Installation Qualification

Test Protocol for Qualification

ULTF 500 / ULTF 700

☐ First qualification

☐ Requalification

Aim of IQ:

Practical test if the unit is installed according to the installation guidelines of the manufacturer.

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

Content

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 1. Documentation approval

IQ 1.1 Prior to performing the IQ

Checked / Approved	Name / Department / Company	Date	Signature

IQ 1.2 After performing the IQ

Checked / Approved	Name / Department / Company	Date	Signature

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 2. Personnel involved with completing the IQ tests

The following table serves for clear identification of signatures/initials of all persons involved with the IQ tests.

Name	Initials	Department / Company	Date	Signature

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 3. List of documents in appendix

Description	Location	Appendix no.

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 4. Unit identification

Aim of test:

The following tests serve to check the identity of the unit.

IQ 4.1 Unit description

Ultra-low temperature freezer 352/528 Eco Premium with microprocessor temperature control for long-term storage of samples in the ultra-low temperature range.

IQ 4.2 Markings on the unit

	Existant and easily legible	
	Yes	No
Type plate	☐	☐
CE conformity marking	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 4.3 Identification acc. to type plate

ULTF 500

		Yes	No
Model	ULTF 500	☐	☐
#		☐	☐
Serial No.		☐	☐
Inventory No.			
Year of construction		☐	☐
Nominal temperature	-90 °C -130 °F	☐	☐
IP protection	IP 20	☐	☐
Nominal power	1.6 kW	☐	☐
Nominal voltage (+/-10%) at indicated power frequency	230 V / 50 Hz	☐	☐
Current type	1 N ~	☐	☐
Nominal current	7.0 A	☐	☐
Max operating pressure in the refrigerating system	28 bar	☐	☐
Filling weight of refrigerant stage 1 R290	0.15 kg	☐	☐
Filling weight of refrigerant stage 2 R170	0.15 kg	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

ULTF 700

		Yes	No
Model	ULTF 700	☐	☐
#		☐	☐
Serial No.		☐	☐
Inventory No.			
Year of construction		☐	☐
Nominal temperature	-90 °C -130 °F	☐	☐
IP protection	IP 20	☐	☐
Nominal power	1.6 kW	☐	☐
Nominal voltage (+/-10%) at indicated power frequency	230 V / 50 Hz	☐	☐
Current type	1 N ~	☐	☐
Nominal current	7.0 A	☐	☐
Max operating pressure in the refrigerating system	28 bar	☐	☐
Filling weight of refrigerant stage 1 R290	0.15 kg	☐	☐
Filling weight of refrigerant stage 2 R170	0.15 kg	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

ULTF 500 (UL Model 120V)

		Yes	No
Model	ULTF 500 (120V)	☐	☐
#		☐	☐
Serial No.		☐	☐
Inventory No.			
Year of construction		☐	☐
Nominal temperature	-90 °C -130 °F	☐	☐
IP protection	IP 20	☐	☐
Nominal power	1.4 kW	☐	☐
Nominal voltage (+/-10%) at indicated power frequency	115 V / 60 Hz	☐	☐
Current type	1 N ~	☐	☐
Nominal current	11.7 A	☐	☐
Max operating pressure in the refrigerating system	28 bar	☐	☐
Filling weight of refrigerant stage 1 R290	0.15 kg	☐	☐
Filling weight of refrigerant stage 2 R170	0.15 kg	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

ULTF 700 (UL Model 120V)

		Yes	No
Model	ULTF 700	☐	☐
#		☐	☐
Serial No.		☐	☐
Inventory No.			
Year of construction		☐	☐
Nominal temperature	-90 °C -130 °F	☐	☐
IP protection	IP 20	☐	☐
Nominal power	1.4 kW	☐	☐
Nominal voltage (+/-10%) at indicated power frequency	115 V / 60 Hz	☐	☐
Current type	1 N ~	☐	☐
Nominal current	11.7 A	☐	☐
Max operating pressure in the refrigerating system	28 bar	☐	☐
Filling weight of refrigerant stage 1 R290	0.15 kg	☐	☐
Filling weight of refrigerant stage 2 R170	0.15 kg	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 5. Accessories and optional equipment

Aim of test:

The following test serves to check the scope of delivery of the unit and the accompanying material and documentation. It is checked if the material complies with the given data and if the documentation is complete.

