



TMRS Medlab
MEDICAL · LABORATORY

QUALITY & CERTIFICATIONS

Quality you can audit



How TMRS Medlab approaches quality and compliance — the standards we align to and the records we hand over.

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STANDARDS

The frameworks we align to

ISO 13485

ISO 15189

ISO 9001

CE Marking

We supply CE-marked medical devices with full conformity documentation, align our processes to ISO 13485 quality-management principles, and design laboratories with ISO 15189 accreditation readiness in mind.

Our commitments

- **Certified devices only** — CE-marked with valid conformity documentation.
- **Full traceability** — serial-level records and documentation packs on handover.
- **Validation & QC** — instrument qualification and quality-control readiness.
- **Controlled processes** — documented, repeatable procedures.
- **Trained delivery** — technicians trained on the systems they install.
- **Auditable service** — calibration and maintenance records ready for inspection.

The cheapest route to accreditation is to build for it from the first drawing — not to reverse-engineer it once you're live.

ACCREDITATION READINESS

We build toward accreditation from day one

Step	What it involves
Design to standard	Layouts, workflows and utilities designed with accreditation requirements in mind.
Qualify equipment	Installation and operational qualification (IQ/OQ) of instruments.
Validate workflows	Performance qualification and quality-control validation.
Document & hand over	Complete documentation to support your accreditation submission.

Accreditation is awarded to your organisation by the national accreditation body. We design, commission and document to make that path as smooth as possible.

Talk to our Zürich team

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Medical equipment supply & laboratory setup — vendor-neutral, end to end.