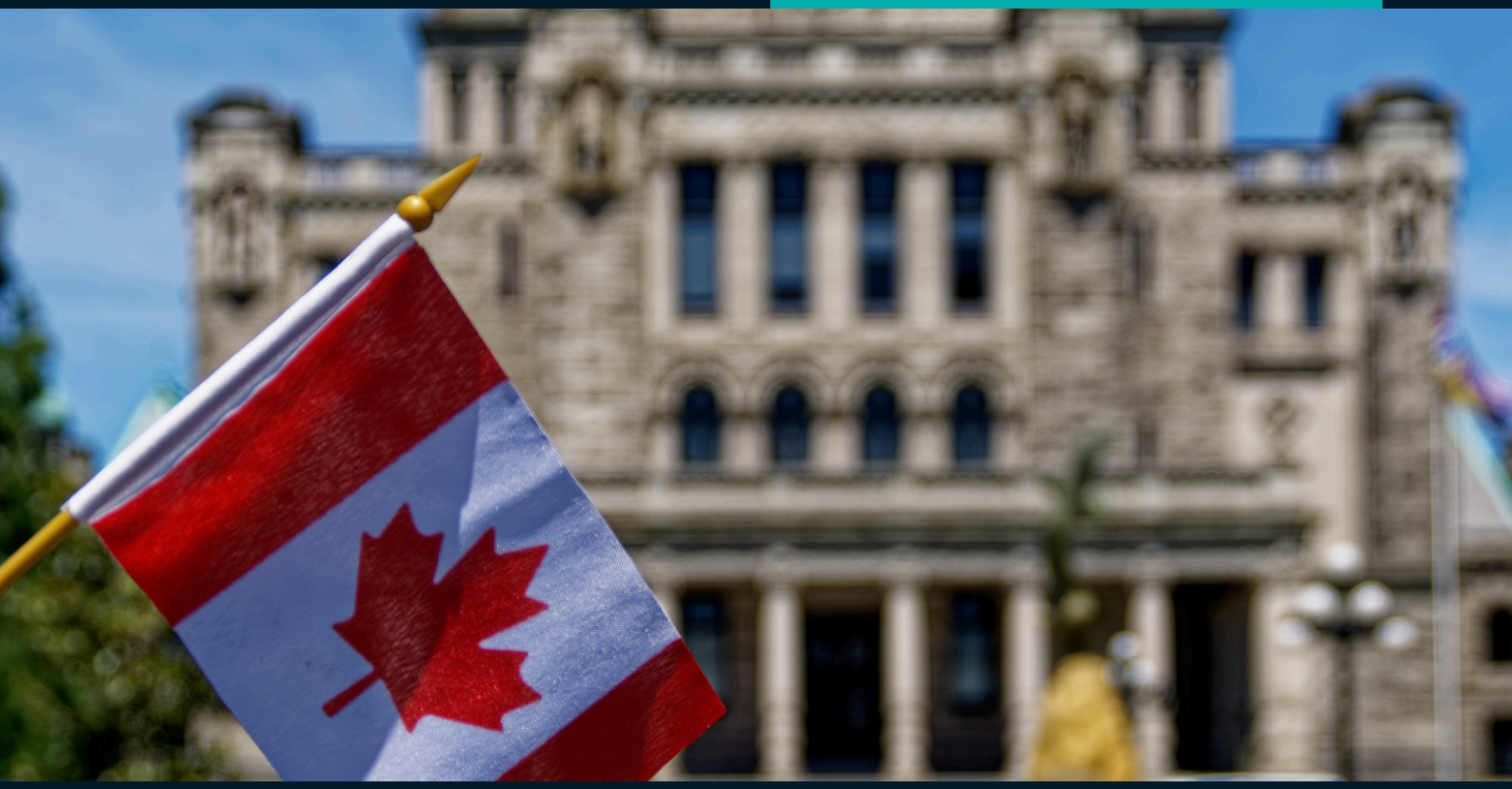
Elexes



Strategic Regulatory Due Diligence for a Hair & Follicle Monitoring Platform (Health Canada)

