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CONFORMITY ASSESSMENT BODY (CAB) - REQUIREMENTS FOR REGISTRATION



Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

- a) Medical Device Act 2012 (Act 737); and
- b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or a capability.

When a requirement is required to be “documented”, it is required to be established, implemented and maintained.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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REQUIREMENTS FOR CONFORMITY ASSESSMENT BODY (CAB) REGISTRATION

1 Introduction

This document is to provide an explanation and to complement the requirements for the registration of Conformity Assessment Bodies (CAB's) conducting conformity assessment of a medical device. This document also serves to provide necessary guidance for the to comply with the requirements of Section 10, 11 and 12 of Act 737 and Part IV of the Medical Device Regulations 2012 (MDR 2012).

2 Scope

This Guidance Document specifies the requirements for registration of CAB with the Authority as prescribed in Fourth Schedule of MDR 2012 to conduct conformity assessment as prescribed in Third Schedule of MDR 2012 as well as Conformity Assessment by way of Verification described in Circular Letter of the Medical Device Authority No. 2 Year 2014.

3 Normative reference

Medical Device Act 2012 (Act 737)

Medical Device Regulations 2012

ISO 13485, *Medical Device – Quality Management Systems – Requirements for regulatory purposes*

4 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, Medical Device Regulations and the following apply:

4.1 auditor

A person who conducts an audit.

4.2 authority

Medical Device Authority established under Act 738.

4.3 guide

Person appointed by the client to assist the audit team.

4.4 impartiality

Presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the certification body.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “openmindedness”, “even-handedness”, “detachment”, “balance”.

4.5 management system consultancy

Participation in establishing, implementing or maintaining a management system

EXAMPLE 1 Preparing or producing manuals or procedures.

EXAMPLE 2 Giving specific advice, instructions or solutions towards the development and implementation of a management system.

Note 1 to entry: Arranging training and participating as a trainer is not considered consultancy, provided that, where the course relates to management systems or auditing, it is confined to the provision of generic information; i.e. the trainer should not provide client-specific solutions.

Note 2 to entry: The provision of generic information, but not client specific solutions for the improvement of processes or systems, is not considered to be consultancy. Such information may include:

- explaining the meaning and intention of certification criteria;
- identifying improvement opportunities;
- explaining associated theories, methodologies, techniques or tools;
- sharing non-confidential information on related best practices;
- other management aspects that are not covered by the management system being audited.

4.6 observer

Person who accompanies the audit team but does not perform the audit.

4.7 technical expert

CAB appointed expert who possess relevant qualification and experience to support specific technology areas in the conduct of specific medical device conformity assessment.

4.8 technical personnel

CAB personnel who possess relevant qualification and experience to conduct medical device conformity assessment on technical documentation and Declaration of Conformity based on his/her areas of expertise in Appendix 1 of Fourth Schedule of MDR 2012.

5 Requirements

CAB shall be a legally defined entity that is registered in Malaysia, evaluated and approved for registration by the Authority.

CAB will be monitored by the Authority for maintenance of their registration.

5.1 Requirements on organisation

5.1.1 The person responsible for the management and operations of the CAB shall be a Malaysian citizen.

5.1.2 If a CAB is part of a larger organisation, the links and relationship between the CAB and the larger organisation shall be clearly defined and documented.

5.1.3 Certification activities shall be structured and managed so as to safeguard impartiality.

5.1.4 The CAB shall identify the top management (board, group of persons, or person) having overall authority and responsibility for each of the following:

- a) development of policies and establishment of processes and procedures relating to its operations;
- b) supervision of the implementation of the policies, processes and procedures;
- c) ensuring impartiality;
- d) supervision of its finances;
- e) development of management system certification services and schemes;
- f) performance of audits and certification, and responsiveness to complaints;
- g) decisions on certification;
- h) delegation of authority to committees or individuals, as required, to undertake defined activities, on its behalf;
- i) contractual arrangements; and
- j) provision of adequate resources for certification activities.

5.1.5 The CAB shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification activities.

5.1.6 A CAB shall take full responsibility and shall retain authority for all tasks required in relation to the scope of the tasks for which it is being registered.

5.1.7 The CAB has the responsibility to assess sufficient objective evidence upon which to base a certification decision. Based on audit conclusions, it makes a decision to grant certification if there is sufficient evidence of conformity, or not to grant certification if there is not sufficient evidence of conformity.

5.1.8 The CAB shall, without delay, inform the Authority within 14 days, of any changes regarding availability of resources, including responsible person, any personnel of the CAB and subcontractor and compliance with designation conditions which may have an impact on the maintenance of the designation and of the assignment of tasks.

5.2 Requirements on resources and technical competency

A CAB shall be a sound organisation with adequate competent staff and appropriate facilities, including test equipment, if applicable, to enable it to carry out the conformity assessment according to the scope for which it is being registered.

At least one (1) lead auditor shall be a permanent employee of the CAB.

5.2.1 Qualification of auditor and technical personnel

5.2.1.1 The auditors and/or technical personnel of CAB shall have the necessary qualifications as detailed out in Table 1. Auditors and technical personnel of CAB shall be registered with the Authority.

5.2.1.2 The CAB shall have a process of selecting and appointing the audit team, including the audit team leader and technical experts as necessary, taking into account the competence needed to achieve the objective of the audit and requirements for impartiality. If there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit.

Table 1. Qualifications and experiences for auditors and technical personnel

| | Requirements | GDPMD | ISO 13485 | Medical Device Conformity Assessment |
|------------------|---|-------|-----------|--------------------------------------|
| Education | <p>Bachelor degree, or equivalent or higher in one or more of the following fields:</p> <ul style="list-style-type: none"> a) medical physics, biomedical engineering b) biology or microbiology or biotechnology or biomedical science; c) chemistry or biochemistry; d) computer and software technology; e) electrical, electronic, mechanical or bioengineering; f) human physiology; g) medicine, dentistry; h) pharmacy; i) physics or biophysics; or j) other relevant fields. <p>Documents to be submitted:</p> <ul style="list-style-type: none"> • Relevant qualification certificate(s). • Resume, stating two (2) referees. | ✓ | ✓ | ✓ |
| Training | <p>Successful completion of Lead Auditor ISO 9001 training</p> <p>Documents to be submitted: Certificate of Lead Auditor ISO 9001</p> | ✓ | N/A | N/A |
| | <ul style="list-style-type: none"> - Successful completion of 5 days Lead Auditor ISO 13485 training; or - Successful completion of Lead Auditor ISO 9001 training and successful completion of 2 days course on the ISO 13485 (in-house/external training) <p>Documents to be submitted: Valid certificates</p> | N/A | ✓ | ✓ |

| | Requirements | GDPMD | ISO 13485 | Medical Device Conformity Assessment |
|---|---|-------|-----------|--------------------------------------|
| | Minimum 1 day ISO 14971 classroom training | | | |
| | Documents to be submitted: Certificate of attendance/ completion | ✓ | ✓ | ✓ |
| | Having attended and passed assessment/ exam for the training sanctioned by Authority. | | | |
| | Documents to be submitted: Relevant certificate(s) issued by MDA | ✓ | ✓ | ✓ |
| Maintaining Qualification & Competence | <p>CAB shall monitor the performance and qualification of its auditors annually. Qualification and competence of auditor and/or technical personnel shall be maintained as according to 5.2.4, Annex A and Annex C.</p> <p>If the above requirements are not met, the registration of personnel will be suspended. In order to have his/ her registration/ qualification re-instated, CAB shall submit periodic review of competence report to the Authority which includes fulfillment of sanctioned training requirement.</p> <p>Documents to be submitted: Periodic Review of Competence Report/ Management Review Meeting Minutes</p> | ✓ | ✓ | ✓ |

5.2.2 Work experience of auditor and technical personnel

5.2.2.1 Work experience of auditor

For registration of the QMS auditor, he/ she shall comply with the following criteria, which shall be demonstrated in audits under guidance and supervision:

- have gained experience in the entire process of auditing medical devices quality management system, including review of documentation and risk management of medical devices, implementation audit and audit reporting. This experience shall have been gained by participation as a trainee in a minimum of four audits for a total of at least 20 days in an accredited QMS program, 50% of which shall be against ISO 13485 preferably in an accredited program, and the rest in an accredited QMS program;
- In addition to criteria a), audit team leaders shall have experienced an audit team leader role under the supervision of a qualified team leader at least three ISO 13485 audits.
- In addition to a), the auditor shall have performed audits in four different organisations as a trainee auditor.

