



Documentation #: IQ Serial NO. 9999999



Protocol Name:	Installation Qualification Protocol
Protocol Number:	FRM630-02.03
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019: 
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019: 
Document Date:	05/06/2019
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
OPTIONS on Sterilizer:	
Fast Cooling:	COOLING50xxELV-D
Super Fast Cooling (FAN support):	FAN-50
Stand-alone Air compressor	COM-050 Serial number: 888888
Vacuum System:	VAC-38/50
Bio Hazard Filter system:	BHF-B
Automatic water filling system:	Included in model
Steam Generator:	N/a
Printer:	THE002-0080
Independent Recording:	IAR-001
Remote PC Reporting Software:	ADD222-0461

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PROTOCOL APPROVALS

Protocol Name:	Installation Qualification Protocol
Protocol Number:	FRM630-02.03
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019
Steam Sterilizer Model:	5075ELV-D
Serial Number:	99999999
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
IQ Date:	

Remarks:

If all signatures below are completed below then this protocol is approved and effective:

Department	Name	Signature	Date
Tuttnauer Distributor Technician			
End User Company Name Quality Control			
End User Company Name Quality Management			

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VALIDATION FINAL REPORT APPROVALS

Protocol Name:	Installation Qualification Protocol
Protocol Number:	FRM630-02.03
Prepared by (Signature / Date):	M. Nijssen (Sales Manager) 05/06/2019
Approved by (Signature / Date):	A. van Gastel (Quality Manager) 05/06/2019
Steam Sterilizer Model:	5075ELV-D
Serial Number:	9999999
Customer:	End User Company Name
Tuttnauer Distributor:	Tuttnauer Distributor
Country:	Country
IQ Date:	

Remarks:

If all signatures below are completed below then this protocol is approved and effective:

Department	Name	Signature	Date
Tuttnauer Distributor Technician			
End User Company Name Quality Control			
End User Company Name Quality Manager			

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1.0 OBJECTIVE

- A. To verify that the autoclave is installed correctly and will consistently perform the intended sterilization process.
- B. All sensors and instruments permanently installed with the equipment will be functioning properly and can be calibrated (if required). Utility connections must be correctly installed. Functional testing and field adjustment of the installed control mechanisms will be made in coordination with the autoclave vendor. This IQ will ensure that the equipment is installed as designed.
- C. The equipment and system will be ready for Operational Qualification.

2.0 DESCRIPTION

- A. This protocol is to be executed prior to OQ and PQ.
- B. Some subsections of the protocol may be repeated following 'significant' changes in the process or operation according to the Change Control Protocol.
- C. The qualification study will establish sterilization exposure time/temperature conditions adequate to assure a probability of non-sterility not greater than 10^{-6} for each approved loading configuration.

3.0 REFERENCES

The following documents are the references for the facility validation.

- A. Standard Operating Procedure System: _____
- B. Calibration Procedure System: _____
- C. Validation Protocol: _____
- D. Autoclave Manual and adequate rev.: _____

4.0 BACKGROUND

Active background provides a reason for executing the installation qualification.

- o Installing a new autoclave
- o Replacing an old autoclave with a new autoclave.
- o Old brand/Type: _____
- o Moving the existing autoclave to a new / other location" _____
- o Old Location / Area: _____
- o Other: _____

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5.0 SCOPE

The scope of the Installation Qualification is limited to the equipment listed in the table below.

Equipment	
AUTOCLAVE:	5075ELV-D Sn: 9999999

6.0 RESPONSIBILITIES

The following roles have been assigned and responsibilities assumed:

A. Advisor (End User Company Name)

1. Review and Approve Validation documents.
2. Provide guidance for the parties involved in the validation effort.

B. Validation Team (Tuttnauer Distributor)

1. Review and Approve Validation document.
2. Execute Validation including Qualification of the systems and subsystems.
3. Provide coordination for the parties involved in the validation effort.
4. Calibration of instrumentation.

C. QA/QC (Tuttnauer Distributor and End User Company Name)

1. Review and Approve Validation documents.
2. Provide GMP and regulatory guidance.
3. Test samples generated from execution of validation protocols.

