



**BORANG PERMOHONAN BADAN  
PENILAIAN PEMATUHAN**

**CONFORMITY ASSESSMENT BODY  
APPLICATION FORM (CABAF)**

**BK-BPPP-028**

**Versi 02**

Tarikh Kuatkuasa

*Effective date*

**27 OGOS 2018**

**Kegunaan Pejabat MDA sahaja (Sila tandakan ✓ jika selesai)**

<input type="checkbox"/> Received form	[Signature&Name: _____]	[Date: _____]
<input type="checkbox"/> CE Office	[Signature&Name: _____]	[Date: _____]
<input type="checkbox"/> Finance Unit	[Signature&Name: _____]	[Date: _____]
<input type="checkbox"/> Head of CAB Unit	[Signature&Name: _____]	[Date: _____]
<input type="checkbox"/> Evaluation officer	[Signature&Name: _____]	[Date: _____]

**A. MAKLUMAT ORGANISASI *Information On The Organisation***

<b>NAMA ORGANISASI</b> <i>Organisation Name</i>			
<b>NOMBOR SSM</b> <i>ROC Number</i>			
<b>ALAMAT SYARIKAT</b> <i>Company Address</i>			
<b>LAMAN SESAWANG</b> <i>Website Address</i>		<b>ALAMAT EMEL</b> <i>Email Address</i>	
<b>NO. TELEFON (PEJABAT)</b> <i>Telephone No (Office)</i>		<b>NOMBOR FAKS</b> <i>Fax Number</i>	
<b>ALAMAT IBU PEJABAT</b> <i>Address of HQ (Applicable For Regional/ Branch)</i>			

**B. ORANG YANG BERTANGGUNGJAWAB *Person Responsible***

<b>NAMA (Seperti di dalam IC)</b> <i>Name (Same as IC)</i>		<b>JANTINA</b> <i>Gender</i>	<b>LELAKI/ PEREMPUAN</b> <i>Male / Female</i>
<b>NO. KAD PENGENALAN</b> <i>IC Number</i>		<b>JAWATAN</b> <i>Designation</i>	
<b>NO. TELEFON (PEJABAT)</b> <i>Contact Number (O)</i>		<b>ALAMAT EMEL</b> <i>Email Address</i>	
<b>NO. TELEFON (HP)</b> <i>Contact Number (HP)</i>		<b>WARGANEGARA</b> <i>Nationality</i>	<b>MALAYSIA</b> <i>Malaysian</i>

**C. SUMBER & PENGURUSAN *Resources & Management***

<b>BILANGAN JURUAUDIT</b> <i>Number of Auditors</i>	( ) TETAP <i>Permanent</i> ( ) SUBKONTRAKTOR <i>Subcontractor</i>	<b>BILANGAN KAKITANGAN PENTADBIRAN</b> <i>Number of Admin Staff</i>	
<b>STATUS UNDANG-UNDANG</b> <i>Legal Status</i>	<b>SUBSIDIARI/ PERKONGSIAN/ AGEN SAH/ LAIN-LAIN:</b> <i>Subsidiary/ Partnership/ Authorised Agent/ Other:</i>		
<b>PERMOHONAN SKOP, SILA TANDAkan (✓)</b> <i>Scope to apply, please tick (✓)</i>	<b>SISTEM PENGURUSAN KUALITI PERANTI PERUBATAN ISO 13485</b> <i>Quality Management System for Medical Devices (ISO 13485)</i>		
	<b>AMALAN PENGEDARAN BAIK PERANTI PERUBATAN (APBPP)</b> <i>Good Distribution Practice for Medical Devices (GDPMD)</i>		
	<b>BIDANG TEKNIKAL PERANTI PERUBATAN (JADUAL KE-4, LAMP1)</b> <i>Medical Device Technical Area (Fourth Schedule, Appendix 1)</i>		

