



**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) : **JULY 25 & 26, 2018 (WEDNESDAY & THURSDAY)**
Time : **8.30 AM – 5.00 PM**
Venue : **BILIK SEMINAR 1, 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

JULY 25, 2018 (WEDNESDAY)

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
02.00 PM Guideline for Registration of Combination Products
02.45 PM Classification of General Medical Device
03.15 PM Classification of *In Vitro* Diagnostic Medical Device
04.00 PM Examination (42 Questions)
05.00 PM Evening Break & End

JULY 26, 2018 (THURSDAY)

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 NURHALIMAH BINTI WAN ABDULLAH (Pn.) at 603-82300307 or nurhalimah@mdb.gov.my
FATTAHILLAH BIN SABARUDIN (En.) at 603-82300312 or fattahillah@mdb.gov.my



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REGISTRATION FORM

| | | | |
|-----------------------------|--|--------------------|-----------|
| *Title | Dato' / 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 | <p>The training fee shall be made through Bank Draft / Local Order and payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN"</p> <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 |
| | Bank Name | | |

*Optional