SINGAPORE IVD REGULATORY MAP

A practical orientation for global RA teams entering Singapore

START HERE: WHAT IS THE PRODUCT IN SINGAPORE?

1 Confirm Singapore regulatory identity

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Classification and product registration route depend on intended use, risk, and HSA's framework.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A

Lowest risk

Generally **exempt** from product registration. Requires product **listing/notification** with HSA.

CLASS B

Low–moderate risk

Product **registration** route under HSA. Moderate risk IVDs with established technologies and performance.

CLASS C

Moderate–high risk

Product **registration** route under HSA. Higher risk IVDs requiring stronger performance evidence and controls.

CLASS D

Highest risk

Product **registration** route under HSA. High/critical risk IVDs requiring the most robust evidence and controls.

3 Build the Singapore market-access infrastructure

HSA framework
Understand IVD regulatory frameworks, classification rules, listing/notification for Class A, and product registration for Classes B–D.

Local registrant / importer-wholesaler setup
Appoint a local registrant licensed by HSA. Ensure importation, storage, distribution, and post-market responsibilities are in place.

Route and dossier readiness
Determine the registration route and submission type. Assemble technical documentation, performance data, risk management, and supporting evidence per HSA requirements.

English labeling / commercialization readiness
Ensure English labeling, instructions for use (IFU), UDI/trackability, and claims align with HSA's expectations.

4 Build the evidence stack

Administrative
Forms, device licence application materials, site information, and market history.

Quality / QMS
QMS aligned with ISO 13485 and HSA QMS requirements; stability / shelf-life.

Analytical performance
Method performance, precision, accuracy, reportable range, interference, and comparability.

Clinical / scientific
Clinical performance or scientific evidence supporting intended use, risk controls, and claims.

Labeling & IFU
English labeling and IFU, symbols, UDI, warnings, claims, and user instructions.

RA TRAP TO AVOID

Do not begin with "the timeline." Start with product identity → classification → route → local registrant → labeling → dossier → submission readiness. Skipping steps leads to costly delays. The timeline is the result of those decisions.

STRATEGIC INSIGHT

Route eligibility, prior approvals, and local registrant setup strongly influence timing. Get these right early to avoid rework and delays.

Training overview — verify current product-specific requirements with HSA and your local registrant. Not legal advice.

SINGAPORE IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

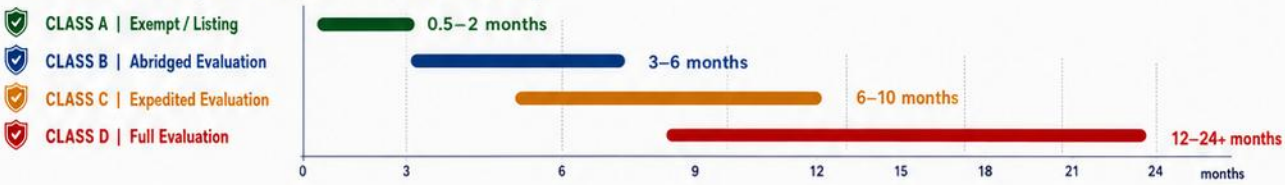
1. **Scope** — Define intended use and product family
2. **Classify** — Apply HSA IVD risk classification (Class A–D)
3. **Route selection** — Confirm regulatory route (Immediate, Abridged, Expedited, or Full Evaluation)
4. **Local registrant setup** — Establish Singapore registrant and ensure license / authorisation if applicable
5. **Evidence** — Analytical performance, clinical performance, and safety evaluation
6. **Submit / register with HSA** — Submit via MeDC@St and obtain MD Registration
7. **Launch / maintain** — Market authorization, post-market controls, changes, vigilance

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Pathway intensity	Exempt / Listing	Abridged Evaluation	Expedited Evaluation	Full Evaluation
Analytical performance	Basic ●	Moderate ●●	High ●●●	Very high ●●●●
Clinical / scientific support	Not usually required	Limited / targeted ●●	Moderate ●●●	Extensive ●●●●
QMS readiness	Basic ●	Moderate ●●	High ●●●	Very high ●●●●
Post-market control	Lower ●	Moderate ●●	Higher ●●●	Highest ●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product complexity, evidence quality, application completeness, HSA workload, and risk signals. Class D (Full Evaluation) can take much longer.



Eligibility for Immediate, Abridged, or Expedited routes depends *on product type, risk, intended use, and supporting evidence.*

HSA review times are guidance only; actual times vary by route, *product complexity, and information quality.*

D Labeling & language essentials

- **English-language support** — English-language labeling and instructions must be provided.
- **Product labeling** — Include required identifiers, intended use, warnings, precautions, and symbols.
- **IFU** — Instructions for use must be clear, accurate, and in English.
- **Claims control** — Claims must be supported by evidence and consistent with intended use.
- **Product identifier / documentation** — Include UDI / Device Identifier, key docs, and traceability records.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Health Sciences Authority (HSA) – Medical Device Overview
  https://www.hsa.gov.sg/medical-devices/overview
- HSA – Registering Medical Devices Overview
  https://www.hsa.gov.sg/medical-devices/registering-medical-devices
- HSA – Guidance Documents for Medical Devices
  https://www.hsa.gov.sg/medical-devices/guidance-documents
- Hopestone Capital & Consulting | *hopestonecapital.com*

IMPORTANT

Product-specific Singapore requirements, current HSA guidance, and other applicable regulatory obligations govern. *Confirm current requirements before filing or execution.*