

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

Medical Device
AUTHORITY
MALAYSIA
PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA



TRAINING DETAILS



29 September 2026



8:30 am - 04:00 pm



**Medical Device Authority (MDA),
Cyberjaya, Selangor**

TRAINING FEES

RM 1,000
PER PARTICIPANT



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

Open until: 11 September 2026

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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

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

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