

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
- CO₂ incubators
- Freezers
- Lab Refrigerators
- Cryomed freezers
- Freeze dryers
- LN₂
- 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.

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Other Asian countries +852 2885 4613

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

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Qualification on BSC Type II (EN12469 standard)

Qualification operation list

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

Installation qualification content list* - Protocol E89003490 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 BSC Type II (EN12469 standard)

Operational qualification content list* - Protocol E89003234 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 Aerosol generator with aerosol liquid, photometer or particle counter with aerosol dilution system
 - o Hot wire air flow anemometer
 - o Smoke tube
 - o Electrical safety analyzer
- Verification of the general functionalities
- Verification of the alarms
- Verification of the filters leakage test with aerosol (photometer or particle counter)
- Verification of the downflow velocity (mapping)
- Verification of the inflow velocity
- Smoke test
- Adjustment (calibration) if required
- Test equipment calibration certificate or verification report
- Verifier authorization certificate
- Operational qualification report review and approval

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

Qualification on BSC Type II (EN12469 standard)

Catalogue number

Product	Qualification	Document English	Package English
BSC type II EN12469	IQ / OQ	IOQDOCE89003488	Please contact your local Thermo Fisher representative
	IQ / OQ / PQ	N.A.	
	MQ	OQDOCE89003488	

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	23-Mar-07	Correcting Protocols reference
f	Benoit Limon	27-Apr-07	MQ reference added

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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

Customer signoff:

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

Customer Name	Date	Customer Signature
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