



CANADA MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Canada

1 START HERE: WHAT IS THE PRODUCT IN CANADA?

Confirm regulatory identity

Confirm intended use, whether the product is a non-IVD medical device, accessory, software, sterile/single-use, implantable, or active device.

Confirm risk-based classification under the Canadian Medical Devices Regulations.



General medical device



Software / SaMD



Sterile / implant / active

2 Choose the regulatory route

CLASS I



Low risk

- No Medical Device Licence (MDL)
- Establish manufacturer/importer obligations
- MDEL may apply for establishments

CLASS II



Low-moderate risk

- Medical Device Licence (MDL) route
- Evidence and QMS expectations

CLASS III



Moderate-high risk

- Medical Device Licence (MDL) route
- Stronger evidence and review burden

CLASS IV



Highest risk

- Medical Device Licence (MDL) route
- Greatest scrutiny and evidence requirements

3 Build the Canada market-access infrastructure



Health Canada framework

Medical Devices Regulations, classification rules, MDL/MDEL obligations.



Manufacturer / importer / distributor clarity

Identify who holds MDEL and who is responsible for Canadian import/distribution activities.



MDSAP / quality readiness

Class II-IV manufacturers generally require a recognized MDSAP quality management system certificate.



Bilingual readiness

English and French labeling requirements must be built into launch planning.

4 Build the evidence stack



Administrative foundation

Forms, registrations, MDEL, importer responsibilities, agreements.



Quality / QMS evidence

QMS documentation, process validation, risk management, CAPA, supplier control.



Design verification & validation

Design inputs/outputs, verification testing, validation (clinical and/or performance).



Clinical / usability / biocompatibility / sterilization / software evidence (as applicable)

Clinical evaluation, usability, biocompatibility, sterilization validation, software lifecycle evidence.



Labeling & IFU package

Bilingual labeling, IFU, claims, symbols, UDI, and supporting justifications.



RA TRAP TO AVOID

Do not confuse MDL with MDEL.
Avoid underestimating bilingual content and change-control obligations.



STRATEGIC INSIGHT

Canada is often predictable when class, MDSAP, and role ownership are settled early.



CANADA MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

Use this page to connect the regulatory route with the decision points a new RA professional should watch.

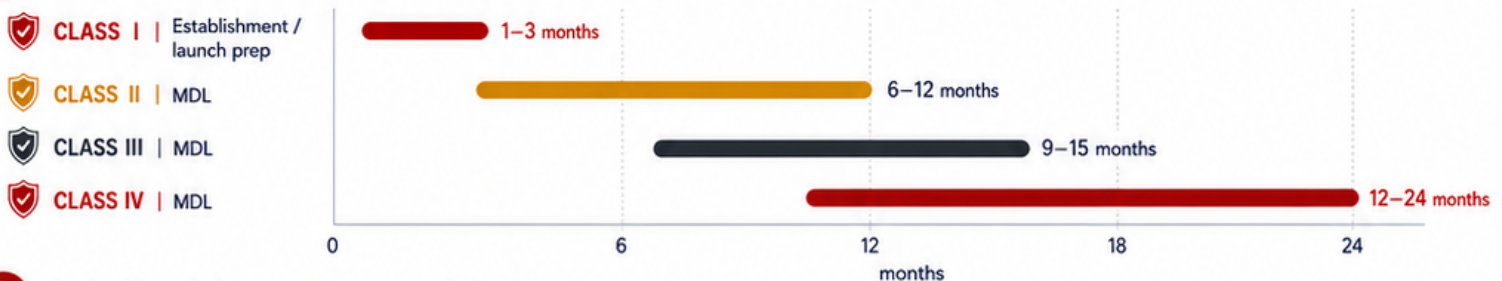
A Program flow



B What gets heavier as the class rises?

	CLASS I	CLASS II	CLASS III	CLASS IV
Premarket pathway	Self-declared	MDL application	MDL application	MDL application
Evidence intensity	Lower evidence	Moderate evidence	Higher evidence	Highest evidence and scrutiny
Clinical / scientific support	Usually limited unless needed	Performance/bench/usability support as applicable	Stronger clinical/performance rationale	Strongest clinical/performance support where applicable
Manufacturing / QMS readiness	Basic QMS	MDSAP-based quality readiness	Stronger QMS	Very high QMS readiness
Post-market control	Lower post-market burden	Moderate post-market burden	Higher post-market burden	Highest post-market burden

C Indicative route-based planning ranges *Hopestone planning ranges only.*



D Labeling & language essentials

Bilingual labeling (English/French)
 All labeling must be provided in both English and French.

IFU and user information
 Instructions for use (IFU) must be clear, complete, and bilingual.

Claims control
 Claims must be truthful, verifiable, and supported by evidence.

UDI / product documentation
 Include UDI as required and maintain device records.

Vigilance & field action communication
 Communicate safety updates and field actions in both official languages.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Health Canada Medical Devices Regulations
- Guidance on Medical Device Licences
- Medical Device Establishment Licence
- Active Licence Listing
- Risk-based Classification Guidance

IMPORTANT: Product-specific requirements and current Health Canada guidance govern. Confirm current requirements before execution.



CANADA MEDICAL DEVICE: EXECUTION DETAILS & HIGH-RISK WATCH-OUTS

Use this page to identify the issues most likely to change route, evidence burden, or launch timing.



E Country-specific decision points

1

MDL vs MDEL



Do not confuse the device licence (MDL) for Class II–IV devices with the establishment licence (MDEL). They are distinct legal instruments that address different obligations.

2

Review targets



Health Canada publishes service standards of 15 calendar days for Class II, 75 calendar days for Class III, and 90 calendar days for Class IV standard licence applications. Overall project time is longer.

3

Licence amendments



Certain changes to licensed Class II–IV devices require a licence amendment before implementation. Class I devices and establishment changes still need controlled implementation.

4

Special routes



Investigational Testing Authorization (ITA) and Special Access (SA) are separate access pathways and should not be treated as routine commercial market access.

F Regulatory readiness checklist

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|--|---|
| ☐ Intended use and claims are stable and justified. | ☐ Verification & validation plan covers standards and hazards. |
| ☐ Classification rationale is documented. | ☐ Clinical and usability evidence is proportional to risk. |
| ☐ Local role ownership (importer / distributor) assigned. | ☐ Labeling, IFU, and software UI language strategy is ready. |
| ☐ QMS certificate and site evidence are ready. | ☐ Registration, listing, and role data are prepared. |



USE THE TIMELINES AS PLANNING RANGES, NOT REGULATORY PROMISES

Actual duration depends on device classification, evidence maturity, authority workload, questions or holds, bilingual content preparation, and manufacturing readiness. Build buffer into your plan and escalate early when delays appear.