Medical Device AUTHORITY MALAYSIA	UNIT PENDAFTARAN CAB **BORANG PERMOHONAN BADAN PENILAIAN PEMATUHAN (CAB)**	**BK-BPPP-028** **Version 01** Effective date: 27 Feb 2015

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.

New Application ☐ Re-Application ☐ Extensions to scope ☐

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	☐ Certificate of registration	
1.8	Legal status of Organisation		
	1.8.1 Supporting document	☐ Form 9; **and** ☐ Form 13; **or** ☐ MNA	

2.0	Responsibilities		
2.1	Name		
2.2	Designation		
	2.2.1 Supporting document	☐ Form 24; **and** ☐ Form 49; **or** ☐ Letter of Authorization; **or** ☐ Letter of Appointment	
2.3	Job description		
	2.3.1 Supporting document	☐ Declaration of Responsibility (DOR); **and** ☐ Job description	
2.4	IC number		
	2.4.1 Supporting document	☐ 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; 3.1.1 Indicate the type of relationship with larger organisation and the relevant supporting documents; 3.1.2 Provide address of the larger organisation outside Malaysia	☐ Yes ☐ No ☐ Subsidiary ☐ Authorized agent ☐ Partnership agreement ☐ Others, please specify; ……	
3.2	Organisation chart	Please provide the organisation chart.	

3.3	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. If yes, please submit the relevant supporting documents;	☐ Yes ☐ No ☐ Document addressing the scope of registration / designation ☐ Others (please specify) ……	

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 5.1.2 Procedure to evaluate & monitor the competence of personnel 5.1.3 Information on technical personnel	*Please refer to the attachment*. *Please refer to the attachment*. ☐ Matrix form ☐ Curriculum Vitae (CV) ☐ Copy of qualification certificate, training attendance or any exam attended (if any) ☐ Copy of Certificate of Proficiency ☐ Others, please specify ……	

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

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	*Please refer to the attachment*.	

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

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

QUALITY MANAGEMENT SYSTEM

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

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

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

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	☐ Matrix form ☐ Curriculum Vitae (CV) ☐ Certificate ☐ Others, please specify; ……	
12.4	Accreditation		
	12.4.1 Supporting document	☐ Certificate ☐ 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	☐ Matrix form ☐ Curriculum Vitae (CV) ☐ Certificate	
12.8	Accreditation		
	12.8.1 Supporting document	☐ Certificate ☐ Others, please specify; ……	
12.9	Contract details	*Please refer to the attachment*.	

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			