




Installation Qualification Protocol

Job:	IQ C-L-25-006
Document N°:	LAB 25-006-IQ G20.0
Equipment:	Genesis 20.0
SN:	G-20.0-R00-25-01
Revision:	00
Manufacturer:	Donaldson Italia Srl
Supplier:	Astori Tecnica S.r.l.
Customer:	Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna "Bruno Ubertini"

Project:	124532	IQ Protocol		
Equipment:	Genesis 20.0	IQ Protocol_C-L-25-006_G20.0_ Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna "Bruno Ubertini"_R00	Page:	2 of 34
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REVIEW AND APPROVAL:

This Installation Qualification Test (IQ) protocol has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

	Position	Name	Date	Signed
Written By	Project leader	Andrea Ferraresi	18/03/25	<i>Andrea Ferraresi</i>
Approved By	Quality Manager	Olga Raschi	18/03/2025	<i>Olga Raschi</i>
Approved by	Customer (Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna "Bruno Ubertini") Quality Assurance Coordinator	ANDREA CACCIAROLI	06/04/25	<i>A. Cacciarioli</i>


1 REVISION TABLE

Revision	Date	Change description
00	18/03/25	First Issue

Project:	124532	IQ Protocol		
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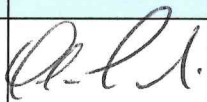

2 RESPONSIBILITIES


The responsibility for the data compilation of the tests results in this protocol is of Donaldson Italia Srl and the Customer (**Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini"**) or representative, as under:

Company	Position	Name	Dated	Signed
IZSCER	Biologo	ANDREA CACCIANALI	06/10/25	

3 FINAL REPORT


The responsibility for the data compilation of the tests results in this protocol is of Donaldson Italia Srl and the Customer (**Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini"**) or representative, as under:


Company	Position	Name	Dated	Signed	Initials
IZSCER	Biologo	ANDREA CACCIANALI	06/10/25		AC
SOLARIS	APP. ENG	MATEO PACOSCHI	06/10/25		MP

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4 OPERATOR TRAINING VERIFICATION

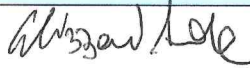


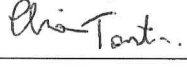
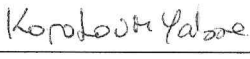
This section identifies the Donaldson Italia Srl personnel authorized to perform this IQ (Installation Qualification). Each person who will be executing this protocol shall complete an entry on the page.

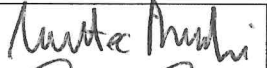

Company	Position	Name	Dated	Signed
DONALDSON	APP. ENGINEER	MATTEO RALOSCHI	6/6/25	


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5 LIST OF PERSONNEL

Attach a list of names and titles of all personnel involved in the execution and review of this document.

Name	Title/Position	Signature	Initials
ANNAUSA GHIZZARDI	TECNICO DI LABORATORIO		AG
Aldo Bonetti	TECNICO DI LABORATORIO		AB
ELENA STOPPANI	TECNICO DI LABORATORIO		ES
CHIARA TONTINI	TECNICO DI LABORATORIO		Ch
KOROTOUM YABRE	TECNICO DI LABORATORIO		KY

Performed by	Name: MATTEO PALOSCHI	date: 6/10/25	Signature: 
Approved by	Name: ANDREA CACCIARINI	date: 6/10/25	Signature: 


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6 INSTALLATION LOCATION

The system is installed in the following location:


Company	IZSCER
Address	VIA A. BIANCHI, 9 BRESCIA
System	GENESIS 20.0 A
Department	LABORATORIO PRODUZIONE VACCINI E REAGENTI.
Room	PALAZZO 12, 2° PIANO
Contact person	AUGUSTA CACCIAVALI

If the system is moved from the location where this IQ was done, the IQ must be repeated.

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8 INTRODUCTION

The purpose of this IQ protocol (Installation qualification) is to describe the activities to ascertain the proper installation of the equipment at the customer site. As a part of the protocol, it will be certified that all the specification and construction documents are present, it will be verified the presence and the assembly of the basic components according to the P&ID and the correct installation of the equipment.

It will be also verified the conformity and the presence of all the necessary services for the start-up.


All the tests on the functioning, on the sequences and on the correct measurement of the sensors will be executed during the OQ phase.

This protocol should apply to the follow equipment:

System	Ref no.
Genesis 20.0	P&ID_C-L-25-006_Genesis 20.0_ASTORI TECNICA_R04
Serial Number	G-20.0-R00-25-01

These tests are performed to ensure that the equipment has been properly built, assembled, and configured according to the associated configuration.

The final report will indicate clearly whether the result of these audits contained in this document is satisfactory.

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9 SAFETY ASPECTS

Everyone involved with the IQ execution at the customer site must know and observe the safety rules.


The Donaldson Italia Srl Genesis fermenter follows the legal requirements in the field of safety in the European Union. In particular, the European and the Italian electrical rules are applied for the electrical system and instrumentation, the machinery directive for the moving parts protection rules.

All the piping line components have the maximum allowable operating temperature above than the operating temperature on the equipment.

All the mechanical and electrical components are CE certified.

Due to the use of potentially asphyxiating gas, the place of use must be aerated and suitable precautionary steps in case of CO₂ gas release must be taken.


