

Organization Name	:	
Organization Address	:	
Scope of Registration	:	Conformity Assessments on Quality Management Systems (ISO 13485 and GDPMD) Conformity Assessment on Technical Documentation Conformity Assessment by Way of Verification
Technical Area	:	
Person Responsible	:	
Designation	:	
Contact Details	:	(Office) (Facsimile) (Email) (Website)

REQUIREMENTS ON ORGANISATION

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
Organization Structure						
4(1)	Is the CAB a legal entity that is registered in Malaysia and shall be registered to the Authority to operate as CAB in Malaysia?	Perakuan Pernerbadanan Syarikat Sendirian (Borang 9), Memorandum Article of Association (MNA)			The CAB must be a legal entity registered in Malaysia.	Submission of the mentioned documents is necessary to validate legal entity status.
4(2)	Nationality person who is in charge of and has overall control over a conformity assessment of body shall be Malaysian citizen (Person responsible).	Identity Card, Form 49 Companies Act or Letter of Appointment, Declaration of responsibility (DOR), Job Functions.			The person in charge and with overall control over the conformity assessment must be a Malaysian citizen.	Submission of the specified documents is required to verify Malaysian citizenship and appointment.
4(3)	Is the CAB a legal entity having an office in Malaysia? The following to be reviewed: Organization structure showing duties and Documentation which clearly shows both the authority and the responsibility of individuals within, and the reporting structure within the CAB, incl. committees established by the organization.	Organization chart, company profile indicating staff information, and documentation demonstrating authority, responsibility, and reporting structure within the CAB.			The CAB must have a legal entity office in Malaysia.	Submission of the specified documents is necessary for assessment.

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			Yes	No		
4(4)	If CAB is part of a larger organization, the links and relationship between the CAB and the larger organization shall be clearly defined and documented.	Letter of Authorization from Parent Company, Organization chart, Details on the HQ.			Clear documentation defining links and relationships between the CAB and its larger organization (if applicable).	Submission of specified documents is essential to establish and understand the connection between the CAB and the larger organization.
Responsibilities						
5(1)	CAB shall take full responsibility and retain authority for all task required in relation to the scope of the task for which it is being registered.	Declaration of Responsibility (DOR), Procedures relating to the scope of conformity assessment applied for registration.			The CAB must take full responsibility and retain authority for all tasks related to the scope for which it is being registered.	Submission of DOR and procedures related to the scope of conformity assessment is required.
5(2)	CAB shall conduct conformity assessment on its clients against the declared procedures and those required by Regulation.	Declared procedures according to Malaysia Requirements (Third Schedule MDR), specifying personnel involvement, responsibilities, activities, and a flow chart of the certification process and product reviewer.			The CAB shall conduct conformity assessments on its clients against declared procedures and those required by regulations.	Submission of declared procedures is required, specifying personnel involvement, responsibilities, activities, and including a flow chart of the certification process and product reviewer.
5(3)	CAB shall ensure: Confidentiality of the information obtained in the course of carrying out its tasks No details, records, results or information of any kind are disclosed to any other party except Authority	Quality manual, procedure ensuring confidentiality, Agreement template.			The CAB must ensure the confidentiality of information obtained during its tasks, disclosing no details to any party except the Authority.	Submission of a quality manual, procedure ensuring confidentiality, and an agreement template is necessary.
5(4)	Does the CAB have a system to inform the Competent Authority of any change regarding the availability of resources including sub-contractors that may have an implication on the registration and assignment of tasks?	Documented procedure to notify any changes to MDA within a reasonable timeframe before undertaking the next assessment.			The CAB must have a system to inform the Competent Authority of any changes regarding resources, including subcontractors, that may impact registration and task assignments.	Submission of a documented procedure for notifying changes to the MDA is required.

