TRAINING ON
CONFORMITY ASSESSMENT BODY REGISTRATION UNDER THE ACT 737
(MEDICAL DEVICE LEGISLATION)

which to be held as follows

Date (Day) : **MARCH 13 & 14, 2023 (MONDAY & TUESDAY)**
Time : **09:00 – 17:00**
Venue : **MEDICAL DEVICE AUTHORITY, CYBERJAYA**

ELIGIBILITY

- Mandatory for those who have never been registered under the Act 737.
- Participants who had failed the previous training's examination.
- Personnel of the establishments, certification bodies & consultant companies, etc.

OBJECTIVES

- To comprehend the Medical Device Act 2012 (Act 737).
- To comprehend the Medical Device Regulations 2012 (MDR 2012).
- To comprehend the Medical Device Regulations 2019 (MDR 2019).
- To comprehend the Medical Device Gazetted Orders, Circular Letters & Guidance Documents.
- To comprehend the Conformity Assessment Procedure on QMS and PMSS (ISO 13485 & GDPMD).

TENTATIVE PROGRAM

March 13, 2023 (Monday)

08:45	Registration
08:55	Briefing
09:00	Medical Device Regulatory Framework (Gazetted Orders, Circular Letters & Guidance Documents)
10:30	Short Break
11:00	Medical Device Act 2012 (Act 737)
12:30	Break
14:00	Medical Device Regulations 2012 (MDR 2012)
15:30	Medical Device Regulations 2019 (MDR 2019)
16:15	CAB Registration Requirements
17:00	End of Session

March 14, 2023 (Tuesday)

08:45	Registration
08:55	Briefing
09:00	Product Classification
09:30	Classification of General & *In Vitro* Diagnostic Medical Devices
10:15	Short Break
10:30	Good Distribution Practice for Medical Device (GDPMD)
12:30	Break
14:00	Conformity Assessment on PMSS
14:30	MS 2058
16:00	Examination (40 Questions)
17:00	End of Session

REGISTRATION & FEE

Training fee per participant: **RM 2400.00**
Application for the training: **REGISTRATION FORM**

Should you have inquiries, please contact the Training Secretariats at
cab.training@mda.gov.my or 03-8230 0335 / 0346 / 0361

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) : **MARCH 15 & 16, 2023 (WEDNESDAY & THURSDAY)**
Time : **09:00 – 17:00**
Venue : **MEDICAL DEVICE AUTHORITY, CYBERJAYA**

ELIGIBILITY

- Mandatory for those who have never been registered under the Act 737.
- Participants who had failed the previous training's examination.
- Personnel of the establishments, certification bodies & consultant companies, etc.

OBJECTIVES

- To comprehend the Conformity Assessment Procedure in accordance to the 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

March 15, 2023 (Wednesday)

08:45	Registration
08:55	Briefing
09:00	Conformity Assessment Procedure (Third Schedule)
10:15	Short Break
10:45	Conformity Assessment by Way of Verification (Including Re-Registration) & DoC
12:00	Classification of *In Vitro* Diagnostic Medical Device
12:45	Break
14:00	Classification of General Medical Device
15:00	Grouping of General Medical Device
16:00	Grouping of *In Vitro* Diagnostic Medical Device
17:00	End of Session

March 16, 2023 (Thursday)

08:45	Registration
08:55	Briefing
09:00	Clinical Investigation
10:00	Short Break
10:30	CSDT & EPSP of *In Vitro* Diagnostic Medical Device
11:30	CSDT & EPSP of General Medical Device
12:30	Break
14:00	Case Study (Group Preparation)
14:30	Case Study (Group Presentation)
16:00	Examination (40 Questions)
17:00	End of Session

REGISTRATION & FEE

Training fee per participant: **RM 2400.00**
Application for the training: **REGISTRATION FORM**

Should you have inquiries, please contact the Training Secretariats at
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