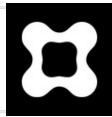


One liner

A deterministic software engine that automates Gap Analysis for medical device compliance (MDR/IVDR), eliminating manual consulting costs.



Mission

To eliminate regulatory friction and bureaucracy from global healthcare, accelerating the market launch of life-saving medical innovations.

Milestones & Traction



Milestone 1

(Q3 2026) | Heavyweight RA Onboarding: Secure a former Notified Body Lead Auditor (e.g., BSI/TÜV SÜD) to join as a late-stage RA Co-founder or Advisory Board.



Milestone 2

(Q4 2026) | Launch our native Microsoft Word Add-in and build API connectors for major enterprise eQMS (Qualio, Veeva, SharePoint).



Milestone 3

(Q1 2027) Achieve ISO 27001 and SOC 2 Type II data security certifications, which are strictly required for handling corporate medical data.



Milestone 4

(Q2 2027) | Onboard the first 15 paid SME/Startup clients on tiered SaaS subscriptions, covering 50% of the core team's operational expenses.



Milestone 5

(Q3 2027) | Reach the commercial traction and ARR thresholds required to successfully open a €2 Million Seed funding round.

Company Overview

Loopal is a RegTech platform that automates Gap Analysis for medical device technical files (MDR/IVDR). We use a deterministic software engine to catch documentation omissions or errors, reducing high manual consulting costs and accelerating time-to-market.

Why Us?

Elite software and infrastructure engineers focused entirely on product execution. Our technical logic is built and guided by a heavyweight Board of Advisors consisting of ex-Notified Body lead auditors and veteran compliance experts.

The Market / Why now?

Medical compliance is a multi-billion-dollar bottleneck. In 2026, mandatory EUDAMED timelines, AI Act's impending arrival. Regional competitors (like Kodesage in Budapest) just raised \$6.6M Seed rounds, proving VC appetite for automated compliance.

Investment Opportunity

We are seeking a €150,000 Pre-Seed round to expand our core technical engineering team, complete the native Microsoft Word integration, and secure our operational runway until reaching our milestone of 15 paid business clients.

Stage

Pre-seed

Industry

MedTech / RegTech / B2B SaaS.

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Your paragraph text

Date

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The Problem

European MDR/IVDR compliance takes up to 3 years and costs over €150k in manual consulting. Forcing startups to launch in the US first, and German firms to slash portfolios by 50%. Eastern Europe has zero local Notified Bodies. Existing platforms are hallucinating or niche.

The Solution

Loopal is a live, cloud-native software that automates pre-audit Gap Analysis. We don't generate creative text; our engine is fully deterministic. We use AI strictly to parse and map technical files against expert-validated regulatory rules.

Unique Value Proposition

100% Deterministic: Zero AI hallucinations; exact compliance mapping.
Workflow-Native: Works directly inside MS Word where engineers write.
QMS Agnostic: Plugs via API into Google Drive, Qualio, or Veeva.

Business Model

Trojan Horse: targeting boutique compliance operators for a B2B2B approach to help them get more clients and do their job faster and they offer us to their clients, or startups and mid firms (under 15 employees).

The Team



Andrei Lupu: CEO, 8 years of life sciences



Alex Benchea: CTO, 8 years of full stack dev in banking



Vlad Istratescu: CISO, cybersecurity expert