



## **Announcement Update: Enhanced Process for managing Classification Risk Disputes between Establishment and CAB**

The Medical Device Authority (MDA) is pleased to announce the implementation of new enhanced process to facilitate the resolution of risk classification disputes between Establishments and Conformity Assessment Bodies (CABs).

This initiative aims to provide clarity and consistency in determining the appropriate classification risk of General Medical Devices (GMD) and In-vitro Diagnostic (IVD) Devices, which is in line with the Medical Device Act 2012 (Act 737).

How to submit a request:

1. Download and complete the Dispute Classification Risk Form from the link below:  
[📎 Dispute Class Risk Form v1.docx](#)
2. Submit the completed form to the appropriate email address based on your device type:
  - General Medical Devices (GMD): [registration@mda.gov.my](mailto:registration@mda.gov.my)
  - In-vitro Diagnostic Devices (IVD): [ivd.registration@mda.gov.my](mailto:ivd.registration@mda.gov.my)

We encourage all stakeholders to utilize this mechanism as the official channel for resolving classification matters. This process is expected to enhance regulatory clarity and facilitate a smoother conformity assessment process.

For further inquiries, please contact MDA at the respective email addresses above.

**Medical Device Registration Unit (MEDRU)**  
**Premarket Control Division**  
**Medical Device Authority (MDA)**

Date: May 26, 2025

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## **Pengumuman Terkini: Penambahbaikan Proses bagi pengurusan Pertikaian Pengelasan Risiko antara Establismen dan Badan Penilaian Pematuhan (CAB)**

Pihak Berkuasa Peranti Perubatan (MDA) ingin memaklumkan pelaksanaan penambahbaikan proses bagi menyelesaikan isu pengelasan risiko peranti perubatan antara Establismen dan Badan Penilaian Pematuhan (CAB).

Inisiatif ini bertujuan untuk memberikan panduan yang jelas dan selaras dalam menentukan pengelasan risiko yang tepat bagi Peranti Perubatan Am (GMD) dan Peranti Perubatan Diagnostik In-vitro (IVD), selaras dengan Akta Peranti Perubatan 2012 (Akta 737).

Cara mengemukakan permohonan:

1. Muat turun dan lengkapkan Borang Permohonan Pengelasan Risiko melalui pautan berikut:  
[🔗 Dispute Class Risk Form v1.docx](#)
2. Hantar borang yang telah lengkap ke alamat e-mel yang berkaitan berdasarkan jenis peranti perubatan:
  - **Peranti Perubatan Am (GMD):** [registration@mda.gov.my](mailto:registration@mda.gov.my)
  - **Peranti Diagnostik In-vitro (IVD):** [ivd.registration@mda.gov.my](mailto:ivd.registration@mda.gov.my)

Pihak MDA menggalakkan semua pihak berkepentingan untuk menggunakan mekanisme ini sebagai saluran rasmi dalam menangani isu pengelasan risiko. Proses ini dijangka dapat meningkatkan penjelasan dari segi regulatori dan memudahkan proses penilaian pematuhan.

Sebarang pertanyaan lanjut boleh dikemukakan ke alamat e-mel yang dinyatakan di atas.

**Unit Pendaftaran Peranti Perubatan (MEDRU)**  
**Bahagian Kawalan Pra-Pasaran**  
**Pihak Berkuasa Peranti Perubatan (MDA)**

Tarikh: 26 Mei 2025