50 Frequently Asked Questions (FAQs)

Conformity Assessment Body (CAB)
Malaysia Medical Device Act 2012 (Act 737)
Medical Device Regulations 2012 (P.U.(A) 500)

1. What is a Conformity Assessment Body (CAB) under the Malaysia Medical Device Act 2012 (Act 737) and Medical Device Regulations 2012?
A Conformity Assessment Body (CAB) is an independent organization registered by the Medical Device Authority (MDA) of Malaysia to assess, audit, and verify the conformity of medical devices and establishments with the applicable regulatory requirements outlined in the Medical Device Act 2012 (Act 737) and its associated regulations.

2. What are the main tasks of a Conformity Assessment Body (CAB)?
CABs play a critical role in the regulatory framework for medical devices. Their main tasks include: (1) Conformity Assessment: CABs evaluate the technical documentation, design, manufacturing processes, and performance characteristics of medical devices to ensure compliance with the relevant standards and regulations. (2) Audits and Assessments: CABs may conduct audits and assessments of medical device manufacturers, authorized representatives, importers, and distributors to verify that they adhere to quality management systems (ISO 13485 and Good Distribution Practice of Medical Devices, GDPMD) based on specific regulatory requirements. (3) Testing and Evaluation: CABs may perform testing and analysis of medical devices to assess their safety, performance, and effectiveness. (4) Certification and Issuance of Conformity Assessment Certificates: Based on successful assessment, CABs issue Conformity Assessment Certificates, indicating that a medical device meets the required standards and regulations.

3. What services are provided by Conformity Assessment Bodies (CABs)?
CABs offer a range of services to medical device manufacturers, authorized representatives, importers, and distributors, including: (1) Technical File Review: Reviewing technical documentation submitted by manufacturers and/or authorized representative to demonstrate conformity with regulatory requirements. (2) Quality System Audits: Auditing manufacturing and/or establishment facilities to assess compliance with quality management system standards. Testing and Analysis: Performing tests to evaluate the safety, performance, and reliability of medical devices. (3) Certification: Issuing certificates indicating that a medical device conforms to the relevant standards and regulations. (4) Assessments: Conducting assessments of manufacturing and/or establishment facilities through surveillance visits to ensure ongoing compliance.

4. How are Conformity Assessment Bodies (CABs) registered in Malaysia?
CABs are registered by the Medical Device Authority (MDA) based on their competence, expertise, and compliance with relevant standards. The registration process involves a thorough assessment of the CAB's technical capabilities and its quality management systems.

5. Are Conformity Assessment Bodies (CABs) the only entities responsible for assessment and certification of medical devices?
No, while CABs play a crucial role in conformity assessment, manufacturers of Class A medical devices also have the option to self-declare the conformity of their medical devices. However, classes of B, C, and D medical devices require assessment by a CAB.

6. How can a medical device manufacturer, authorized representative, importer, or distributor choose a suitable Conformity Assessment Body (CAB)?
Manufacturers, authorized representatives, importers, and distributors should consider factors such as the CAB's expertise in the relevant medical device category, its valid registration status under the Act 737, and geographic coverage when selecting a CAB for assessment and certification services.

7. Can Conformity Assessment Bodies (CABs) operate internationally?
Yes, some CABs may have the capability to operate internationally and provide assessment services beyond Malaysia's borders. This is especially relevant for manufacturers seeking to distribute their medical devices in multiple countries. But to distribute medical devices on the Malaysian market, the conformity assessments must be performed by Conformity Assessment Bodies (CABs) registered under the Act 737.

8. How often are medical device manufacturers, authorized representatives, importers, and distributor required to engage with Conformity Assessment Bodies (CABs)?
The frequency of engagement with CABs depends on factors such as the type of medical device, its risk classification, and regulatory changes. Manufacturers, authorized representatives, importers, and distributor may need to engage with CABs during initial assessment, for ongoing compliance, and for recertification.

9. What role do Conformity Assessment Bodies (CABs) play in post-market surveillance?
CABs may be involved in post-market surveillance activities by conducting periodic audits, assessments, and tests on medical devices that are already on the market to ensure continued compliance with regulations and standards.

