# Solita Health RegOps

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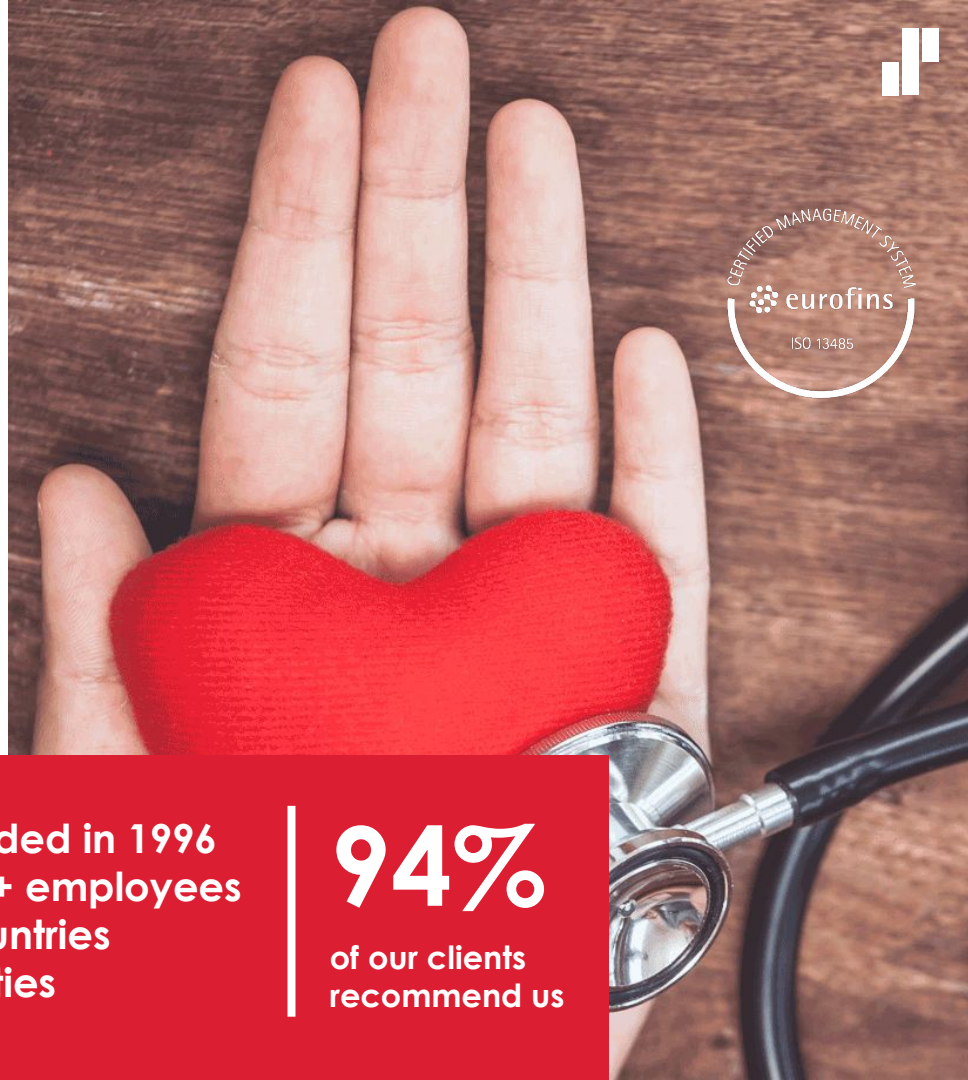
# We harness human insight and intelligent technologies to create impact that lasts.

