

# Qualification Services

## by the Experts

### Specification Sheet



Our Qualification Services document that your Stirling freezers are installed, operating, and performing according to manufacturer's specifications and user requirements. Selecting the right compliance service provider to deliver your qualification service is essential for the success and efficiency of your regulated laboratory.

As an original equipment manufacturer (OEM) Stirling UltraCARE 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, and comprehensive reports. You'll have peace of mind knowing we're supporting your quality management systems, traceability, and audit readiness.

Qualification/Service	Description
Installation & Operational Qualification (IQOQ)	<p><b>Installation Qualification:</b></p> <ul style="list-style-type: none"><li>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 are documented.</li><li>Verifies that the installation site and equipment environment meet manufacturer-specified environmental requirements.</li></ul> <p><b>Operational Qualification:</b></p> <ul style="list-style-type: none"><li>Verifies important equipment functions and ensures that the equipment operates as expected by the manufacturer and in conformance to requirements.</li><li>Verifies the performance of the cold storage equipment, which ensures safety for the user, for the samples, and for the environment.</li></ul> <p><b>Key Tests:</b> Initial Product Start-up and set point functionality, alarm set up, tests and alerts, PIN security / access level verification, event log verification, temperature chart verification, engine diagnostics, battery health, service log activities and single point temperature calibration.</p>
Temperature Mapping	<p><b>Temperature Map Test:</b></p> <ul style="list-style-type: none"><li>Verifies temperature uniformity across the chamber space. Multi-Point Temperature Mapping for a 24-hour period at one-minute data sample intervals, with reference measurement probes strategically placed to cover the usable space in the chamber.</li><li><b>Door Open Test:</b> Opening the door(s) for a specified time and recording temperatures throughout the chamber until the unit is recovered to set-point.</li><li><b>Power Failure Test:</b> Record temperatures until one point is out of specified range after power failure.</li></ul> <p>We offer additional Temperature Mapping services to align with your quality requirements. Please contact your regional sales representative.</p>

Installation of equipment is not included as part of our IQ services. Additional fees apply for inside delivery shipping method or for full installation and setup of equipment. Visit [www.stirlingultracold.com](http://www.stirlingultracold.com) 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:

- IQOQ Protocol
- Temperature Mapping Protocol
- Temperature Mapping Data
- Control Sensor Calibration
- Performance Charts/Graphs
- Reference Meter(s) Calibration Certificate
- Field Service Engineer Training Certificates

## From the Minds Who Made It, For Those Who Rely on It



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

Our OEM 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 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.

**UltraCARE** provides a full-service solution for installing, repairing, qualifying, and mitigating risks so your cold products are qualified and available for use, allowing your research to stay 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.

Compliance services are only available in the U.S.

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