



SINGAPORE MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the Singapore market.

START HERE: WHAT IS THE PRODUCT IN SINGAPORE?

1 Confirm the Singapore regulatory identity

Confirm the intended purpose, technology, and claims. Determine whether the device is sterile, measuring, active, software, implantable, or higher-risk. This defines classification, eligibility for routes (including Abridged), and required evidence.



Intended purpose



Technology



Risk characteristics



Claims & features

2 Choose the regulatory route

CLASS A



Low risk

Many non-sterile, non-measuring devices are exempt from product registration.

CLASS B



Low-to-moderate risk

Devices with moderate risk to patients; require product registration.

CLASS C



Moderate-to-high risk

Higher-risk devices; require product registration and stronger evidence.

CLASS D



High risk

Highest-risk devices; require product registration and full evaluation.

Classification is based on the First Schedule of the Medical Devices Regulations. Class A devices meeting exemption criteria are not required to be registered.

3 Build the Singapore market-access infrastructure



HSA framework

Understand the Health Sciences Authority (HSA) regulations, guidance, and classification rules.



Local registrant

Appoint an HSA-licensed local registrant responsible for device registration, post-market obligations, and communications.



Dealer's licence / importer-wholesaler setup

Ensure the importation channel is authorised and aligned with HSA licensing requirements.



Registration pathway / reliance strategy

Select Standard (Full) or Abridged route, or rely on accepted regulatory systems where eligible.

4 Build the evidence stack



Administrative
Device description, intended use, indications, claims, and regulatory history.



Quality / QMS
QMS aligned with ISO 13485 and HSA expectations for design, manufacturing, and vigilance.



Safety & performance
Bench, analytical, and performance data demonstrating safety and intended performance.



Clinical evidence
Clinical evaluation and literature supporting safety and performance of the device.



Labeling / English readiness
English labeling and IFU per HSA content requirements.



RA TRAP TO AVOID

Class A exceptions, local registrant duties, reliance route eligibility, and post-market obligations can change the plan. Validate early.



STRATEGIC INSIGHT

Choosing the right registration route and building a complete evidence package early helps Singapore move efficiently.



SINGAPORE MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch.

A Program flow

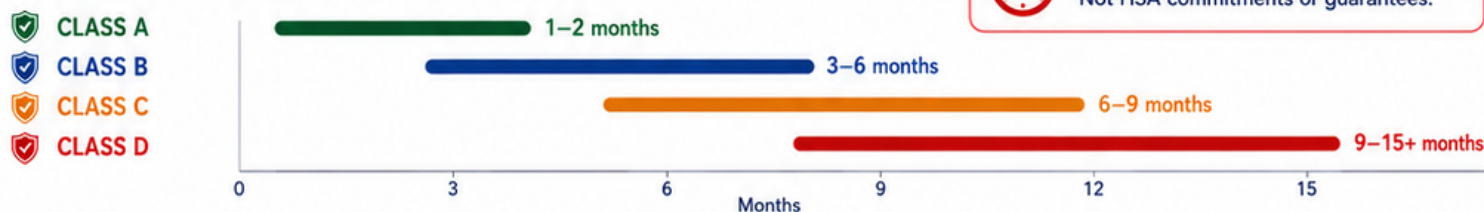


B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Pathway intensity	Low	Moderate	High	Very high
Evidence intensity	Basic	Moderate	High	Very high
Clinical support	Not usually required	Limited	Moderate	Extensive
QMS readiness	Basic	Moderate	High	Very high
Post-market control	Low	Moderate	High	Very high

C Indicative route-based planning ranges

Hopstone planning estimates for timing only — actual time depends on product complexity, evidence quality, application completeness, and HSA review workload.



Timelines are Hopstone estimates only. Not HSA commitments or guarantees.

D Labeling & language essentials

English labeling
All labeling must be in English.

IFU readiness
Provide clear IFU in English for safe use.

Claims control
Claims must be evidence-based and appropriate for indication.

Local registrant / dealer details
Include registrant name, address, and contact on labeling.

Vigilance / recalls
Include reporting information for adverse events and recalls.

E High-impact Singapore decision points

Class A exemption nuances
Understand what is exempt vs. requires registration.

Route selection
Choose Full, Abridged, or Immediate / Expedited where eligible.

Software / connected devices
Confirm SaMD classification, cybersecurity, and data considerations.

Change notification & lifecycle
Plan changes, variation reporting, and ongoing compliance.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Health Sciences Authority (HSA) — Medical Devices Regulatory Overview
<https://www.hsa.gov.sg/medical-devices/regulatory-overview>
- HSA — Registering a Medical Device
<https://www.hsa.gov.sg/medical-devices/registering-a-medical-device>



IMPORTANT

Current product-specific requirements and HSA guidance govern.
Confirm classification, evidence, labeling, and submission obligations before execution.