REQUIREMENTS ON RESOURCES AND TECHNICAL COMPETENCY

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
Resources						
6	A CAB shall be sound organization with: Adequate competent staff Appropriate facilities, incl. test equipment (if applicable) To enable it carry out the conformity assessment according to the scope for which it is being registered.	Organization chart, CVs with supporting documents for key staff members, Quality Manual, Organization History, Ownership by the parent company, Financial Statement (last 6-month bank statement).			The CAB must be a sound organization with adequate competent staff. The CAB must have appropriate facilities, including test equipment if applicable.	Submission of specified documents is necessary to demonstrate competency, qualifications of staff, organization stability, and capability to maintain required facilities.
Technical competency						
7(1)	A CAB shall: Determine the competency required for any personnel to undertake any assignment under its scope of registration Establish and implement procedures to ensure the competence levels of its personnel	Procedures on identification on competency of the personnel. Records on evaluation of the competency of personnel during on-site audits.			The CAB must determine the competency required for personnel and establish procedures to ensure their competence.	Submission of procedures for identifying personnel competency and records of personnel competency evaluation during on-site audits is necessary for validation.
7(2)	The CAB shall possess sufficient scientific and technical personnel within the organization according to the technical area specified in Appendix 1 of the fourth Schedule (Please refer to Appendix 1). Or are supported by its associates with adequate experience and knowledge on: Handling the technical & administrative task such as: Allocation of appropriate assessment personnel Review of assessment output To advise on certification for the specific task and products has been registered to cover.	CVs (with copy of IC and recent photo) with Relevant Certificate, Competency matrices for technical personnel, and similar documentation for associates.			The CAB must possess sufficient scientific and technical personnel or be supported by associates with adequate experience.	Submission of CVs, certificates, and competency matrices is required to demonstrate the expertise of technical personnel and associates.
7(3)	Does CAB ensure, the qualification and experience of the technical personnel of CAB as required in 7 (2) shall accordance with the requirements as specified in Appendix 2 of the Fourth Schedule. (Please refer to Appendix 2)	Copy of Qualification Certificate, Procedure to access and verify staff knowledge and experience, Records of training of technical personnel, Copy of Certificate of Proficiency by the Authority,			Qualification and experience of technical personnel must comply with requirements specified	Submission of specified documents is necessary for validation.

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
		Copy of Certificate (Quality Management System e.g. ISO 13485), Copy of Lead Auditor Certificate.			in Appendix 2 of the Fourth Schedule.	
7(4)	Does CAB maintain records of qualification and experience of its personnel as prescribed in subparagraph 7 (3).	List of technical personnel involved, Records of personnel qualification and experience.			The CAB must maintain records of qualification and experience of its personnel as specified in 7(3).	Submission of a list of technical personnel involved and records of personnel qualification and experience is required.
7(5)	The CAB shall ensure when carrying out QMS audit, the team of auditors shall comprise of at least one member who is experienced in evaluation of the technologies used by the manufacturer.	Procedure on auditing specifying the inclusion of an experienced member in the audit team, Record on auditing (e.g., audit log for each audit personnel).			When conducting QMS audits, the audit team must include at least one member experienced in evaluating the technologies used by the manufacturer.	Submission of an auditing procedure and records of auditing is necessary for validation.
7(6)	The CAB shall ensure when conducting an audit of QMS of an establishment, the CAB shall ensure that it is conducted by a team that includes at least a member who is competent in the review on specific technical areas or technologies pertaining to the medical device that the establishment is dealing with or specific processes involved in the production or handling of the medical devices.	Audit Procedure complying with 7(6) requirements, Record on auditing (e.g., audit log for each audit personnel).			When auditing QMS of an establishment, the team must include at least one member competent in the review of specific technical areas or technologies.	Submission of an audit procedure and records of auditing is necessary for validation.

REQUIREMENTS ON SUBCONTRACTOR

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
8	If CAB uses the services of sub-contractor, the CAB shall: Be responsible for all contracted tasks Be liable for the subcontractor as if the CAB itself performs the task	Legally enforceable Agreement between CAB and Sub-contractor.			The CAB must be responsible for all contracted tasks and liable for the subcontractor as if the CAB itself performs the task.	A legally enforceable agreement is required to establish and clarify CAB's responsibility for contracted tasks and liability for subcontractors.

