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COMPLIANCE FOR MODERN MEDICAL DEVICE TEAMS

Leida.ai

Terveysteknologian regulaatio tekoälyn aikakaudella

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LAURA AHONEN

Founder & CEO · Leida Tech Oy

- Innovation & product leader for 12+ years
- First startup: 2014. Faced the regulatory problem firsthand
- Accenture & Deloitte: design lead + FDA/MDR medtech clients
- Leida: founded 2025

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AI-assisted regulatory infrastructure for medical device companies

Perustettu	2025
Tiimi	6 henkilöä · AI / DATA / MDR / FDA
Sijainti	Tampere + Helsinki + Kalifornia + Sveitsi
Markkinat	EU · USA
Standardi	MDR · IVDR · FDA · AI Act · ISO 13485

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MEDTECH COMPLIANCE HAS NOT
BEEN REINVENTED YET, IT STILL RELIES ON HEAVY, MANUAL
PROCESSES.

AI SHIFTS THE FOCUS FROM FRAGMENTED SYSTEMS TO CONNECTED,
REAL TIME INFRASTRUCTURE.

THE NUMBERS CONFIRM WHAT EVERYONE ALREADY FEELS

THE NOTIFIED BODY FEE IS JUST THE TIP OF THE ICEBERG

You budget for certification.
Close your funding round.
Celebrate getting certified.
Then the maintenance bills start arriving.
Every year.

By year five, you have spent twice what you planned. And you haven't built anything new.

€2.9M
Average total regulatory lifecycle · IVDR

€4.8M
Average total regulatory lifecycle · MDR

73–74%
Of total cost is manufacturer personnel time

6%
Is Notified Body fees. The rest is hidden.

MISSÄ STARTUPIT KOMPASTUVAT

01

Dokumentaatio alkaa liian myöhään

Tuotteen kehitys on jo aloitettu, kun regulaatio tulee kuvaan. Design history file, risk management, software lifecycle — kaikki pitää rekonstruoida jälkikäteen. Hidasta ja kallista.

02

Versiointi hajoaa käsiin

Ohjelmisto päivittyy sprinteissä. Regulaatiotilanne päivittyy manuaalisesti. Softan rakentamisessa koko ohjelmistoa ei aina kannata sertifioida, haasteena pysyä raamien sisällä.

03

MDR ja laajentuminen FDA

EU-sertifiointi tehty, laajentuminen FDA:han. Kaikki on kirjoitettu MDR:n logiikalla. FDA haluaa eri rakenteen, eri nimeämiskäytännöt, eri näyttöketjun.

04

AI Act tuli MDR:n päälle

Startup on rakentanut MDR-dokumentaation. Nyt AI Act vaatii lisäksi läpinäkyvyysdokumentaation ja riskiluokituksen. Lääkinnällisten laitteiden siirtymäaika päättyy elokuussa 2027.

HOW DO YOU INNOVATE BOLDLY IN A SYSTEM DESIGNED TO PREVENT MISTAKES?

Innovation does not happen despite regulation.
It happens inside it. Or not at all.

EUROPE DOES NOT HAVE A REGULATION PROBLEM
WE HAVE A TOOLING PROBLEM

We still operate as if compliance is a static document exercise.
While innovation has become continuous, software-driven, and system-level.

The companies that win treat regulation as a design constraint from day one.
Not a legal checklist at the end.

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AI DOES NOT JUST SPEED UP COMPLIANCE IT MAKES IT POSSIBLE AT SCALE

A single medical device generates thousands of interconnected requirements, documents, risk records, software versions, clinical data points and change events — across multiple regulatory frameworks simultaneously. No human team can keep this current manually.

AI handles volume

What humans cannot do at scale

Cross-reference instantly

AI reads every requirement in MDR, IVDR, FDA, AI act and ISO standards simultaneously and maps your evidence to all of them in real time.

Zero drift

When a document changes, AI propagates the update through every linked requirement, risk record and audit trail entry. Automatically.

No context loss

A team member leaving takes institutional knowledge. AI retains the full traceability chain regardless of who is on the team.

AI reads structure in chaos

Turning unstructured data into compliance evidence

Unstructured sources

GitHub commits, Jira tickets, Word documents, PDFs, spreadsheets, test logs. AI extracts regulatory-relevant signals from all of them.

Pattern recognition

AI identifies which design change affects which GSPR clause, which risk control needs updating, which clinical claim requires new evidence.

Gap detection

AI surfaces missing evidence before the auditor does. The gap report is live, not a quarterly exercise.

Human judgment stays central

AI as infrastructure, not as decision-maker

AI proposes, humans decide

Every AI-generated mapping, gap finding or document draft is reviewed and approved by the QA or RA professional. The audit trail records who, when and why.

Explainable outputs

Every AI conclusion links directly to the source regulation text, the document and the timestamp. Full transparency, no black box.

Scales with the team

A two-person startup and a 200-person medtech company use the same infrastructure. The AI absorbs the complexity so the team can focus on the device.

