

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)
 : FEBRUARY 14 & 15, 2022 (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

FEBRUARY 14, 2022 (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

FEBRUARY 15, 2022 (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 1600.00** Application for the training shall be made via provided **Registration Form by Clicking <u>HERE</u>**

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