evidence to be examined for verification process.	20th Jan 2017
Revision 3	**Removal** of Verification steps for Class A (active, sterile or with measuring function) medical device	15th Apr 2019
Revision 4	<u>Table 1: Recognised foreign regulatory authorities and notified bodies:</u> 1. **Amendment and addition** of approval type issued by NB: • EC Certification (CE Marking) against EU Medical Device Regulations and EU IVD Regulations; or • Listed in European Database on Medical Devices (EUDAMED) 2. **Addition** of MHRA, UK as recognised foreign RA and its approval type for Great Britain and Northern Ireland: • Public Access Database for Medical Device Registration; or • UKCA Certification; or • EC (CE Marking) and UKNI Certification	13th Oct 2021

Revision	Description of Amendment	Effective Date
Revision 5	<u>Table 1: Recognised foreign regulatory authorities and notified bodies:</u> **Re-addition** of EC Certification (CE Marking) against EU MDD, EU IVDD and EU AIMDD, as below: For general medical device: ▪ Annex II Section 3 or Annex V of MDD (for Class IIA) ▪ Annex II Section 3 or Annex III coupled with Annex V of MDD (for Class IIB) ▪ Annex II Section 3 and 4 of MDD (for Class III) ▪ Annex II Section 3 and 4 of AIMDD (for active implantable medical device) For IVD medical device: ▪ Annex IV (Including Section 4 and 6) of IVDD (for List A IVD) ▪ Annex IV (excluding Section 4 and 6) or Annex V coupled with Annex VII of IVDD (for List B and self-testing IVD) ▪ Annex III, EC declaration of conformity (Section 1 to 5 of Annex III). Applicable for only Class B IVD medical device in accordance with Medical Device Regulation 2012; <u>Annex A: Conformity Assessment Report Template:</u> **Improvement** on Common Submission Dossier Template (CSDT) elaboration under 3) Conformity Assessment of Technical Documentation.	25th Apr 2022