



**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) : **NOVEMBER 19 & 20, 2019 (TUESDAY & WEDNESDAY)**
Time : **8.30 AM – 5.00 PM**
Venue : **BILIK SEMINAR 1 & 2, LEVEL G, PRIMA 9, 63000 CYBERJAYA**

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

NOVEMBER 19, 2019 (TUESDAY)

08.30 AM Registration
09.00 AM Conformity Assessment Procedure (Third Schedule)
10.45 AM Morning Break
11.15 AM Conformity Assessment by Way of Verification & DoC
01.00 PM Lunch Break
02.15 PM Classification of General Medical Device
03.15 PM Classification of *In Vitro* Diagnostic Medical Device
04.00 PM Examination (40 Questions)
05.00 PM Evening Break & End

NOVEMBER 20, 2019 (WEDNESDAY)

08.30 AM Registration
09.00 AM Grouping of General Medical Device
09.30 AM Grouping of *In Vitro* Diagnostic Medical Device
10.00 AM Morning Break
10.30 AM CSDT & EPSP of *In Vitro* Diagnostic Medical Device
11.15 AM CSDT & EPSP of General Medical Device
12.00 PM Case Study (Group Discussion)
01.00 PM Lunch Break
02.00 PM Case Study (Group Presentation)
04.00 PM Examination (40 Questions)
05.00 PM Evening Break & End

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:
WAN HUSNIATI BINTI WAN ABDULLAH (Pn.) at 03-8230 0398 or whusniati@mda.gov.my
MOHD FADHULLAH BIN ABD HALIM (En.) at 03-8230 0356 or fadhullah@mda.gov.my
FATTAHILLAH BIN SABARUDIN (En.) at 03-8230 0312 or fattahillah@mda.gov.my
MUHAMMAD IZZUDIN BIN ABDUL JALIL (En.) at 03-8230 0313 or izzudin@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"> • Inclusive of refreshments, lunch, training materials, examination & certificate. • Training fee does not include accommodation & travelling costs. • Confirmation of registration will be valid upon the receipt of the Registration Form & enclosed with the copy of the bank draft. • Please submit the copy of bank draft (.pdf format) to training@mdb.gov.my. 		
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"> • 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. • Payment receipt will be issued upon the receipt of the original bank draft during the registration day. 		
	*Bank Draft / Local Order No.		Amount RM 1400.00
	Bank Name		

*Please select your option