SIIRTYMÄ MANUAALISESTA TYÖSTÄ OHJAAMISEEN

VANHA MALLI

Staattinen dokumenttiharjoitus

Compliance on erillinen projekti kehitystyön lopussa. Laite on rakennettu, ja regulaatio seuraa perässä.

Manuaalinen jäljitettävyys

Excel-taulukot, Word-dokumentit, sähköpostit. Jokainen muutos vaatii käsin tehtävän päivityksen useaan paikkaan.

Reaktiivinen

Puutteet löytyvät auditissa. Siinä vaiheessa korjaaminen on kallista ja hidasta.

→

UUSI MALLI · LEIDA

Jatkuva compliance

Regulaatiotyö alkaa samana päivänä kuin kehitys. Muutos koodissa tai dokumentissa päivittää vaatimustilan automaattisesti.

AI-pohjainen jäljitettävyys

Leida rakentaa yhtenäisen näyttöketjun vaatimuksesta dokumenttiin ja muutoslokiin. Automaattisesti. Reaaliajassa.

Ennakoiva

Puutteet näkyvät heti. Leida ehdottaa mitä pitää päivittää kun muutos tapahtuu.

PRODUCT

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NO MEDTECH TEAM WILL BUILD THE SAME WAY AGAIN

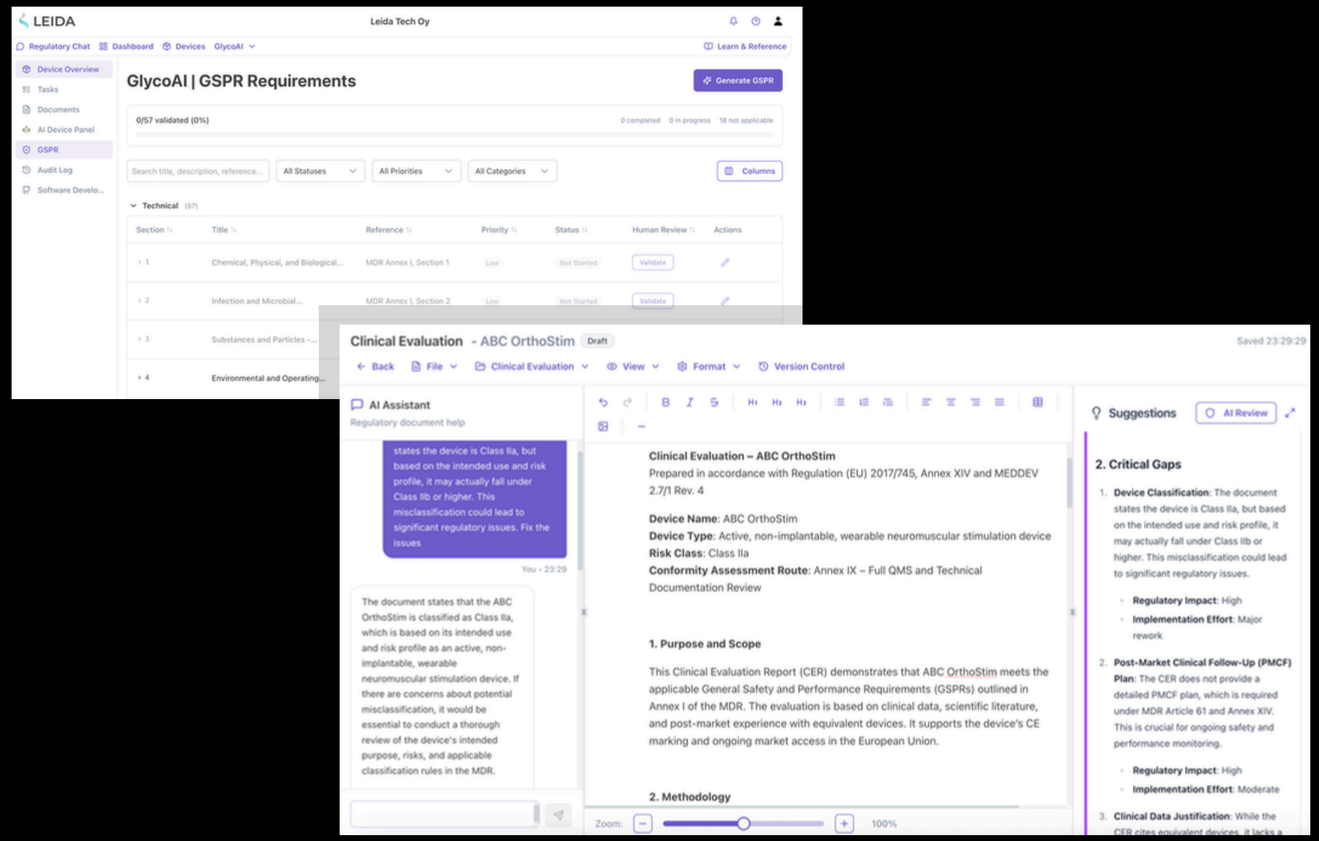
COMPLIANCE BAKED INSIDE THE BUILD

MEDICAL DEVICE SOFTWARE HAS ALWAYS BEEN BUILT IN TWO SEPARATE TRACKS — ENGINEERING AND COMPLIANCE.LEIDA UNIFIES THEM INTO ONE

