

	<p>UNIT PENDAFTARAN CAB</p> <p>BORANG PERMOHONAN BADAN PENILAIAN PEMATUHAN (CAB)</p>	<p>BK-BPPP-028</p> <p>Version 00</p> <p>Effective date: 27 Feb 2015</p>
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Note:

- This form should also be used for making applications for re-application and extensions to scope. Provide only relevant information.
- Please use separate sheet if necessary.
- Please **tick** the relevant supporting documents in Column 2.
- Please **number** all the attach document submitted with this application form and enter the indication number in the respective **non-coloured cell** in Column 3.

REQUIREMENT ON ORGANISATION

1.0	Organisation Structure	Column 2	Column 3
1.1	Name of Organisation		
1.2	Address		
1.3	Telephone number		
1.4	Fax number		
1.5	E-mail address		
1.6	Website		
1.7	ROC number		
	1.7.1 Supporting document	<input type="checkbox"/> Certificate of registration	
1.8	Legal status of Organisation		
	1.8.1 Supporting document	<input type="checkbox"/> Form 9; and <input type="checkbox"/> Form 13; or <input type="checkbox"/> MNA	

2.0 Responsibilities			
2.1	Name		
2.2	Designation		
	2.2.1 Supporting document	<input type="checkbox"/> Form 24; and <input type="checkbox"/> Form 49; or <input type="checkbox"/> Letter of Authorization; or <input type="checkbox"/> Letter of Appointment	
2.3	Job description		
	2.3.1 Supporting document	<input type="checkbox"/> Declaration of Responsibility (DOR); and <input type="checkbox"/> Job description	
2.4	IC number		
	2.4.1 Supporting document	<input type="checkbox"/> Copy of IC number	
2.5	Telephone no. (h/p) (office)		
2.6	Email address		

3.0 Organisation Structure			
3.1	Do you have any relationship/ link with the larger organisation outside Malaysia? If yes, please;	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	3.1.1 Indicate the type of relationship with larger organisation and the relevant supporting documents;	<input type="checkbox"/> Subsidiary <input type="checkbox"/> Authorized agent <input type="checkbox"/> Partnership agreement <input type="checkbox"/> Others, please specify;	
	3.1.2 Provide address of the larger organisation outside Malaysia		
3.2	Organisation chart	Please provide the organisation chart.	

3.3	<p>3.3.1 The organisation already registered/ designated as a Certification Body in the field of medical device or; One or more related fields accredited to ISO 17021 or equivalent.</p> <p>If yes, please submit the relevant supporting documents;</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input type="checkbox"/> Document addressing the scope of registration / designation <input type="checkbox"/> Others (please specify)</p>	
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REQUIREMENT ON RESOURCES AND TECHNICAL COMPETENCY

4.0 Scope Applied

Conformity Assessment on;

- ISO 13485 including Post Market Surveillance System**
- Good Distribution Practice Medical Device (GDPMD)**
- Technical Documentation**

Please provide all necessary information in the **matrix** specified by MDA (refer to **Annex I**).

Personnel	MD scope expression

5.0 Requirements on Technical Competency		
5.1	Personnel	
	5.1.1 Procedure to identify the competency of personnel	<i>Please refer to the attachment.</i>
	5.1.2 Procedure to evaluate & monitor the competence of personnel	<i>Please refer to the attachment.</i>
	5.1.3 Information on technical personnel	<input type="checkbox"/> Matrix form <input type="checkbox"/> Curriculum Vitae (CV) <input type="checkbox"/> Copy of qualification certificate, training attendance or any exam attended (if any) <input type="checkbox"/> Copy of Certificate of Proficiency <input type="checkbox"/> Others, please specify

6.0 Requirement on Sub-contractor		
6.1	Sub-contractor	
	6.1.1 Procedure and records on sub-contractor control.	<i>Please refer to the attachment.</i>
	6.1.2 Procedure on assessment, monitoring and verification of the sub-contractor.	<i>Please refer to the attachment.</i>