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
8(c)	Where subcontractors carry out specific task relating to conformity assessment, does the CAB ensure that these subcontractors conform to the same requirements of the regulation (including documentation requirements) that would apply if the task had been performed by its own personnel.	Procedures on conformity assessment, Legally enforceable Agreement between CAB and Sub-Contractor.			Subcontractors carrying out specific tasks must conform to the same requirements of the regulation.	Procedures on conformity assessment and a legally enforceable agreement are necessary for compliance.
8(d)	Does a CAB establish and implement procedure and maintain records on the assessment of the subcontractor's qualification and task carried out by the subcontractor on behalf of the conformity assessment body?	Procedure on assessment and monitoring competency of personnel involved in the conformity assessment activity.			The CAB must establish and implement procedures and maintain records on the assessment of the subcontractor's qualification and tasks.	Submission of a procedure for assessing and monitoring the competency of subcontractor personnel is required.
8(e) 8(j)	Does the CAB have documented procedures to ensure that it will not subcontract the overall responsibility for reviewing the outcome of assessment and verification activities, which are the essential tasks for which it was registered, and ensure subcontractors are restricted to factual reporting and/or supported recommendations?	Procedures on conformity assessment, Legally enforceable Agreement between CAB and Sub-Contractor.			The CAB must have documented procedures to ensure that it will not subcontract the overall responsibility for reviewing the outcome of assessment and verification activities, which are essential tasks for which it was registered.	Procedures on conformity assessment and a legally enforceable agreement are essential. These procedures should clearly outline the tasks that can and cannot be subcontracted.
8(g)	Does the agreement between CAB and the Subcontractor reflect the requirements on subcontracted tasks, including confidentiality, impartiality, provision of access by the Authority and prohibition of the subcontractors from further subcontracting their duties?	Legally enforceable Agreement between CAB and Sub-Contractor			The agreement between the CAB and the subcontractor must reflect requirements on subcontracted tasks, including confidentiality, impartiality, provision of access, and prohibition of further subcontracting.	A legally enforceable agreement is necessary to ensure compliance.
8(h)	Does this agreement prohibit subcontractors from further subcontracting their scope?	Legally enforceable Agreement between CAB and Sub-Contractor.			The agreement between the CAB and the subcontractor must reflect requirements on subcontracted tasks, including confidentiality, impartiality, provision of access, and prohibition of further subcontracting.	A legally enforceable agreement is necessary to ensure compliance.

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
8(i)	Does the CAB ensure that the subcontracted activities are carried out according to detailed documented procedures which are the same as, or judged by the CABs to be equivalent to, those followed by the CABs itself in the context of conformity assessment?	Legally enforceable Agreement between CAB and Sub-Contractor, Procedures on conformity assessment.			Subcontracted activities must be carried out according to detailed documented procedures equivalent to those followed by the CAB itself.	A legally enforceable agreement and procedures on conformity assessment are required.
8(j)	Does CAB ensure their subcontractor is restricted to factual report and/or supported recommendations on the basis of which the conformity assessment body shall make assessments and judgments in relation to the requirements of the regulation?	Legally enforceable Agreement between CAB and Sub-Contractor.			Subcontractors must be restricted to factual reporting and/or supported recommendations.	A legally enforceable agreement is necessary to define and enforce this restriction.
8(k)	Does the CAB inform the Medical Devices Authority of its intention to subcontract duties in relation to the scope for which it was registered?	Declaration of subcontract activities (addressed in the application form), Record of the Sub-Contractor, List of Subcontractor information.			The CAB must inform the Medical Devices Authority of its intention to subcontract duties.	Declaration of subcontract activities and maintaining records of the subcontractor are necessary for compliance.
8(m)	Does the CAB maintain documentary evidence that the subcontractor has the necessary technical competence and facilities to carry out the subcontracted activities?	Procedure on assessment and monitoring competency of personnel involved in the conformity assessment activity.			The CAB must maintain documentary evidence that the subcontractor has the necessary technical competence and facilities.	Procedures on the assessment and monitoring of competency of personnel involved in conformity assessment activities are required.
8(n)	Does the CAB maintain the relevant documents and records of assessment of the qualification of the subcontractor in relation to the work contracted to the subcontractor?	Procedure on assessment and monitoring competency of personnel involved in the conformity assessment activity, Record of qualification and competency of personnel involved in the conformity assessment activity.			The CAB must maintain documentary evidence that the subcontractor has the necessary technical competence and facilities.	Procedures on the assessment and monitoring of competency, along with records, are necessary for compliance.
8(l) 8(o)	CAB shall maintain an up to date register of all its subcontractors, which shall include the following information: The name of subcontractor organization. The legal status and details of any relationship with a parent company, group of companies, or	Records/list of the sub-contractor and its personnel			The CAB must maintain an up-to-date register of all subcontractors with specified information.	Records or a list of subcontractors and their personnel, including relevant details, are necessary for compliance.

