

Validation Protocols for Laboratory Equipment Qualification

Multi- Qualification and validation services

Thermo Fisher Scientific helps you keep pace with the growing challenges facing today's labs. Our specialty is helping you to improve your productivity while meeting today's regulatory compliance needs. Our equipment qualification and validation service supports a broad range of equipment types.

Our suite of validation option packages will ensure that you comply with applicable Installation, Operational and Performance Qualification standards (IQ/OQ/PQ). Our certified validation engineers will verify that your equipment meets designated acceptance criteria at time of installation and throughout its operational life. We can provide you with all the supporting documentation you need to meet today's increasingly stringent regulatory requirements.

Why Thermo Scientific?

- Peace of mind... As the manufacturer, we should be the preferred supplier to validate your Thermo Scientific product.
- Time saving and convenient... Validation can be planned and scheduled for you at the time of instrument purchase or at a later date to meet your project timeline.
- Exclusive validation warranty policy... As product manufacturer, we can offer you our exclusive re-validation policy. If we validate your Thermo Scientific product and it experiences any failure during warranty period, we cover the cost of any subsequent re-validation at no further charge.
- Cost Saving... Discounts apply to validation and other services for Thermo Scientific service contract customers.

Worldwide support

Compliance services can be arranged in all major countries across the world for the following product lines:

- | | | |
|---|---------------------|------------------------------|
| • Centrifuges | • Ovens | • CO ₂ incubators |
| • Freezers | • Lab Refrigerators | • Cryomed freezers |
| • Freeze dryers | • LN ₂ | • Vacuum concentrators |
| • Shakers | • Thermocycler PCR | • Autoclaves |
| • Laminar-flow cabinets | | |
| • Biological safety cabinets (Type I and Type II NF, EN, & NSF) | | |

Contact your Thermo Fisher representative to learn more about these services or to develop a customized plan to meet your specific needs.

supplyLAB

www.supplylab.pt
geral@supplylab.pt

Cacém Park - Edifício 9
Estrada de Paço de Arcos nº88
2739-512 Agualva Cacém
T +(351) 21 4278700
F +(351) 21 4278709

www.thermo.com

North America: USA/Canada +1 866 984 3766

Europe: Austria +43 1 801 40 0, Belgium +32 2 482 30 30,
Finland +358 9 329 100, France +33 2 2803 2000,
Germany national toll free 08001-536 376,
Germany international +49 6184 90 6940, Italy +39 02 95059 1,
Netherlands +31 76 571 4440, Russia/CIS +7 095 225 11 15,
Spain/Portugal +34 93 223 09 18,
Switzerland +41 44 454 12 12, UK/Ireland +44 870 609 9203

Asia: China +86 21 6865 4588 or +86 10 5850 3588,
India +91 22 5542 9494, Japan +81 45 453 9220,
Other Asian countries +852 2885 4613

Countries not listed: +49 6184 90 6940 or +33 2 2803 2000

© 2007 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific Inc. and its subsidiaries. Specifications, terms and pricing are subject to change. Not all products are available in all countries. Please consult your local sales representative for details.

BRO-TLS-Compliance-0007

Qualification on High Temperature Furnace

Qualification operation list

- Qualification protocol review and approval
- Qualification content review
- Verifier and client responsibilities review

Installation qualification content list* - Protocol E89003467 DELIVERED WHEN IQ / OQ ORDERED

- Reference instrument required:
(Calibrated at the "setting" with uncertainty at least 2 times better than the "acceptance criteria")
 - o Thermometer for ambient air temperature
 - o Multimeter for main voltage and hertz
- Verification of order form and deliveries
- Verification of goods received
- Verification of installation site and ambient condition
- Verification of equipment power supply
- Verification of equipment and associated accessories installation
- Verification of equipment power on
- Delivery of user training if requested
- List of components, service contract and documentation
- Test equipment calibration certificate or verification report
- Verifier training certificate
- Installation qualification report review and approval

*** For additional test, please contact us**

Qualification on High Temperature Furnace

Operational qualification content list* - Protocol E89003468 DELIVERED WHEN IQ / OQ or IQ / OQ / PQ or MQ ORDERED

- Reference instrument required:
(Calibrated at the "setting" with uncertainty at least 2 times better than the "acceptance criteria")
 - o 1 probe temperature thermometer
- Verification of the general functionalities
- Verification of the alarms
- Verification of the unit temperature instrumentation, against here under specification, placing a calibrated reference probe at the center of the chamber
- Adjustment (calibration) if required
- Test equipment calibration certificate or verification report
- Verifier authorization certificate
- Operational qualification report review and approval

Product	Setting	Acceptance criteria
High Temperature Furnace	Maximum Operating Temperature	+/-25 °C

The unit passes the test if, at the setting, the difference between the average unit display and the corrected average reference display is within the above specified acceptance criteria.

*** For additional test, please contact us**

SPECIFICATION SHEET

E89003504e

The world leader in serving science

Qualification on High Temperature Furnace

Catalogue number

Product	Qualification	Document English	Package English
Drying Oven	IQ / OQ	IOQDOCE89003504	Please contact your local Thermo Fisher representative
	IQ / OQ / PQ	N.A.	
	MQ	OQDOCE89003504	

Document] You receive the qualification binder customized for your equipment (protocols included), you complete the document.

Package] The local Thermo Fisher Scientific representative authorized verifier completes the customized document on site (document and labor included).

Change control

Version	Author	Date	Summary of Change
a	Benoit Limon	01-Jan-06	Original Document
b	Benoit Limon	15-Nov-06	Reformatting lay out
c	Benoit Limon	21-Dec-06	Added test equipment
d	Benoit Limon	14-Fev-07	Reformatting lay out
e	Benoit Limon	27-Apr-07	MQ reference added

SPECIFICATION SHEET

E89003504e

The world leader in serving science

Qualification on High Temperature Furnace

Customer overall responsibilities:

Provide one dedicated professional representative to obtain all necessary records and documentation
Provide and assure ready access to all relevant equipment, related documentation, work orders, etc
Provide training on the required policies and procedures
Provide with the appropriate workspace, computers and building access
Provide installation site meeting unit ambient condition requirements listed on user manual.
Approve all documents as soon as possible

Thermo Fisher Scientific qualification warranty policy:

Product Age & Qualification Performance	Repair Cost Responsibility	Re-Qualification Cost
Unit is under warranty, but failed the qualification test due to the unit	Thermo Fisher representative	Thermo Fisher representative
Passed qualification, but a performance component fails during warranty period	Thermo Fisher representative	Thermo Fisher representative
Not under warranty, not under service contract including qualification	Customer	Customer
Not under warranty, under service contract including qualification	Thermo Fisher representative	Thermo Fisher representative
Qualification test is interrupted due to customer intervention or power loss	---	Customer
<i>All other scenarios will be based on the discretion of Thermo Fisher Scientific representative Regional Service Manager & Qualification Manager</i>		

Customer signoff:

Customer reviewed / approved terms for qualification listed on that specification sheet:

_____	_____	_____
Customer Name	Date	Customer Signature