Our Ref: (§) dlm. MDA. 100-1/8/5
Date : 22 May 2014

CIRCULAR LETTER OF THE MEDICAL DEVICE AUTHORITY
NO. 2 YEAR 2014

POLICY ON IMPLEMENTATION AND ENFORCEMENT UNDER THE MEDICAL
DEVICE ACT 2012 (ACT 737):

CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICE APPROVED
BY RECOGNISED COUNTRIES

PURPOSE

1) The purpose of this circular is to set the policy for implementation and enforcement under the Medical Device Act 2012 (Act 737) relating to conformity assessment procedure for medical device approved by recognised countries.

BACKGROUND

2) Section 7 of Act 737 requires the carrying out of conformity assessment by the conformity assessment body registered within Section 10 of Act 737. This is a precondition for having a medical device registered under the Act.

3) However, there are various medical device which have undergone conformity assessment and approved to be placed in certain recognized countries. The conformity assessment done by the respective countries are similar to the requirements under Act 737.

POLICY DECISION FOR IMPLEMENTATION AND ENFORCEMENT

4) Recognition means adopting conformity assessment and approval of medical devices placed in the market of certain countries. This recognition will prevent a repetition of the process of conformity assessment and approval granted on a medical device and therefore will simplify, reduce costs and accelerate the registration of medical devices in this country.

5) For reasons stated above, the Medical Device Authority Meeting No. 2/2014 has decided to set the policy for implementation and enforcement as follows:

a. To recognize the conformity assessment and approval of medical devices placed in the market of a particular country, being a recognized country.

b. For medical devices that have undergone conformity assessment and approval for placement in the market of the recognized countries, it
only needs to undergo a simpler conformity assessment process, which is through the process of verification of evidence-based compliance obtained from the manufacturer of the medical device.

c. The verification process shall be conducted by the conformity assessment body registered under section 10 of Act 737 in accordance with the procedures as set out in Appendix 1.

USAGE AND EFFECTIVE DATE

6) Circular issued shall be used as part of requirements under Act 737 and this circular shall be effective from the date it is issued.

ENQUIRIES

7) Any enquiries relating to this circular can be forwarded to:

Chief Executive  
Medical Device Authority  
Ministry of Health Malaysia  
Level 5, Menara Prisma, No. 26  
Jalan Persiaran Perdana, Presint 3  
62675 Putrajaya, MALAYSIA  
Tel. : (+603) 8892 2400, Fax: (+603) 8892 2500  
Email: mdb@mdb.gov.my

Thank you.

"BERKHIDMAT UNTUK NEGARA"

(Y. BHG. DATUK DR. NOOR HISHAM B ABDULLAH)  
Chairman  
Medical Device Authority  
Ministry of Health Malaysia
Appendix 1

**Directive on Conformity Assessment for the Purpose of Registration of Medical Devices under Medical Device Act 2012 (Act 737): Verification of Evidence of Conformity of Imported Medical Devices**

**Objective**

(1) This Directive is intended to provide guidance to authorized representative (AR) and conformity assessment body (CAB) in Malaysia for conducting conformity assessment procedure on the evidence of conformity obtained by the AR from its foreign manufacturer on imported medical devices that have been approved by regulatory authorities or notified bodies recognized by Medical Device Authority (MDA).

(2) It identifies the requirements of the conformity assessment procedure, eligibility of CAB to perform the conformity assessment procedure and the manner in which MDA approves the conformity assessment certificate and report issued by CAB.

(3) It also provides AR and CAB with suggestion on the indicative man-hour for conformity assessment on the evidence of conformity of medical device obtained by the AR from its foreign manufacturer.

(4) This Directive is made pursuant to Section 79(2)(e) and (f) of Act 737.

**Scope and Application**

(5) The scope of this Directive covers conformity assessment to be conducted by CAB on the evidence of conformity collected by the local ARs of the imported medical devices. It is applicable to imported medical devices of all classes except for medical devices which are exempted from registration.

(6) Regulatory authorities and notified bodies and the approval types recognized by MDA are shown in Table 1.