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
	any other organization to which the subcontractor is a part. Names of the staff carrying out the subcontracted tasks and evidence that they are competent to do so; the task performed by the subcontractor (e.g. quality system assessment, testing, etc.) and details of the procedures used in carrying out the subcontracted task.					

REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
Independence and Impartiality						
9(1)	Are the CAB (especially the personnel involved in the assessment) independent and not related to its client and not involved in the designing, manufacturing, importing or distributing the product category for which the CAB has been registered?	Policy on Independence and Impartiality			The CAB, especially personnel involved in assessment, must be independent and not related to its client, and not involved in designing, manufacturing, importing, or distributing the product category for which the CAB is registered.	A policy on independence and impartiality is required to demonstrate the commitment to maintaining independence.
9(2)	The CAB shall be free from all pressures and inducement, particularly financially, which might influence their judgment or the result of the inspections, especially from persons or groups of persons with an interest in the result of the assessments. This requirement should be documented	Policy on Independence and Impartiality, Corporate Directive to address the code of ethics for employees and auditor, Procedure on monitoring technical personnel activities.			The CAB shall be free from all pressures and inducements, especially financial, which might influence their judgment or inspection results.	Documentation of these policies and procedures is essential.

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
	Is this Documented?					
9(3)(a)	Has the CAB involve in consultancy activities relating to the scope of activities it is registered	Procedure on assessment and management of the risk of interest of the personnel involved.			The CAB must not be involved in consultancy activities related to its registered scope, and personnel should not provide consultancy services to establishments seeking certification under its jurisdiction.	A procedure on the assessment and management of the risk of interest of the personnel involved is required to address these issues.
9(3)(b)	Has the CAB or subcontracted personnel been involved in consultancy services to establishment which seeking certification under its own jurisdiction	Procedure on assessment and management of the risk of interest of the personnel involved.			The CAB must not be involved in consultancy activities related to its registered scope, and personnel should not provide consultancy services to establishments seeking certification under its jurisdiction.	A procedure on the assessment and management of the risk of interest of the personnel involved is required to address these issues.
9(3)(c)	Does marketing material for the CAB give the impression those consultancy activities are offered?	Procedure on assessment and management of the risk of interest of the personnel involved and marketing material.			Marketing material for the CAB should not give the impression that consultancy activities are offered.	Evaluation of marketing material to ensure it does not imply consultancy services are offered.
9(4)	Does the CAB have documented procedures for identification, review, resolution and prevention of conflicts of interest where conflicts of interest are suspected or proven (including subcontracted personnel)? Does the CAB keep records of such reviews and decisions?	Procedures for identification, review, and resolution of conflict of interest, Impartiality and Conflict of Interest Statement, Records of identification, review, and resolution of conflict of interest.			The CAB must have documented procedures for identification, review, resolution, and prevention of conflicts of interest. Records of such reviews and decisions must be maintained.	Procedures for identification, review, and resolution of conflicts of interest, along with an impartiality and conflict of interest statement, are necessary. Records of identification, review, and resolution should be maintained.
9(5)	Does the CAB require all staff acting on its behalf to declare any potential conflicts of interest?	Records on declaration of conflict of interest by each of technical personnel.			The CAB must require all staff acting on its behalf to declare any potential conflicts of interest.	Records of declarations of potential conflicts of interest by each technical personnel should be maintained.
9(6)	Does the CAB shall maintain records of such declarations any potential conflicts of interest.	Procedure addressing the record-keeping requirement for declarations of conflict of interest.			The CAB must maintain records of declarations of potential conflicts of interest by its staff.	A procedure addressing the record-keeping requirement for declarations of conflict of interest is necessary.