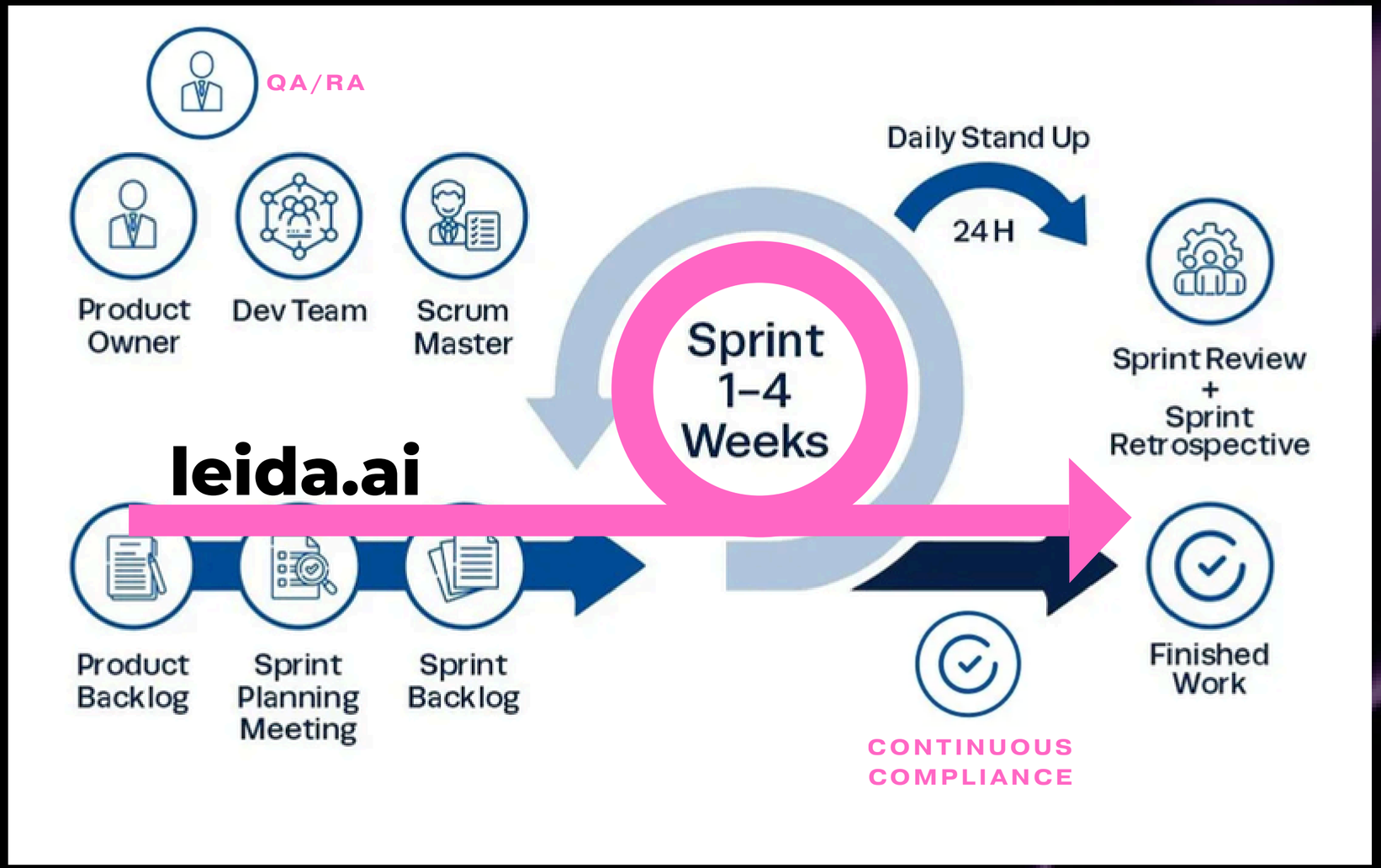
Lives where the work happens. Connects to GitHub, Jira, and your quality systems. Compliance runs inside the dev workflow, not after it

Stays current automaticallyEvery product change flows through the evidence record: no manual rebuild, no compliance debt

Generates submission-ready dossiers. One evidence graph, every market: EU, US, and beyond, always audit-ready by default



GitHub | GitLab | Jira | Confluence | SharePoint | PLM | QMS


QA/RA
Daily Stand Up
24H
Product Owner
Dev Team
Scrum Master
Sprint 1–4 Weeks
Sprint Review + Sprint Retrospective
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Product Backlog
Sprint Planning Meeting
Sprint Backlog
Finished Work
CONTINUOUS COMPLIANCE

WE ARE BUILDING THE MAP FOR THE MAZE

LEIDA CORE

Centralised Workspace For Regulatory Intelligence

The logic engine

INPUTS

Pull change signals and existing evidence from the tools already in use.