5.2.2.2 Work experience of technical personnel

5.2.2.2.1 To qualify for a technical area, the CAB shall ensure that technical personnel have adequate experience to perform their tasks. In general, technical personnel to qualify for a technical area shall have a minimum of four years of full-time work experience in medical device related industry, including at least two years of work experience in one or more of the following:

- a) closely related industries and the workplace such as research and development, manufacturing;
- b) the application of the device technology and its use in health care services and with patients;
- c) testing the devices concerned for compliance with the relevant national or international standards;
- d) conducting performance testing, evaluation studies or clinical trials of the devices; or
- e) substantial relevant experience in e.g. the diagnostic, medical devices or pharmaceutical industries, the health care professions, medical laboratories or test institute.

5.2.2.2.2 The number of years for total work experience may be reduced if the technical personnel has completed appropriate post-tertiary education. The reduction shall be as follows in the relevant technical area:

- a) Masters – 1 year
- b) PhD – 3 years

5.2.2.2.3 For extension to a new technical area involving class B medical device (only), the technical personnel shall have competence through relevant education and training in the new technical area, and either:

- a) a minimum of one year work experience in the technology of the technical area; or
- b) participated in ISO 13485 audits in four organisations under the supervision of a registered auditor in the technical area.

5.2.3 Qualification and Experience of Technical Expert

For a technical expert, as an equivalent to a degree in the relevant fields, a lower level of tertiary/ post-secondary education supported by a minimum of eight years' experience in the technological area with regards to the areas of expertise as listed in Fourth Schedule Appendix 1 of MDR 2012 is accepted, or by a minimum of five years' experience in the technological area when combined with further independently examined technical training as follows:

- a) minimum of three weeks cumulative manufacturer training on a particular medical device; or
- b) successfully completed a minimum of three weeks cumulative technical training on a particular medical device by competent training provider with examination.

Qualification and competence of technical expert shall be demonstrated as according to Annex C and furnished to the CAB prior to audit activity.

5.2.4 Maintaining competence and registration

The validity of CAB registration period is 3 years. The validity of registration of its technical personnel or auditors shall follow that of the validity of CAB registration. CAB shall resubmit a registration application 12 months prior to the expiry date of the registration.

5.2.4.1 For the purpose of re-registration, the CAB shall meet all registration requirements and maintain competence of its auditors and technical personnel.

- a) For maintaining the competence of ISO 13485 auditors, he/ she shall have performed at least two ISO 13485 audits, within the registration period.
- b) For maintaining the competence of GDPMD auditors, he/ she shall have performed at least two GDPMD audits, within the registration period.
- c) For maintaining the competence of the technical personnel, he/ she shall have performed at least two ISO 13485 audits.
- d) For maintaining registration, auditors and technical personnel shall attend and pass assessment/ exam for the sanctioned training as determined by the Authority

5.2.4.2 CAB shall maintain an audit log for all auditors and technical personnel as per Annex B.

5.2.4.3 In addition to the base qualifications reflected in Table 1, CAB shall maintain training records, work experience, education and audit experience according to Summary of Technical Competency Template detailed in Annex C.

5.2.5 Subcontracting/ outsourcing to another organisation/ external auditor/ external technical expert

The CAB shall have a process in which it describes the conditions under which outsourcing (which is subcontracting to another organisation to provide part of the conformity assessment activities including product testing, relevant test equipment and testing protocols, on behalf of the CAB) may take place, or when employing external auditor and/or external technical expert. The CAB shall:

- a) be responsible for all contracted tasks;
- b) be liable for the subcontractor as if the conformity assessment body itself performs the tasks;
- c) ensure that its subcontractors conform to all the requirements of the regulations that would apply had the task is performed by the personnel of the conformity assessment body (refer to clause 5.2.1.1);
- d) establish and implement procedure and maintain records on the assessment of the subcontractor's qualifications, experience and the task carried out by the subcontractor on behalf of the conformity assessment body;
- e) not subcontract overall responsibility for reviewing the outcome of assessment and verification activities, which are the essential tasks for which it was registered;

- f) restrict the subcontractor to only perform the subcontracted tasks;
- g) draw up a documented agreement between the CAB and the subcontractor reflecting the requirements on the subcontracted tasks, including the requirements on confidentiality, impartiality, provision of access by the authority and prohibition of the subcontractors from further subcontracting their duties;
- h) prohibit the subcontractor from further subcontracting its duties;
- i) ensure that the subcontracted tasks carried out by the subcontractor is carried out according to detailed documented procedures which are the same as, or judged by the CAB to be equivalent to, those followed by the CAB itself;
- j) ensure that the subcontractor fulfils only an objective role, that is, one which is restricted to factual reporting and/or supported recommendations, on the basis of which the CAB shall make assessments and judgements in relation to the requirements of the regulation;
- k) inform the Authority of its intention to subcontract duties in relation to the task for which it was registered;
- l) maintain an up to date register of all its subcontractors, which shall be provided to the Authority without delay upon request;
- m) maintain documented evidence that the subcontractor has the necessary technical competence and facilities to carry out the subcontracted activities;
- n) maintain the relevant documents and records of assessment of the qualifications of the subcontractor in relation to the work contracted to the subcontractor;
- o) maintain subcontractor register which shall include the following information:
 - i. the name of the outsourcing/subcontracted organisation;
 - ii. its legal status and details of any relationship with a parent company, group of companies, or any other organisation of which the outsourcing/subcontracted organisation is a part;
 - iii. names of staff carrying out the outsourced/subcontracted tasks and evidence that they are competent to do so; and
 - iv. the task performed by the outsourcing/subcontracted organisation and details of the procedures used in carrying out the outsourced task.
- p) For the purpose of registration of external auditor/ external technical personnel, an official letter shall be submitted to the Authority stating details of external auditor/ external technical personnel, scope and responsibilities.

The Authority may register the external auditor subject to qualification/ experience of the external auditor, and confirmation from previous CAB that there are no pending issues/ breach of contract/ agreement by the external auditor (if applicable).

5.3 Requirement on independence and impartiality

5.3.1 The CAB and its auditors shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be:

- a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device under assessment;
- b) involved in the design, construction, implementation or maintenance of the quality management system being audited; and
- c) the person responsible of the client organisation, nor represent the parties engaged in these activities.

Note. Allowing a minimum period of two years to elapse following the end of the relationship is one way of reducing the threat to impartiality to an acceptable level.

5.3.2 The CAB shall be free from all pressures and inducement, particularly financially, which might influence their judgement or the result of the conformity assessments, especially from persons or groups of persons with an interest in the result of the assessments.

