ISRAEL IVD REGULATORY MAP

A practical orientation for global RA teams entering Israel.

1 START HERE: WHAT IS THE PRODUCT IN ISRAEL?

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer / instrument, or software / other. Approvals are handled through the Ministry of Health Medical Accessories & Devices Department (AMAR).

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

LOWER-RISK PLANNING BAND

Typically for established, well-understood products with mature technology and strong reference-market performance.

Expect more streamlined review paths. Still requires alignment with current Ministry of Health (MOH) requirements and local representation.

MODERATE-RISK PLANNING BAND

For products with greater complexity, higher claims, or emerging technologies.

Pathways may involve additional technical review and evidence. Expect more detailed documentation and potential questions.

HIGHER-RISK PLANNING BAND

For innovative, high-impact, or novel products and technologies.

Generally face deeper review and broader evidence expectations, which may include expert input, site review, and post-market commitments.

The precise route depends on product type, supporting reference-market evidence, and current MOH requirements.

3 Build the Israel market-access infrastructure

MOH / AMAR framework
Understand current MOH Medical Accessories & Devices Department (AMAR) requirements, applicable guidance, and submission pathways.

Local registration holder / importer / representative
Appoint a local entity responsible for submissions, communications with MOH, vigilance, and ongoing compliance as required.

Hebrew localization & market-facing materials
Prepare Hebrew labels, IFU, ads, brochures, and website content as required by MOH and local market expectations.

Product-specific standards / evidence / QMS readiness
Ensure alignment with relevant standards and robust QMS compliance to support review and post-market obligations.

4 Build the evidence stack

Administrative
Product identity, intended use, authorization letters, CE/FDA/other references, and company registration details.

Quality
QMS, manufacturing information, supplier controls, risk management, and process validation.

Analytical performance
Performance data, method comparison, precision, accuracy, reference materials, and stability.

Clinical / scientific
Clinical or performance studies, literature support, PMCF where required, and rationale for claims.

Labeling & IFU
Hebrew-ready labels and IFU with required content, contraindications, warnings, symbols, and unique device ID (where applicable).

RA TRAP TO AVOID

Do not assume that evidence accepted in another market automatically defines the Israel route. Product type, claims, and local requirements may drive a different pathway. Align early with MOH / AMAR through your local partner.

STRATEGIC INSIGHT

Local representation, current MOH expectations, and high-quality localization of market-facing materials are key execution points that influence review efficiency, market entry timing, and sustainability.

ISRAEL IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

1. **Scope**
   Define intended use, test menu, target population, and use environment.
2. **Route planning**
   Confirm risk class under AMAR and map submission strategy.
3. **Local representative setup**
   Appoint an Israel authorized representative (AR).
4. **Standards / evidence**
   Build an evidence strategy aligned to AMAR, Israeli standards, and international norms.
5. **Documentation**
   Prepare technical file, labeling, and localization per AMAR requirements.
6. **Submit / align**
   Submit via the Ministry of Health portal and address queries / inspections.
7. **Launch & maintain**
   Obtain listing in the MoH database and maintain compliance with ongoing updates and vigilance.

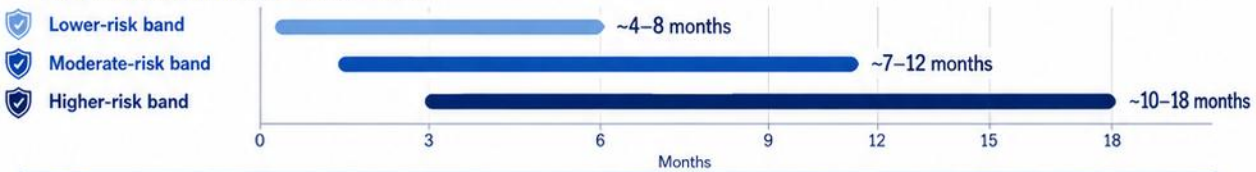
B What gets heavier as the route intensity rises?

Signal	Lower-risk band	Moderate-risk band	Higher-risk band
Premarket pathway	Class A / B (self-declare)	Class C (notified body)	Class D (notified body)
Evidence intensity	Low ●○○○○	Moderate ●●○○○	High ●●●●○
Analytical performance	Basic ●○○○○	Comprehensive ●●○○○	Extensive ●●●●○
Clinical / scientific support	May not be required ●○○○○	As applicable ●●○○○	Extensive ●●●●○
Manufacturing / QMS readiness	Basic ●○○○○	Strong ●●●○○	Very strong ●●●●○
Post-market control	Basic monitoring ●○○○○	Enhanced ●●●○○	Comprehensive ●●●●○

Note: Exact requirements are product-dependent. The table reflects typical increases in burden as regulatory route intensity rises.

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual duration depends on product category, precedent, evidence package, local representation, and Ministry of Health review needs.



These are Hopestone planning estimates, not official clocks. Actual duration depends on the product category, precedent, evidence package, local representation, and Ministry of Health review needs.

D Labeling & language essentials

- **Hebrew-language support**
  Provide Hebrew versions of all end-user-facing materials as required.
- **Product labeling**
  Labels must be in Hebrew, clear, and accurate; include required symbols and local details.
- **Instructions for use**
  IFU must be localized in Hebrew, complete, and consistent with approved use.
- **Claims control**
  Claims must align with approved intended use and be truthful, verifiable, and substantiated.
- **Product identifier & documentation**
  Use UDI (where applicable), retain controlled records, and ensure full traceability.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Israel Ministry of Health — Health Registries Service / Device Database
- Israel Ministry of Health — AMAR regulations / collectors pages
- hopestonecapital.com

IMPORTANT: Product-specific requirements, standards, and current regulatory changes govern. Confirm current requirements before execution.