<b>D. ORANG UNTUK DIHUBUNGI/ Contact Person</b>			
<b>NAMA (Seperti di dalam IC)</b> <i>Name (Same as IC)</i>		<b>JANTINA</b> <i>Gender</i>	<b>LELAKI/ PEREMPUAN</b> <i>Male / Female</i>
<b>NO. TELEFON (PEJABAT)</b> <i>Contact Number (O)</i>		<b>ALAMAT EMEL</b> <i>Email Address</i>	
<b>NO. TELEFON (HP)</b> <i>Contact Number (HP)</i>		<b>WARGANEGARA</b> <i>Nationality</i>	<b>MALAYSIA</b> <i>Malaysian</i>

<b>E. DOKUMEN SOKONGAN Supporting Documents</b>	
<b>LAMPIRAN 1</b> <i>Attachment 1</i>	<i>Copy of Bank Draft Receipt (Application Fee)</i>
<b>LAMPIRAN 2</b> <i>Attachment 2</i>	<i>Copy of Certificate of Registration (ROC) - Form 9/ Form 13</i>
<b>LAMPIRAN 3</b> <i>Attachment 3</i>	<i>Copy of Form 49</i>
<b>LAMPIRAN 4</b> <i>Attachment 4</i>	<i>Copy of Form 24</i>
<b>LAMPIRAN 5</b> <i>Attachment 5</i>	<i>Letter of Authorisation (if applicable) for Person Responsible</i>
<b>LAMPIRAN 6</b> <i>Attachment 6</i>	<i>Declaration of Responsibility (DOR) as attached at Page 5</i>
<b>LAMPIRAN 7</b> <i>Attachment 7</i>	<i>List of Job Description(s)/Function(s)</i>
<b>LAMPIRAN 8</b> <i>Attachment 8</i>	<i>Copy of Identity Card (Person Responsible)</i>
<b>LAMPIRAN 9</b> <i>Attachment 9</i>	<i>Copy of Identity Card (Contact Person)</i>
<b>LAMPIRAN 10</b> <i>Attachment 10</i>	<i>Letter of Authorisation for Contact Person</i>
<b>LAMPIRAN 11</b> <i>Attachment 11</i>	<i>Copy of Memorandum &amp; Article of Association (MNA)</i>
<b>LAMPIRAN 12</b> <i>Attachment 12</i>	<i>Relevant Document(s) of the Relationship/Link with the Larger Organisation(s)</i>
<b>LAMPIRAN 13</b> <i>Attachment 13</i>	<i>Organisation Chart(s)</i>
<b>LAMPIRAN 14</b> <i>Attachment 14</i>	<i>Copy(ies) of Accreditation Certificate(s) (e.g. ISO 17021 Certificate)</i>
<b>LAMPIRAN 15</b> <i>Attachment 15</i>	<i>Matrix of Competency for Personnel</i>
<b>LAMPIRAN 16</b> <i>Attachment 16</i>	<i>Curriculum Vitae</i>
<b>LAMPIRAN 17</b> <i>Attachment 17</i>	<i>Copy of Identity Card (Personnel)</i>
<b>LAMPIRAN 18</b> <i>Attachment 18</i>	<i>Copy of Service-Appointment Agreement Internal Auditor</i>
<b>LAMPIRAN 19</b> <i>Attachment 19</i>	<i>Contract Agreement with Subcontractor</i>
<b>LAMPIRAN 20</b> <i>Attachment 20</i>	<i>Copy of Qualification Certificate</i>
<b>LAMPIRAN 21</b> <i>Attachment 21</i>	<i>Copy of MDA Proficiency Certificate</i>
<b>LAMPIRAN 22</b> <i>Attachment 22</i>	<i>Copy of Attended Training Certificate</i>
<b>LAMPIRAN 23</b> <i>Attachment 23</i>	<i>Procedure to Identify the Auditor Competency</i>
<b>LAMPIRAN 24</b> <i>Attachment 24</i>	<i>Procedure to Evaluate &amp; Monitor the Personnel Competency</i>
<b>LAMPIRAN 25</b> <i>Attachment 25</i>	<i>Procedure on Assessment, Monitoring and Verification of the Subcontractor</i>

