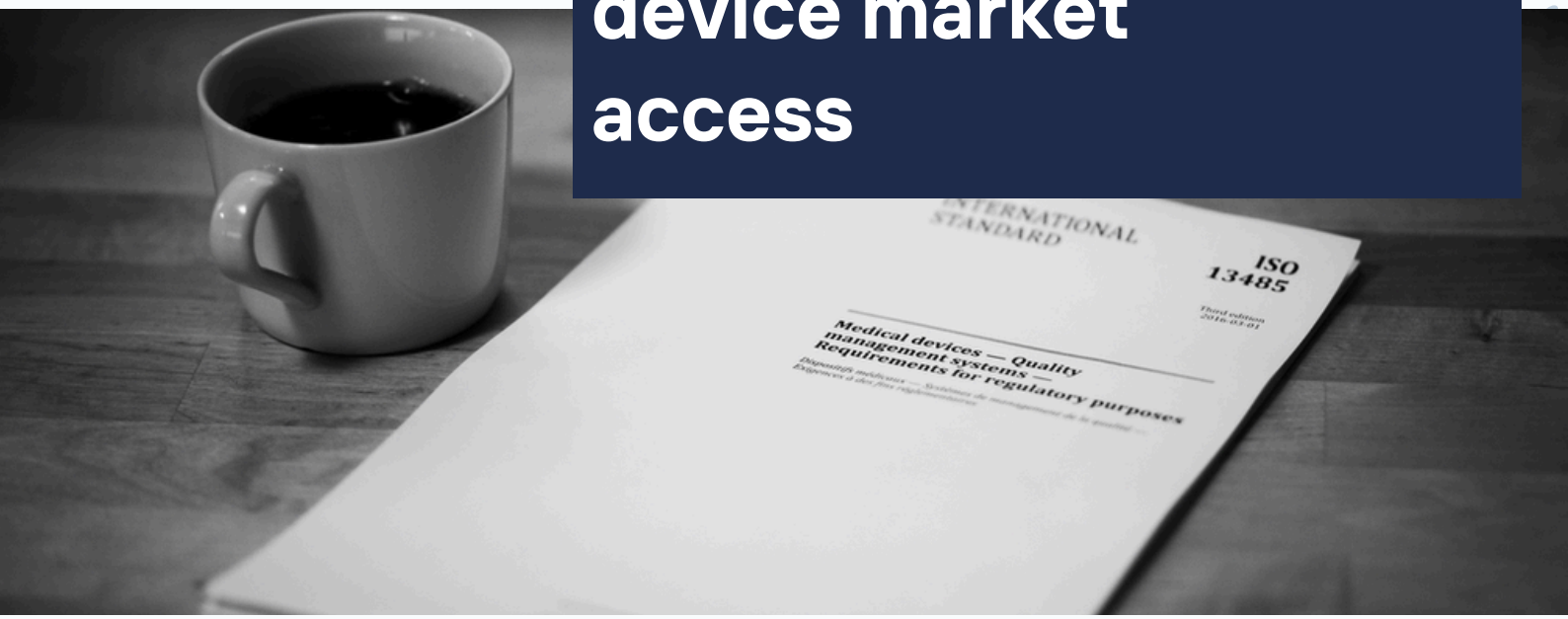
Nometech

# Your strategic partner for medical device market access




## Medical device regulatory and quality services

We provide medical device regulatory and quality services to health tech and medical device companies operating in regulated markets such as the EU and the United States. Our work starts by helping teams understand what regulations actually require and how those requirements affect product development in practice.

## Our services

- **Kickstart packages:** Gain a structured view of regulatory requirements.
- **Quality Management System**: We help you build and maintain a practical, risk-based Quality Management System that supports regulatory compliance and everyday work.
- **Medical Device Technical Documentation as a Service**: We help you prepare, review, and maintain technical documentation that meets regulatory expectations and supports efficient submissions and assessments.
- **Training and Internal Audits**: We support training and internal audit activities that strengthen understanding, improve processes, and help organizations address findings in a structured and sustainable way.
- **Medical Device Development:** We provide regulatory-focused project management for medical device development

**Katja Koskinen**
CEO / Regulatory Specialist

+358 400 533 914
https://nometech.eu/
katja.koskinen@nometech.fi

Scan for more information

# Typical Headaches of MedTech start ups

## Expert guidance to satisfy investors and accelerate your market entry.

For Medtech startups, finding the right experts and securing funding are the first hurdles. Investors need to see a clear plan. Nometech's Kickstart packages provide an agile, cost-effective way to navigate the regulatory path with confidencegiving you the roadmap you need to lead.

**Regulatory pathway Kickstart** : Gain a structured view of regulatory requirements. We determine your device classification and map out the entire submission package to reduce uncertainty.

**What You Get:**

- Clear Output: Regulatory classifications, gap assessments, and a structured document framework.
- Lean Compliance: Practical steps and document lists required for your specific device category.
- Investor-Ready Roadmap: An estimation of prices and realistic timeline that demonstrates professional control over your regulatory path.

**The Nometech Kickstart: Stop guessing. Start building. Contact us for a Kickstart session to map out your costs and schedule.**