



TRAINING FOR RENEWAL OF REGISTRATION FOR CAB AUDITORS AND TECHNICAL PERSONS (FOR THE PURPOSE OF MEDICAL DEVICE REGISTRATION UNDER THE ACT 737)

which to be held as follows

Date (Day) : **June 29 & 30, 2022 (WEDNESDAY & THURSDAY)**
Time : **9.00 AM – 5.00 PM**
Venue : **BILIK SEMINAR 1, LEVEL G, MDA**

ELIGIBILITY

- Mandatory for those who have the expired or expiring Certificate of Proficiency.
- This refresher course is only for the **renewal** of CAB registration. Certificate of Proficiency from this refresher course shall not be valid for the new registration of CAB.
- Failing to attend this training shall affect the renewal of registration
- Personnel of the establishment, certification bodies, consultant companies, or any interested parties.

OBJECTIVES

- To comprehend the Conformity Assessment Procedure in accordance with the Third Schedule of the Medical Device Regulations 2012
- To comprehend the Conformity Assessment Procedure by Way of Verification in accordance with Circular Letter Number 2 Year 2014

TENTATIVE PROGRAM

JUNE 29, 2022 (WEDNESDAY)

08.45 AM Registration
08.55 AM Briefing
09.00 AM Regulatory Updates
10.00 AM Classification of General Medical Device & IVD
11.00 AM Issues in Conformity Assessment of Medical Device

- Full Conformity Assessment
- Way of Verification

01.00 PM Break
02.00 PM Grouping of General Medical Device & IVD
02.30 PM Grouping of *In Vitro* Diagnostic Medical Device
03.00 PM CSDT & EPSP of *In Vitro* Diagnostic Medical Device
04.00 PM CSDT & EPSP of General Medical Device
05.00 PM End of session

JUNE 30, 2022 (THURSDAY)

08.45 AM Registration
08.55 AM Briefing
09.00 AM Conformity Assessment on PMSV
10.30 AM Compliance Issue on CAB Personnel
11.30 AM How to Conduct GDPMD and Evidence Expected
01.00 PM Break
02.00 PM Case Study Conducting an Audit on GDPMD
03.00 PM Self-Study
04.00 PM Examination (40 Questions)
05.00 PM End of session

REGISTRATION & TRAINING FEE

Training fee per participant: **RM 2,400.00**

Application for the training shall be made via provided **Registration Form** by **Clicking [HERE](#)**

Should you have any inquiries, please do not hesitate to contact the Training Secretariats:
CAB TRAINING (cab.training@mda.gov.my) at 03-8230 0240 / 0355 / 0211 / 0223