


MASTERING RISK CLASSIFICATION & GROUPING OF IVD MEDICAL DEVICES (IVDS)

TRAINING DETAILS

 8 April 2026 (Wednesday)

 8:30 am - 04:00 pm

 Seminar Room, Level G, Medical Device Authority (MDA), Cyberjaya, Selangor

TRAINING FEES

RM 1,000

PER PARTICIPANT



This Training aims to:

1. Enhance understanding of risk-based classification principles under Malaysian regulatory requirements.
2. Provide structured methodologies for applying the 7 classification rules.
3. Strengthen industry capability in determining appropriate risk classes (A-D).
4. Improve compliance through correct application of device grouping principles.
5. Reduce regulatory delays caused by misclassification and improper grouping.
6. Align industry practices with ASEAN harmonisation and international regulatory approaches.



Key Topics Covered

- Principles of Risk-Based Classification
- Application of the 7 Classification Rules
- Assigning Devices into Classes A-D
- Regulatory Documentation & Justification Requirements
- ASEAN Harmonisation & International Comparisons
- Principles and Application of Device Grouping
- Case Studies and Regulatory Decision Simulation

Register Now !

BEFORE : 16 APRIL 2026



or click Here to Register

Upon submission of your registration, an invoice for payment, along with the payment method details, will be issued within 2-3 working days. This program is claimable under the SBL Scheme. Please refer here for the [SBL Scheme terms and conditions](#)

Participants will gain practical competencies to:

- Apply classification rules accurately and consistently
- Prepare defensible regulatory justifications
- Determine risk classes aligned with regulatory expectations
- Apply grouping strategies for efficient submissions
- Avoid common compliance deficiencies

Training Agenda

Time	Session
8:30 am – 9:10 am	Registration and Briefing
9:10 am – 10:10 am	Session 1: Principles of Risk-Based Classification
10:10 am – 10:30 am	Morning Break
10:30 am – 12:00 pm	Session 2: - Application of the 7 Classification Rules - Assigning Devices into Classes A–D
12:00 pm – 13:00 pm	Session 3: Principles & Application of Device Grouping
13:00 pm – 14:00 pm	Lunch Break
14:00 pm – 15:00 pm	Case Studies & Hands-On Exercises
15:00 pm – 15:15 pm	Tea Break
15:15 pm – 16:00 pm	Continue session: Case Studies & Hands-On Exercises
16:00 pm	End Session