


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