CASE STUDY

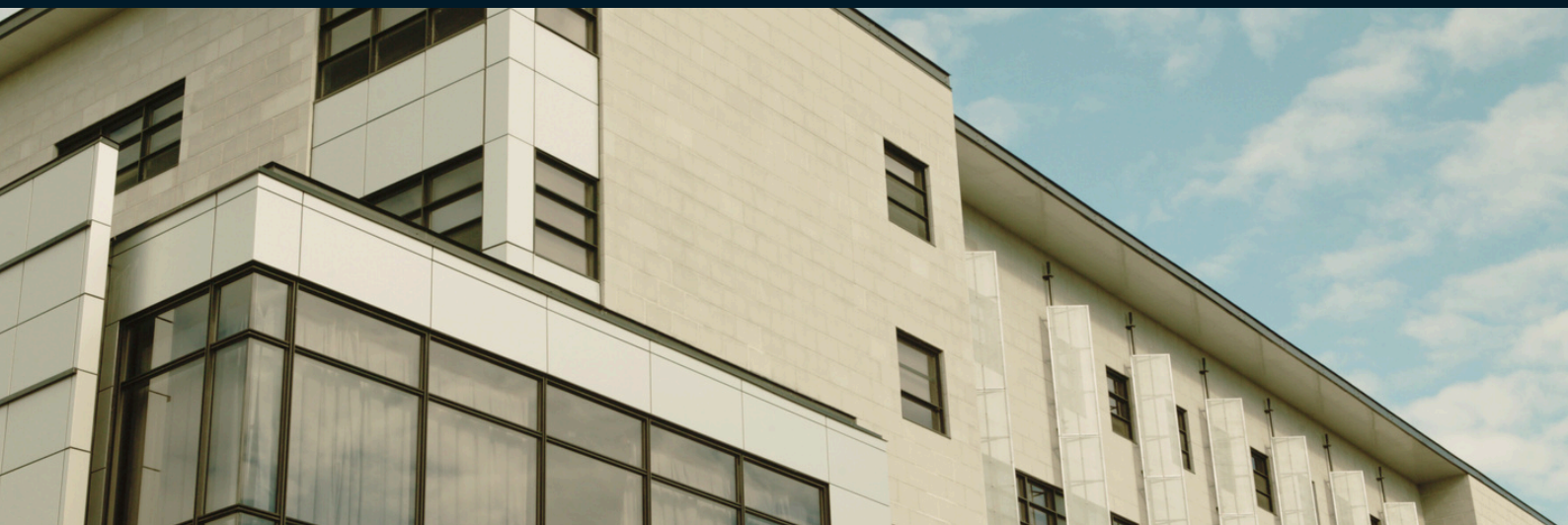
Website:

www.elexes.com

Overview

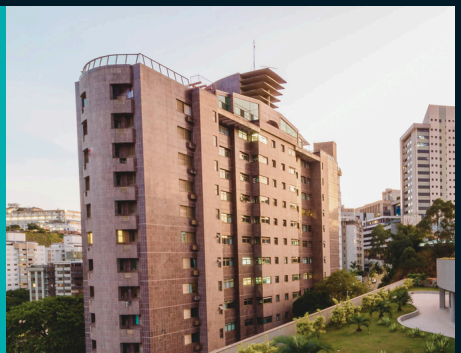
- An early-stage digital health company developing a software-led follicle monitoring solution engaged Elexes Medical Consulting to clarify whether their product qualified as a medical device under Health Canada regulations.

- The engagement focused on reducing regulatory uncertainty, avoiding premature compliance investment, and defining a clear path forward aligned with the company's business and product strategy.



Client Context

- The client is a health technology startup building a follicle and hair monitoring platform intended to support users and professional partners in tracking hair density and follicle trends over time.
- The solution is primarily software-driven, with the use of off-the-shelf imaging accessories.
- The company planned to enter the Canadian market first, followed by staggered expansion into the U.S. and Europe depending on funding and regulatory clarity.
- At the time of engagement, the client had no formal QMS in place and was intentionally holding off on testing and documentation due to uncertainty around regulatory classification.



The Challenge

↘ The core challenge was determining whether the product:

- Qualified as a medical device under Health Canada's CMDR
- Could remain a general wellness/non-medical product, depending on claims

↘ This uncertainty had direct implications for:

- The need for QMS and MDSAP certification
- Design History File (DHF) creation
- Documentation, testing, and timelines
- Overall cost and go-to-market strategy

The client needed fast, defensible clarity before committing resources.

Elexes' Approach

Elexes recommended starting with targeted regulatory due diligence, rather than immediately moving into full regulatory execution. The approach was intentionally customer-centric and risk-based.

