Chief Technology Officer (CTO) – YON E Health

Location: Hungary, Budapest

Reports to: CEO & Board of Directors

Compensation: parttime TRL4, 2000,00 euros / Fulltime 5.000,00

About YON E Health

YON E is a pioneering FemTech company developing a Class IIa medical device that measures and monitors vaginal health biomarkers (pH and temperature) to transform fertility, menstrual health, and intimate wellbeing. We are at the intersection of medical innovation, digital health, and women's empowerment—bringing clinical-grade rigor to a field long overlooked.

With pending patents in the EU and UK, a validated TRL2/3 testing roadmap, and early partnerships with leading medical institutions, IONI is entering a critical phase: building prototypes, aligning with CE MDR and FDA requirements, and scaling toward commercialization.

Role Overview

We are seeking a seasoned Chief Technology Officer (CTO) with extensive experience in Class IIa medical devices to lead YON E's technical vision, product development, and regulatory alignment. The CTO will be responsible for translating scientific and clinical insights into a scalable, compliant, and high-performing device ecosystem, integrating both hardware and software.

This is a mission-critical leadership role shaping the trajectory of IONI—from TRL3 prototyping through CE marking, FDA clearance, and global commercialization.

Key Responsibilities

Strategic Leadership

- Define and drive YON E technology strategy across hardware, firmware, and software in alignment with regulatory and clinical milestones.
- Act as the technical voice at board level, advising on risk, scalability, and innovation.
- Build and oversee a world-class R&D and engineering team.

Product & R&D Leadership

- Lead development of prototypes from TRL3 to TRL6, ensuring feasibility, repeatability, and clinical robustness.
- Oversee integration of ISFET-based pH and temperature sensors into an intravaginal form factor with proven usability and biocompatibility.
- Ensure design controls (per ISO 13485 & IEC 62304) are implemented from the earliest stage.
- Align development with CE MDR requirements (anticipated Class IIa, Rule 10).

Quality & Regulatory Excellence

- Partner with Regulatory & Clinical teams to ensure compliance with:
    - ISO 13485:2016 (Quality Management System for medical devices).

    - ISO 14971:2019 (Risk Management).
    - ISO 10993 (Biological Evaluation/Biocompatibility).
    - IEC 62304 (Medical Device Software Lifecycle).
    - IEC 62366 (Usability Engineering).

- Collaborate with regulatory consultants, ensuring readiness for CE mark and FDA pathway (510(k)/De Novo).
- Lead documentation for Design History File (DHF), Device Master Record (DMR), and Technical File.

Cross-Functional Leadership

- Work with CEO, CFO, CDO, CCO, COO and medical team to align technical development with clinical protocols, usability studies, and safety testing.
- Collaborate with data/AI leads to define secure, scalable data architecture in line with GDPR/HIPAA.
- Drive strong communication between engineering, clinical, and commercial teams.

Innovation & Risk Management

- Scout emerging sensor technologies, materials, and manufacturing methods to maintain competitive advantage.
- Define and manage technical risk registers, ensuring mitigation strategies are in place.
- Build and maintain partnerships with manufacturers, suppliers, and academic labs.

Ideal Candidate Profile

- 10+ years' experience in medical device development, with proven leadership in Class IIa (or higher) products from concept through CE/FDA approval.
- Advanced knowledge of ISO/ESO standards, QMS, and MDR pathways.
- Deep expertise in biosensors, microelectronics, or implantable/insertable medical devices.
- Proven track record in leading multidisciplinary teams (hardware, software, clinical, regulatory).
- Strong experience in building Design History Files and Technical Documentation for CE/FDA submissions.
- Experience in scaling prototypes to mass manufacturing, including vendor and partner management.
- Excellent communication skills—able to translate complex technical concepts for investors, regulators, and clinicians.
- Passion for women's health, preventive medicine, and technology for social good.

What We Offer

- Opportunity to shape a first-in-class women's health device that addresses a multi-billion euro market.
- Executive leadership role with equity options.
- A values-driven, international team at the forefront of FemTech innovation.
- Direct impact on women's health outcomes globally—from fertility to long-term vaginal health.