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
9(7)	Does the CAB implement documented procedures to ensure that the remuneration of internal and subcontracted staff is free from pressures and inducements and not dependent on the number or outcome of inspections/ verifications carried out or the result of their activities?	Procedures to ensure the man-day audit (audit duration) is implemented according to IAF-MD5-2011.			The CAB must implement documented procedures to ensure that the remuneration of internal and subcontracted staff is free from pressures and inducements and not dependent on the number or outcome of inspections/verifications.	Procedures to ensure the man-day audit (audit duration) is implemented according to IAF-MD5-2011 are necessary.
Liability						
10	Does the CAB have public liability insurance commensurate with the scope of its services? The CAB should document this requirement.	Declaration by the CAB on having public liability insurance and its certificate.			The CAB must have public liability insurance commensurate with the scope of its services.	The CAB should provide a declaration affirming the possession of public liability insurance and submit the corresponding certificate as documentation. This insurance is crucial for mitigating risks and liabilities associated with the services provided by the Conformity Assessment Body.
Confidentiality						
11(1) to 11(3)	CAB shall observe strict professional confidentiality with regard to all information obtained in carrying out their task. The professional confidentiality to be observed by the CAB shall not affect obligation of the CAB with regard to legally required reporting and dissemination of warnings, nor its obligation to provide information under criminal and/or civil law. The CAB shall make appropriate arrangement to ensure that no details, records, results or information of any kind are disclosed to any other party except to the Authority.	Any procedure, policy or document addressing requirements on professional confidentiality			The CAB shall observe strict professional confidentiality concerning all information obtained during the execution of its tasks. The confidentiality requirements should not impede legal reporting obligations or the dissemination of warnings. The CAB must ensure that no details, records, results, or information are disclosed to any other party except to the Authority.	Any procedure, policy, or document addressing the requirements on professional confidentiality is necessary. This document should outline how the CAB maintains confidentiality while meeting legal obligations, and it must establish arrangements to prevent unauthorized disclosure of information to parties other than the Authority.

REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM

No.	Requirement	Required Supporting Document	Compliance		Criteria	Remark
			Yes	No		
12(1)	Does CAB establish, maintain and implement within its organization an appropriate quality management system pertaining to its management and operation.	Certificate on Accreditation ISO 17021 or the requirement of accreditation for ISO 17021			The CAB must establish, maintain, and implement an appropriate quality management system (QMS) pertaining to its management and operation.	Submission of a certificate on accreditation, such as ISO 17021, or evidence of compliance with the accreditation requirements for ISO 17021 is necessary to demonstrate the establishment and implementation of a QMS within the organization.
12(2)	Does the CAB have established and maintained up to date documented procedures and records which, together, demonstrates its compliance with the Act and Regulation, this documentation shall include the following:	Quality Manual and Quality Procedures and Records forms.			The CAB must have established and maintained up-to-date documented procedures and records demonstrating compliance with the Act and Regulation.	Documentation must include details such as the legal entity of the CAB, relationships with the parent company, responsibilities and reporting structure, scope of services, fees, records of assessment personnel, procedures for assessment and verification.
(a)	Description of the legal entity of the CAB, and where so applicable, its links and relationship with its parent company including affiliates and subsidiaries if relevant.	Description of the legal entity, links, and relationships with the parent company. Submission of the Quality Manual and relevant documents outlining the legal entity, links, and relationships.			The CAB must have established and maintained up-to-date documented procedures and records demonstrating compliance with the Act and Regulation.	Description of the legal entity, links, and relationships with the parent company: Submission of the Quality Manual and relevant documents outlining the legal entity, links, and relationships.
(b) (c)	Documentation showing the responsibilities and reporting structure of the CAB.	Documentation showing responsibilities and reporting structure. Inclusion of documentation illustrating the responsibilities and reporting structure of the CAB.			The CAB must have established and maintained up-to-date documented procedures and records demonstrating compliance with the Act and Regulation.	Documentation showing responsibilities and reporting structure: Inclusion of documentation that illustrates the responsibilities and reporting structure of the CAB.
(d)	The scope of services provided and the fees for conduct of conformity assessment	Scope of services provided and fees. Documentation, including a fee structure aligned with the scope of services provided.			The CAB must have established and maintained up-to-date documented procedures and records demonstrating compliance with the Act and Regulation.	Scope of services provided and fees: Documentation, including a fee structure aligned with the scope of services provided.