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Approval Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Australia</td>
<td>Therapeutic Goods Administration (TGA) licence</td>
</tr>
<tr>
<td>(ii) Canada</td>
<td>Health Canada licence</td>
</tr>
<tr>
<td>(iii) European Union (EU)</td>
<td>For general medical device :</td>
</tr>
<tr>
<td></td>
<td>• Annex II Section 3 or Annex V of MDD (for Class IIA)</td>
</tr>
<tr>
<td></td>
<td>• Annex II Section 3 or Annex III coupled with Annex V of MDD (for Class IIB)</td>
</tr>
<tr>
<td></td>
<td>• Annex II Section 3 and 4 of MDD (for Class III)</td>
</tr>
<tr>
<td></td>
<td>• Annex II Section 3 and 4 of AIMDD (for active implantable medical device)</td>
</tr>
<tr>
<td></td>
<td>For IVD medical device :</td>
</tr>
<tr>
<td></td>
<td>• Annex IV (Including Section 4 and 6) of IVDD (for List A IVD)</td>
</tr>
<tr>
<td></td>
<td>• Annex IV (excluding Section 4 and 6) or Annex V coupled with Annex VII of IVDD (for List B and self-</td>
</tr>
<tr>
<td>(iv) Japan</td>
<td>Ministry of Health, Labour and Welfare (MHLW) licence</td>
</tr>
<tr>
<td>(v) United States of America (USA)</td>
<td>• US FDA 510(k) clearance letter [510(k) exempted products do not qualify for abridged evaluation route]; or</td>
</tr>
<tr>
<td>(vi) Any other notified bodies or regulatory authorities recognized by MDA from time to time</td>
<td>• To be determined by MDA from time to time</td>
</tr>
</tbody>
</table>

Table 1: Regulatory authorities and notified bodies and the approval types recognized by MDA

(7) For imported medical devices which have been subjected to conformity assessment by the regulatory authorities or notified bodies recognized by MDA, such medical devices will be assessed according to the procedures described in clauses (17) to (19) of this Directive in accordance with the legal basis as described in clauses (9) through (11) of this Directive. In this case, the conformity assessment procedures carried out by the CABs shall be focused and tailored to the verification of the evidence of conformity assessment.

(8) This Directive does not apply to imported medical devices which have not been subjected to any conformity assessment. Such imported medical devices are required to undergo full conformity assessment by any CAB in Malaysia.

Legal Basis

(9) Section 7(1)(a) of Act 737 prescribed 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.

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

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

Legal Responsibility of Authorized Representative

(12) Paragraph 10(1) of Third Schedule of MDR 2012 requires that for an imported medical device, the AR shall obtain the evidence of conformity as required under paragraphs (3) to (10) of the same Schedule from its foreign manufacturer.

(13) Paragraph 10(2) of Third Schedule of MDR 2012 requires that upon receipt of evidence of conformity from its foreign manufacturer, the AR shall be responsible to appoint a registered CAB to conduct conformity assessment as required under paragraphs (3) to (10) of Third Schedule of MDR 2012.

(14) The underlying rationales for the above being—

(i) Registered CABs conduct conformity assessment on behalf of MDA to ensure compliance to Malaysian medical device regulatory requirements;

(ii) Differences in the foreign conformity assessment procedures which may not necessary meet the Malaysian medical device regulatory requirements;
(iii) Differences in the competency and integrity of notified bodies and foreign regulatory authorities.

**Eligibility and liability of CABs**

(15) It is recognized that Act 737 has delegated conformity assessment duties to the CABs. Hence, it is pertinent that the CABs shall carry out the responsibility with due diligence without compromising on the various regulatory requirements as stipulated in the Act and its subsidiary regulations. The CABs shall be independent and impartial with regards to the performance of its conformity assessments duties as stipulated in Section 10(3)(a) of Act 737 and paragraphs 9(2) and 9(7) of Fourth Schedule of MDR 2012.

(16) The eligibility of the CABs for the conformity assessment of a medical device is for those who are registered under Section 10 of Act 737.

