



COMPANY OVERVIEW

Engineering for MedTech products and production

I am Filip Jaromczyk and I run Techkrates in Zurich. I lead every project myself, with documentation that holds up in QA and regulatory review. Electronics is developed with Patrick Keller, with specialist partners when needed.

2 months

Two cleanroom production machines qualified, DQ to PQ incl. stability testing. Planned and run by Filip, who also wrote the FAT/SAT.

10+ years

MedTech electronics: PCB, firmware, IEC 60601, EMC

Ypsomed & Agilent

Agilent: Design Responsible for an IVD pathology instrument. Ypsomed: design verification of autoinjectors, test stands, cobot.

SERVICES

A Product development

Mechanical design, electronics and PCB, firmware, design for IEC 60601 safety and EMC, verification, transfer to production.

B Equipment qualification + FAT/SAT

Risk-based DQ/IQ/OQ/PQ, acceptance criteria, execution support, QA-ready reports and evidence packages. Machinery safety and CE for in-house built equipment.

C Test stands and fixtures

Verification rigs, fixtures and small test stands with in-house electronics, data logging and GR&R/MSA.

D CSV & CSA

Risk-based validation of software and connected systems: intended use, traceability, data integrity.

E Sustaining engineering

Design Responsible as a service: ECR/ECO, DHF updates, obsolescence, changes at the contract manufacturer, IEC 62304.

STANDARDS WE WORK WITH

Quality & regulatory

ISO 13485 • ISO 14971 • FDA 21 CFR 820 (QMSR) • 21 CFR Part 11 • MDR • IVDR

Device design

IEC 60601-1 • IEC 60601-1-2 • IEC 62366-1 • IEC 62304 • ISO 10993 • ISO 11608

Manufacturing & validation

ISO 14644 • GAMP 5 • EU GMP Annex 11

Machinery safety

ISO 12100 • ISO 13849-1 • IEC 60204-1

TEAM

Filip Jaromczyk FOUNDER • PROJECT LEAD

Mechanical/mechatronics engineer. Equipment qualification from URS to PQ, test stands, ISO 10993, FDA 21 CFR 820. Design Responsible at Agilent, design verification at Ypsomed.

Patrick Keller ELECTRONICS ENGINEERING LEAD

More than ten years in MedTech electronics: circuit and PCB design, firmware, IEC 60601 safety and EMC, IEC 62366-1, testing.

Specialist partners for PLC/SPS integration and machining, coordinated by the project lead.

WAYS TO START

Qualification Gap Check 3 working days, from CHF 750

FAT/SAT Acceptance Pack 1 week, from CHF 1500

CSV/CSA Scope & Risk Review 3 working days, from CHF 950

Test Bench / Fixture Sprint 1 week, from CHF 5500

Equipment Concept for Capex Approval 1 to 2 weeks, from CHF 3900

Development work package scoped individually

Fixed price and fixed delivery date, agreed in writing upfront.