<b>LAMPIRAN 26</b> <i>Attachment 26</i>	<i>Procedure on Impartiality and Independence</i>
<b>LAMPIRAN 27</b> <i>Attachment 27</i>	<i>Copy of Insurance Policy</i>
<b>LAMPIRAN 28</b> <i>Attachment 28</i>	<i>Copy of Insurance Certificate</i>
<b>LAMPIRAN 29</b> <i>Attachment 29</i>	<i>Procedure on Confidentiality between the Organisation, Personnel, Subcontractor and the Client</i>
<b>LAMPIRAN 30</b> <i>Attachment 30</i>	<i>Quality Manual System</i>
<b>LAMPIRAN 31</b> <i>Attachment 31</i>	<i>Procedure on Document Control</i>
<b>LAMPIRAN 32</b> <i>Attachment 32</i>	<i>Procedure on Record Control</i>
<b>LAMPIRAN 33</b> <i>Attachment 33</i>	<i>Procedure on Management Review</i>
<b>LAMPIRAN 34</b> <i>Attachment 34</i>	<i>Procedure on Internal Audit</i>
<b>LAMPIRAN 35</b> <i>Attachment 35</i>	<i>Procedure on Corrective Action</i>
<b>LAMPIRAN 36</b> <i>Attachment 36</i>	<i>Procedure on Preventive Action</i>
<b>LAMPIRAN 37</b> <i>Attachment 37</i>	<i>Procedure on Sales and Marketing</i>
<b>LAMPIRAN 38</b> <i>Attachment 38</i>	<i>Procedure on Certification Assessment</i>
<b>LAMPIRAN 39</b> <i>Attachment 39</i>	<i>Procedure on Transfer of Certificate</i>
<b>LAMPIRAN 40</b> <i>Attachment 40</i>	<i>Procedure on Appeal, Complaint &amp; Dispute</i>
<b>LAMPIRAN 41</b> <i>Attachment 41</i>	<i>Procedure on Suspension, Withdrawal &amp; Refusal of Issued Certificate</i>
<b>LAMPIRAN 42</b> <i>Attachment 42</i>	<i>Procedure of Conformity Assessment on QMS ISO 13485 &amp; GDPMD Audit</i>
<b>LAMPIRAN 43</b> <i>Attachment 43</i>	<i>Procedure on Technical Documentation under Malaysia Medical Device Regulations</i>
<b>F. PENGAKUAN PEMOHON Applicant's Declaration</b>	
<p><b>Saya seperti nama di bawah ini mengisytiharkan bahawa maklumat mengenai borang dan dokumen yang dilampirkan adalah TERKINI dan BETUL dan saya mengakui adalah menjadi kewajipan saya untuk memenuhi keperluan Peranti Peranti Perubatan 2012.</b></p> <p><i>I as name as below hereby declare that information on this form and documents attached are current and correct and I acknowledge my obligation to meet the requirements of the Medical Device Regulations 2012.</i></p>	
<b>Tandatangan Orang Yang Bertanggungjawab</b> <i>Person Responsible signature</i>	<b>Cop Rasmi Syarikat</b> <i>Organisation/ Company Stamp</i>
<b>Nama</b> <i>Name</i>	
<b>Jawatan</b> <i>Designation</i>	
<b>Tarikh</b> <i>Date</i>	

**PERAKUAN PEMOHON UNTUK PERMOHONAN PENDAFTARAN CAB**  
**ATTESTATION BY APPLICANT FOR CAB REGISTRATION APPLICATION**

[Untuk dicetak pada kepala surat syarikat syarikat]  
[To be printed on company letterhead of applicant]

**KEPADA : PIHAK BERKUASA PERANTI PERUBATAN**  
**TO : MEDICAL DEVICE AUTHORITY**

Tarikh *Date* : .....

Tuan,  
*Dear Sir,*

**PERAKUAN PEMOHON UNTUK PERMOHONAN PENDAFTARAN CAB**  
**ATTESTATION FOR CAB REGISTRATION APPLICATION**

Saya (..... nama Orang yang Bertanggungjawab.....) , (..... nombor kad pengenalan.....) dengan ini membuktikan bahawa maklumat yang diberikan untuk permohonan ini dan mana-mana dokumen yang dilampirkan, sijil yang telah disahkan benar adalah salinan yang tepat, benar dan terkini sehingga ke tarikh ini.