10. How does the Malaysia Medical Device Act 2012 (Act 737) ensure the competence of Conformity Assessment Bodies (CABs)?
The Act empowers the Medical Device Authority (MDA) to establish and maintain a register of registered CABs. This registration process includes evaluating the CAB's competence, independence, and compliance with relevant standards.

11. What are the different types of Conformity Assessment Bodies (CABs) registered under the Act 737?
CABs can be categorized into different types based on the scope of their services. These may include conformity assessment on quality management system (ISO 13485 and Good Distribution Practice of Medical Devices, GDPMD), conformity assessment on technical documentation, or conformity assessment by way of verification.

12. How can I verify if a Conformity Assessment Body (CAB) is legitimate and registered by MDA?
You can verify the legitimacy of a CAB by checking the official register maintained by the Medical Device Authority (MDA). This register will provide a list of registered CABs that are authorized to perform conformity assessments under the Act 737. Link to registry: https://mda.gov.my/industry/conformity-assessment-body-cab/status.html

13. Are Conformity Assessment Bodies (CABs) required to maintain any specific accreditations?
CABs are often required to obtain accreditation voluntarily from relevant accreditation bodies. Accreditation ensures that the CAB meets specific technical competence and operational criteria. Accredited CABs demonstrate their capability to provide reliable and accurate conformity assessment services.

14. Can a manufacturer, authorized representative, importer, or distributor choose any Conformity Assessment Body (CAB) for their medical device assessment, or are there limitations?
While manufacturers, authorized representatives, importers, or distributors have some flexibility in choosing a CAB, it's essential to consider the CAB's specific registered scopes so that assessment to your medical device can be fulfilled.

15. Can a Conformity Assessment Body (CAB) charge fees for their services?
Yes, CABs typically charge fees for their services, including assessment, testing, certification, and assessments. These fees may vary based on the complexity of the device, the scope of assessment, and other factors.

16. Can a Conformity Assessment Body (CAB) revoke a Conformity Assessment Certificate?
Yes, a CAB has the authority to revoke a Conformity Assessment Certificate if it becomes evident that the medical device no longer meets the required regulatory standards. This can happen due to changes in the device's design, manufacturing processes, or other relevant factors.

17. Can a medical device manufacturer, authorized representative, importer, or distributor switch Conformity Assessment Bodies (CABs) during the certification process?
While it is possible to switch CABs, it's important to consider the implications of such a decision. Switching CABs mid-process may cause delays and additional costs. Manufacturers, authorized representatives, importers, or distributors should communicate their intentions clearly and ensure a smooth transition.

18. Are there specific guidelines for the information that should be included in a Conformity Assessment Certificate?
Yes, MDA has outlined the essential information that should be included in a Conformity Assessment Certificate. This includes details about the manufacturer, authorized representative, importer, or distributor, the device, the CAB, and references to the relevant regulations and standards.

19. Can Conformity Assessment Bodies (CABs) provide assistance to manufacturers, authorized representatives, importers, or distributors in preparing their documentation?
CABs can provide guidance and support to manufacturers, authorized representatives, importers, or distributors regarding the preparation of technical documentation. However, manufacturers, authorized representatives, importers, or distributors are ultimately responsible for ensuring that the documentation accurately demonstrates conformity to regulatory requirements.

20. How frequently are Conformity Assessment Bodies (CABs) inspected or reviewed for their own compliance?
CABs themselves are subject to periodic inspections and assessments by MDA to ensure their ongoing competence and compliance with registration requirements. This helps maintain the integrity of the Conformity Assessment Bodies (CABs).

21. Are there specific qualifications or requirements for individuals working within Conformity Assessment Bodies (CABs)?
Yes, individuals working within CABs, especially in roles related to assessments, testing, and quality management, are often required to possess relevant qualifications, training, and expertise in medical devices, quality systems, and regulatory compliance.

22. Can a manufacturer, authorized representative, importer, or distributor challenge a decision made by a Conformity Assessment Body (CAB) regarding their device's conformity?
Yes, manufacturers, authorized representatives, importers, or distributors have the right to challenge decisions made by CABs if they believe the assessment was incorrect or unfair. The process for challenging such decisions should be outlined with relevant facts.

23. Are Conformity Assessment Bodies (CABs) responsible for evaluating clinical data related to medical devices?
CABs primarily focus on the technical and quality aspects of medical devices. The evaluation of clinical data often falls under the purview of other regulatory authorities, such as ethics committees and regulatory agencies.

