



ISRAEL MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Israel

START HERE: WHAT IS THE PRODUCT IN ISRAEL? ▶

1 Confirm Israeli regulatory identity

Confirm intended purpose, users, claims, technology, and whether the item is a medical device under Israeli Ministry of Health expectations. Identify whether it is a general device, sterile / special configuration, software / active / connected device, or implantable / higher-risk device. Determine whether the product can leverage reference-market approvals or needs a fuller AMAR review and local registration strategy.



General medical device



Reference-market supported



Software / active / implantable

2 Choose the Israeli market-entry route

LOW RISK



Lowest risk

Existing lower-risk device with lighter registration expectations.

REFERENCE-SUPPORTED



Reliance pathway

Pathway leveraging recognized foreign approvals / evidence where accepted.

STANDARD REVIEW



Standard assessment

Standard AMAR dossier review for devices needing local evaluation.

HIGH-RISK / NOVEL



Higher-risk review

Higher-risk, implantable, active, or novel devices with deeper evidence and review expectations.

Route and review depth depend on device risk, novelty, reference approvals, and dossier completeness.

3 Build the Israel market-access infrastructure



MOH / AMAR framework

Medical Device Division / AMAR registration under the Ministry of Health.



Israeli registration holder

Appoint and define the local registration holder / representative responsibilities.



Importer / quality readiness

Align licensed importer, quality documentation, and core dossier materials.



Hebrew labeling / launch readiness

Plan Hebrew labeling, user information, and claims review early; any professional-use exceptions require case-specific validation.

4 Build the evidence stack



Administrative

Intended purpose, classification, AMAR route, local holder agreement, importer arrangement, prior approvals.



Quality / QMS

ISO 13485-aligned QMS, supplier controls, process validation, and CAPA.



Safety / performance

Bench testing, biocompatibility, EMC / electrical safety, sterilization, software validation, risk management.



Clinical / scientific support

Clinical evaluation, performance data, risk analysis, PMCF / PMS plan supporting intended use.



Labeling & claims

Hebrew labeling, IFU, claims, symbols, UDI, and professional-use statements as applicable.



RA TRAP TO AVOID

Do not assume CE or FDA status alone guarantees immediate Israeli launch; local holder, importer setup, AMAR route selection, and Hebrew readiness matter.



STRATEGIC INSIGHT:

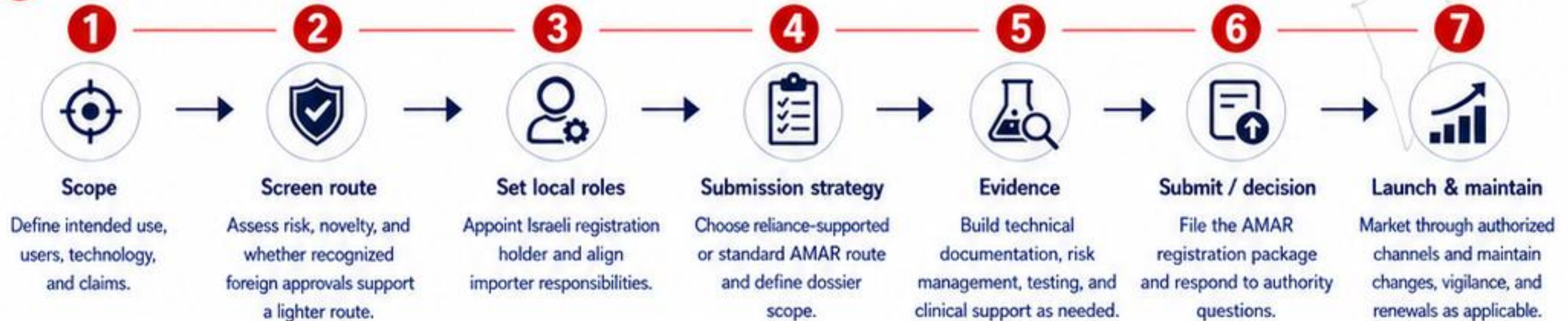
Qualify the reliance-supported route early; it can accelerate launch, but higher-risk or novel devices may still need deeper review.



ISRAEL MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

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

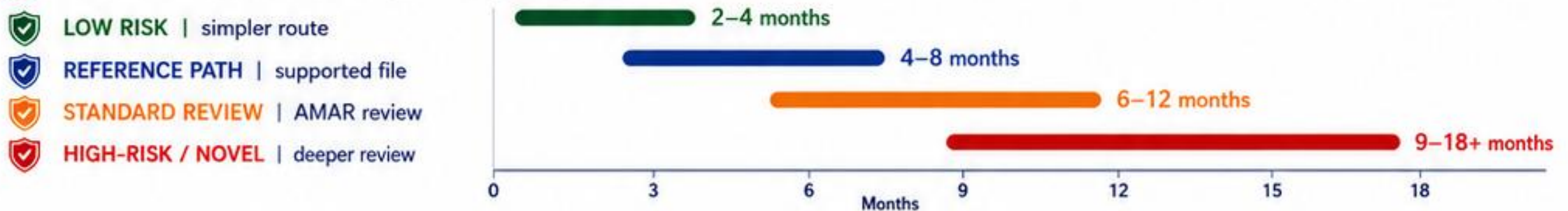
A Program flow



B What gets heavier as risk and novelty rise?

Signal	LOW RISK	REFERENCE PATH	STANDARD REVIEW	HIGH-RISK / NOVEL
Pathway intensity	Simpler ● ● ● ● ●	Streamlined reliance ● ● ● ● ●	Standard AMAR review ● ● ● ● ●	Deeper review ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical / scientific support	Usually not required ● ● ● ● ●	Tailored / some ● ● ● ● ●	Often required ● ● ● ● ●	Extensive ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges



Planning ranges are Hopestone estimates, not Ministry promises; actual timing depends on route, dossier quality, recognized approvals, translations, and questions.



Local-holder readiness, importer setup, and labeling readiness often affect launch timing.

D Labeling & language essentials



Hebrew-language support
Plan Hebrew labeling and IFU early; accurate, validated translations are expected.



Labeling content
Include safe-use information, intended purpose, warnings, precautions, and symbols aligned to approved claims.



Instructions for use
Provide a Hebrew IFU when required, with intended use, limitations, and step-by-step instructions.



Claims control
Claims must align with approved intent; evidence must support intended use.



Traceability / records
Maintain registration, import, distribution, and vigilance records per Ministry requirements.



ISRAELI MINISTRY OF HEALTH RESOURCES

- Israeli Ministry of Health – Medical Devices Division
<https://www.health.gov.il/English/UnitsOffice/MedicalDevices/>
- National Database – Approved Medical Devices
<https://www.old.health.gov.il/MedicalDevices/Pages/default.aspx>
- Hopestone Capital & Consulting — hopestonecapital.com



IMPORTANT

Product-specific Israeli requirements, local-holder obligations, and current authority expectations govern. Confirm current requirements before execution.