5.3.3 The CAB or its subsidiaries shall not –

- a) involve in consultancy activities relating to the scope of activities it is registered;
- b) provide consultancy services to establishment and seeking certification under its' own jurisdiction

5.3.4 The CAB shall have a documented procedure to ensure independence and impartiality, such as records of identification, review and resolution of all cases where conflict of interest is suspected or proven.

5.3.5 The situations hereafter are examples where impartiality is compromised in reference to the criteria defined in a) to c):

- a) the auditor having a financial interest in the client organisation being audited (e.g. holding stock in the organisation);
- b) the auditor being employed currently by a manufacturer producing medical devices; and
- c) the auditor being a member of staff from a research or medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices.

5.3.6 The CAB shall require all staff acting on its behalf to declare any potential conflict of interest and maintain records of such declaration.

5.3.7 The CAB shall ensure that the outcome of assessment activities will not influence the income or remuneration of its personnel.

5.3.8 The CAB shall evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

5.3.9 Liability

5.3.9.1 The CAB shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

5.3.9.2 The CAB shall have public liability insurance commensurate with the scope of its services or a minimum of RM 500,000.00.

5.3.10 Confidentiality

- a) The CAB shall observe strict professional confidentiality with regards to all information obtained in carrying out their tasks. To gain the privileged access to information that is needed for the CAB to assess conformity to requirements for certification adequately, it is essential that a CAB does not disclose any confidential information.
- b) The professional confidentiality to be observed by the CAB shall not effect obligation of the CAB with regards to legally required reporting and dissemination of warnings, nor its obligation to provide information under criminal and/or civil law.
- c) The CAB shall make appropriate arrangements to ensure that all details, records, results or information of any kind are only provided upon request by the Authority.
- d) The CAB shall be responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf.
- e) The CAB shall inform the client, in advance, of the information it intends to place in the public domain. All other information, except for information that is made publicly accessible by the client, shall be considered confidential.
- f) Except as required in this clause, information about a particular certified client or individual shall not be disclosed to a third party without the written consent of the certified client or individual concerned.
- g) When the CAB is required by law or authorized by contractual arrangements (such as with the accreditation body) to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided.
- h) Information about the client from sources other than the client (e.g. complainant, regulators) shall be treated as confidential, consistent with the CAB's policy.
- i) Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the CAB's behalf, shall keep confidential all information obtained or created during the performance of the CAB's activities except as required by law.
- j) The CAB shall have processes and where applicable equipment and facilities that ensure the secure handling of confidential information.

5.4 Requirements of QMS

The CAB shall document its organisational structure, duties, responsibilities and authorities of management (including identification of responsible person) and other personnel involved in certification (including external auditor and technical personnel) and any committees. When the CAB is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

The scope of QMS shall commensurate with the services provided, and the fees for the conduct of conformity assessment shall be documented.

- a) For the scope of GDPMD certification, the fee calculation shall be in accordance with Annex F.
- b) For Conformity Assessment by way of verification, the fee calculation shall be in accordance with Circular Letter No 2/2014 Conformity Assessment Procedures for Medical Device Approved by Recognised Countries.
- c) For the scope of ISO 13485 certification, the fee calculation shall be based on audit time requirement of Annex D of IAF MD9:2017.

5.4.1 Options

The CAB shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirement of this Guidance Document. The CAB shall implement a management system in accordance with either:

- a) general management system requirement (see 5.4.2): or
- b) management system requirements for CAB certified with ISO 9001 (see 5.4.3)

5.4.2 Option A: General management system requirements

5.4.2.1 General

The CAB's top management shall establish and document policies and objectives of its activities. The top management shall provide evidence of its commitment to the development and implementation of its management system in accordance with the requirements of this Guidance Document. The top management shall ensure that the policies are understood, implemented and maintained at all levels of the CAB's organisation.

The CAB's top management shall assign responsibility and authority for:

- a) ensuring that processes and procedures needed for the management system are established, implemented and maintained; and
- b) reporting to top management on the performance of the management system and any need of improvement.

5.4.2.2 Management system manual

All applicable requirements of this Guidance Document shall be addressed either in a manual or in associated documents. The CAB shall ensure that the manual and relevant associated documents are accessible to all relevant personnel.

5.4.2.3 Control of documents

The CAB shall establish procedures to control the documents (internal and external) that relate to fulfilment of this Guidance Document. The procedures shall define the controls needed to:

- a) approve documents for adequacy prior to issue;
- b) review and update where necessary and re-approve documents;
- c) ensure that changes and the current revision status of documents are identified;
- d) ensure that the relevant versions of applicable documents are available at point of use;
- e) ensure that documents remain legible and readily identifiable;
- f) ensure that documents of external origin are identified and their distribution controlled; and
- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Note. Documentation can be in any form or type of medium.

5.4.2.4 Control of records

The CAB shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its record related to the fulfilment of this Guidance Document.

The CAB shall establish procedures for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangement.

5.4.2.5 Management review

- a) General

The CAB's top management shall establish procedures to review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this this Guidance Document. These reviews shall be conducted at least once a year.

- b) Review inputs

The input to the management review shall include information related to:

- i. results of internal and external audits;
- ii. feedback from clients and interested parties;
- iii. safeguarding impartiality;
- iv. the status of corrective actions;
- v. the status of actions to address risks;
- vi. follow-up actions from previous management reviews;
- vii. the fulfilments of objectives;
- viii. changes that could affect the management system; and
- ix. appeals and complaints.

c) Review outputs

The outputs from the management review shall include decisions and actions related to:

- i. improvement of the effectiveness of the management system and its processes;
- ii. improvement of the certification services related to the fulfilment of this Guidance Document;
- iii. resources needs;
- iv. revisions of the organisation's policy and objectives.

5.4.2.6 Internal audits

- a) The CAB shall establish procedures for internal audits to verify that it fulfils the requirements of this Guidance Document and that the management system is effectively implemented and maintained.
- b) An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.
- c) Internal audits shall be performed at least once every 12 months. The frequency of internal audits may be reduced if the CAB can demonstrate that its management system continue to be effectively implemented according to this Guidance Document and has proven stability.
- d) The CAB shall ensure that:
 - i. internal audits are conducted by component personnel knowledgeable in certification, auditing and the requirements of this Guidance Document;
 - ii. auditors do not audit their own work;
 - iii. personnel responsible for the area audited are informed of the outcome of the audit;

- iv. any actions resulting from internal audits are taken in a timely and appropriate manner; and
- v. any opportunities for improvement are identified.

5.4.2.7 Corrective actions

The CAB shall establish procedures for identification and management of nonconformities in its operations. The CAB shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall define requirements for:

- a) identifying nonconformities (e.g. from valid complaints and internal audits);
- b) determining the causes of nonconformity;
- c) correcting nonconformities;
- d) evaluating the need for actions to ensure that nonconformities do not recur;
- e) determining and implementing in a timely manner, the actions needed;
- f) recording the results of actions taken;
- g) reviewing the effectiveness of corrective actions.

5.4.3 Option B: Management system requirements for CAB certified with ISO 9001

5.4.3.1 General

The CAB shall establish and maintain a management system, in accordance with the requirements of ISO 9001.

5.4.3.2 Scope

For application of the requirements of ISO 9001, the scope of the management system shall include the particular certification services to be conducted by the CAB.

5.4.3.3 Customer focus

For application of the requirements of ISO 9001, when developing its management system, the CAB shall consider the credibility of certification and shall address the needs of all parties that rely upon its audit and certification services, not just its clients.

5.4.3.4 Management review

For application of the requirements of ISO 9001, the CAB shall include as input for management review, information on relevant appeals and complaints from users of certification activities and a review of impartiality.