D. Equipment Maintenance (Tuttnauer Distributor)

1. Review and approve Validation documents.
2. Develop Preventative Maintenance program for the plant.
3. Develop spare parts list and purchase spare parts.
4. Provide technical support to validation effort.
5. Assist with calibration of instruments.
6. Assist in execution instrument calibration and loop(s).
7. Number of verifications agreed on: _____

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7.0 INSTALLATION QUALIFICATION

The Installation Qualification is the documentation process which verifies that the physical components of a system have been installed according to design specifications. The installation of the system will be verified by reviewing the equipment installed using the referred attachments provided in this protocol. The forms will be utilized to document the installation of the system and to verify that the system components conform to design specifications.

A. Identification (Attachment #10.1A to #10.1C)

Name, ID number, location, equipment manufacturer, purchase order numbers, model number, serial number: any other specified data such as finish, materials of construction and dimensions. Pressure vessels will require a Certification Number for test ratings from the Government Agency.

B. Basic Utility Verification (Attachment #10.2A to #10.2G)

Verify that utilities are as described in the specification and that connections are made correctly per the drawings.

Utilities for autoclave model 5075ELV-D:

Attachment	Utility	Description
10.2A	Electrical Power	3-Ph+N+E 16A-400V 180°/6h
10.2B	City Water	2-3 bar ; connection: 1/2" or 3/4" Male
10.2C	DEMI Water	2 - 3 bar; connection 1/2" or 3/4" Male
10.2D	Drain	40 - 50 mm Open or Vented
10.2E	Compressed Air	6 - 8 bar ; 50 l/min; connection Schneider Female NW7,2
10.2F	Other	Room Temp; 5 - 40 °C Relative Humidity: 85 % Air Conditions: etc.
10.2G	Installation Tests	Tests to be carried out during / after installation

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C. Engineering Documentation (Attachment #10.3A)

The existence and location of all equipment maintenance manuals and documentation will be verified as to location to include all applicable drawings.

D. Critical and Reference Instrument List (Attachment #10.4A & #10.4B)

List, identify, and verify all instruments and gauges used during the Installation Qualification. Designate the instruments as critical or reference only. Where applicable, instruments will be calibrated. Verification will be made that all test procedures have been written and approved for instrument/gauge calibration to include the required intervals for recertification. A final report, to include all data on instrument/gauge parameters, will be submitted stating that installation qualifications are in accordance with the specifications.

E. Preventive Maintenance Verification (Attachment #10.5A)

In order to complete this form, the following must be verified: equipment name & tag number, existence of an approved PM program that follows manufacturer's recommendations and verifications that the PM has been performed as scheduled.

F. Installation Qualification Summary (Attachment #10.6A)

In order to complete the document, there is a summary of the Installation Qualification performed by the technician from Tuttnauer Distributor.

G. Comment / Action Items (Attachment #10.7A)

Together with the summary this shows an overview of open actions for follow up defining the actions to be taken and those responsible.

H. Comment / Action Form (Attachment #10.7B)

In order to complete the document, there is a follow-up form for the Comment / Action to be performed by the technician from Tuttnauer Distributor.

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8.0 IQ ACCEPTANCE CRITERIA

All inspections, reviews and documentation requirements for the system will be completed and approved. The installation qualification will document that the system has been installed in accordance with applicable specifications and is ready for the operational qualification.

8.1 Utility Requirement

Unless otherwise specified, voltage range must be within 10% of nominal voltage. Current must not exceed specified current rating of breaker.

8.2 Documentation

Turn over Package (ToP) for system includes documents specified by the project, engineering and validation departments.

TOP	Document	Description
1	O & M Manual	Operation & Maintenance Manual 5075ELV-D MAN999-99999999EN Revision : Rev X
2	Technical Manual	Technical Manual 5075ELV-D MAN888-88888888EN Revision : Rev Y
3	FCP	Factory Calibration Report
4	Cert SVL	Certificate of Safety Valve sterilizer
5	Cert SG-SVL	Certificate of Safety Valve Steam Generator (If Applicable)
6	DoC	Declaration of Conformity: <ul style="list-style-type: none"> - General Data Sheet - Drawing sterilizer chamber - BOM (Bill of Materials) - Hydrostatic Test Report
7	LB	Autoclave Logbook
8	YWC	Yellow Warranty Card

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8.3 Instrument Calibration

Measurement Instruments must be classified as either Critical or Reference Only. Critical instruments must conform to drawings, specifications, and data sheets. Instruments must be calibrated according to Local traceable standard and be within its calibration interval. Instrument linked to a recorder or controller must be loop calibrated.