- A trusted R&D partner in the Nordics and Europe
- ISO 13485 certified medical device developer and RegOps practioner
- Clinical partners: Duodecim (primary health care), Coxa Hospital (specialized health care, Orthopedics)
- 200+ professionals in health sector projects
- Examples: Finnish Covid-19 tracking app, Omaolo symptoms assessment service, Oravizio risk assessment service, Pulse ward management system




**Growth per annum**
**20%**

**Turnover in 2020**
**132M**

**Founded in 1996**
**1100+ employees**
**6 countries**
**12 cities**

**94%**
**of our clients recommend us**

# Your medical device partner for better healthcare solutions

MDR professionals

Agile development that complies with regulation

**Our ISO 13485 Quality Management System (QMS) guarantees both high quality and safe medical devices**

ORAVIZIO

CERTIFIED MANAGEMENT SYSTEM
eurofins
ISO 13485

ORAVIZIO

# WORLD'S FIRST CE MARKED MEDICAL SOFTWARE SERVICE FOR ASSESSING THE RISKS OF JOINT REPLACEMENT SURGERIES.

ORAVIZIO HELPS YOU TO

- estimate the risks of an individual operation
- communicate the risks to the patient

...in order to make the best possible decision, together with the patient.

This AI-powered tool uses the data from 44,000+ surgeries performed at Coxa during 2008-2019.

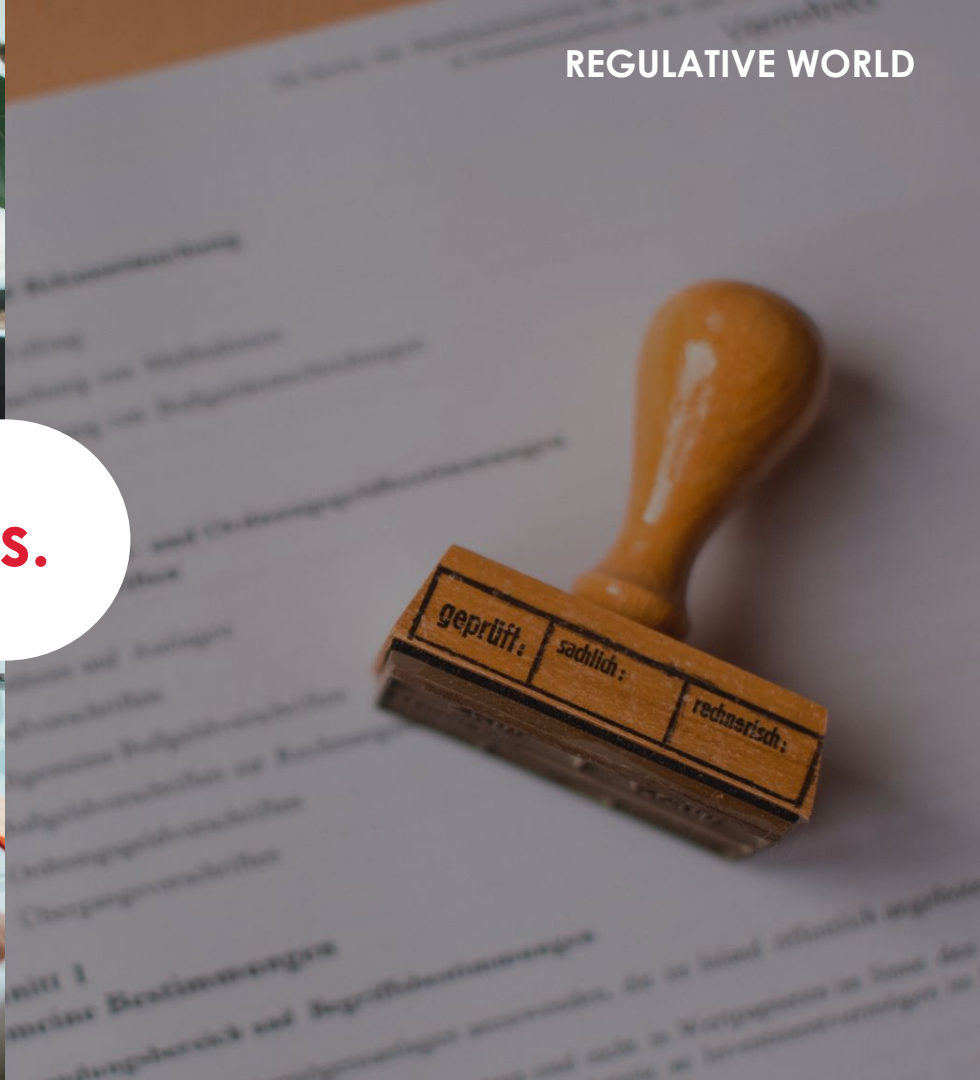
This CE marked medical device software is manufactured by Solita. Our clinical partner is Coxa.

