Installation Qualification Report

Cold-chain monitoring system · Site Visp · Revision 3

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Reviewer	A. Rossi (QA)	**Status**	Approved
System	Cold-chain monitoring	**Scope**	IQ / OQ

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1. Purpose and scope

This report documents the installation qualification of the cold-chain monitoring system installed at the Visp site during July 2026. It covers the twelve monitored enclosures listed in section 3, the associated wireless gateways, and the data-acquisition server. Operational qualification of the alarm escalation chain is documented separately in OQ-2026-118.

Acceptance criteria follow the site validation master plan, revision 7, and the temperature limits specified in the product storage matrix. Where a deviation was recorded, its disposition is given in section 5.

2. Applicable documents

- Validation Master Plan VMP-07, section 4.3
- Storage matrix SM-2026-02
- Supplier factory acceptance test FAT-4471
- Calibration certificates, annex B
- ISO 13485:2016, clause 7.5.6

3. Monitored enclosures

Each enclosure was mapped with nine calibrated probes over a 24-hour period at steady state.

Tag	Type	Set point	Tolerance	Min °C	Max °C	Result
FR-101	Freezer	−20 °C	±5 K	−22.4	−17.9	Pass
FR-102	Freezer	−20 °C	±5 K	−23.1	−18.2	Pass
UF-201	Ultra-low	−80 °C	±10 K	−83.7	−74.8	Pass
UF-202	Ultra-low	−80 °C	±10 K	−84.2	−76.1	Pass
CR-301	Cold room	+5 °C	±3 K	2.9	7.4	Pass
CR-302	Cold room	+5 °C	±3 K	2.1	8.6	Deviation
IN-401	Incubator	+37 °C	±1 K	36.4	37.5	Pass
IN-402	Incubator	+37 °C	±1 K	36.6	37.4	Pass
LN-501	LN_2 vessel	−190 °C	±15 K	−196.0	−178.3	Pass
TR-601	Transport box	+5 °C	±3 K	3.2	7.1	Pass
TR-602	Transport box	+5 °C	±3 K	3.4	6.9	Pass
WH-701	Warehouse	+15/25 °C	—	17.2	24.6	Pass

4. Probe calibration

All probes were calibrated against a dry-block calibrator traceable to a national standard, before and after the mapping campaign. The post-campaign drift did not exceed 0.08 K on any channel, which is well inside the 0.25 K allowance.

Calibration points: −80 °C, −20 °C, 0 °C, +5 °C, +37 °C.

5. Deviations

One deviation was recorded. Cold room CR-302 exceeded its upper limit by 0.6 K for 41 minutes during the defrost cycle on 12 July.

Deviation	Root cause	Disposition
DEV-2026-33 — CR-302 peak 8.6 °C	Defrost heater cycle not inhibited while the door contact was open.	Controller firmware updated to 4.2.1; excursion re-tested on 19 July with a peak of 6.8 °C. Accepted.

6. Conclusion

The installation qualification is **accepted**, subject to closure of DEV-2026-33, which was verified on 19 July 2026.

Requalification is due within 24 months, or after any change to the enclosure population, the gateway topology or the acquisition server.

Annex A — Probe assignment (landscape)

Probe	Enclosure 1	Enclosure 2	Enclosure 3	Enclosure 4	Enclosure 5	Enclosure 6	Enclosure 7	Enclosure 8
P-01	15.64	-29.51	-9.26	21.68	-37.13	-17.31	-37.06	-15.21
P-02	-1.83	-21.88	22.16	-38.86	1.79	-5.83	20.23	-41.54
P-03	-20.79	-31.73	19.69	-4.43	-18.83	-20.44	2.46	-23.71
P-04	-24.53	-38.84	-20.18	16.79	-9.29	-26.92	-50.16	-78.13
P-05	-76.10	2.27	-17.39	-9.18	7.51	-49.67	-36.38	-61.07
P-06	-52.15	15.77	-52.38	-52.02	-60.44	-39.44	-41.55	-82.74
P-07	-7.63	1.83	1.32	-10.42	-79.17	-5.35	11.42	-19.29
P-08	-2.18	-81.64	-35.76	-5.10	-23.97	8.00	13.02	8.93
P-09	-25.16	23.48	-27.06	10.21	-43.13	-24.23	-68.05	-8.66