Ingest requirements and tickets, code changes and releases, test results, and current documentation so the evidence chain stays grounded in real work.

CORE REASONING

Build a living map of the device program, then follow the ripple effect of change through requirements, risks, controls, verification, and records.
Turn that impact into a clear set of proposed updates and evidence needs.

- Draft documents
- Edit documents
- Create impact map
- Trace updates
- Create evidence checklist

OUTPUTS

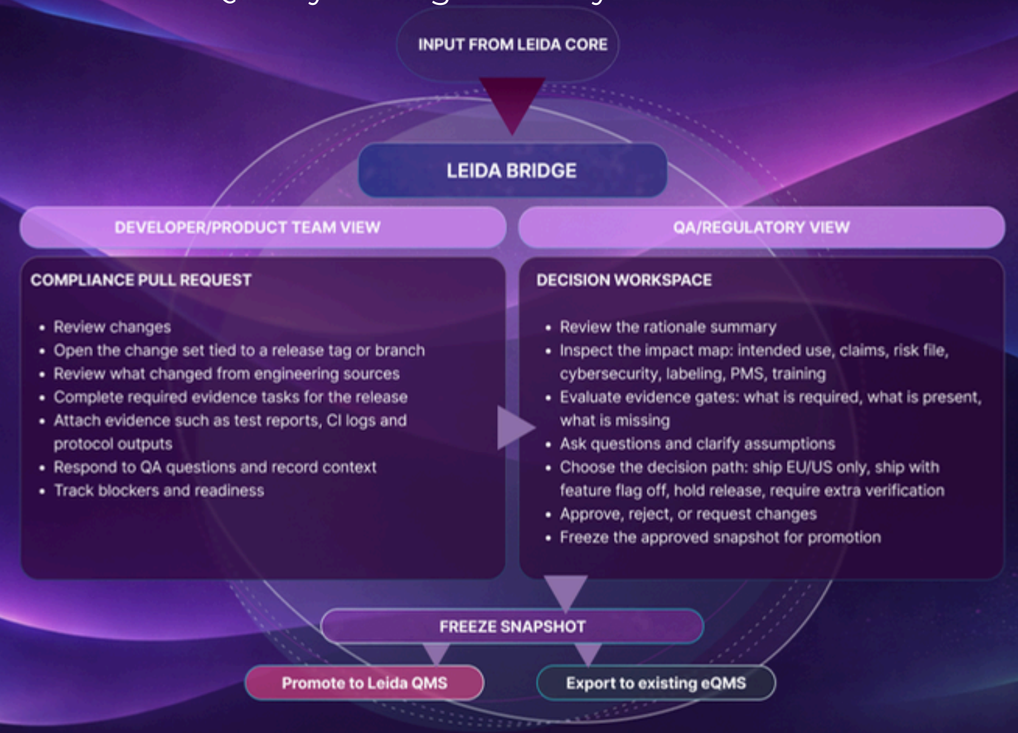
Build a living map of the device program
Connect what the product is meant to do to what was built, what could go wrong, how it is controlled, and how it was tested so it stays clear what proves what.

Do the detective work when things change
Track a change as it moves through the system and show exactly which requirements, risks, tests, and documents it touches, then produce a clear list of what to update next.

Create and update regulated documentation with AI
Write the first draft of documentation and keep it current as the product evolves, producing ready-to-review edits instead of starting from a blank page.

LEIDA BRIDGE

A Shared Workspace Between Developers And QA
+ Quality Management System of record



COMPLIANCE WORK STARTS WHEN CHANGE HAPPENS, NOT AFTER RELEASE

01

Connect your sources

GitHub, GitLab, Jira, Confluence, SharePoint. Leida starts from what you already use.

02

Map evidence once

Import requirements, risks, tests. Leida builds an evidence graph and trace baseline.

03

Changes trigger impact

A PR or release triggers an impact map. Leida proposes required updates.

04

Review in real time

QA/RA reviews, approves, signs off. Logged with who, when, and why.

05

Export audit-ready

Audits become exports instead of a scramble across folders and spreadsheets.

MITEN REGULAATIO AI TOIMII KÄYTÄNNÖSSÄ

LEIDA CORE

Regulatory Chat

Kysy MDR-vaatimuksista, saat vastauksen lähdeviittauksella suoraan asetustekstistä. Luokittelusäännöt, Annex-rakenteet, GSPR-tulkinta. Regulatory co-pilot..