5.5 Product testing

5.5.1 If the scope of the CAB covers product testing, the following shall be available:

- a) relevant test equipment and test protocols;
- b) standard in-house facilities;
- c) list of subcontractors the CAB propose to use (if applicable); and
- d) relevant accreditations held by either the CAB or the subcontractor (e.g. GLP Status for biocompatibility testing and ISO 17025 accreditation for electrical, mechanical and chemical testing).

5.5.2 If the testing is subcontracted, the requirements in 5.2.5 shall apply.

5.6 Conformity assessment process

5.6.1 Documents

A CAB shall establish, maintain and implement the following documents;

- a) Any documentation, including general terms and conditions, marketing materials, application forms and contracts, that a CAB would propose sending to potential new clients if registered;
- b) Procedures to assess clients' medical device conformity against the following elements (where applicable):
 - i. quality management system (QMS);
 - ii. post-market surveillance system;
 - iii. technical documentation giving particular attention on the following elements where applicable:
 - design dossier reviews;
 - assessment of clinical and bio-compatibility data;
 - medical device containing animal tissues;
 - sterile medical device;
 - other specialised technologies; and
 - clinical pathology aspects of in vitro diagnostic, etc;
 - iv. declaration of conformity.
- c) Procedure for conformity assessment for medical device approved by recognised countries as specified in latest revision of Appendix 1 of Circular Letter 2 Year 2014.
- d) Procedure on how to take account of existing certifications from other CAB and/or registrations from other regulatory authorities.
- e) Procedures to ensure conformity assessment certificate are only issued after a full assessment of all relevant information and that this assessment is subject to an independent check; and
- f) Procedures aimed at ensuring the independence and impartiality of assessment and certification decisions.

A CAB shall submit the above documents to the Authority upon CAB registration application.

5.6.2 Audit team selection and assignments

5.6.2.1 General

- a) The CAB shall have a process for selecting and appointing the audit team, including the audit team leader and technical experts as necessary, taking into account the competence needed to achieve the objectives of the audit and requirements for impartiality. If there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit. The audit team shall have the totality of the competences identified by the CAB for the audit.

For conducting specific Medical Device Conformity Assessment, the CAB technical personnel shall be registered with related technical areas as prescribed in Appendix 1 Fourth Schedule, of MDR 2012.

- b) In deciding the size and composition of the audit team, consideration shall be given to the following:
- i. audit objectives, scope, criteria and estimated audit time;
 - ii. whether the audit is a combined, joint or integrated;
 - iii. the overall competence of the audit team needed to achieve the objectives of the audit (see Table A.2);
 - iv. certification requirements (including any applicable statutory, regulatory or contractual requirements); and
 - v. language and culture.
- c) The necessary knowledge and skills of the audit team leader and auditors may be supplemented by technical experts, translators and interpreters who shall operate under the direction of an auditor. Where translators or interpreters are used, they shall be selected such that they do not unduly influence the audit.
- Note. The criteria for the selection of technical experts are determined on a case-by-case basis by the needs of the audit team and the scope of the audit.
- d) Auditors-in-training may participate in the audit, provided an auditor is appointed as an evaluator. The evaluator shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training.
- e) The audit team leader, in consultation with the audit team, may assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives.

5.6.2.2 Observers, technical experts and guides

a) Observers

The presence and justification of observers during an audit activity shall be agreed to by the CAB and client prior to the conduct of the audit. The audit team shall ensure that observers do not unduly influence or interfere in the audit process or outcome of the audit.

Note. Observers can be members of the client's organisation, consultants, witnessing accreditation body personnel, regulators or other justified persons.

b) Technical experts

The role of technical experts during an audit activity shall be agreed to by the CAB and client prior to the conduct of the audit. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor.

Note. The technical experts can provide advice to the audit team for the preparation, planning or audit.

c) Guides

Each auditor shall be accompanied by a guide, unless otherwise agreed to by the audit team leader and the client. Guide(s) are assigned to the audit team to facilitate the audit. The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit.

Note 1. The responsibilities of a guide can include:

- a) establishing contacts and timing for interviews;
- b) arranging visits to specific parts of the site or organisation;
- c) ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;
- d) witnessing the audit on behalf of the client;
- e) providing clarification or information as requested by an auditor.

Note 2. Where appropriate, the auditee can also act as the guide.

5.6.3 Certification decision

5.6.3.1 General

- a) The CAB shall ensure that the person(s) or committees that make the decisions for granting or refusing certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification are different from those who carried out the audits. The individual(s) appointed to conduct the certification decision shall have appropriate competence (refer Table A.1).
- b) The person(s) (excluding members of committees) assigned by the CAB to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with either the CAB or an entity under the organisational control of the CAB. A CAB's organisational control shall be one of the following:

- i. whole or majority ownership of another entity by the CAB;
 - ii. majority participation by the CAB on the board of directors of another entity;
 - iii. a documented authority by the CAB over another entity in a network of legal entities (in which the CAB resides), linked by ownership or board of director control.
- c) The CAB shall record each certification decision including any additional information or clarification sought from the audit team or other sources.

5.6.3.2 Actions prior to making a decision

The CAB shall have a process to conduct an effective review prior to making a decision for granting certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification, including, that

- a) the information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;
- b) for any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions;
- c) for any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action.

5.6.3.3 Information for granting initial certification

- a) The information provided by the audit team to the CAB for the certification decision shall include, as a minimum:
 - i. the audit report;
 - ii. comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client;
 - iii. confirmation of the information provided to the CAB used in the application review;
 - iv. confirmation that the audit objectives have been achieved;
 - v. a recommendation whether or not to grant certification, together with any conditions or observations.
- b) If the CAB is not able to verify the implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of stage 2, the CAB shall conduct another stage 2 prior to recommending certification.
- c) When a transfer of certification is envisaged from one CAB to another, the accepting CAB shall have a process for obtaining sufficient information in order to take a decision on certification.

Note. Certification schemes can have specific rules regarding the transfer of certification.

5.6.3.4 Information for granting recertification

The CAB shall make decisions on renewing certification based on the results of the recertification audit, as well as the results of the review of the system over the period of certification and complaints received from users of certification.

5.7 Notice of changes by the CAB

5.7.1 The CAB shall give its certified clients due notice of any changes to its requirements for certification. The CAB shall verify that each certified clients complies with the new requirements.

5.7.2 CAB shall have a procedure for communication with other organisations, including the Authority relating to issuance, refusal, suspension, and withdrawal of, or restrictions placed on a certificate, including records of all communications and action taken as a result of such communications.

5.7.3 CAB shall notify the Authority of any suspension and withdrawal of certificate within five working days and a copy of the certificate shall be provided.

5.8 Notice of changes by a certified client

The CAB shall have legally enforceable arrangements to ensure that the certified client informs the CAB, without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification. These include, for example, changes relating to:

- a) the legal, commercial, organisational status or ownership;
- b) organisation and management (e.g. person responsible, contact person, key managerial, decision-making or technical staff);
- c) contact address and sites;
- d) scope of operations under the certified management system;
- e) major changes to the management system and processes.

The CAB shall take action as appropriate.

6 How to apply for CAB registration

6.1 All applications for CAB registration are to be submitted via the online Medical Device Centralised Online Application System (MeDC@St) at MDA Portal, www.mda.gov.my. Process flow of registration of CAB is as per Figure 1.