(e)	Record of the names of assessment personnel, both internal and subcontracted, their assessment responsibilities and records of relevant training and experience and justification/rationale for the defined scope of assessment responsibilities	Record of technical personnel (internal/external) on competency training and experience. Record of names of assessment personnel, their responsibilities, and training. Maintain records of assessment personnel (internal and subcontracted), including their responsibilities, relevant training, and experience, along with justification for the defined scope of assessment responsibilities.			The CAB must have established and maintained up-to-date documented procedures and records demonstrating compliance with the Act and Regulation.	Record of names of assessment personnel, their responsibilities, and training: Maintain records of assessment personnel (internal and subcontracted), including their responsibilities, relevant training, and experience, along with justification for the defined scope of assessment responsibilities.
(f)	Procedures to carry out assessment and verification during conformity assessment on the clients which include:	Procedures to carry out assessment and verification.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(i)	Procedures to review on the completeness of the application against the details provided under which conformity assessment has been sought	Procedures to review the completeness of the application.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(ii)	Procedures to review and verify on the compliance of the clients with the scope being assessed.	Procedures to review and verify compliance of clients with the assessed scope.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(iii)	conclusion of the assessment the compliance of the clients with the scope being assessed	Procedures for the conclusion of assessment.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(iv)	Procedures of issuance, refusal, suspension, and withdrawal of, or restrictions placed on the certificate	Procedures for issuance, refusal, suspension, and withdrawal of certificates.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(v)	Procedures of communication with other organizations, including the Authority relating to issuance, refusal, suspension, and withdrawal of, or restriction placed on the certificate, including records of all communications and action taken as a result of such communications	Procedures for communication with other organizations.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.

f(vi)	Procedures for assessing and monitoring the competence of the subcontractor, if used.	Procedures for assessing and monitoring subcontractor competence.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(vii)	Details of CAB record keeping facilities including means to ensure security and confidentiality.	Details of CAB record-keeping facilities.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(viii)	Procedures for the consideration of appeal against decisions made by the CAB regarding the interpretation of classification rules (including referral to the Competent Authority if necessary), and manufacturers compliance with the requirements of the Act and Regulations.	Procedures for the consideration of appeals against decisions.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
f(ix)	Procedures describing the means by which assessment and consultancy services are separated, whether these services are carried out by the CAB or any part of larger organization to which it is linked, or its subcontractor, if relevant.	Procedures describing the means by which assessment and consultancy services are separated.			The CAB must have documented procedures for carrying out assessment and verification during conformity assessment on clients.	Submission of relevant procedures and documentation as specified.
(g)	Records on the conclusion of assessment including a reasoned evaluation of the manufacturer's compliance with the standards specified.	Records on conclusion of assessment including a reasoned evaluation of the manufacturer's compliance with the standards specified.			The CAB must maintain records on the conclusion of assessment, including a reasoned evaluation of the manufacturer's compliance with specified standards.	Submission of records demonstrating the conclusion of assessments and evaluations of compliance with specified standards.
h(i)	Does the CAB maintain a system to control all quality system documentation and to ensure that current issues of procedures are available at all relevant locations?	Documentation showing the maintenance of an effective quality management system.			The CAB must maintain a system to control all quality system documentation and ensure current issues of procedures are available at all relevant locations.	Submission of documentation demonstrating the maintenance of an effective quality management system.
h(ii)	Ensure that the defined quality management system is effectively implemented	Procedures demonstrating how the defined quality management system is effectively implemented.			The CAB must maintain a system to control all quality system documentation and ensure current issues of procedures are available at all relevant locations.	Submission of procedures detailing how the defined quality management system is effectively implemented.
Product Testing						