Read more & check the demo at **oraviz.io**

AGILE WORLD

vs.

REGULATIVE WORLD



# RegOps framework in Solita

## THE ROAD TO AGILE SW DEVELOPMENT IN REGULATED ENVIRONMENT

### SCOPE

**Combine modern agile software development methods with regulated business environment.**

However, RegOps doesn't directly solve the process challenges related to getting products into market in medical device industry.

### GOALS

**Efficient product development**. Making most out of the resources by finding correct tools and methods for daily work.

**High quality products:** as output from the development process, medical device products are safe, reliable, effective and secure.

### DESIGN

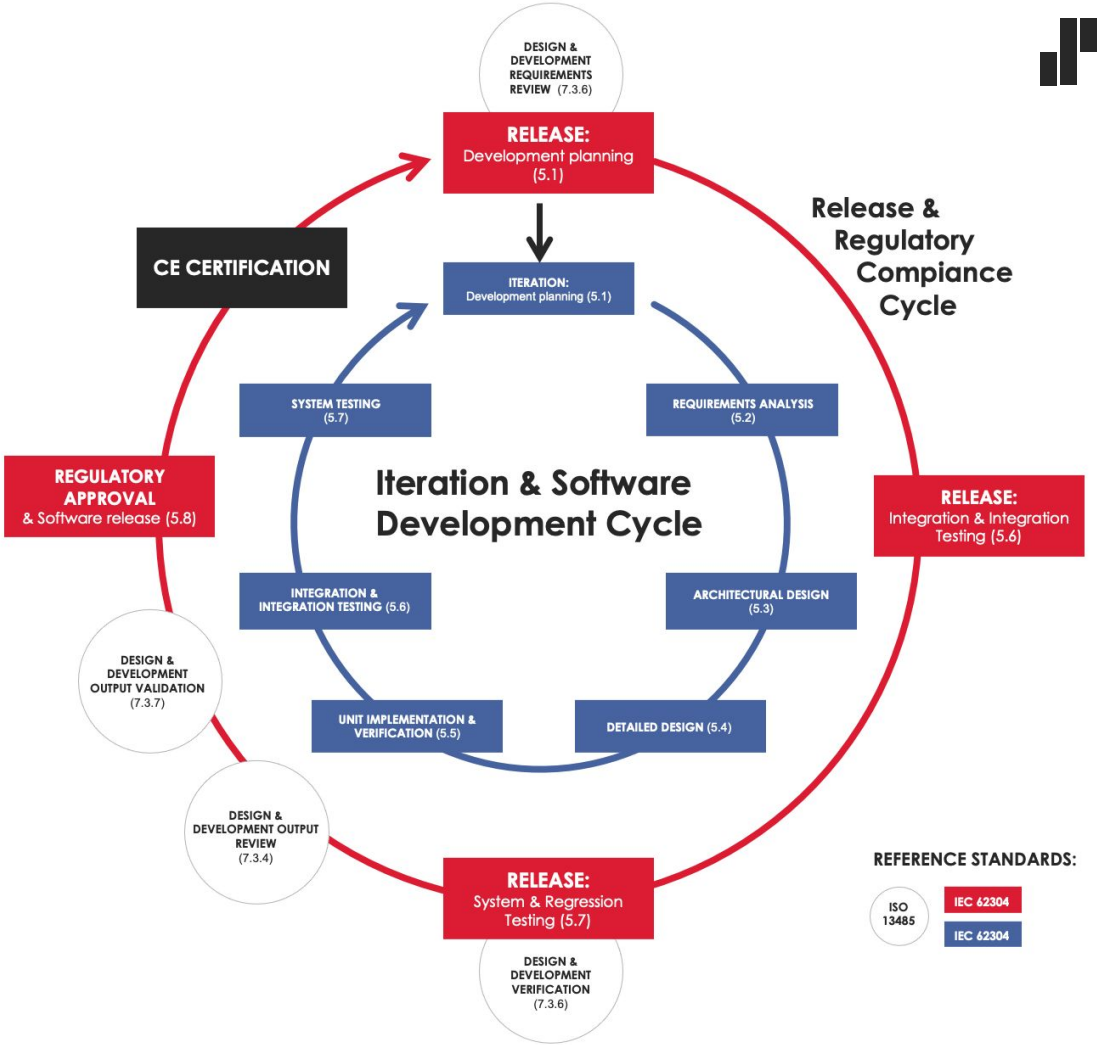
**Calm compliance.** The regulatory requirements are built into the processes and workflows, allowing developers to concentrate on development related tasks.