IQ 5.1 Standard accessories

	Supplied	Missing
Short user manual with information where to download the instruction manual	☐	☐
Ethernet interface	☐	☐
USB interface	☐	☐
3 shelves and 12 shelf holders with 6 screws	☐	☐
DIN plug for the zero-voltage relay alarm output (connected)	☐	☐
Set of 2 spacers for rear wall distance.	☐	☐

	Yes	No
Accessories completely present	☐	☐

If not:

Measures taken:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 5.2 Documentation supplied with the qualification folder

	Supplied	
	Yes	No
Certificate DIN EN ISO 9001	☐	☐
EU Conformity declaration of the manufacturer	☐	☐
Test protocol for Installation Qualification IQ	☐	☐
Test protocol for Operational Qualification OQ	☐	☐
Wiring diagram and refrigeration cycle diagram with list of components	☐	☐
Spare parts list	☐	☐
Service manual	☐	☐
Instruction manual	☐	☐

	Yes	No
Documentation completely present	☐	☐

If not:

Measures taken:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 6. Location of the unit

Aim of test:

This chapter defines the site of installation of the unit. The location must be the same when executing the qualification.

Note: Generally, no qualification can be assigned to other locations!

Address	
Building	
Department	
Room No.	
User group/Laboratory area	
User	

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 7. Responsible person for this unit

Aim of test:

This chapter mentions a person who is responsible for installation and operation of the unit. This determination is optional.

Following Responsible person was determined:

Name	
Department	
Signature	

No responsible person was determined.	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 8. User's documents

Aim of test:

This chapter lists if an operating book or one or more SOP were applied and defines their location. Further criteria (e.g., access right) can be defined. These determinations are optional.

IQ 8.1 Operation log book

	Yes	No
An operation log book was applied.	☐	☐

If yes:

Identification number	
Designation	
Depository	

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 8.2 Standard operation procedures (SOP)

	Yes	No
One or several standard operation procedures) (SOP) were applied.	☐	☐

If yes:

	SOP	SOP (optional)
Identification, version umber		
Period of validity or expiration date		
Depository		

	SOP (optional)	SOP (optional)
Identification, version umber		
Period of validity or expiration date		
Depository		

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 9. Installation

Aim of test:

The following tests serve to assure correct installation of the unit.

See instruction manual chap. 4 and 5

	ok	Not ok	Corrected
Transport seals of the shelves and any transportation protection devices and adhesives inside and outside the unit and at the doors were removed.	☐	☐	☐
The unit is visually clean and undamaged	☐	☐	☐
The operating manuals and accessory equipment were removed from the interior	☐	☐	☐
The freezer is set up inside a building on an even surface, free from vibration and in a well-ventilated, dry location.	☐	☐	☐
Blocking of the front castors with the breaks	☐	☐	☐
Plane installation (control by means of a spirit level).	☐	☐	☐
Spacers for rear wall distance were installed	☐	☐	☐
Minimum distance of 100 mm / 3.94 in to the ventilation openings on the chamber front and rear observed	☐	☐	☐
Lateral minimum distance to the next unit 250 mm / 9.84 in	☐	☐	☐
Lateral minimum wall distance laterally, on the side without door hinge: 100 mm / 3.94 in	☐	☐	☐
Lateral minimum wall distance laterally, on the side with door hinge: 240 mm / 9.45 in	☐	☐	☐
Ambient humidity 70% r.H. max. non-condensing Measured value: _____ % r.H.	☐	☐	☐
Max. ambient temperature 32 °C / 89.6 °F Measured value: _____ °C	☐	☐	☐