Esimerkki: 'Mitkä ovat luokan IIa laitteen vaatimukset MDR Rule 8 mukaan?' → Vastaus 82% relevanssilla, lähde MDR > 6.3, Rule 11

LEIDA CORE

Dokumenttien linkitys + AI Review

Lataat kliinisen arvioinnin tai teknisen tiedoston. Leida tunnistaa puutteet, ristiristiriidat ja luokitteluongelmat. Ei pelkkä tarkistuslista, vaan toimenpide-ehdotus jokaiselle löydökselle.

Esimerkki: Luokitteluvirhe tunnistettu CER-dokumentissa. Regulatory Impact: High. Implementation Effort: Major rework.

LEIDA BRIDGE

GitHub-integraatio + Audit Log

GitHub yhdistettynä. Jokainen commit, PR ja release kirjautuu audit logiin automaattisesti. GSPR-vaatimusmatriisi generoitavissa napin painalluksella.

Esimerkki: CT-Scan CNN-algoritmi. Kaikki branchit auditoitu. Muutokset: Document created · Muokkaajan nimi · Aikaleima: Apr 1, 2026

SAIRAALAT VALMISTAVAT ENEMMÄN LAITTEITA KUIN ARVATAANKAAN

Ja jokainen omavalmiste vaatii oman dokumentaation, laatujärjestelmän ja riskienhallinan

MDR artikla 5(5) ja IVDR artikla 5(5) sallivat terveydenhuollon yksiköille omavalmistuksen ilman CE-merkintää silloin kun kaupallista vaihtoehtoa ei ole tai se ei täytä erityistarpeita. Koskee fyysisiä laitteita ja ohjelmistoja. Valvova viranomainen Suomessa on Fimea.

Miksi tämä on vaikea ongelma:

AI yhdistää hajallaan olevan tiedon

- Omavalmisteiden dokumentaatio syntyy eri osastoilla, eri järjestelmissä ja eri henkilöillä. Potilastietojärjestelmä, laadunhallinta, kehitystiimi ja sähköposti ovat kaikki eri siiloja.
- Tekoäly lukee, indeksoi ja kytkee tiedon eri lähteistä yhteen näkymään automaattisesti ilman manuaalista kopiointia tai yhteenvetoja.

AI ylläpitää kompleksisia riippuvuuksia

- Laite päivittyy. Prosessi muuttuu. Vastuuhenkilö vaihtuu. Yhdellä sairaalalla voi olla kymmeniä omavalmisteprojekteja samanaikaisesti eri vaiheissa.
- Tekoäly tunnistaa muutoksen vaikutukset ja pitää versiointihistorian, muutoslokin ja jäljitettävyyden ajan tasalla.

Ihminen tekee aina päätökset

- Tekoäly ei hyväksy, ei allekirjoita eikä vastaa turvallisuudesta. Se kerää, järjestää ja ehdottaa. Kliininen asiantuntija, QA-tiimi ja lääkäri päättävät.
- Auditoitavuus ja läpinäkyvyys ovat sisäänrakennettuja. Fimean edellyttämä dokumentaatio rakentuu automaattisesti prosessin sivutuotteena.