13(1)	Any relevant test equipment and testing protocols, standards used in house facilities and any subcontractors the applicant proposes to use shall be submitted including any relevant accreditation held by the either the applicant or the subcontractor, if the scope of the CAB covers product testing.	Procedures on in-house testing, Accreditation held by Sub-Contractor (if applicable).			The CAB must submit any relevant test equipment and testing protocols, as well as standards used in in-house facilities and by any subcontractors proposed for use. Relevant accreditations held by the applicant or subcontractor should also be provided if the scope of the CAB covers product testing.	Submission of procedures on in-house testing, along with accreditations held by subcontractors (if applicable), is necessary to demonstrate compliance with testing requirements.
13(2)	If the testing is subcontracted, the CAB shall ensure that the requirements on the subcontractors as specified in Para 8 are comply.	Address in 8			If testing is subcontracted, the CAB must ensure that subcontractors comply with the requirements specified in 8.	Reference to the requirements specified in Paragraph 8 (related to subcontracting) and ensuring compliance with those requirements is crucial when subcontracting testing services.
Conformity Assessment Process						
14(1)	CAB shall establish the following:					
i	Documentation incl. general terms and conditions, marketing material, application forms and contracts, that and contracts, that an applicant propose sending to potential new clients if registered.	Marketing material, Sample of application forms and contracts.			Documentation, including general terms and conditions, marketing material, application forms, and contracts that an applicant proposes sending to potential new clients if registered.	Submission of marketing material and samples of application forms and contracts is required.
ii	Procedures to assess clients' conformity with the appropriate conformity assessment requirements and essential principles of safety and performance, incl. as applicable. Those procedure specific to: Design dossier reviews Assessment of clinical and bio-compatibility data Medical devices containing animal tissues Sterile medical device Other specialized technologies Clinical pathology aspects of in-vitro diagnostics, etc.	Procedures on Design dossier reviews, Standard testing procedures for each test conducted.			Procedures to assess clients' conformity with the appropriate conformity assessment requirements and essential principles of safety and performance. Specific procedures for design dossier reviews, assessment of clinical and bio-compatibility data, medical devices containing animal tissues, sterile medical devices, other specialized technologies, clinical pathology aspects of in-vitro diagnostics, etc.	Procedures for various conformity assessment processes and testing procedures for each test conducted are needed.

iii	Procedures how to take account of existing certifications and registration received by the applicant from other conformity assessment bodies or other regulatory authorities	Procedures of transfer certificate from another CAB.			Procedures on how to take account of existing certifications and registrations received by the applicant from other conformity assessment bodies or other regulatory authorities.	Procedures for transferring certificates from another CAB are required.
iv	Procedures to ensure conformity assessment certificates are only issued after a full assessment of all relevant information and this assessment is subject to an independent check.	Procedures on certificate issuance			Procedures to ensure conformity assessment certificates are only issued after a full assessment of all relevant information, and this assessment is subject to an independent check.	Submission of procedures on certificate issuance is necessary.
v	Procedures aimed to ensure the independent and impartiality of assessment and certification decisions.	Address in Part V 9(1)			Procedures aimed to ensure the independence and impartiality of assessment and certification decisions.	This is addressed in Part V 9(1), and relevant procedures must be provided.

PART C – CONCLUSION

Based on the evaluation, the CAB has established and implementing the quality management system and

Evaluated by,

Name:
Designation:
Division:
Date:

Reviewed by,

Name:
Designation:
Division:
Date: