A MEDTECH QUALITY STORY

1.3385

IN THE CODE

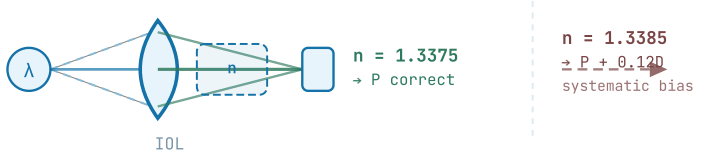
1.3375

ISO 11979-2 §5.1

One wrong digit.
14 instruments.
5 countries.

The refractive index of aqueous humour in IOL optical power measurement. A single digit in a config file, changed by a contractor, not caught in code review.

WHY THE OFFSET OCCURS · LENSMAKER EQUATION



n = 1.3385	→ P reads +0.12D too high
n = 1.3375	→ P correct per ISO 11979-2

Δn = 0.001 · Systematic offset +0.11 to +0.12D across all IOL power ranges

THE INSTRUMENT

Automated IOL inspection. 14 units. 5 countries. Firmware v2.4.1.

OptiLens LensQC 200 — a benchtop optical measurement system used by IOL manufacturers for release decisions. Every lens shipped to a cataract surgeon was measured on one of these instruments.

14
instruments on affected firmware

8
days from second report to root cause

Nov '26
ISO 13485 certificate

CYCLEQA · CALIBRATION MODULE

METROLOGICAL TRACEABILITY CHAIN · OL-OPTBENCH-001

Equipment
OL-OPTBENCH-001 · test_equipment · Metrology Lab, Kongsberg HQ

↓ calibrated via

Cal. Record · OL-CAL-2026-002
pass · 15 Mar 2026 · OL-CAL-PROC-001

↓ reference standard

Ref. Standard · OL-STD-002
±0.015D optical power · ±0.010D (k=2) · exp. 15 Mar 2027

↓ auth. body

Physikalisch-Technische Bundesanstalt (PTB)
Braunschweig, Germany · cert. PTB-2026-OPT-LQ200-0034

✓ Traceability chain complete and current PTB-2026-OPT-LQ200-0034

FIELD REPORTING — ANYWHERE

Completeness enforced. Not by training. By the tool.

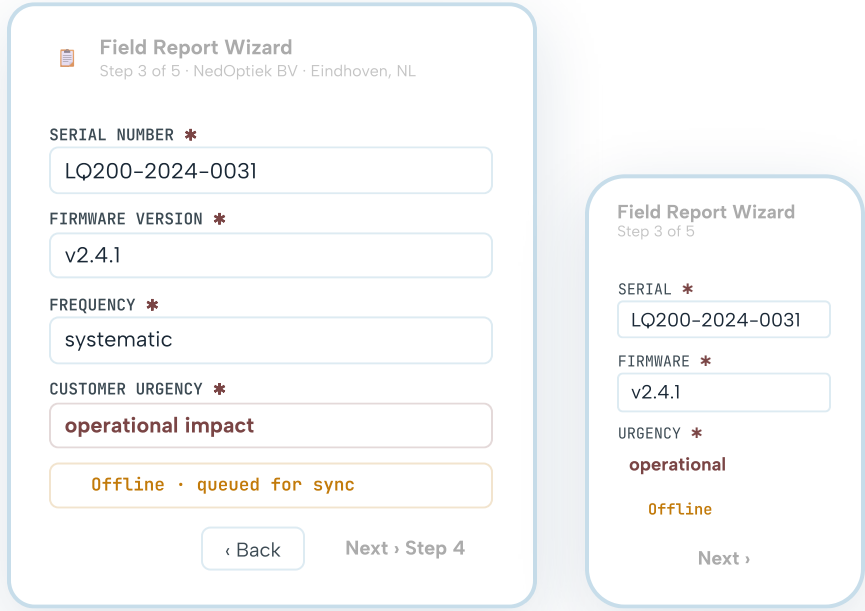
Serial number, firmware version, frequency, urgency — required fields. The wizard won't advance until each step is complete. You cannot submit an incomplete report from any device.

WIZARD — MUST COMPLETE EACH STEP TO ADVANCE

1 ✓ Customer › 2 ✓ Equipment › 3 • Issue › 4 Context › 5 Submit

★ OFFLINE-FIRST — SAME STRUCTURED WORKFLOW, NO CONNECTIVITY REQUIRED

Reports queue locally, sync automatically. FR-OL-2026-002 was submitted from an A2 motorway rest stop — Anna had the complete structured report before Erik reached the highway exit.



Tablet or phone · required fields enforced on every device

This report triggered the investigation that led to ISO 13485.

NCR-OL-2026-001 · 8D REPORT

Root cause in 8 days. Every step on record.

In a spreadsheet environment, the test engineer would have spent those 8 days emailing colleagues asking "do you have the calibration cert from November?" In CycleQA, the calibration record, the incoming inspection, and both field reports were one click from the NCR — timestamped, linked, already there.

- 05 Nov 2025
  IQC-2025-001 — borderline artifact +0.048D, accepted
- 14 Jan 2026
  FR-OL-2026-001 — +0.12D offset, München
- 03 Feb 2026
  FR-OL-2026-002 — +0.11D, Eindhoven · offline sync
- 03 Feb 2026
  NCR raised · risk score 15 HIGH · FSCA assessed
- 11 Feb 2026
  D4 confirmed · n=1.3385 vs 1.3375 · IQC-2025-001 named
- 03 Nov 2026
  ISO 13485 certificate · DNV AS · zero major findings

Why the old inspection record mattered

Nov 2025: reference artifact accepted at +0.048D — inside ±0.05D, at 96% of the limit. That positive bias partially masked the firmware error during v2.4.1 internal testing. Three months later the record was still there, timestamped, traceable. It became the D4 named contributing factor.

The calibration record was the smoking gun

OL-CAL-2026-001: As Found v2.4.1 +0.112D — FAIL. As Left v2.4.2 +0.003D — PASS. PTB-traceable (Physikalisch-Technische Bundesanstalt, Germany's national metrology institute). Proof of problem and proof of fix in one record. One click from the NCR.

The incident became the evidence package

DNV AS asked for traceability from complaint to correction to standard compliance. Every link already existed. The incident OptiLens feared would delay ISO 13485 became the proof their QMS worked under real conditions. Certificate: November 2026.

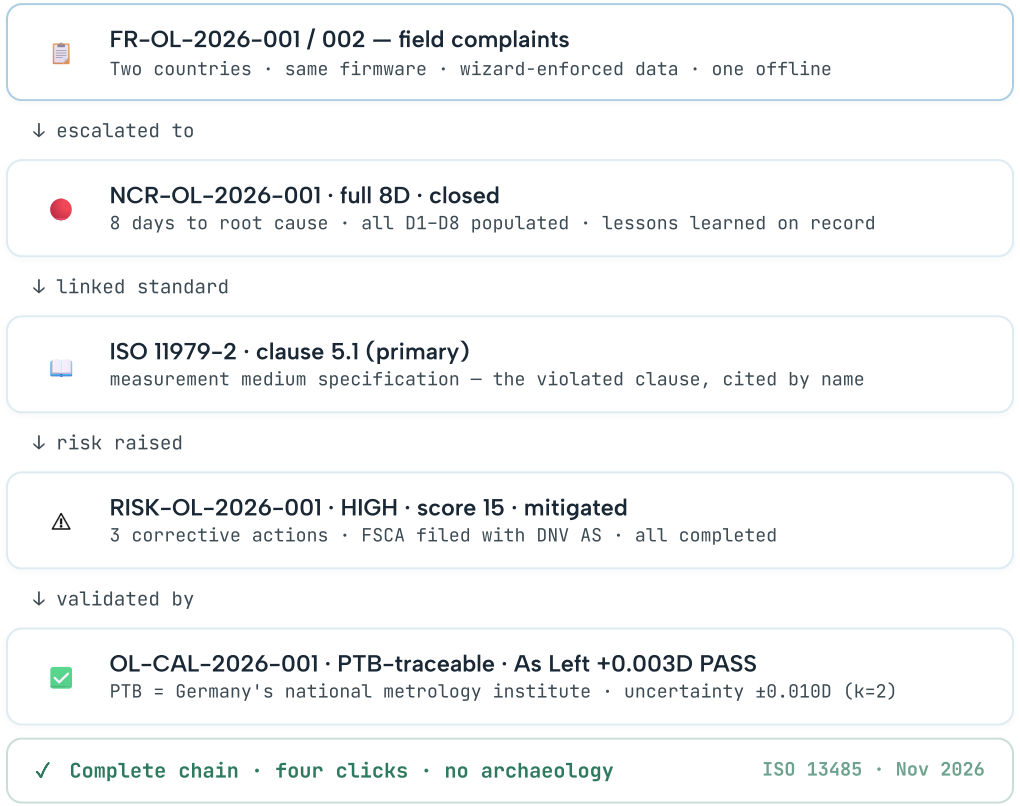
ISO 13485 — MARKET ENTRY

"Show me your traceability from complaint to corrective action to standard compliance."

For a medtech manufacturer selling into the EU under MDR, ISO 13485 is not optional. Without it, your product doesn't ship.

OptiLens needed ISO 13485 to grow their customer base. A firmware incident threatened to delay it. The QMS didn't just manage the incident — it generated the audit evidence package that proved to DNV AS that the system worked under real conditions.

The incident became the proof.



3 Nov 2026

ISO 13485 Certificate

DNV AS · zero major findings · incident was the evidence.

18 Dec 2026

LQ200 Rev B
EU MDR Type Approval

Market access restored. PTB-traceable calibration chain certified.

One system. Every connection already made.

Built for the QA manager who needs audit-ready traceability without the archaeology. For the field engineer on a customer site without connectivity — the same structured workflow, offline, queued, synced automatically. For the company that reaches ISO 13485 because the QMS captured everything, not because they prepared for it.

cycleqa.com

PLATFORM

🔒 JWT auth · session tokens

📋 Full audit logging

EU EU servers · Hetzner

🐘 PostgreSQL · your data export

🔗 HTTPS · Caddy

If you manage quality at a medtech, maritime, or industrial electronics company — what does your complaint-to-CAPA chain actually look like when the auditor asks?