**Criteria for conformity assessment procedures**

(17) The following criteria shall apply for the eligibility of CABs for performing conformity assessment on the evidence of conformity assessment of medical devices obtained by AR from its foreign manufacturer—

(i) Where a medical device has its conformity assessment already done by a recognized foreign notified body, then the notified body's subsidiary registered with MDA as CAB in Malaysia shall not be allowed to do the conformity assessment of the same medical device; however the conformity assessment of the said medical device may be done by any other CABs;

(ii) For medical devices which have been subjected to conformity assessment by recognized foreign regulatory authorities, eg US FDA, Health Canada, TGA Australia or MHLW Japan, the conformity assessment of the said medical device may be done by any CABs;

(iii) Where a medical device has its conformity assessment already done by a recognized foreign notified body, and at the same time has been subjected to one or more conformity assessment by other recognized foreign regulatory authorities, eg US FDA, Health Canada, TGA Australia or MHLW Japan, then the criteria in sub clause (i) shall similarly apply; and

(iv) Where a medical device has its conformity assessment already done by any other regulatory authorities recognized by MDA from time to time, then the criteria in sub clause (i) shall apply.

**Parameters to be verified for each conformity assessment element**

(18) This section describes the verification process to be carried out by CAB. The conformity assessment elements to be verified comprise the following—

(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 classification of the medical device. This verification procedure shall apply to any medical devices as in clause (17). The conformity assessment elements and the parameters to be verified for each element are shown in Table 2.
<table>
<thead>
<tr>
<th>Conformity assessment element</th>
<th>Parameters to be verified</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Conformity assessment of quality management system</td>
<td>(i) Authenticity of the manufacturer’s ISO 13485:2003 certificate issued by foreign recognized notified body or regulatory authority granting the certificate; (ii) Scope; (iii) Standards used; (iv) Validity; (v) Evidence that quality management system has been established, maintained and implemented.</td>
</tr>
<tr>
<td>(2) Conformity assessment of post-market surveillance system</td>
<td>(i) Audit report on post market surveillance system; (ii) Evidence of continued conformity of its medical device to essential principles of safety and performance throughout the post market stage.</td>
</tr>
<tr>
<td>(3) Conformity assessment of technical documentation</td>
<td>(i) Authenticity of CE mark certificate and/or certificate of approval by recognized foreign regulatory authority; (ii) Technical file assessment report on technical documentation.</td>
</tr>
<tr>
<td>(4) Declaration of conformity</td>
<td>(i) Attestation of compliance; (ii) Adequacy of the declaration of conformity including supporting documents.</td>
</tr>
</tbody>
</table>

Table 2: Regulatory authorities and notified bodies and the approval types recognized by MDA

**Recommended man-hours and issuance of certificates**

(20) The recommended man-hours required for carrying out the verification processes, report writing and issuance of certificates shall be in accordance with Table 3.

<table>
<thead>
<tr>
<th>Class</th>
<th>Recommended man-hours required</th>
</tr>
</thead>
<tbody>
<tr>
<td>A sterile &amp; with measurement function</td>
<td>4</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
</tr>
<tr>
<td>B - System</td>
<td>4</td>
</tr>
<tr>
<td>C</td>
<td>6</td>
</tr>
<tr>
<td>C- System</td>
<td>8</td>
</tr>
<tr>
<td>D</td>
<td>8</td>
</tr>
<tr>
<td>D - System</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 3: Recommended man-hours for carrying out the verification process, report writing and issuance of certificate
Scope of Conformity Assessment Certification

(21) The conformity assessment certification shall specify the following—

(i) scope of safety and performance of the medical devices dealt with by the establishment; and

(ii) applicable sections of the Act 737 and its subsidiary legislations.

(22) The information on establishment seeking certification (which include name, address and contact information) shall be indicated in the certification of conformity assessment.

(23) The certificate issued by the CAB shall bear the following information—

(i) particulars of CAB issuing the certificate which include the name and address, company logo, registration number and the name and signature of the certification manager of the CAB; and

(ii) particulars of the certificate issued to the establishment which include the number, validity and expiry date of the certificate

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