



Loopal

The Intelligence Layer for MedTech

A Continent-Wide Bottleneck

EU MDR has **doubled compliance costs** across the MedTech industry. Manual audits take months, legacy devices are being abandoned, and thousands of orphan devices are stranded in regulatory limbo — blocking patient access and destroying shareholder value. 92% of European devices are produced by medium size firms and startups who don't have the budgets of large corporations for compliance.

34K+

EU Companies

MedTech companies currently struggling with the MDR transition

2x

Cost Surge

EU MDR has doubled compliance costs versus the previous MDD framework

"Generative AI is too dangerous for MedTech — hallucinations lead to lethal regulatory risks and multi-million euro delays."

Auditing, Not Generating

Loopal is a Regulatory QA Agent

We use **expert-validated logic gates** and **RAG (Retrieval-Augmented Generation)** to guarantee zero hallucinations. Loopal compares your technical files directly against the law with 100% deterministic precision — no guessing, no generating, no risk.

01

Ingest Technical File

Upload PDF or Docx from any QMS source — no migration needed

03

Deterministic Output

Instant gap analysis with direct legal citations for every flag found

02

Logic Gate Analysis

Expert-validated rules check every clause against EU MDR requirements

Built for Precision, Designed for Every QMS

QMS-Agnostic

No data migration required. Works with PDF and Docx files from **any existing QMS source**. Plug in and audit immediately.

Instant Gap Analysis

Automated identification of every compliance gap in your technical documentation — results in minutes, not months.

Traceability Matrix

Automated end-to-end traceability matrix generation, fully aligned with EU MDR Annex II and III requirements.

Direct Legal Citations

Every flag is backed by a precise, direct citation to the relevant EU MDR article — zero ambiguity, full auditability.

High Cost vs. Real Automation — Where Loopal Wins



Traditional Consultancies

Deloitte, Big Four

Extremely expensive. 100% manual. Slow and completely unscalable. Months per audit.



Legacy QMS Platforms

Certhub & peers

Overpriced, long adoption cycles, requires full data transfer and re-implementation.



US/FDA-Focused Platforms

Greenlight Guru, RegDesk

Rigid workflows built for FDA. The complex EU MDR market is left deeply underserved.



Similar but Limited

MB&A (FDA-acquired), Klaris

Similar architecture but narrow scope, small market share.

✔ **Loopal Advantage:** Affordable, QMS-agnostic, deterministic AI automated auditing — built specifically for the complex EU MDR framework.

A €600B Market Ready for a Compliance Revolution

34,000+ European MedTech companies are struggling with the MDR transition. The regulatory burden is only growing — and no scalable, affordable solution exists yet.



TAM

€600B Global MedTech Market



SAM

€15B European Regulatory Affairs & Compliance



SOM

€150M Initial target — DACH region & UK

With 34,000+ companies currently navigating the MDR transition and compliance costs doubling industry-wide, Loopal is positioned at the exact inflection point of regulatory urgency and technological readiness.

\$ ADVISORY BOARD

Backed by Industry Titans

Loopal is guided by **10+ strategic advisors** from the world's most trusted names in AI infrastructure, MedTech, and regulatory affairs

Amazon Medtech Imports

Head of regulatory for MDR, imports from Asia

Boston Scientific

Senior regulatory affairs specialist

Boutique RA Firms

Market validation from specialist Regulatory Affairs consulting firms with deep EU MDR trenches experience.



Microsoft Founders Hub: Loopal is supported with **\$150,000 in Azure credits** — validating our technical architecture at the highest level.
EUSAIR AI ACT SUPPORT

Bypassing Slow Enterprise Sales Cycles

We don't knock on the boardroom door first. We target the people doing the work — and let them pull us in.

1

Target RA Consultants

Independent Regulatory Affairs consultants are overwhelmed. Loopal makes them **10x faster**.

2

Trojan Horse Entry

Consultants adopt Loopal, then introduce it to their **large enterprise clients** — bypassing lengthy sales cycles.

3

Enterprise Expansion

From consultant tool to enterprise platform via **Microsoft Marketplace** and **Atlassian Marketplace** integrations.

Built for Profitability



The Ask

€150,000 via SAFE at €1.5M Cap



Break-Even Math

Only **38 active enterprise clients** needed to reach full break-even

Use of Funds

1 ISO 27001 Certification

Establishing enterprise-grade security credentials required for MedTech clients and regulated environments.

1

2 FDA Database Mapping

Expanding Loopal's deterministic rule engine to cover FDA workflows alongside EU MDR — unlocking the US market.

2

3 Core Sales Team

Hiring the first dedicated sales reps to activate the RA consultant channel and convert early enterprise leads.

3

The People Breaking the MDR Bottleneck

Andrei Lupu— CEO

Business strategy, partnerships, and commercial vision. **8 years** in hard sciences and pharma. Bridges deep domain expertise with entrepreneurial execution.

Alex Benchea — CTO

Architecture and engineering leadership. **8 years** building mission-critical banking software. Brings rigorous, high-reliability systems thinking to Loopal's deterministic AI core.

Vlad Istratescu — CISO

Cybersecurity expert and **GAMP5** specialist. Ensures Loopal meets the highest standards for data integrity and regulated-industry compliance.

Extended Team

Senior developers, AI engineers, and world-class domain experts in regulatory affairs and MedTech strategy.

Join us in breaking the MDR bottleneck.

www.loopal.eu · andrei@aiudit.tech

Thank You

We appreciate your time and interest in Loopal. We are now open for any questions you may have.

Join us in breaking the MDR bottleneck.

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