Table 2. Explanation on the information/ particulars required for CAB registration

| No | Details | Descriptions |
|------------|--|--|
| 1.0 | REQUIREMENTS ON ORGANIZATION | |
| 1.1 | Information on the Organisation | |
| 1. | Organisation Name | Please write your organisation's name same as stated in Form 9 |

| | | |
|------------|--|--|
| 2. | Organisation details :Address | Please provide the address of the organisation consist of postcode, City and state. |
| 3. | Telephone No | Please provide telephone number of organisation |
| 4. | Fax. No | Please provide facsimile number of organisation |
| 5. | Email address | Please provide email address of organisation |
| 6. | website address | Please provide website address of organisation |
| 7. | Business Reg. Number (ROC No.) | Please provide business registration number of your company as issued by the Registrar of Company (ROC), Lesen perniagaan (Sabah) or Sijil Pendaftaran Ordinan Nama-nama Perniagaan (CAP64) (Sarawak) |
| 8. | Number Of Organization Staff | Please state number of staff for administration and technical staff. |
| 9. | Accredited With ISO 17021 | <p>Please tick the status of the organisation's accreditation with ISO 17021</p> <p>If the organisation has accredited with ISO 17021, please provide evidence which addressing the scope of registration/ designated as a Certification Body or a copy of Accreditation Certificate (e.g. ISO 17021 accreditation certificate).</p> |
| 10. | Copy Of Form 9 | Please upload a copy of Form 9 |
| 11. | Copy Of Form 13 | Please upload a copy of Form 13 |
| 12. | Copy Of Form 24 | Please upload copy of Form 24: Return Of Allotment Of Shares |
| 13. | Copy Of Form 49 | Please upload a copy of Form 49: Return Giving Particulars in Register of Directors, Managers and Secretaries and Changes of Particulars |
| 14. | Copy Of Memorandum & Articles Of Association (M&A) | Please upload a copy of Memorandum & Articles Of Association (M&A) |
| 15. | Organization Chart | Please upload a copy of your organisation chart structure (including the link with the larger organisation) |
| 1.2 | Information on Person Responsible | |
| 16. | Details of person responsible | <p>Please provide the particulars of the person responsible as required in the appropriate fields consist of salutation, name, NRIC/Passport, designation, handphone number, office number, email address.</p> <p>Person Responsible shall be a Malaysian citizen.</p> <p>Letter of Authorisation for Person Responsible is required if the person responsible is not from the person listed in Form 49.</p> |
| 17. | Job Duties And Responsibilities List | Please provide job duties and responsibilities list of the person responsible |

| | | |
|------------|--|--|
| 18. | Copy Of Person Responsible's Identity Card (IC) | Please upload a copy of Person Responsible's Identity Card (IC) |
| 19. | Declaration Of Responsibility (DOR) | Please upload Declaration Of Responsibility (DOR) accordance to Annex D |
| 1.3 | Information of contact person | |
| 20. | Details of contact person | <p>Please provide the particulars of the contact person as required in the appropriate fields consist of salutation, name, NRIC/Passport, designation, handphone number, office number, email address.</p> <p>Person Responsible shall be a Malaysian citizen.</p> <p>Letter of Authorisation for Person Responsible is required if the person responsible is not from the person listed in Form 49.</p> |
| 21. | Job Duties And Responsibilities List | Please provide job duties and responsibilities list of the contact person. |
| 22. | Copy Of Person Responsible's Identity Card (IC) | Please upload a copy of contact person's Identity Card (IC) |
| 23. | Copy Of Letter Of Authorization (LoA) For Contact Person | Please upload a copy of letter of authorization (LoA) for contact person |
| 1.4 | Information of larger organisation | |
| 24. | Is Organization Having Any Relationship / Link With Any Larger Organization Outside Malaysia? | <p>Please tick Yes/No whether Organization Having Any Relationship / Link With Any Larger Organization Outside Malaysia.</p> <p>Please provide any document(s)/ information in regards to relationship/ link between the company and the larger organisation(s) (if applicable).</p> |
| 2.0 | REQUIREMENT ON RESOURCES AND TECHNICAL COMPETENCY | |
| 2.1 | Information on the scope to be applied | |
| 25. | Scope of Application: i. QMS ISO 13485 ii. QMS Good Distribution Practice Medical Device iii. Medical Device Technical area | Please tick (✓) where necessary |
| A. | CAB Personnel Application | |
| | i. Personnel details | Please provide details of personnel consist of salutation, name, nationality, NRIC/passport. |
| | ii. Copy of Identity Card (IC) / Passport / Work Permit : | Please upload a copy of identity card (IC) / passport / work permit |
| | iii. Employment Status | Please state employment status either permanent or subcontract |
| | iv. Copy of Employment Letter or Subcontractor Agreement | Please upload a copy of employment letter or subcontractor agreement |
| | v. Handphone No | Please provide handphone number |
| | vi. Office No | Please provide office telephone number |
| | vii. Bachelor Degree details | Please provide Bachelor Degree details consist of main course, name of university, and graduation year. |

| | | |
|--|---|---|
| | | Please upload a copy of education certificate (Bachelor) |
| | viii. Master Degree details | Please provide Master Degree details consist of main course, name of university, and graduation year if applicable. Please upload a copy of education certificate (Master) |
| | ix. Personnel Scope to be applied | Please tick scope to be applied and provide the related work experience in the field provided. Please provide information on the required and relevant training and attach a copy of training certificate and proficiency certificate attended by the auditor/technical personnel Please provide information on total audit days for the scope applied. |
| 2.2 Information on technical competency | | |
| 26. | Procedure On How To Identify Personnel Competency | Please upload a copy of procedure on how to identify personnel competency. |
| 27. | Procedure On How To Evaluate & Monitor Your Personnel Competency | Please upload a copy of procedure on how to evaluate & monitor your personnel competency |
| 2.3 Information of subcontractor | | |
| 28. | Procedure and Record on Subcontractor Control | Please upload a copy of procedure and record on subcontractor control. |
| 29. | Procedure on Assessment, Monitoring and Verification of the Subcontractor | Please upload a copy of procedure on assessment, monitoring and verification of the subcontractor. |
| 3.0 REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY | | |
| 3.1 Information on independence and impartiality | | |
| 30. | Procedure by which the Organisation Ensures the Impartiality/Independence of its Employee and Subcontractor | Please upload a copy of procedure by which the organisation ensures the impartiality/independence of its employee and subcontractor |
| 3.2 Information of liability | | |
| 31. | Copy of Insurance Policy | Please upload a copy of insurance policy |
| 32. | Copy of Insurance Certificate | Please upload a copy of insurance certificate |
| Information of confidentiality | | |
| 33. | Procedure on Maintaining the Confidentiality between the Organisation and the Client | Please upload a copy of Procedure on Maintaining the Confidentiality between the Organisation and the Client |
| 34. | Procedure on Maintaining the Confidentiality between the Organisation and the Subcontractor | Please upload a copy of Procedure on Maintaining the Confidentiality between the Organisation and the Subcontractor |
| 35. | Procedure on Maintaining the Confidentiality between the Organisation and the Personnel. | Please upload a copy of Procedure on Maintaining the Confidentiality between the Organisation and the Personnel : |