24. How does the Medical Device Act 2012 (Act 737) address conflicts of interest within Conformity Assessment Bodies (CABs)?
The Act may include provisions to prevent conflicts of interest within CABs, ensuring that their assessments remain impartial and unbiased. CABs are mandatorily required to maintain their independence and act in the interest of public health and safety.

25. Can Conformity Assessment Bodies (CABs) provide consulting services to manufacturers, authorized representatives, importers, or distributors to help them meet regulatory requirements?
While some CABs may offer consulting services, there is a potential conflict of interest if the same organization both assesses and consults on regulatory compliance. It's generally advisable for CABs to maintain a clear separation between their assessment and consulting functions.

26. How do Conformity Assessment Bodies (CABs) stay updated with evolving regulations and standards?
CABs must always stay informed about updates to regulations and standards relevant to medical devices. This can be achieved through continuous training, participation in industry forums, and collaboration with regulatory authorities. Attending CAB Proficiency Trainings sanctioned by MDA is mandatory and all personnel of CABs must sit an examination and pass it to maintain their proficiency. The passing mark is set 80% and above by MDA.

27. What happens if a Conformity Assessment Body (CAB) fails to meet its obligations or violates regulations?
If a CAB fails to meet its obligations, violates regulations, or compromises the integrity of the assessment process, MDA can take enforcement actions, including suspension or revocation of the CAB's registration.

28. Can a Conformity Assessment Body (CAB) operate as an independent entity, or does it need to be affiliated with a larger organization?
A CAB can operate as an independent entity, but it must meet the necessary requirements for designation and demonstrate its competence and ability to carry out conformity assessments effectively.

29. How can manufacturers, authorized representatives, importers, and distributors address issues if they are dissatisfied with the services provided by a Conformity Assessment Body (CAB)?
Manufacturers can raise their concerns or complaints with MDA overseeing CABs. This may involve reporting issues related to assessment quality, professionalism, or any conflicts of interest.

30. Can Conformity Assessment Bodies (CABs) provide expedited assessment services for medical devices in urgent situations?
CABs may offer expedited assessment services for certain urgent cases. However, these cases are typically evaluated on a case-by-case basis, and the priority is still given to ensuring the safety and efficacy of the medical device.

31. Can Conformity Assessment Bodies (CABs) conduct remote assessments, especially in cases where on-site visits are challenging?
Yes, remote assessments may be possible in certain situations, particularly when on-site visits are not feasible or deceases outbreak. CABs should have procedures in place to ensure the effectiveness and accuracy of remote assessments and must obtain approval from MDA to proceed.

32. Are there specific requirements for reporting adverse events or incidents related to medical devices to Conformity Assessment Bodies (CABs)?
Adverse events or incidents related to medical devices are typically reported to MDA, and in some cases, to the CAB responsible for the assessment. CABs may play a role in post-market surveillance by assisting in the investigation of such events.

33. Can a Conformity Assessment Body (CAB) provide assistance to manufacturers, authorized representatives, importers, or distributors in preparing for regulatory requirements imposed by MDA?
CABs may offer guidance and support to manufacturers, authorized representatives, importers, or distributors to help them prepare for regulatory requirements, particularly by providing insights into the type of assessments and documentation that may be reviewed by MDA during inspections. But there is a potential conflict of interest if the same CAB assesses and assists on regulatory compliance. It's generally advisable for CABs to maintain a clear separation between their assessment and assisting functions.

34. Can a manufacturer, authorized representative, importer, or distributor request a re-assessment by a different Conformity Assessment Body (CAB) if they disagree with the results of the initial assessment?
While manufacturers, authorized representatives, importers, or distributors may have the right to challenge an assessment's results, requesting a re-assessment by a different CAB may not be a common practice. It's advisable to follow the established appeal or dispute resolution process.

35. Are there any limitations on the geographic areas where Conformity Assessment Bodies (CABs) can operate?
CABs may operate within no boundary in geographic regions in Malaysia, depending on their registration and capabilities. However, they must adhere to registration conditions to operate as a CAB.