8.4 Preventive Maintenance (PM) Verification

- PM program exists for the system.
- Manufacturers approved Preventative Maintenance schedule.
- PM has been scheduled as suggested.

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9.0 COMMENTS/ACTION ITEMS (Attachment # 10.7A; # 10.7B)

All comments, action and follow-up items are attached in Attachments 10.7A & 10.7B.

10.0 IQ ATTACHMENTS

- 10.1A. Identification: Autoclave
- 10.1B. Identification: (Internal / External) Steam Generator
- 10.1C. Identification: Parts supplied with the Autoclave
- 10.2A. Utility Requirement: Electrical
- 10.2B. Utility Requirement: City Water
- 10.2C. Utility Requirement: DEMI Water
- 10.2D. Utility Requirement: Drain
- 10.2E. Utility Requirement: Compressed Air
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- 10.4C. Instrument Calibration: Reference Instrument
- 10.5A. Preventive Maintenance Verification
- 10.6A. Installation Qualification Summaries
- 10.7A. Comments/Action Items
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ATTACHMENT #10.1A
IDENTIFICATION: AUTOCLAVE

Contract No:	
Customer:	End User Company Name
Location:	
Area:	
Item No:	
Item Name:	
Model:	5075ELV-D
Serial Number:	9999999
Software Version:	9.9.9
Software Revision No:	.9
Software Revision Date:	x-xx-yyyy
Installed By:	Tuttnauer Distributor
Approved By:	End User Company Name
Volume (Total in Liters):	28
Chamber Dimensions:	
Diameter (mm):	500
Depth (mm):	750
Outside Dimensions:	
Width (mm):	870
Length (mm):	770
Height (mm):	1090
Weight (kg):	190
Operating Temp (°C):	105 - 137
Operating Pressure (bar):	0 - 2,52
Design Pressure (bar):	2,8 absolute (142°C)
Volume Reservoir (l):	N/a
Internal Finish:	
Material of Construction:	AISI 316 L
Electro Polish:	Yes
External Finish:	
Material of Construction:	AISI 304

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

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ATTACHMENT #10.1B

IDENTIFICATION: (INTERNAL / EXTERNAL) STEAM GENERATOR

Contract No:	
Customer:	End User Company Name
Model:	5075ELV-D
Serial Number:	99999999
Software Version:	9.9.9
Software Revision No:	.9
Software Revision Date:	x-xx-yyyy
Location:	
Area:	
Item No:	
Item Name:	
Installed By:	Tuttnauer Distributor
Approved By:	End User Company Name
Steam Generator Information	
Serial Number:	9999999
Volume (Liters):	N/a
Voltage (V):	N/a
Power (W):	N/a
Operating Pressure (bar):	N/a
Design Pressure (bar):	N/a
Position of Steam Generator:	N/a

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

Documentation #: IQ Serial NO. 9999999

ATTACHMENT #10.1C

IDENTIFICATION: PARTS SUPPLIED WITH THE AUTOCLAVE

Contract No:		
Customer:	End User Company Name	
Model:	5075ELV-D	
Serial Number:	9999999	
Software Version:	9.9.9	
Software Revision No:	.9	
Software Revision Date:	x-xx-yyyy	
Location:		
Area:		
Item No:		
Item Name:		
Installed By:	Tuttnauer Distributor	
Approved By:	End User Company Name	
Parts Supplied with Autoclave	Article number	Checked
Bottom Plate / Tray holder + (x* Trays) ;Tray handle:	CMT507-0089	<input type="checkbox"/>
Tap Water connection hose (St. St. 2m):	GAS086-0102 + TB-MET-0710445	<input type="checkbox"/>
Pressure reducer 1,5 bar for Tap water:	SUA109-0049	<input type="checkbox"/>
DEMI Water connection hose (St. St. 2m):	GAS086-0102 + TB-MET-0710445	<input type="checkbox"/>
Pressure reducer 1,5 bar for DEMI water:	SUA109-0049	<input type="checkbox"/>
Drain connection hose (black 2m):	GAS084-0031	<input type="checkbox"/>
Drain Tube (Manual Draining):	N/a	<input type="checkbox"/>
Compressed air connection hose (blue 5m):	D740012	<input type="checkbox"/>
Electrical Power cord:	Fixed connection 3-P+N+E 16A-400V 180°/6h	<input type="checkbox"/>
Power Conversion Box:	ELE387-1610	<input type="checkbox"/>
UTP Cable for Ethernet connection:	CABLE-UTP-2M	<input type="checkbox"/>
Auxiliary Dry Contacts (Conn. to BM-System):	ADC-001	<input type="checkbox"/>
Shelve system:	N/a	<input type="checkbox"/>
Wire Basket(s) Model I (Qty) / Model II (Qty):	WBA50-23 ((3)) / WBA50-35 ((2))	<input type="checkbox"/>
Closed Basket(s) Model I (Qty) / Model II (Qty):	CBA50-23 ((3)) / CBA50-35 ((2))	<input type="checkbox"/>
Loading / Lifting Systems:	LIFT-001	<input type="checkbox"/>
Support Tables (Table) / (wheels/panels):	N/a / N/a	<input type="checkbox"/>

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

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ATTACHMENT #10.2A UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES - ELECTRICITY

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:	Separate group required	<input type="checkbox"/>
Purpose:	Power for control system and heating	
Voltage (VAC):	400 Measured values: L1-N : L2-N : L3-N : L-L :	<input type="checkbox"/>
Current (A):	13 Measured values (Heater): L1 : L2 : L3 :	<input type="checkbox"/>
Phase (Ph):	3+N+E	<input type="checkbox"/>
Power (W):	9000	<input type="checkbox"/>
Circuit Breaker (A):	=> 16	<input type="checkbox"/>
Frequency (Hz):	50	<input type="checkbox"/>
Connection on autoclave:	Cord with plug 3-Ph+N+E 16A-400V 180°/6h	<input type="checkbox"/>
Connection required on-site:	3-Ph+N+E 16A-400V 180°/6h	<input type="checkbox"/>
Conductor Material:		<input type="checkbox"/>
Conductor Size:		<input type="checkbox"/>
Insulation Material:		<input type="checkbox"/>
Conduit Size:		<input type="checkbox"/>
Grounding:	Non-Floating	<input type="checkbox"/>

Comments: _____

Utility Requirements Satisfied:

Yes _____

No _____

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

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ATTACHMENT #10.2B
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – CITY WATER

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		<input type="checkbox"/>
Purpose:	Cooling of exh; Fast Cooling; Vacuum System	
Pressure (bar):	2-3	<input type="checkbox"/>
Shut-off tap required:	Required (Not supplied)	<input type="checkbox"/>
Pressure Regulator Installed (1,5 bar):	Required (Supplied) Mount direct on Tap	<input type="checkbox"/>
Temperature (°C):	±15	<input type="checkbox"/>
Hardness (TDS):	between 0.7 mmol/l and 2.0 mmol/l	<input type="checkbox"/>
Back Flow Prevention:	Required (Not supplied)	<input type="checkbox"/>
Connection on autoclave:	1/2" Male	<input type="checkbox"/>
Connection required on-site:	1/2" or 3/4" Male	<input type="checkbox"/>
Pipe Material:		<input type="checkbox"/>
Pipe Size:		<input type="checkbox"/>
Pipe Insulation:		<input type="checkbox"/>

Comments: _____

Utility Requirements Satisfied:

Yes

No

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

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**ATTACHMENT #10.2C
UTILITY REQUIREMENT**

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – DEMI WATER

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		<input type="checkbox"/>
Purpose:	Steam Production	
Pressure (bar):	2 - 3	<input type="checkbox"/>
Shut-off tap required:	Required (Not supplied)	<input type="checkbox"/>
Pressure Regulator Installed (1,5 bar):	Required (Supplied) Mount direct on Tap	<input type="checkbox"/>
Temperature (°C):	15 - 22	<input type="checkbox"/>
Water Quality (compliance with EN285):	According to EN285:2006	<input type="checkbox"/>
Back Flow Prevention:	Required (Not supplied)	<input type="checkbox"/>
Connection on autoclave:	1/2" Male	<input type="checkbox"/>
Connection required on-site:	1/2" or 3/4" Male	<input type="checkbox"/>
Pipe Material:		<input type="checkbox"/>
Pipe Size:		<input type="checkbox"/>
Pipe Insulation:		<input type="checkbox"/>

