



**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) : **DECEMBER 21ST & 22ND, 2020 (MONDAY & TUESDAY)**
Time : **8.30 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

DECEMBER 21, 2020 (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

DECEMBER 22, 2020 (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**

Should you have any enquiries, please do not hesitate to contact the Training Secretariats:
FEZRI BIN AZIZ (En.) at 03-8230 0395 or fezriaziz@mda.gov.my
NUR RASIDAH BINTI NGASBON (Pn.) at 03-8230 0211 or nurrasidah@mda.gov.my



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REGISTRATION FORM

*Title	Dato' / Datuk / Datin / Prof. / Assoc. Prof / Dr. / Ir. / Mr. / Mrs. / Puan / Ms.		
Full Name			
Name on ID Card		*IC / Passport No.	
Organization Name & Address			
Telephone No.		Facsimile No.	
Handphone No.		E-mail Address	
*Vegetarian?	Yes / No	*Required Invoice?	Yes / No
Training Fee	RM 1400.00 / participant <ul style="list-style-type: none"> <i>Inclusive of refreshments, lunch, training materials, examination & certificate.</i> <i>Training fee does not include accommodation & travelling costs.</i> <i>Confirmation of registration will be valid upon the receipt of the Registration Form & enclosed with the copy of the bank draft.</i> <i>Please submit the copy of bank draft (.pdf format) to cab.training@mdb.gov.my.</i> 		
Payment Mode	The training fee shall be made through Bank Draft / Local Order and payable to “KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN” <ul style="list-style-type: none"> <i>Information on the CAB TRAINING FEE & PHONE NO. OF PARTICIPANT must be written at the back of the bank draft but not in the existing table.</i> <i>Payment receipt will be issued upon the receipt of the original bank draft during the registration day.</i> 		
	*Bank Draft / Local Order No.		Amount
	RM 1400.00		
	Bank Name		

*Please select your option