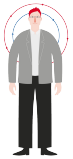
**Modern agile methods**. Finding correct tools and processes to form the optimal setup in the company for developing software for medical devices.

# Bringing clarity to a rather complex regulatory environment

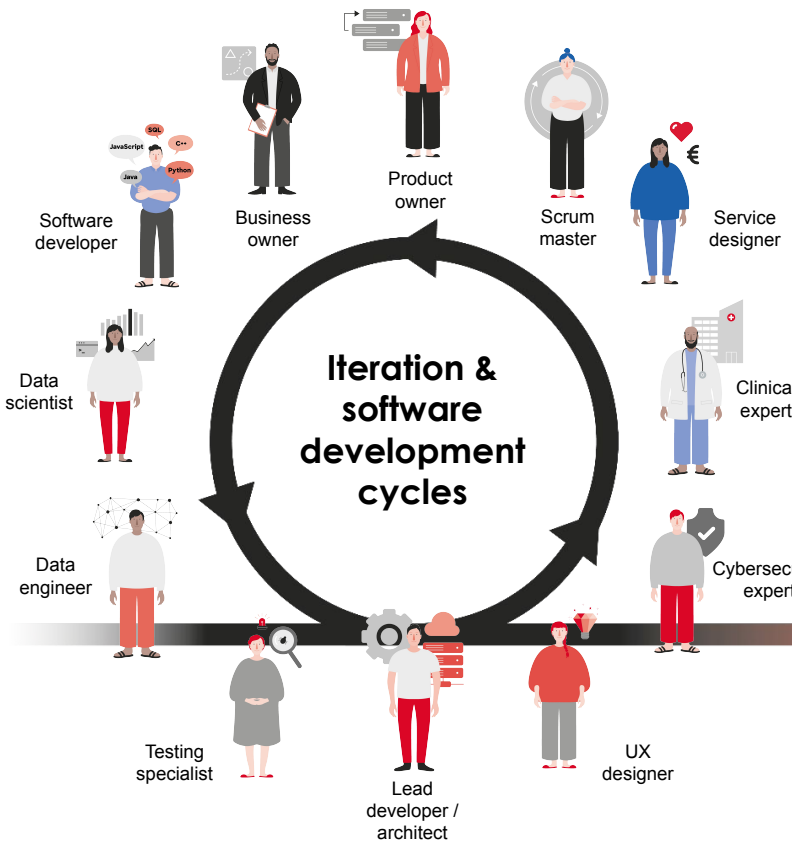
Solita RegOps framework maps how relevant standards are connected