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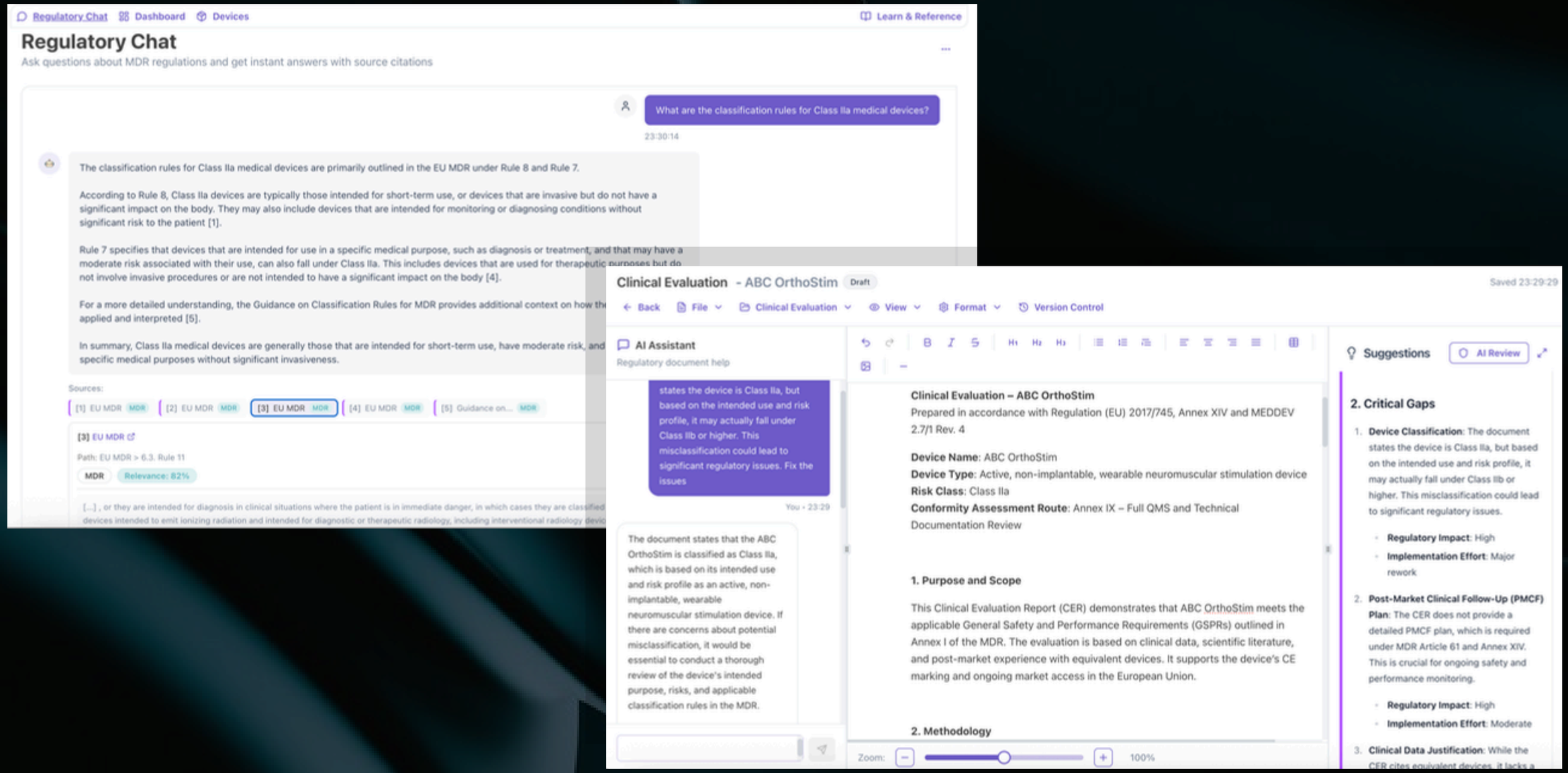
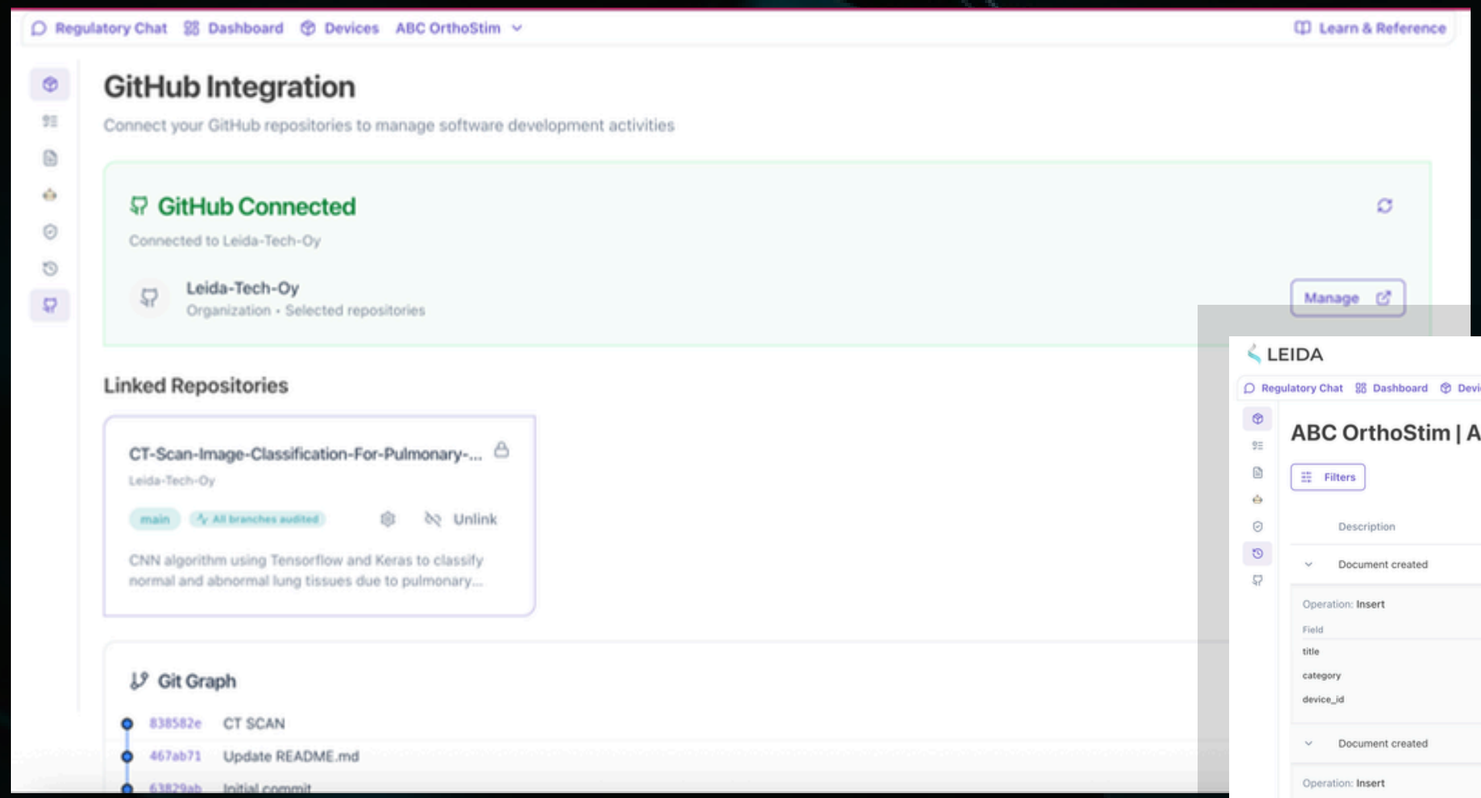
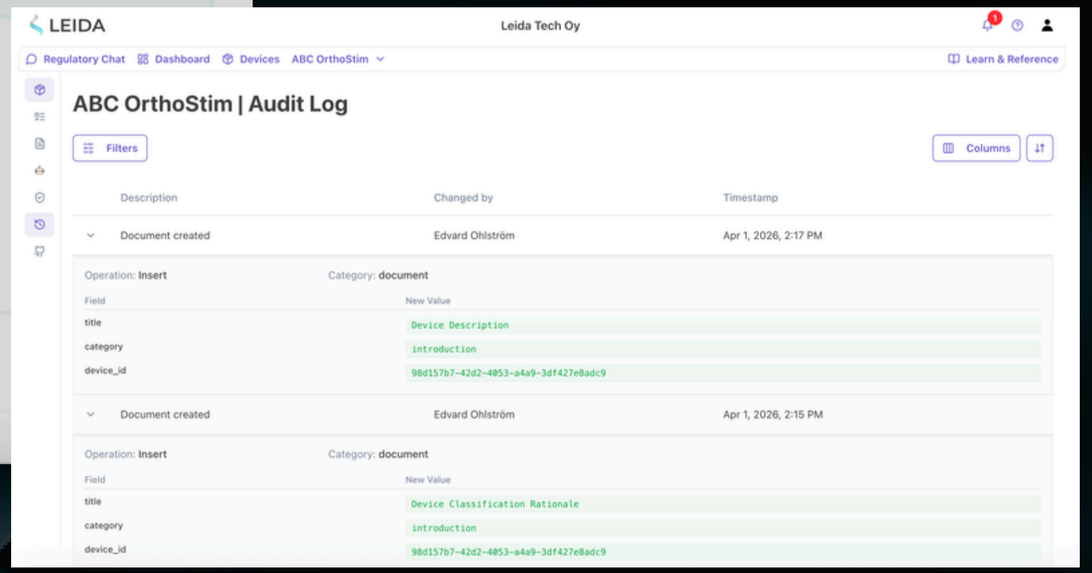