STEP 1

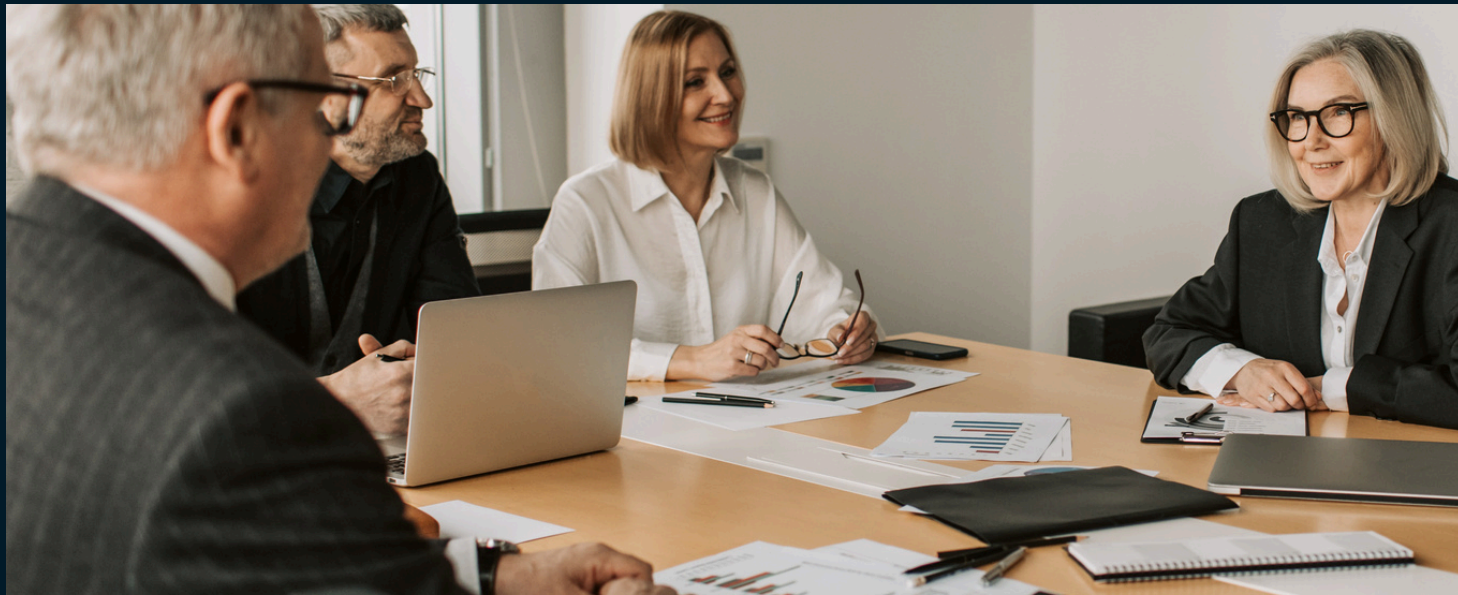
Regulatory Qualification & Due Diligence

STEP 2

Classification Scenarios & Decision Framework

STEP 3

Strategic Next-Step Options



Step 1:
Regulatory Qualification & Due Diligence

Elexes conducted a focused review of:

- Intended use and product functionality
- Planned claims across labeling and marketing
- Software outputs and user interaction
- Alignment with Health Canada's definition of a medical device

Using this analysis, Elexes evaluated the product against Health Canada's CMDR framework.

Step 2:
Classification Scenarios & Decision Framework

↘ Elexes presented three defensible regulatory outcomes, explicitly tied to claims:

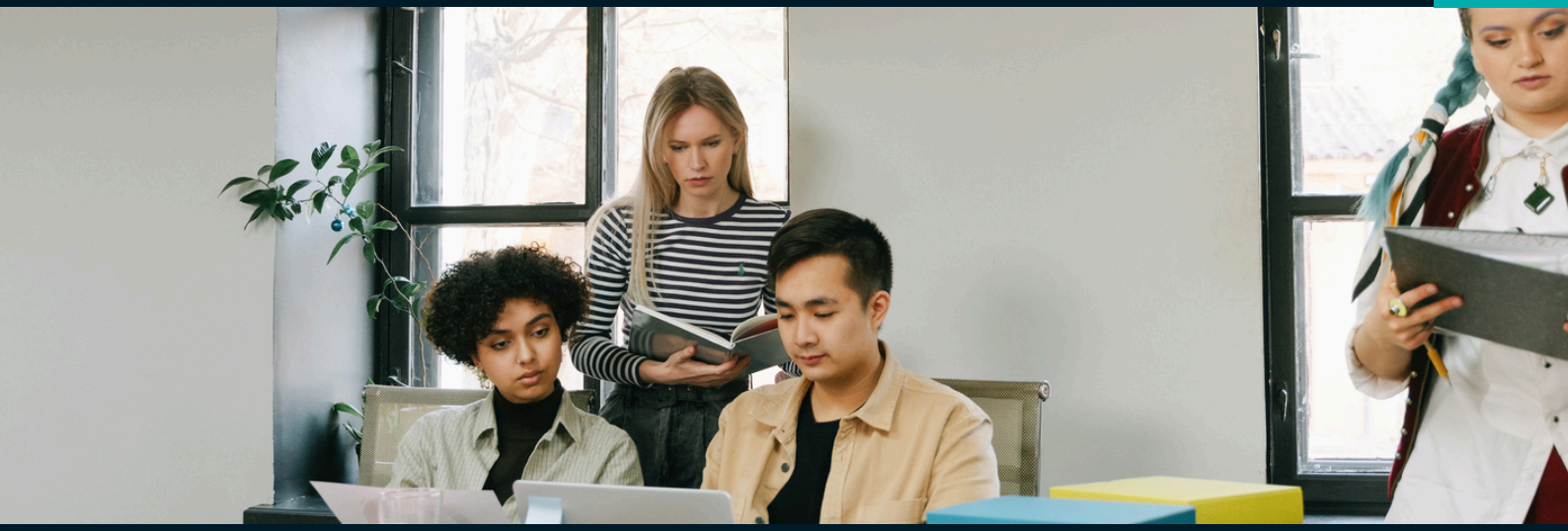
- General Wellness / Non-Medical
- Class I Medical Device
- Class II Medical Device

↘ Each scenario outlined:

- Regulatory implications
- Documentation expectations
- QMS and MDSAP impact
- Strategic pros and cons

Crucially, Elexes highlighted that final classification is driven by claims, while considering the underlying technology.

Step 3:
Strategic Next-Step Options



Based on the outcomes, Elexes outlined tailored next steps:

- If positioned as exempt/wellness, explore the feasibility of obtaining written clarification from Health Canada (with clear disclosure that HC does not offer FDA-style formal determinations)

- If Class I or II, proceed with a phased roadmap covering:
  - QMS implementation aligned with MDSAP
  - Regulatory documentation planning
  - DHF creation and submission preparation

All recommendations were framed to support founder decision-making and investor discussions.

What Elexes Delivered

- A concise regulatory due diligence assessment
- Clear classification scenarios tied to claims
- A structured decision framework for leadership
- Practical guidance on avoiding unnecessary compliance build-out
- A defensible foundation for Canada-first, multi-market expansion planning

Outcomes & Impact

- Reduced regulatory ambiguity at an early stage
- Prevented premature investment in QMS, MDSAP, and DHF activities
- Enabled informed decisions on product positioning and claims
- Provided clarity that could be shared with internal stakeholders and investors
- Positioned the client for faster execution once a regulatory path is selected

Why This Matters

- Many digital health and monitoring products sit at the intersection of wellness and regulated medical devices.
- Moving too quickly into full compliance can significantly increase cost and timelines, while moving too slowly can expose companies to regulatory risk.
- This engagement demonstrates the value of strategic regulatory due diligence as a first step, particularly in Healthcare, where classification hinges heavily on intended use and claims.

Who Could Benefit from This?

This approach is particularly relevant for:

- Digital health, wellness, and monitoring platforms
- Software-led products using off-the-shelf accessories
- Startups without an existing QMS
- Companies planning Canada-first or multi-market entry

How This Translates to Other Products & Markets

The same methodology applies to:

- Skin imaging and dermatology platforms
- Fertility and hormone tracking solutions
- AI-enabled analysis and monitoring tools
- Diagnostics-adjacent wellness products

While this engagement focused on Health Canada, the early qualification and claim-driven strategy directly supports future FDA and EU MDR planning.

Next Steps

Once the client finalizes intended claims and positioning, Elexes can seamlessly transition into:

QMS implementation aligned with MDSAP

Regulatory documentation and DHF creation

Health Canada MDL submission and follow-up

Note: Final regulatory classification is subject to Health Canada interpretation and depends on finalized claims and intended use.