




# MASTERING RISK CLASSIFICATION SYSTEM & GROUPING FOR GENERAL MEDICAL DEVICES (GMD)

## TRAINING DETAILS

-  7 April 2026 ( Tuesday)
-  8:30 am - 04.00 pm
-  Seminar Room, Level G, Medical Device Authority (MDA), Cyberjaya, Selangor

**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 16 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.

**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](#)

### Key Topics Covered

- Principles of Risk-Based Classification
- Application of the 16 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

## 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 16 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>