| | | |
|------------|---|---|
| 4.0 | REQUIREMENT ON QUALITY MANAGEMENT SYSTEM | |
| 4.1 | Documentation related to conformity assessment | |
| 36. | Management Quality Manual | Please upload a copy of management quality manual |
| 37. | Procedure on Document Control | Please upload a copy of procedure on document control |
| 38. | Procedure on Record Control | Please upload a copy of procedure on record control |
| 39. | Procedure on Management Review | Please provide a copy of procedure on management review |
| 40. | Procedure on Internal Audit | Please upload a copy of procedure on internal audit |
| 41. | Procedure on Corrective Action | Please upload a copy of procedure on corrective action |
| 42. | Procedure on Preventive Action | Please provide a copy of procedure on preventive action |
| 4.2 | Documentation related to conformity assessment | |
| 43. | Procedure on Sales and Marketing | Please upload a copy of procedure on sale and marketing |
| 44. | Procedure on Certification Process | Please upload a copy of procedure on certification assessment |
| 45. | Procedure on Transfer of Certificate | Please upload a copy of procedure on certificate transfer |
| 46. | Procedure on Appeal, Complaint & Dispute | Please upload a copy of procedure on appeal, complaint and dispute |
| 47. | Procedure on Suspension, Withdrawal & Refusal of Issued Certificate | Please upload a copy of procedure on suspension, withdrawal and refusal of issued certificate |
| 48. | Procedure of Conformity Assessment on Technical Documentation | Please upload a copy of procedure of conformity assessment on technical documentation |
| 49. | Procedure of Conformity Assessment on QMS ISO 13485 | Please upload a copy of procedure on ISO 13485 |
| 50. | Procedure of Conformity Assessment on GDPMD Audit | Please upload a copy of procedure on GDPMD certifications |
| 51. | Procedure of Conformity Assessment by Way of Verification | Please upload a copy of procedure of conformity assessment by way of verification |
| 5.0 | Attestation | |
| 5.1 | Attestation for CAB application | |
| 52. | Attestation Letter | <p>Please click the button to confirm that person responsible agrees and accepted all the rules and regulation therein.</p> <p>Please upload a copy of attestation for CAB application. Person responsible shall sign the application form and accompanied by company/ organisation stamp</p> |

6.2 Each application shall be accompanied with an application fee of RM1500.

6.3 Applications will be screened and evaluated, and if it is not complete, notice will be issued to the applicant for additional information or documentation, which is to be provided within 30 days from the date of the request.

6.4 If any additional information, particulars or document required is not provided within 30 days or any extension of time granted by the Authority, the application shall be deemed to be withdrawn. The applicant may make a fresh application.

6.5 After complete submission of application and relevant documentation by CAB the Authority may conduct an inspection of the premises of the CAB.

6.6 Once the application is approved, the applicant will be informed in writing on the following:

- a) application decision; and
- b) payment advice for registration fee of RM8,000

6.7 Upon receipt of registration fee, a registration certificate shall be issued to the CAB.

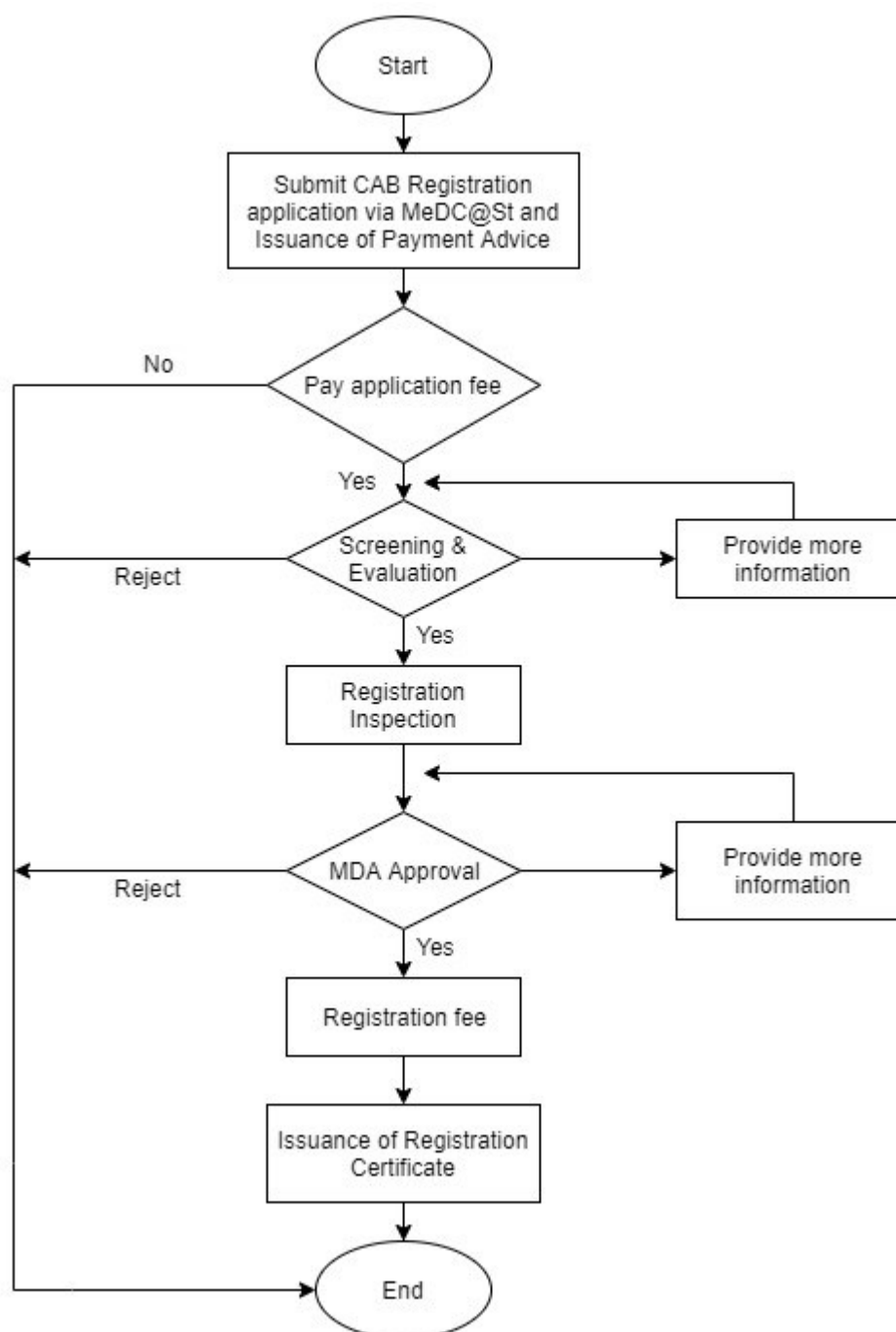


Figure 1. Process flow for CAB Registration application

7 Registration conditions

7.1 A registered CAB shall be subjected to annual surveillance audit or at least once within the registration period (3 years) by the Authority to ensure continuous compliance with all requirements. Frequency of the surveillance audit shall be determined by the Authority.

7.2 A registered CAB shall maintain and keep records of competence of auditors and technical personnel.

7.3 CAB shall comply with all instructions issued by the Authority from time to time.

7.4 The Authority reserves the right to conduct visit or inspection at any time without prior notice.

7.5 The Authority can suspend or revoke the registration certificate or take legal action if the CAB:

- a) has contravened any provision of Act 737 or the regulations under it;
- b) has breached any condition of the registration; or
- c) has been convicted of an offense under Act 737 or the regulations under it.

7.6 Registration certificate issued by the Authority shall not be transferred to any other person.

7.7 Registration certificate shall be displayed at the CAB premise that can be easily seen and shall be presented upon request by any authorized officer.

7.8 CAB shall submit a registration application 12 months prior to the expiry date of the registration for continuity of its operations.

7.9 CAB shall not allow the Registration Certificate to be abused in any way by individual/ another party.

7.10 Any abatement of the scope of conformity assessment shall be notified to the Authority and any evaluation activities under that scope shall be discontinued immediately from the date of notification to the Authority.

