TT MEDICAL MANAGEMENT

Malaysia Medical Device Registration Checklist

For foreign manufacturers registering under Medical Device Act 2012 (Act 737)

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STEP 1 Pre-Registration Preparation

- [ ] **Confirm device classification (Class A, B, C or D)**
  Use MDA classification tool or seek regulatory advice first
- [ ] **Determine assessment route**
  Full Assessment or Verification Route (prior FDA / CE / HSA / TGA required)
- [ ] **Appoint a Licensed Local Authorised Representative**
  Must hold valid MDA Establishment Licence and current GDPMD certificate
- [ ] **Sign LAR agreement and issue Letter of Authorization**
  LoA must be device-specific; signed by an authorised company signatory
- [ ] **Select a registered Conformity Assessment Body (CAB)**
  Required for Class B, C, and D only — Class A is exempt

STEP 2 CSDT Core Documents

- [ ] **Declaration of Conformity (DoC)**
  Signed by top management; must reference applicable EPSPs
- [ ] **ISO 13485 certificate (or MDSAP / US FDA QMSR / Japan MO 169)**
  Must be current and valid at time of CAB submission
- [ ] **Essential Principles checklist (EPSPs)**
  Maps each principle to supporting technical evidence in the dossier
- [ ] **Risk management file (ISO 14971)**
  Risk analysis, evaluation, controls, and residual risk assessment
- [ ] **Clinical or performance evaluation report**
  Class B–D: must incorporate current post-market data
- [ ] **Device description and specifications**
  Intended use, indications, contraindications, materials, dimensions
- [ ] **Labelling and Instructions for Use (IFU)**
  Must display MDA registration number and LAR name and address
- [ ] **Sterilisation and biocompatibility data (if applicable)**
  ISO 11135 and/or ISO 10993 series where device is sterile or patient-contact

STEP 3 CAB Conformity Assessment

- [ ] **Submit CSDT dossier to your chosen registered CAB**
  Class A devices are exempt from CAB assessment entirely
- [ ] **Receive CAB conformity assessment certificate**
  Full route: approx 4–6 weeks. Verification route: 30 working days target
- [ ] **Resolve any CAB technical queries promptly**
  Delayed responses extend the timeline — budget time for at least one query round

STEP 4 MDA Submission via MeDC@St

- [ ] **LAR activates MeDC@St 2.0+ account for your device**
  All MDA submissions must go through the LAR — not the manufacturer directly
- [ ] **Pay application fee on submission**
  Class A: RM 500 · Class B: RM 250 · Class C: RM 500 · Class D: RM 750
- [ ] **Submit complete dossier via MeDC@St 2.0+**
  Includes CAB certificate, DoC, CSDT, LoA, labelling, and EPSP checklist
- [ ] **Respond to MDA queries within the specified timeframe**
  Non-response may result in rejection — monitor MeDC@St inbox regularly
- [ ] **Pay registration fee upon MDA approval**
  Class A: RM 750 · Class B: RM 1,000 · Class C: RM 2,000 · Class D: RM 3,000
- [ ] **Receive MDA registration certificate**
  Valid 5 years from date of issue. Registration number assigned to device.

STEP 5 Post-Approval Setup

- [ ] **Update labelling with MDA registration number and LAR details**
  Required before commercial distribution begins in Malaysia
- [ ] **Obtain ePermit / DagangNet account (mandatory from 1 July 2027)**
  Import permit required per shipment; apply at least 7 working days before
- [ ] **Establish post-market surveillance (PMS) system**
  Mandatory for all classes; governed by Act 737 Sections 37–42 and MDA/GD/0070
- [ ] **Set up mandatory vigilance reporting process via MeDCReSt**
  48 hrs (public health threat) · 10 days (death/serious injury) · 30 days (risk)
- [ ] **Set up distribution records system**
  Must capture lot/batch, quantity, recipient, and date for full traceability

P 6 — ONGOIN Ongoing Compliance

- [ ] **Maintain active PMS system and annual PMS report**
  MDA/GD/0070 2nd Ed: 3 years of post-market data required for re-registration
- [ ] **Submit vigilance reports within MDA deadlines via MeDCReSt**
  Report incidents in Malaysia and overseas (specific exemptions apply)
- [ ] **Submit Change Notifications before implementing device changes**
  Cat 1: new registration · Cat 2: MDA endorsement · Cat 3: notify and proceed
- [ ] **Keep LAR Establishment Licence and GDPMD certificate current**
  Lapsed licence puts all device registrations under that LAR at risk
- [ ] **Submit re-registration 12 months before certificate expiry**
  Automated Re-Registration Route available from 13 July 2026 for eligible devices

Typical Timeline:

Documentation prep	CAB — Full route	CAB — Verification	MDA review	Total (Full route)	Total (Verification)
4–8 wks	4–6 wks	6 wks	2–4 wks	3–5 months	2–4 months

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