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

	ok	Not ok	Corrected
Operating instructions are kept clearly visible with the unit at all times	☐	☐	☐
Do not place unit in non-ventilated niches.	☐	☐	☐
The unit is accessible for operation, maintenance, and calibration. The power plug is easily accessible and can be easily pulled in case of danger.	☐	☐	☐
Location outside potentially explosive safety areas (Ex zones)	☐	☐	☐

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

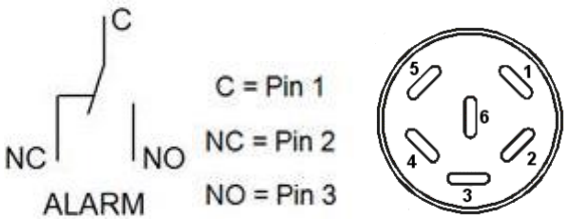
IQ 10. Connection to the zero-voltage relay alarm contact

Aim of test:

The following tests serve to assure correct connection to the zero-voltage relay alarm contact.

See chap. 15.5 of the instruction manual

The zero-voltage relay alarm output switches when the red LED △\ lights up on the controller display and in case of a power failure.



Zero-voltage contacts circuit diagram and pin allocation of DIN socket (9)

Description of the central alarm facility

The alarm contacts shall **not** be used at the moment.	☐

In case the alarm contacts are used:

The transfer and evaluation of the alarm contacts should be described following:

Description:

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Author	

Sketch of location and wiring:

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 11. Electrical power supply

Aim of test:

The following test serves to assure correct connection of the unit to the power supply.

	ok	Not ok	Corrected
Electrical connection of the chamber carried out according data on type plate	☐	☐	☐
The socket must provide a protective conductor	☐	☐	☐
The protective conductors of the socket and plug must be compatible.	☐	☐	☐

	ok	Not used	Corrected
Use of a residual current circuit breaker (recommended)	☐	☐	☐

Please see instruction manual chap. 5.4

Comments:

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 12. Result of the IQ-Test protocol

If all tests of the present protocol are passed with either OK or Corrected, it is ensured that the chamber is installed according to the installation guidelines of the manufacturer. Deviations have to be substantiated.

The chamber is now ready to perform the OQ. It is recommended to take the chamber into operation according to the OQ test protocol after having read the operating manual entirely.

Signature was created electronically

Vestfrost

IQ 12.1 Summary assessment and comments

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

IQ 12.2 Summary of IQ test results

	Designation of test / title	Test passed		Date / Name (abbrev.)
		Yes	No	
IQ 1.	Documentation approval	☐	☐	
IQ 1.1.	Prior to performing the IQ	☐	☐	
IQ 1.2.	After performing the IQ	☐	☐	
IQ 2.	Personnel involved with completing the IQ tests	☐	☐	
IQ 3.	List of documents in appendix	☐	☐	
IQ 4.	Unit identification	☐	☐	
IQ 4.1	Unit description	☐	☐	
IQ 4.2	Markings on the unit	☐	☐	
IQ 4.3	Identification acc. to type plate	☐	☐	
IQ 5.	Accessories and optional equipment	☐	☐	
IQ 5.1	Standard accessories	☐	☐	
IQ 5.2	Documentation supplied with the qualification folder	☐	☐	
IQ 6.	Location of the unit	☐	☐	
IQ 7.	Responsible person for this unit	☐	☐	

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	

	Designation of test / title	Test passed		Date / Name (abbrev.)
		Yes	No	
IQ 8.	User's documents	☐	☐	
IQ 8.1	Operation log book	☐	☐	
IQ 8.2	Standard operation procedures (SOP)	☐	☐	
IQ 9.	Installation	☐	☐	
IQ 10.	Connection to the zero-voltage relay alarm contact	☐	☐	
IQ 11.	Electrical power supply	☐	☐	
IQ 12.	Result of the IQ-Test protocol	☐	☐	
IQ 12.1	Summary assessment and comments	☐	☐	
IQ 12.2	Summary of IQ test results	☐	☐	

Carried out by:	Date:
Checked by:	Date:

Generation date:	Date of alteration:
Author	