



**TRAINING ON
CONFORMITY ASSESSMENT PROCEDURES ON TECHNICAL DOCUMENTATION & VERIFICATION
(FOR THE PURPOSE OF MEDICAL DEVICE REGISTRATION UNDER THE ACT 737)**

which to be held as follows

Date (Day) : **OCTOBER 25TH & 26TH, 2021 (MONDAY & TUESDAY)**
Time : **9.00 AM – 5.00 PM**
Venue : **ONLINE TRAINING**

ELIGIBILITY

- Mandatory for registered CAB with at least one scope of MD Technical Areas
- Registered technical personnel and auditors attached to CAB
- Participants who had failed the previous training's examination
- Those who have the expired Certificate of Proficiency
- Personnel of the establishment, certification bodies, consultant companies, etc.

OBJECTIVES

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

TENTATIVE PROGRAM

OCTOBER 25, 2021 (MONDAY)

08.45 AM Registration
08.55 AM Briefing
09.00 AM Conformity Assessment Procedure (Third Schedule)
10.45 AM Conformity Assessment by Way of Verification & DoC
12.30 PM Classification of General Medical Device
01.30 PM Break
02.30 PM Classification of *In Vitro* Diagnostic Medical Device
03.30 PM Self-Study
04.00 PM Online Examination (40 Questions)
05.00 PM End of session

OCTOBER 26, 2021 (TUESDAY)

08.45 AM Registration
8.55 AM Briefing
09.00 AM Grouping of General Medical Device
09.30 AM Grouping of *In Vitro* Diagnostic Medical Device
10.00 AM CSDT & EPSP of *In Vitro* Diagnostic Medical Device
11.00 AM CSDT & EPSP of General Medical Device
12.00 AM Case Study (Individual Presentation)
01.00 PM Break
02.00 PM Case Study (Individual Presentation)
03.30 PM Self-Study
04.00 PM Examination (40 Questions)
05.00 PM End of session

REGISTRATION & TRAINING FEE

Training fee per participant : **RM 1400.00**

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

Should you have any enquiries, please do not hesitate to contact the Training Secretariats:
CAB TRAINING (cab.training@mdb.gov.my) at 03-8230 0395 / 0240 / 0211 / 0318