*I (..... name of Person Responsible.....) ; (..... identity card number.....) hereby attest that the information provided on this application and any attached documents, certificates which had been duly certified true copy are accurate, correct and complete and current to this date.*

Saya faham dan mengakui bahawa ia adalah menjadi kesalahan di bawah Seksyen 76 Akta Peranti Perubatan 2012 (Akta 737) dengan membuat penandaan atau memberi apa-apa perisytiharan, perakuan atau dokumen lain yang tidak benar, tidak tepat atau mengelirukan.

*I understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 (Act 737) to make signs or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.*

Terima kasih  
*Thank you.*

Yang Benar,  
*Yours Sincerely,*

Tandatangan  
*Signature* : .....

Nama  
*Name* : .....

Tarikh  
*Date* : .....

Cop rasmi  
*Official stamp* : .....

**PENGISTIHARAN TANGGUNGJAWAB**  
**DECLARATION OF RESPONSIBILITY**

Saya, <silalah nyatakan nama orang yang bertanggungjawab untuk mendaftarkan badan penilaian pematuhan> dengan ini mengisytiharkan bahawa dokumen-dokumen yang dikemukakan dan maklumat di bawah adalah -

*I, <please provide the name of the person responsible for registering the conformity assessment body>, hereby declare that the submitted documents and below information -*

- i. mematuhi semua kehendak di bawah Akta; dan  
*comply with all the requirements under the Act; and*
- ii. mematuhi kehendak sebagaimana yang dinyatakan dalam Jadual keempat mengenai Keperluan Pendaftaran Badan Penilaian Kesesuaian di bawah Peranti Peranti Perubatan 2012.  
*conform to the requirements as specified in Fourth Schedule on Requirements For The Registration Of Conformity Assessment Bodies under the Medical Device Regulations 2012.*

**(A) MAKLUMAT ORGANISASI Particulars of organization**

Nama Organisasi *Organisation Name*: .....

Alamat Organisasi *Organisation Address*: .....

Nombor Telefon (Pejabat) *Telephone Number (Office)*: .....

Nombor Faksimili *Facsimile Number*: .....

Alamat Emel *E-mail Address* : .....

**(B) PERMOHONAN SKOP PENDAFTARAN (pilih yang berkenaan)**

*For the applied scope of registration (select where necessary)*

- Penilaian Pematuhan terhadap Sistem Pengurusan Kualiti bagi ISO13485;  
*Conformity Assessment of Quality Management System for ISO 13485;*
- Penilaian Pematuhan terhadap Sistem Pengurusan Kualiti bagi GDPMD;  
*Conformity Assessment of Quality Management System for GDPMD;*
- Penilaian Pematuhan terhadap Dokumen Teknikal (Bidang Teknikal Peranti Perubatan, Lampiran 1, Jadual Keempat, Peraturan-Peraturan Peranti Perubatan 2012).  
*Conformity Assessment of Technical Documentation (APPENDIX 1 of the Fourth Schedule on Medical Device Technical Areas under the Medical Device Regulations 2012).*

Saya bertanggungjawab sepenuhnya terhadap semua maklumat yang diberikan dalam perisytiharan ini. Pengisytiharan tanggungjawab ini adalah sah dari tarikh tandatangan yang dibuat di bawah.  
*I am fully responsible with all the information provided in this declaration. This declaration of responsibility is valid from the below signatory date.*

Saya memahami sepenuhnya dan mengakui bahawa ia adalah satu kesalahan di bawah Seksyen 76 Akta Peranti Perubatan 2012 (Akta 737) untuk membuat, menandatangani atau memberi apa-apa perisytiharan, perakuan atau dokumen lain yang tidak benar, tidak tepat atau mengelirukan.  
*I fully understand and acknowledge that it is an offence under the Section 76 of the Medical Device Act 2012 (Act 737) to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.*

Tandatangan yang diberi kuasa,  
*Authorised Signatory,*

Cop Rasmi Syarikat  
*Organisation/ Company Stamp*

\_\_\_\_\_  
[Nama Orang Bertanggungjawab *Person Responsible Name*]

[Jawatan *Position*]

[Tarikh *Date*]