REQUIREMENT ON INDEPENDENCE AND IMPARTIALITY

7.0 Independence and Impartiality		
7.1	Procedures by which the Organisation ensures impartiality/ independence of its employees and subcontractors	<i>Please refer to the attachment.</i>

8.0 Liability		
8.1	Please provide insurance policy & Insurance certificate. (Cover Malaysia region)	<i>Please refer to the attachment.</i>

9.0 Confidentiality			
9.1	Procedure on maintaining confidentiality between the Organisation and;	<i>Please refer to the attachment.</i>	
	9.1.1 Its clients		
	9.1.2 Sub-contractor		
	9.1.3 Personnel		

QUALITY MANAGEMENT SYSTEM

10.0 Documentation Related to Management Operation			
Supporting document;			
<input type="checkbox"/> Copy of certificate of accreditation (if any)			
Requirement		Documents required	
10.1	Management System Manual	<i>Please refer to the attachment.</i>	
10.2	Procedure on Control of Document	<i>Please refer to the attachment.</i>	
10.3	Procedure on Control of records	<i>Please refer to the attachment.</i>	
		<i>Please refer to the attachment.</i>	
10.4	Procedure on Management review	<i>Please refer to the attachment.</i>	
10.5	Procedure on Internal Audits	<i>Please refer to the attachment.</i>	
10.6	Procedure on Corrective actions	<i>Please refer to the attachment.</i>	
10.7	Procedure on Preventive actions	<i>Please refer to the attachment.</i>	

11.0 Documentation Related to Conformity Assessment			
11.1	Procedure on Sales and Marketing	<i>Please refer to the attachment.</i>	
11.2	Procedure on Certification Assessment	<i>Please refer to the attachment.</i>	
11.3	Procedure on Transfer of Certificate	<i>Please refer to the attachment.</i>	
11.4	Procedure on Appeal, Complaint and Dispute	<i>Please refer to the attachment.</i>	
11.5	Procedure on Suspension, Withdrawal and Refusal of Certificate Issued	<i>Please refer to the attachment.</i>	
11.6	Procedure Conformity Assessment on QMS ISO 13485 and GDPMD Audit	<i>Please refer to the attachment.</i>	

11.7	Procedure on Technical Documentation under Malaysia Medical Device Regulation	<i>Please refer to the attachment.</i>	
11.8	Others, please specify;	<i>Please refer to the attachment.</i>	

12.0 Resources for Organisation Offering Product Testing			
In-house			
12.1	Address of facilities		
12.2	Type of test		
12.3	Name of Personnel		
	12.3.1 Supporting document	<input type="checkbox"/> Matrix form <input type="checkbox"/> Curriculum Vitae (CV) <input type="checkbox"/> Certificate <input type="checkbox"/> Others, please specify;	
12.4	Accreditation		
	12.4.1 Supporting document	<input type="checkbox"/> Certificate <input type="checkbox"/> Others, please specify;	
Out-source (Test laboratories sub-contracts)			
12.5	Name of laboratories		
12.6	Address of laboratories		
12.7	Name of personnel		
	12.7.1 Supporting document	<input type="checkbox"/> Matrix form <input type="checkbox"/> Curriculum Vitae (CV) <input type="checkbox"/> Certificate	
12.8	Accreditation		
	12.8.1 Supporting document	<input type="checkbox"/> Certificate <input type="checkbox"/> Others, please specify;	
12.9	Contract details	<i>Please refer to the attachment.</i>	

ATTESTATION BY APPLICANT FOR CAB APPLICATION

[To be printed on company letterhead of applicant]

Medical Device Authority

Date: (.....date.....)

Dear Sir,

Attestation for CAB Application

I (.....name.....), (.....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.

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.

Yours Sincerely,

Signature :

Name :

Official stamp:

Date :

For office use only	Approved/ Rejected	Date received	
Verified by			
Name of officer		Date	
Approved by			
Name of Officer		Date	
Signature			