Comments: _____

Utility Requirements Satisfied:

Yes

No

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by: _____ Date: _____

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**ATTACHMENT #10.2D
UTILITY REQUIREMENT**

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – DRAIN

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		<input type="checkbox"/>
Purpose:	Automatic Draining	
Open or Vented:	Open or Vented	<input type="checkbox"/>
Temperature resistant (°C):	80 constant ; 120 in case of malfunction	<input type="checkbox"/>
Temperature resistant min. length (m):	3	<input type="checkbox"/>
Max. height of the drain-pipe (mm):	20	<input type="checkbox"/>
Connection on autoclave:	1/2" Male	<input type="checkbox"/>
Connection required on-site:	40 - 50	<input type="checkbox"/>
Pipe Material:		<input type="checkbox"/>
OVERFLOW connection:		
Location on autoclave:	N/a	<input type="checkbox"/>
Connection on autoclave:	N/a	<input type="checkbox"/>
Connection required on-site:	N/a	<input type="checkbox"/>

Comments: _____

Utility Requirements Satisfied:

Yes

No

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

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ATTACHMENT #10.2E
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – COMPRESSED AIR

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		<input type="checkbox"/>
Purpose:	Cooling Back Pressure	
Air Flow (l/min):	50	<input type="checkbox"/>
Pressure (bar):	6 – 8	<input type="checkbox"/>
Shut-off tap:	Required (Not supplied)	<input type="checkbox"/>
Pressure Regulator Installed (1,5 bar):	Yes (Build-In)	<input type="checkbox"/>
Connection on autoclave:	1/2" Male with fitted Schneider Male NW7,2	<input type="checkbox"/>
Connection required on-site:	Schneider Female NW7,2	<input type="checkbox"/>
Water:	Free of water droplets > 25µm	<input type="checkbox"/>
Oil:	Free of Oil droplets > > 2µm	<input type="checkbox"/>
Pipe Material:		<input type="checkbox"/>
Pipe Size:		<input type="checkbox"/>

Comments: _____

Utility Requirements Satisfied:

Yes

No

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ATTACHMENT #10.2F
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – OTHER

	Specified	Checked
Model:	5075ELV-D	
System:		
Source:		<input type="checkbox"/>
Purpose:	General	
Surface to place the sterilizer on:	Leveled	<input type="checkbox"/>
Support table carrying weight:	N/a	<input type="checkbox"/>
Free space around the autoclave:	For maintenance and service purposes	<input type="checkbox"/>
Room Temperature (°C):	5 - 40	<input type="checkbox"/>
Room Relative Humidity (Max. %):	85	<input type="checkbox"/>
Conditioned Room:	N/a	<input type="checkbox"/>
Air Replacements per hour:	N/a	<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

Comments: _____

Utility Requirements Satisfied:

Yes _____

No _____

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ATTACHMENT #10.2G
UTILITY REQUIREMENT

Equipment/System Item No.: _____

Equipment/System Description: _____

UTILITIES – INSTALLATION TESTS

	Remarks	Checked
Model:	5075ELV-D	
System:		
Source:		<input type="checkbox"/>
Purpose:	Testing	
Integrity Check:	Visual check to verify that there are no dents, scratches, broken gauges, etc.	<input type="checkbox"/>
Leveling Check:	Check that the sterilizer is leveled	<input type="checkbox"/>
Utility Check 1:	All Utilities according to requirements	<input type="checkbox"/>
Utility Check 2:	Check that all Utilities are working and shut-off taps are opened	<input type="checkbox"/>
Leakage Check:	Check all connections to the sterilizer for leakages:	<input type="checkbox"/>
Grounding Check:	Check the ground connection of the customers power supply:	<input type="checkbox"/>
Leakage current Check:	Test the current leakage relay of the customers power supply:	<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

Comments: _____

Utility Requirements Satisfied:

Yes

No

Document any discrepancies on the Installation Qualification Summary.