36. Can a Conformity Assessment Body (CAB) also be involved in the certification of personnel for medical device-related tasks?
While CABs primarily assess devices, some may also be involved in certifying personnel, such as medical device auditors or assessors, to ensure they possess the necessary competence, but MDA will not be liable of misinformation disseminated to their personnel on any regulatory requirements.

37. How can Conformity Assessment Bodies (CABs) ensure the confidentiality of sensitive information shared during assessments?
CABs are required to have confidentiality measures in place to protect sensitive information provided by manufacturers, authorized representatives, importers, or distributors during the assessment process. Confidentiality Declaration is required to be signed by personnel yearly basis by MDA.

38. Can a Conformity Assessment Body (CAB) offer expedited assessment timelines for an additional fee?
Expedited assessment timelines may be offered by CABs in some cases, but this should not compromise the thoroughness and accuracy of the assessment process. MDA will not be liable on the additional fee to be imposed for such service.

39. Are there requirements for Conformity Assessment Bodies (CABs) to maintain records of their assessment activities?
Yes, CABs are generally required to maintain records of their assessment activities, including documentation related to their evaluation, testing, certification decisions, and communication with manufacturers, authorized representatives, importers, or distributors.

40. How do Conformity Assessment Bodies (CABs) handle cases where a medical device's design or intended use changes after initial certification?
CABs may require manufacturers to inform them about any significant changes to the medical device's design, intended use, or manufacturing processes. Depending on the nature of the changes, a re-assessment or notification to MDA is necessary.

41. Can Conformity Assessment Bodies (CABs) provide guidance on labeling and packaging requirements for medical devices?
CABs may provide general guidance on labeling and packaging requirements, but manufacturers, authorized representatives, importers, or distributors are ultimately responsible for ensuring compliance with the specific labeling regulations outlined in the Medical Device Regulations 2012.

42. How do Conformity Assessment Bodies (CABs) verify the authenticity and accuracy of technical documentation submitted by manufacturers?
CABs may use various methods to verify technical documentation, including review, testing, and verification of data. Manufacturers are expected to provide accurate and complete documentation.

43. Are Conformity Assessment Bodies (CABs) involved in the evaluation of software or digital health applications integrated into medical devices?
Yes, CABs may assess software components and digital health applications integrated into medical devices to ensure their safety, performance, and compliance with relevant standards.

44. Can Conformity Assessment Bodies (CABs) provide manufacturers, authorized representatives, importers, or distributors with a preliminary assessment of their medical device before formal certification?
No. CABs should not offer pre-assessment or consulting services to help manufacturers, authorized representatives, importers, or distributors understand the potential gaps and requirements for compliance before the formal assessment process begins.

45. Are there provisions for appealing the decisions made by Conformity Assessment Bodies (CABs)?
Yes, manufacturers, authorized representatives, importers, or distributors typically have the right to appeal decisions made by CABs. The appeal process should be in lined with the MDA guidelines.

46. Can a Conformity Assessment Body (CAB) offer training to manufacturers, authorized representatives, importers, or distributors on regulatory requirements and assessment procedures?
Yes, some CABs may provide training sessions or workshops to manufacturers to help them better understand the regulatory requirements and the assessment process, but MDA will not be liable of misinformation disseminated to manufacturers, authorized representatives, importers, or distributors.

47. How do Conformity Assessment Bodies (CABs) address situations where a medical device is manufactured by a third party (OEM or contract manufacturer) on behalf of the manufacturer?
CABs may assess the quality management system and processes of both the manufacturer and the third-party manufacturer (OEM or contract manufacturer) to ensure compliance with regulatory requirements.

48. Can a Conformity Assessment Body (CAB) collaborate with other international CABs for assessments that cross borders?
Yes, CABs may collaborate with other international CABs for assessments that involve devices distributed across multiple countries, especially in cases where mutual recognition agreements exist. But final conformity assessment certificate and report must be issued by registered CABs under the Act 737.

49. How are Conformity Assessment Bodies (CABs) monitored for their ongoing performance and compliance?
CABs are subject to regular monitoring and assessment by MDA to ensure they maintain their competence and compliance with their registration scopes.

50. Can Conformity Assessment Bodies (CABs) provide manufacturers with a list of requirements before beginning the assessment process?
Yes. CABs may provide manufacturers with a general overview of the assessment process and requirements, but the specific requirements will depend on the type and classification of the medical device.