CONFORMITY ASSESSMENT BODY (CAB)

APPLICATION FORM

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 number all the attach document submitted with this application form and enter the number in the respective cell in this column mark with *

1. Please state here the name of the organization applying, the full postal address, telephone number, fax number and where available the E-Mail address.

Organization Profile				*
1	Name of Organisation			
2	Address:			
3	Address outside Malaysia * if any			
4	Telephone number:			
5	Fax number:			
6	E-mail address:			
7	Website:			
8	Certification Manager	Name		
		Position		
		Address		
		Telephone no.		
		Fax no.		
		Email address		
9	Local Representative	Name		
		Position		
		Address		

		Telephone no.		
Organisation Profile				
		Fax no.		
		Email address		
10	Organization Chart	*Please attach as attachment*		
11	Business Organization (Please tick)	Certification		
		Product certification		
		Testing		
		Others		
12	Legal status of Organization (Please provide documentation that can identify its status)			
13	Number of employees			
14	Address outside Malaysia			
15	Has the Organization already registered/designated as a Conformity Assessment Body in the field of medical devices or one or more related fields. If yes please provide details (including the scope of designation and supporting documents)			
16	If Organization is part of larger organization, please provide details about this larger organization and its structure, indicating in particular its relationship with the Organization.			

2. Applied scope of registration

Scope of registration	Please tick
Assessments on Quality Management System	
Assessment on Good Distribution Practice	
Product Approval Reviews (Technical Reviewer)	

3. What are the medical devices technical areas which your organization seeks for registration? **Please list it according to Appendix C of TD6.*

CODE	***MD scope expression, non-active medical devices***

4. Resources of Organization

No	Resources	
i	Test facilities. Please state their addresses and test capabilities and give details, including documentary proof, of any accreditation.	
ii	In-house expert/specialist/auditor. Please list their names and their areas of competence and provide their CVs.	
iii	Sub-contracts. Please specify theirs names, addresses, contract details, and their areas of competence. For sub-contract test laboratories, please state their testing capabilities. **Please give details, including documentary proof, of any accreditation they have claimed.*	
iv	Public Liability insurance taken out by Organization (The insurance must cover its conformity assessment activities) (*Please provide a copy of the insurance certificate)*	Sum Insured: Insurer's name and address: Renewal date:

5. Further Information for Assessment

No	Detail Information	
i.	Please submit a copy of the system documentation of Organization's Quality management system (QMS). Detailed work instructions may be excluded from this submission.	Please attach.
ii.	Procedures by which cases of conflicts of interest or potential conflicts of interest are identified and resolved.	Please indicate where in the QMS documentation these procedures can be located. _____
iii.	Procedures by which the Organization ensures impartiality of its employees and sub-contractors	Please indicate where in the QMS documentation these procedures can be located. _____
iv.	Procedures for sub-contracting including documented procedures for monitoring sub-contractor's performance.	Please indicate where in the QMS documentation these procedures can be located. _____
v.	Mechanisms that ensure confidentiality between the Organization and its clients	Please indicate where in the QMS documentation these procedures can be located. _____
vi.	Procedures according to which conformity assessment within the scope of recognition will be carried out by the Organization (and its sub-contractors if any)	Please indicate where in the QMS documentation these procedures can be located. _____
vii.	Agreements between the Organization and its subcontractors	Please attach if available

APPLICATION OF DECLARATION

I declare that the information given in this form is current and correct and I acknowledge my obligation to meet the requirements of the Medical Device Regulation 2012, if registered

Applicant's signature:
Name:
Date:

For office use only: Approved/Rejected

Date received:

Verified by:

Name of officer:

Date:

Approved by:

Sign:

Name of Officer:

Date:

Documents need to be submitted:

1. Copy of the organization chart

2. Job descriptions of the key personnel

3. List and job descriptions of qualified auditors

4. Qualification and job descriptions of qualified auditors/personnel/assessors/testers

5. Statements with respect to independence and impartiality

**If the organization provides consultancy services, please provide details on how the consultancy is separated from the organization activity.*

5. Details on how the CAB activities being applied for would fit into the current structure and be financed

6. Internal Quality Management including:

- internal Quality Manual
- details of document control procedures
- procedures for corrective and preventive actions including complaint handling
- procedures regarding internal audits and management review

7. Personnel

- Technical qualification and experience of expert held within the applicant organization
- Document agreement with the appointed sub-contractors and copies of their auditor qualifications and experiences
- Procedure(s) for authorization and monitoring of assessment and verification staff
- Overview of training programs related to medical devices regulation requirements, ISO 13485, etc.
- Procedures to ensure the avoidance of conflicts of interest and ensuring confidentiality
- Copy of MDA Certificate of Attendance and Competency certificate

8. Details of relevant in-house and sub-contractors facilities, relevant accreditations (if any) and terms of agreements of the sub-contractors.

9. Copies of any document that would propose sending to potential new clients if registered (e.g. General terms and conditions, marketing materials, application form and contracts)

10. Procedures to assess client's conformity with the appropriate Conformity Assessment Requirement and ERSP

11. Procedures to take account of existing certifications and registrations

12. Details of procedures to ensure conformity assessment

13. Procedures aimed at ensuring the independence and impartiality of assessments and certification decisions.