



COMPANY OVERVIEW

Engineering for MedTech products and production

Techkrates is an engineering company based in Zurich. We develop mechanical and electronic systems, build test equipment, verify products and qualify production equipment and processes, with documentation that holds up in QA and regulatory review. Each project has one technical lead from scoping to handover.

2 months Two cleanroom production machines qualified, DQ to PQ incl. stability testing	10+ years MedTech electronics: PCB, firmware, IEC 60601, EMC	Ypsomed & Agilent R&D hardware and verification background of our founder
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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.

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.

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. R&D experience at Ypsomed and Agilent.

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	2–4 hours
FAT/SAT Acceptance Pack	6–10 hours
CSV/CSA Scope & Risk Review	4–8 hours
Test Bench / Fixture Sprint	1–2 weeks
Development work package	scoped individually