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ATTACHMENT #10.3A
DOCUMENTATION

Equipment/System Item No.: _____

Equipment/System Description: _____

DOCUMENTS

Document	Specified	Available
Title:	O & M Manual	<input type="checkbox"/>
Number:	MAN999-9999999EN	<input type="checkbox"/>
Revision No.:	Rev X	<input type="checkbox"/>
Storage Location of Document:		
Title:	Technical Manual	<input type="checkbox"/>
Number:	MAN888-8888888EN	<input type="checkbox"/>
Revision No.:	Rev Y	<input type="checkbox"/>
Storage Location of Document:		
Title:	Safety testing Manual	<input type="checkbox"/>
Number:	MOD777-77777EN	<input type="checkbox"/>
Issue Date:	Rev Z	<input type="checkbox"/>
Storage Location of Document:		
Title:		<input type="checkbox"/>
Number:		<input type="checkbox"/>
Issue Date:		<input type="checkbox"/>
Storage Location of Document:		

Comments: _____

Document any discrepancies on the Installation Qualification Summary.

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**ATTACHMENT #10.4A
INSTRUMENT CALIBRATION**

Equipment/System Item No.: _____

Equipment/System Description: _____

CRITICAL INSTRUMENTATION 1 of 2

ID 1 :	
Type 1:	
Range 1:	
Scale Division 1:	
Manufacturer 1:	
Use 1:	
MOC 1:	
Calibration Date 1:	
Calibration Interval 1:	
Calibration Cert. No. 1:	
ID 2 :	
Type 2:	
Range 2:	
Scale Division 2:	
Manufacturer 2:	
Use 2 :	
MOC 2:	
Calibration Date 2:	
Calibration Interval 2:	
Calibration Cert. No. 2:	
ID 3:	
Type 3:	
Range 3:	
Scale Division 3:	
Manufacturer 3:	
Use 3:	
MOC 3:	
Calibration Date 3:	
Calibration Interval 3:	
Calibration Cert. No. 3:	

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CRITICAL INSTRUMENTATION 2 of 2

ID 4:	
Type 4:	
Range 4:	
Scale Division 4:	
Manufacturer 4:	
Use 4:	
MOC 4:	
Calibration Date 4:	
Calibration Interval 4:	
Calibration Cert. No. 4:	
ID 5:	
Type 5:	
Range 5:	
Scale Division 5:	
Manufacturer 5:	
Use 5:	
MOC 5:	
Calibration Date 5:	
Calibration Interval 5:	
Calibration Cert. No. 5:	
ID 6:	
Type 6:	
Range 6:	
Scale Division 6:	
Manufacturer 6:	
Use 6:	
MOC 6:	
Calibration Date 6:	
Calibration Interval 6:	
Calibration Cert. No. 6:	

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

Documentation #: IQ Serial NO. 9999999

ATTACHMENT #10.4B

CALIBRATION VALUES BACSOFT (FRM 630-05.00)

Model:	5075ELV-D	Serial number:	9999999
Request number:		Engineer:	

Chamber Temperature (J2)		Ref Temperature (J3)	
Actual Value	Read value	Actual Value	Read value
80.0 °C		80.0 °C	
130.0 °C		130.0 °C	

Drain Temperature (J5)		Bio Hazard Filter Temperature (J6)	
Actual Value	Read value	Actual Value	Read value
20.0 °C		80.0 °C	
80.0 °C		130.0 °C	

Actual Value	Read value	Actual Value	Read value
°C		°C	
°C		°C	

Chamber Pressure (J7:1)		Generator Pressure (J7:2)	
Actual Value	Read value	Actual Value	Read value
kPa	kPa	kPa	kPa
kPa	kPa	kPa	kPa

Actual Value	Read value	Actual Value	Read value
kPa	kPa	kPa	kPa
kPa	kPa	kPa	kPa

Calibration equipment			
ID:		Description:	
ID:		Description:	

