

Specification Sheet

Reduce the risk of non-compliant instruments with our qualification services for cold storage equipment

Qualification services verify and document that instruments and equipment are installed, operating, and performing according to manufacturer's specifications and user requirements. Selecting the right compliance service provider and partner to deliver your qualifications is essential for the success and efficiency of your regulated laboratory.

As an original equipment manufacturer (OEM) service provider for Thermo Fisher Scientific, Unity™ Lab Services offers qualification services that ensure your laboratory equipment meets global standards and mitigates the risk of regulatory non-compliance.

With our services, you'll receive a full range of qualification capabilities that provide improved productivity, single-vendor convenience, a no-charge requalification guarantee*, and comprehensive documentation reports. You'll have peace of mind knowing we're supporting your quality management systems, traceability, and audit readiness.



Qualification/Service	Description
Installation Qualification (IQ)*	<ul style="list-style-type: none"> Verifies that the equipment, manuals, supplies and any other accessories arrived undamaged as specified in the sales order. Verifies equipment and any other accessories are assembled and installed. Any abnormal event(s) observed during the IQ is documented in the IQ protocol. Verifies that the installation site and equipment environment meet manufacturer-specified environmental requirements.
Operation Qualification (OQ)	<ul style="list-style-type: none"> System component information: detailed configuration information for each system component has been recorded (as applicable). Verifies important equipment functions and ensures that the equipment operates as expected by the manufacturer and in conformance to standards and requirements. The Operation Qualification verifies the performance of the cold storage equipment, which ensures safety for the user, for the samples, and for the environment <p>Key Tests: Door Ajar, Power Failure, Temperature Alerts</p>
Temperature Mapping	<ul style="list-style-type: none"> Identifies temperature variations across the chamber space. Identifies temperature variation at a single set-point. <ol style="list-style-type: none"> Temp Map Test: Multi-Point Temperature Mapping for a 24-hour period with one-minute data intervals with X amount of points — typically between nine and 15, depending on the model. Probes are spaced out to cover all the usable space in the chamber. Temperature Mapping can be completed on the cold storage equipment full or empty. Door Open Test: Opening a door for a specified time and recording temperatures throughout the chamber until the unit is recovered to set-point. Power Failure Test: Record temperatures until one point is out of specified range after Power Failure. <p>For additional Temperature Mapping, please contact your regional sales representative.</p>

*Installation of equipment is not included within our IQ services. Additional fees apply for inside delivery shipping method or for full installation and setup of equipment.

Visit unitylabservices.com/complianceservices for more information about our compliance offerings.

What's included

All documentation will be provided to you in a qualification binder upon acceptance of the IQOQ results.

Example documentation is as follows:

- IQ report
- OQ procedure/worksheets
- Temperature Mapping procedure /worksheets
- Temperature Mapping data
- Sensor calibration/verification
- Charts
- Equipment certificates
- Reference meter(s) calibration certificate
- Field service engineer training certificates: product and qualification

Documentation is available in English, German, and French.

Our requalification guarantee



Stay compliant with our industry-exclusive, no-charge requalification guarantee*

With Unity Lab Services qualification services, you'll be confident that your instruments maintain compliance should an unexpected audit arise. Unlike other OEM service providers who charge for requalification services, **we are the only provider to offer a guarantee and promise to requalify instruments and equipment at no charge if a key component fails while under the original factory warranty or a qualifying instrument service plan.**



Pass audits the first time with our robust and easy-to-understand OEM qualification protocols and harmonized documentation

Our factory-developed qualification protocols are written to support accepted industry standards and regulatory requirements. Our qualification services provide consistent, audit-ready documentation that meets pre-determined and/or user specifications. In addition, our harmonization of qualification protocols and documentation across all instruments saves you administrative work, review time, and complicated approval processes, helping to ensure the best audit outcome.



Stay on schedule with our full-range, single-source support from experienced engineers

Unity Lab Services provides a full-service solution for installing, repairing, qualifying, and mitigating risks so your instruments (including other manufacturers' units) get up and running faster and your research stays on schedule. Our factory-certified validation engineers are product experts with experience in regulated environments, ensuring your qualifications are delivered efficiently and effectively to industry standards.



Industry-Exclusive, No-Charge Requalification Guarantee*

Unity Lab Services is the only OEM service provider to offer a guarantee and promise to requalify instruments and equipment at no charge if a key component fails while under the original factory warranty or a qualifying instrument service plan.

*Our no-charge requalification guarantee applies only to instruments under the original factory warranty or a qualifying Unity Lab Services instrument service plan and covers requalification on the corrective maintenance repair at no additional charge. Terms and conditions apply.

**Compliance services are only available in select countries including U.S., Germany, France, U.K., Ireland, Spain, Portugal, Italy, Austria, Switzerland, Norway, Sweden, Denmark, Netherlands. For other locations please contact your local country organization.

For quote customizations or additional services, please contact your regional sales representative.

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