7.11 Schedule of audit performed for the current month and audit scheduled for the following month under the approved scope shall be submitted to the Authority every last day of the month. This reporting shall be in the form of a notice using the template in Annex G.

7.12 The Authority may at any time conduct inspection and/or request any record and/or additional information related to the conformity assessment activity being conducted.

7.13 All registration certificate is the property of the Authority and shall be returned when the registration of CAB is revoked.

7.14 Any loss or damage of the registration certificate shall be notified to the Authority and the CAB shall obtain a replacement certificate from the Authority.

ANNEX A (informative)

Knowledge and skills for technical personnel

A.1 The process flow in Figure A.1 shows one way of determining competence for personnel by identifying the specific tasks to be completed; identifying the specific knowledge and skill needed to achieve the intended result.

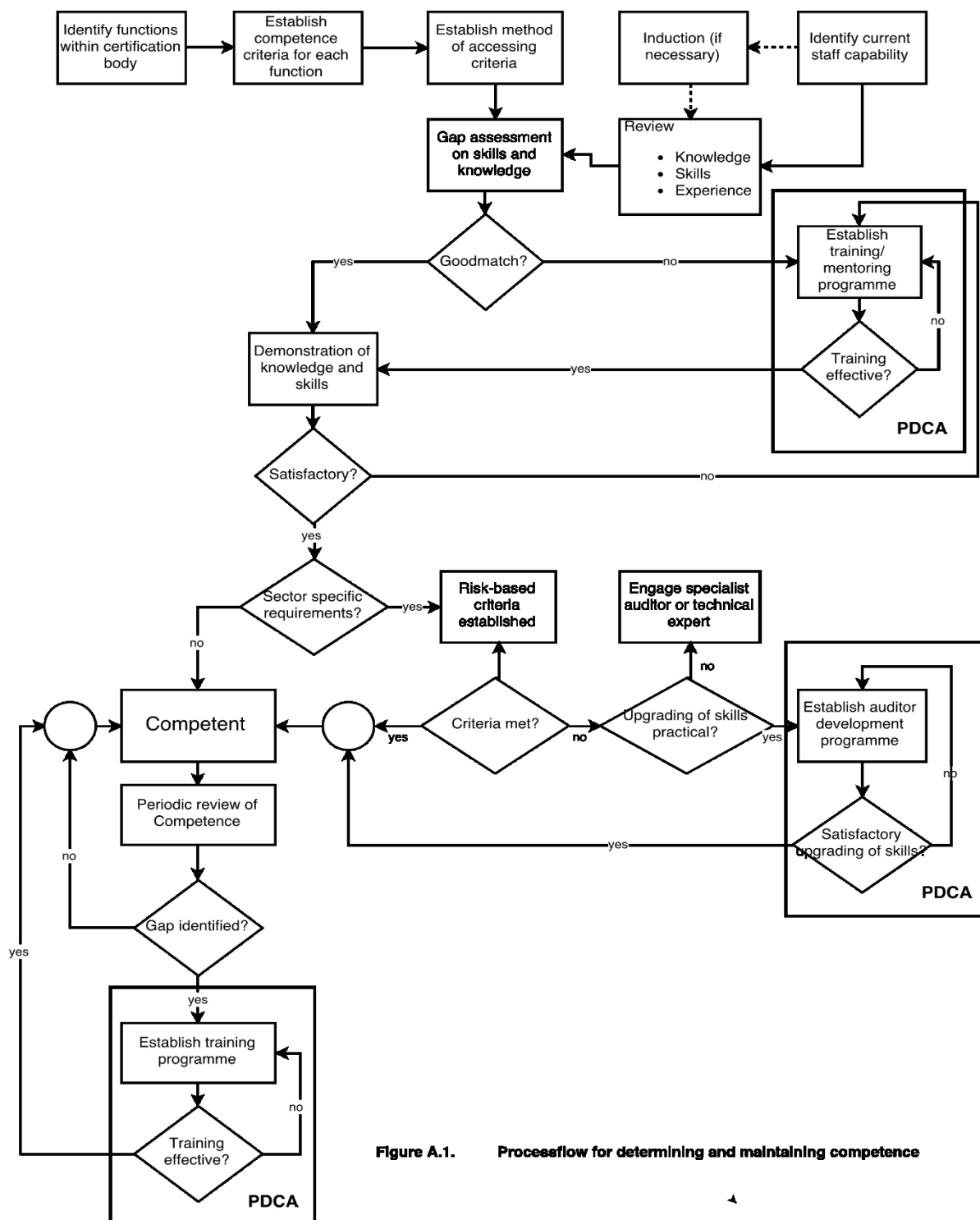


Figure A.1. Processflow for determining and maintaining competence

A.2 The following table specifies the type of knowledge and skills that a CAB shall define for specific functions in addition to A.1

Table A.1 Required types of knowledge and skills for personnel.

| <div>Functions</div> <div>Knowledge and skills</div> | Personnel conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit duration | Personnel reviewing audit reports and making certification decisions (refer 5.6.3.1) | Auditor | Personnel managing program | Technical personnel |
|--|--|--|---------|----------------------------|---------------------|
| Knowledge of generic quality management system practices | x | x | x | x | x |
| Knowledge of legal framework of regulations and role of the CAB | x | x | x | x | x |
| Knowledge of medical device risk management, e.g. ISO 14971 | x | x | x | x | x |
| Knowledge of intended use of medical devices | | | x* | | x |
| Knowledge of risks associated with the medical device | | | x* | | x |
| Knowledge of relevant product standards in the assessment of medical devices | | | x* | | x |
| Knowledge of CAB's ISO 13485 processes | x | x | x | x | x |
| Knowledge of Medical Device business/technology | x | x | x* | x | x |

* The knowledge in the areas marked with *could be provided by a technical expert.

ANNEX B
(normative)

Auditor Audit Log

(ON COMPANY LETTERHEAD)

AUDIT LOG

Name of Auditor: **Chong**
 Name of CAB : **ABC Certification Sdn Bhd**
 Position : **Lead Auditor**

| Company name & address | | Medical device | Audit team | Role in audit | Type of audit | Standard/reference | Date of audit (on-site) | No of days (on-site) | No of days (off site) |
|------------------------|---|---------------------------------|-----------------------------|---------------|-----------------------|--------------------|-------------------------|----------------------|-----------------------|
| 1 | XYZ Sdn Bhd No 6 Jalan 2 Pusat Perniagaan Setia 40700 Shah Alam Selangor | Surgical and examination gloves | Ahmad (L) Chong Muthu | Auditor | Recertification audit | ISO 13485:2016 | 13 - 15/8/2017 | 3 | 1 |
| 2 | | | | | | | | | |
| 3 | | | | | | | | | |

Total days of audit

ISO 13485 :
 GDPMD :

Auditor Signature:

Name:

Date:

Approved by:

Name:

Date :

ANNEX C

(normative)

Summary of technical competency template

A CAB shall maintain a summary of technical competency for all its auditors/ technical personnel/technical expert as per the template below.