Regulatory Chat
Dashboard
Devices
Learn & Reference
Regulatory Chat
Ask questions about MDR regulations and get instant answers with source citations
What are the classification rules for Class IIa medical devices?
23:30:14
The classification rules for Class IIa medical devices are primarily outlined in the EU MDR under Rule 8 and Rule 7.
According to Rule 8, Class IIa devices are typically those intended for short-term use, or devices that are invasive but do not have a significant impact on the body. They may also include devices that are intended for monitoring or diagnosing conditions without significant risk to the patient [1].
Rule 7 specifies that devices that are intended for use in a specific medical purpose, such as diagnosis or treatment, and that may have a moderate risk associated with their use, can also fall under Class IIa. This includes devices that are used for therapeutic purposes but do not involve invasive procedures or are not intended to have a significant impact on the body [4].
For a more detailed understanding, the Guidance on Classification Rules for MDR provides additional context on how the
applied and interpreted [5].
In summary, Class IIa medical devices are generally those that are intended for short-term use, have moderate risk, and
specific medical purposes without significant invasiveness.
Sources:
[1] EU MDR MDR
[2] EU MDR MDR
[3] EU MDR MDR
[4] EU MDR MDR
[5] Guidance on... MDR
[3] EU MDR
Path: EU MDR > 6.3. Rule 11
MDR
Relevance: 82%
[...] , or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified
devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devic
Clinical Evaluation - ABC OrthoStim
Draft
Saved 23:29:29
Back
File
Clinical Evaluation
View
Format
Version Control
AI Assistant
Regulatory document help
states the device is Class IIa, but based on the intended use and risk profile, it may actually fall under Class IIb or higher. This misclassification could lead to significant regulatory issues. Fix the issues
You · 23:29
The document states that the ABC OrthoStim is classified as Class IIa, which is based on its intended use and risk profile as an active, non-implantable, wearable neuromuscular stimulation device. If there are concerns about potential misclassification, it would be essential to conduct a thorough review of the device's intended purpose, risks, and applicable classification rules in the MDR.
Clinical Evaluation – ABC OrthoStim
Prepared in accordance with Regulation (EU) 2017/745, Annex XIV and MEDDEV 2.7/1 Rev. 4
Device Name: ABC OrthoStim
Device Type: Active, non-implantable, wearable neuromuscular stimulation device
Risk Class: Class IIa
Conformity Assessment Route: Annex IX – Full QMS and Technical Documentation Review
1. Purpose and Scope
This Clinical Evaluation Report (CER) demonstrates that ABC OrthoStim meets the applicable General Safety and Performance Requirements (GSPRs) outlined in Annex I of the MDR. The evaluation is based on clinical data, scientific literature, and post-market experience with equivalent devices. It supports the device's CE marking and ongoing market access in the European Union.
2. Methodology
Zoom:
100%
Suggestions
AI Review
2. Critical Gaps
1. Device Classification: The document states the device is Class IIa, but based on the intended use and risk profile, it may actually fall under Class IIb or higher. This misclassification could lead to significant regulatory issues.
Regulatory Impact: High
Implementation Effort: Major rework
2. Post-Market Clinical Follow-Up (PMCF) Plan: The CER does not provide a detailed PMCF plan, which is required under MDR Article 61 and Annex XIV. This is crucial for ongoing safety and performance monitoring.
Regulatory Impact: High
Implementation Effort: Moderate
3. Clinical Data Justification: While the