It clarifies who / which roles are required in each phase & cycle

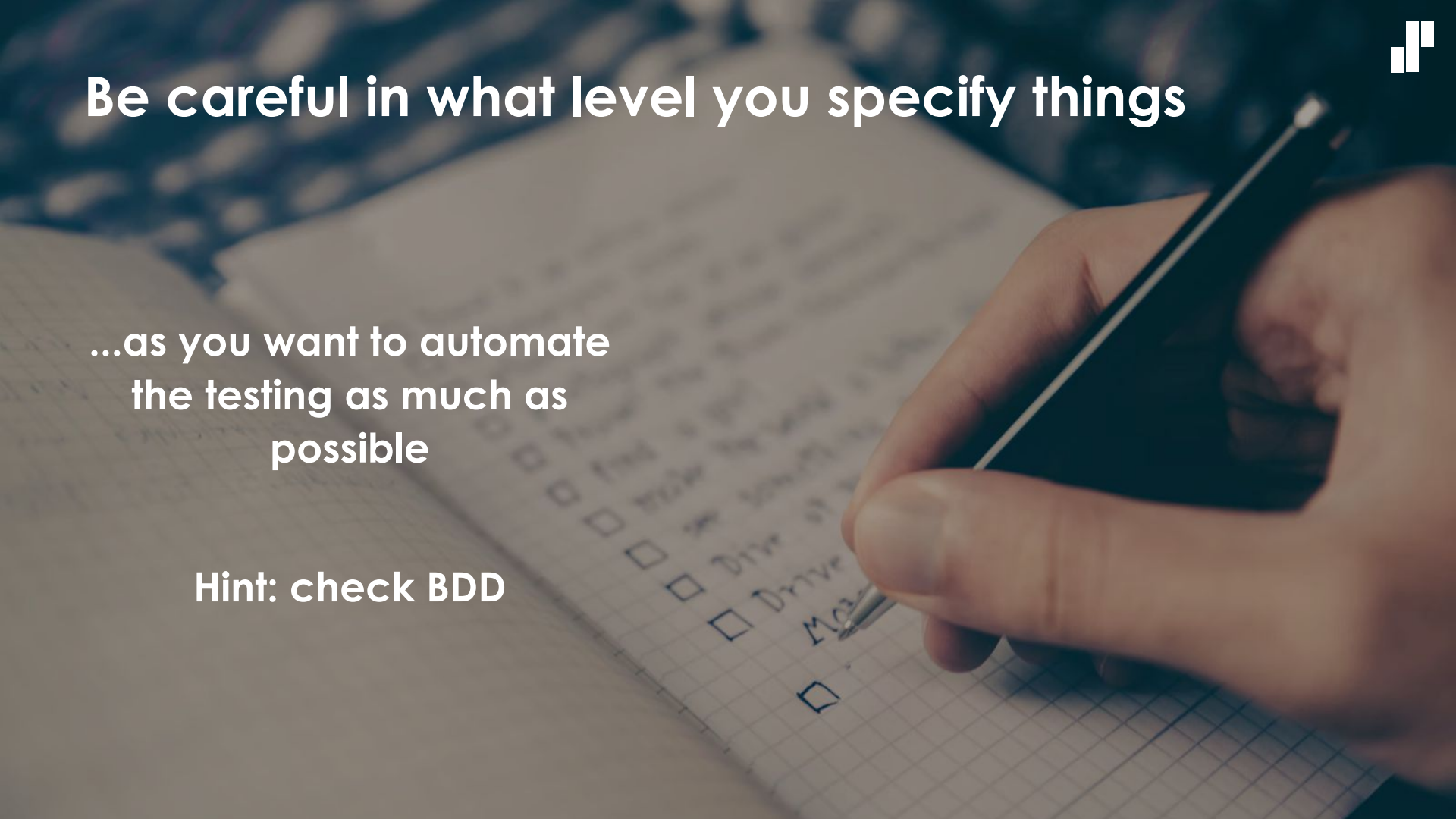




A RegOps coach helps organization to change




# Be careful in what level you specify things



...as you want to automate the testing as much as possible

Hint: check BDD

# RegOps is a journey

Changing the
"Way of working"
will require a lot of
decisions, smaller and
bigger

It won't happen overnight

...but it will be worth it.

# Solita's RegOps - further reading

**Blogs:**

- Is it possible to develop medical software with agile methods – is RegOps the next step?
- RegOps – diving into the dilemma of agile software development in regulated industry
- Cybersecurity in medical devices – new challenges ahead
- MDR era finally started - now is the time to work even harder for compliance

**White paper:**

- Foundations of medical device software cybersecurity compliance

**Research papers:**

- On Medical Device Software CE Compliance and Conformity Assessment
- On Medical Device Cybersecurity Compliance in EU
- MLOps Challenges in Multi-Organization Setup: Experiences from Two Real-World Cases
- Extending SOUP to ML Models When Designing Certified Medical Systems
- Towards Regulatory-Compliant MLOps: Oravizio's Journey from a Machine Learning Experiment to a Deployed Certified Medical Product
- Towards RegOps: A DevOps Pipeline for Medical Device Software (accepted to PROFES'21)