Calibration checked by: _____

Date: _____

Documentation #: IQ Serial NO. 9999999

ATTACHMENT #10.4C
INSTRUMENT CALIBRATION

Equipment/System Item No.: _____

Equipment/System Description: _____

REFERENCE INSTRUMENTATION 1 of 2

ID 11:	
Type 11:	
Range 11:	
Scale Division 11:	
Manufacturer 11:	
Use 11:	
MOC 11:	
Calibration Date 11:	
Calibration Interval 11:	
Calibration Cert. No. 11:	
ID 12:	
Type 12:	
Range 12:	
Scale Division 12:	
Manufacturer 12:	
Use 12:	
MOC 12:	
Calibration Date 12:	
Calibration Interval 12:	
Calibration Cert. No. 12:	
ID 13:	
Type 13:	
Range 13:	
Scale Division 13:	
Manufacturer 13:	
Use 13:	
MOC 13:	
Calibration Date 13:	
Calibration Interval 13:	
Calibration Cert. No. 13:	

Documentation #: IQ Serial NO. 9999999

REFERENCE INSTRUMENTATION 2 of 2

ID 14:	
Type 14:	
Range 14:	
Scale Division 14:	
Manufacturer 14:	
Use 14:	
MOC 14:	
Calibration Date 14:	
Calibration Interval 14:	
Calibration Cert. No. 14:	
ID 15:	
Type 15:	
Range 15:	
Scale Division 15:	
Manufacturer 15:	
Use 15:	
MOC 15:	
Calibration Date 15:	
Calibration Interval 15:	
Calibration Cert. No. 15:	
ID 16:	
Type 16:	
Range 16:	
Scale Division 16:	
Manufacturer 16:	
Use 16:	
MOC 16:	
Calibration Date 16:	
Calibration Interval 16:	
Calibration Cert. No. 16:	

Document any discrepancies from the design specification on the Installation Qualification Summary.

Compiled by: _____ Date: _____

Reviewed by: _____ Date: _____

Documentation #: IQ Serial NO. 99999999

ATTACHMENT #10.5A
PREVENTIVE MAINTENANCE VERIFICATION

Equipment/System Item No.: _____

Equipment/System Description: _____

PM Document Title:	
PM Document No.:	
Revision Date:	
Storage Location of Document:	
Manufacturers PM Document Title:	N/a (part of MAN999-99999999EN-Rev X)
Manufacturers PM Document No.:	N/a (part of MAN999-99999999EN-Rev X)
PM has been performed as Scheduled:	

Is the current PM document in accordance to the Manufacturers Document?

Comments: _____

PM Verification Satisfied:

Yes

No

Document any discrepancies on the Installation Qualification Summary.

Compiled by: _____ **Date:** _____

Reviewed by _____ **Date:** _____

Documentation #: IQ Serial NO. 9999999

ATTACHMENT #10.6A
INSTALLATION QUALIFICATION SUMMERY

Equipment/System Item No.: _____

Equipment/System Description: _____

Discrepancy/variation _____

Resolution: _____

Satisfactorily completed?: (Y/N) _____

Signature _____

Date _____

Discrepancy/variation: -----

Resolution: _____

Satisfactorily completed?: (Y/N) _____

Signature _____

Date _____

SUMMARY: _____

All items in the Installation Qualification section of this protocol have been satisfactorily completed and all variations or discrepancies satisfactorily resolved. Therefore, this system is ready for Operational Qualification.

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

Documentation #: IQ Serial NO. 99999999

**ATTACHMENT #10.7A
COMMENT / ACTION ITEMS**

Equipment/System Item No.: _____

Equipment/System Description: _____

This attachment contains a listing of all issue, deviations, and exceptions that were recorded during protocol execution. A listing of all items is included below, and Comment/Action item forms are attached. This comment form summarizes those items as well as any corrective actions taken or responsive justifications.

Comment #	Who	Date Added	Follow Up Required (Yes/No)	Signature	Date Follow Up Completed
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>

Compiled by: _____ Date: _____

Reviewed by _____ Date: _____

Documentation #: IQ Serial NO. 9999999

ATTACHMENT #10.7B
COMMENT / ACTION ITEM FORM

Equipment/System Item No.: _____

Equipment/System Description: _____

Comment: _____

Response/Corrective Action/Justification: _____

Follow-up Required: (Yes/No) _____

Requested by: _____

Explanation of Follow-up: _____

Completed Date: _____

Signature: _____

Compiled by: _____

Date: _____

Reviewed by _____

Date: _____