Regulatory Chat
Dashboard
Devices
ABC OrthoStim
Learn & Reference
GitHub Integration
Connect your GitHub repositories to manage software development activities
GitHub Connected
Connected to Leida-Tech-Oy
Leida-Tech-Oy
Organization • Selected repositories
Manage
Linked Repositories
CT-Scan-Image-Classification-For-Pulmonary-...
Leida-Tech-Oy
main
All branches audited
Unlink
CNN algorithm using Tensorflow and Keras to classify normal and abnormal lung tissues due to pulmonary...
Git Graph
838582e CT SCAN
467ab71 Update README.md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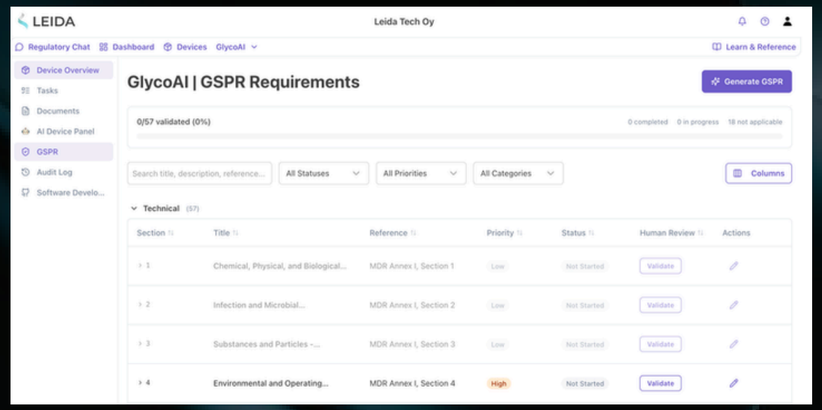
Learn & Reference
ABC OrthoStim | Audit Log
Filters
Columns
Description
Changed by
Timestamp
Document created
Edvard Ohlström
Apr 1, 2026, 2:17 PM
Operation: Insert
Category: document
Field
New Value
title
Device Description
category
introduction
device_id
98d157b7-42d2-4053-a4a9-3df427e8adc9
Document created
Edvard Ohlström
Apr 1, 2026, 2:15 PM
Operation: Insert
Category: document
Field
New Value
title
Device Classification Rationale
category
introduction
device_id
98d157b7-42d2-4053-a4a9-3df427e8adc9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Dashboard
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GlycoAI
Learn & Reference
Device Overview
Tasks
Documents
AI Device Panel
GSPR
Audit Log
Software Develo...
GlycoAI | GSPR Requirements
Generate GSPR
0/57 validated (0%)
0 completed
0 in progress
18 not applicable
Search title, description, reference...
All Statuses
All Priorities
All Categories
Columns
Technical (57)
Section
Title
Reference
Priority
Status
Human Review
Actions
Chemical, Physical, and Biological...
MDR Annex I, Section 1
Infection and Microbial...
MDR Annex I, Section 2
Substances and Particles -...
MDR Annex I, Section 3
Environmental and Operating...
MDR Annex I, Section 4
Not Started
Validate

STOP ASKING HOW TO MOVE FASTER AROUND REGULATION

START ASKING HOW TO MODERNIZE THE REGULATORY LAYER ITSELF

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NOT A COMPLIANCE TOOL

WE ARE BUILDING THE REGULATORY OPERATING SYSTEM FOR MODERN MEDTECH COMPANIES

STREAMLINE COMPLIANCE FROM EVERY REGULATORY AREA AND MANAGE REAL TIME STRUCTURE, AUTOMATION, AND AUDIT-READY EVIDENCE BY DEFAULT

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