| No. | Personnel details | Education | Work experience | Training attended | Other relevant information |
|-----|--|--|---|---|---|
| 1 | Salutation: XXXXX Name: XXXXX Applied for: XXXXX Employment status: XXXXX | Bachelor Of: XXXXX University: XXXXX Year: XXXX - XXXX | Total experience-years in medical device industry: XX YEARS 1. XXXXX SDN. BHD. Manufacturing of: XXXXX Total years: XX YEARS Position: XXXXX Job description: XXXXX 2. XXXXX SDN. BHD. Manufacturing of: XXXXX Total years: XX YEARS Position: XXXXX Job description: XXXXX Please specify other previous companies (if applicable). | Training sanctioned by the Authority: TRAINING ON CONFORMITY ASSESSMENT BODY REGISTRATION Type of certificate: CERTIFICATE OF PROFICIENCY Issued date: XXXXX Training sanctioned by the Authority: TRAINING ON CONFORMITY ASSESSMENT PROCEDURES BY WAY OF VERIFICATION Type of certificate: CERTIFICATE OF PROFICIENCY Issued date: XXXXX ISO 9001 QUALITY MANAGEMENT SYSTEM LEAD AUDITOR TRAINING COURSE Type of certificate: CERTIFICATE OF COMPLETION Training dates: XX – XX XX XXXX (X DAYS) ISO 13485 MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM LEAD AUDITOR TRAINING COURSE Type of certificate: CERTIFICATE OF COMPLETION Training dates: XX – XX XX XXXX (X DAYS) ISO 14971 RISK MANAGEMENT FOR MEDICAL DEVICE TRAINING COURSE Type of certificate: CERTIFICATE OF COMPLETION / PARTICIPATION / ATTENDANCE Training dates: XX – XX XX XXXX (X DAYS) Please specify other training courses (if applicable). | Previously registered under the Act 737 for: ISO 13485 AUDITOR GDPMD AUDITOR Registered since: XX XX XXXX Registered for: INTERNATIONAL REGISTER OF CERTIFICATED AUDITOR (IRCA) Registered since: XX XX XXXX Certification No. : XXXXX Total audit-days for ISO 9001 certification: XX DAYS Total audit-days for ISO 13485 certification: XX DAYS |

ANNEX D (normative)

TO BE PRINTED ON ORGANISATION'S LETTERHEAD

DECLARATION OF RESPONSIBILITY

I, < please provide the name of the person responsible for registering the conformity assessment body >, hereby declare that I am the person responsible for this application and hereby confirm that the organisation, in its capacity as a CAB;

- i. comply with the requirements of the Act;
- ii. comply with the requirements of the Medical Device Regulations 2012.

(A) Particulars of organisation

Organisation Name: _____
 Organisation Address: _____
 Organisation Telephone Number (General): _____
 Organisation Facsimile Number (General): _____
 Organisation E-mail Address (General): _____
 Organisation WEB Address: _____

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

- a. Conformity Assessment of Quality Management System + Post-Market Surveillance System for ISO 13485;
- b. Conformity Assessment of Quality Management System + Post-Market Surveillance System for GDPMD;
- c. Conformity Assessment of Technical Documentation (based on APPENDIX 1 of the Fourth Schedule on Medical Device Technical Areas under the Medical Device Regulations 2012).

I am fully responsible with all the information provided in this declaration. This declaration of responsibility is valid from the below signatory date.

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.

Authorised Signatory,

Organisation's official stamp:

 [Name of Person Responsible]
 [Position of Person Responsible]

Signatory Date: [Day][Month][Year]

ANNEX E
(normative)

**ATTESTATION BY PERSON RESPONSIBLE FOR CAB REGISTRATION
APPLICATION**

[To be printed on company letterhead of applicant]

Medical Device Authority

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

Dear Sir,

Attestation for CAB Registration 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 :

ANNEX F
(normative)

FEE CALCULATION FOR GDPMD CERTIFICATION

| Number of Site | | Required Man-Day | Calculation |
|---|---|------------------|----------------------|
| Initial Audit | | | |
| 1 site | Annex 1 – (4) Eight (8) scopes of activities | 3 (Maximum) | A |
| Additional site | | 0.25 / site | B |
| For site with the increase of every 100 headcounts | | 1 | C |
| For additional product group | | 0.5 / product | D |
| Total | | | A + B + C + D |
| Surveillance Audit | | | |
| 1 site | | 2 (Maximum) | E |
| Additional site/ additional product group/ extension of scope | | 0.5 / site | F |
| Total | | | E + F |

ANNEX G
(normative)

NOTICE FOR CONFORMITY ASSESSMENT ACTIVITIES TEMPLATE

CAB LETTERHEAD

NOTICE FOR CONFORMITY ASSESSMENT ACTIVITIES

NAME OF CONFORMITY ASSESSMENT BODY || **XXXXX SDN. BHD.**

A. CONFORMITY ASSESSMENT ACTIVITIES SCHEDULED FOR THE MONTH OF XXXX 20XX

It is to inform that our organization will conduct the conformity assessment activities as per below table for this month.

| NO. | ESTABLISHMENT | DATE TO EXECUTE | | | | AUDIT TEAM ¹ | REMARK ² |
|-----|---------------|-----------------|------------|---|--------------|-------------------------|---------------------|
| | | ISO 13485 | GDPMD | MEDICAL DEVICE CONFORMITY ASSESSMENT | VERIFICATION | | |
| 1 | XXXXX | XX.XX.XXXX | XX.XX.XXXX | XX.XX.XXXX | XX.XX.XXXX | XXXXX | XXXXX |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | | | | | | | |

¹Please state role of Lead Auditor/ Auditor/ Technical Personnel/ Technical Expert

²Please state product name in remark column

B. CONFORMITY ASSESSMENT ACTIVITIES PERFORMED FOR THE MONTH OF XXXX 20XX

It is to inform that our organization has conducted the conformity assessment activities as per below table for this month.

| NO. | ESTABLISHMENT | DATE OF EXECUTION | | | | AUDIT TEAM ¹ | REMARK ² |
|-----|---------------|-------------------|------------|---|--------------|-------------------------|---------------------|
| | | ISO 13485 | GDPMD | MEDICAL DEVICE CONFORMITY ASSESSMENT | VERIFICATION | | |
| 1 | XXXXX | XX.XX.XXXX | XX.XX.XXXX | XX.XX.XXXX | XX.XX.XXXX | XXXXX | XXXXX |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | | | | | | | |

**Total of approved certifications/ ISO 13485
certificates to be issued³**

|| **XX**

Total of issued Full Assessment certificate³

|| **XX**

Total of issued GDPMD certificate³

|| **XX**

Total of issued Verification certificate³

|| **XX**

¹Please state role of Lead Auditor/ Auditor/ Technical Personnel/ Technical Expert

²Please state product name in remark column

³Total of certificate is based on the issuance certificate for the stated month

C. CERTIFICATION STATUS REPORT FOR THE MONTH OF XXXX 20XX

This is to inform that our CAB has issued the certification as per below table for this month.

| NO . | ESTABLISHMENT | DATE OF ISSUANCE & CERTIFICATE NUMBER | | | | REMARKS |
|---------|---------------|--|--|--|--|---------|
| | | ISO 13485 | GDPMD | MEDICAL DEVICE CONFORMITY ASSESSMENT | VERIFICATION | |
| 1 | XXXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | XXXXXX |
| 2 | | | | | | |
| 3 | | | | | | |
| 4 | | | | | | |

This is to inform that our CAB has suspended / terminated / withdrawn the certification as per below table for this month.

| NO . | ESTABLISHMENT | DATE TO EXECUTE & CERTIFICATE NUMBER | | | | STATUS | REASON |
|---------|---------------|--|--|--|--|---|--------|
| | | ISO 13485 | GDPMD | MEDICAL DEVICE CONFORMITY ASSESSMENT | VERIFICATION | | |
| 1 | XXXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | DATE: XX.XX.XXXX CERTIFICATE NO.: XXXXX | SUSPENSION / TERMINATION / WITHDRAWAL | XXXXXX |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |

Person responsible

|| XXXXX

Signature

|| XXXXX

Date

|| XX.XX.XXXX

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MEDICAL DEVICE AUTHORITY

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