The safety discharges and the exhaust gas discharges must be properly confined towards outside, or in an alternative towards inside, if these are properly bubbled in water or confine in a safe zone and maintaining, however, the place sufficiently aerated.

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10 TEST PLAN


The tests to be performed are listed in the below table.

Test ID	Test title
TT-IQ-01	Critical utilities
TT-IQ-02	System check
TT-IQ-03	Documentation check
TT-IQ-04	User manual
TT-IQ-05	Piping matching test
TT-IQ-06	Software installation
TT-IQ-07	Hardware installation

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The protocol has been approved?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Comments:	

Acceptance status			
<input checked="" type="checkbox"/> conform		<input type="checkbox"/> Not conform	
		<input type="checkbox"/> deviation report: TDev_____	
Comments			
Number of pages attached			
Performed by	Name: <i>MATTEO DALGOSCH</i>	date: <i>06/10/25</i>	Signature: <i>Matteo Dalgosch</i>
Approved by	Name: <i>ANDREA CACCIAPIGLI</i>	date: <i>06/10/25</i>	Signature: <i>Andrea CacciapiGLI</i>

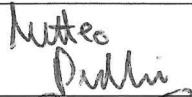

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11 REQUIREMENTS FOR THE IQ EXECUTION

The purpose of this section is to verify that the connection to the services of the equipment have been executed correctly, and to provide a list of some documents and tests that, if not available or incomplete, may slow down the execution of this document.

The purpose of this section is to verify that the protocol is approved, and the preliminary FAT and SAT protocols had a positive result, or all deviations have been solved.


Has the IQ protocol been approved?	<input checked="" type="checkbox"/> Y <input type="checkbox"/> NO <input type="checkbox"/> N/A
Have the FAT and SAT protocols successfully been executed?	<input type="checkbox"/> Y <input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A

Performed by	Name: MATEO DLOSCINI	date: 06/10/25	Signature: 
Approved by	Name: ANDREA CACCIAFACCI	date: 06/10/25	Signature: 

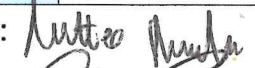
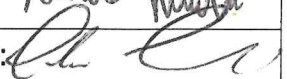
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11.1 Critical utilities:

Test ID	Test title		
TT-IQ-01	Critical utilities		
Objective			
Verify that the utilities are suitable for running the equipment			
Test preparation			
N/A			
Test protocol			
Check the configurator, with blue pen, mark the present item. Item missing should be listed into the comment section			
Acceptance criteria			
<ul style="list-style-type: none"> - Each item on the configurator list must be present. - The test is compliant when all the criteria are met. In case of non-compliance with criteria, a deviation form must be filled.			
Type			
Power supply	220V; 50 Hz; 2kW	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
Electrical heaters power supply	3x380 Vac (3P+GND) 50 Hz 1,5 KW each heater	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
Air (dry and oil free)	Pressure 6-6.5 bar(g)	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
Oxygen (dry and oil free)	Pressure 2-2.5 bar(g)	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
Nitrogen (dry and oil free)	Pressure 2-2.5 bar(g)	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
Carbon Dioxide (dry and oil free)	Pressure 2-2.5 bar(g)	<input type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
C-WATER (softened between 5 and 10°F; filtered 5µm)	Pressure 1-1.5 bar(g)	<input type="checkbox"/> YES	<input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A
CHWS (chilled water Send)	Pressure 1-3.5 bar(g)	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
CIP-S (cleaning in Place solution)	Pressure 2-2.5 bar(g)	<input type="checkbox"/> YES	<input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A

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C-STEAM (clean steam)	Pressure 2-3.0 bar(g)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
DCW (drain condensate waste)	Open drain	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
WASTE (water waste)	Open drain	<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> N/A
CHW-R (chilled water return)	Open drain	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A


Acceptance status			
<input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev _____			
Comments			
Number of pages attached			
Performed by	Name: MATEO PALOSCHI	date: 06/10/25	Signature: 
Approved by	Name: ANDREA CACCIALANCI	date: 06/10/25	Signature: 

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12 SYSTEM DESCRIPTION


Test ID	Test title
TT-IQ-02	System check
Objective	
Describe the system	
Test preparation	
Rule, distilled water	
Test protocol	
<p>The components are listed according to the tables in this section. All expected information checked should match the actual.</p> <p>All tables shall be completely compiled into fulfill the acceptance criteria.</p> <p><u>Control Module</u>: The fermenter is equipped with measurement and control system that can execute and register the controls and the functions, as required, automatically with a software system set in the industrial PC/PLC supplied which contains the information regarding the control that you intend to run.</p> <p>The fermenter is equipped with electrical devices and cables, check visually all the parts in the control module table.</p>	
Acceptance criteria	
<ul style="list-style-type: none"> - Each item on the configurator list must be present. - The test is compliant when all the criteria are met. <p>In case of non-compliance with criteria, a deviation form must be filled.</p>	

Vessel – GENESIS 1	Actual
Equipment type: bioreactor	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A


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Geometrical volume: 20 liters	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Max working volume: 15 liters (75%)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Min working volume: 5 liters (25%)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Construction modules:	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
- Vessel	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
- Piping	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
- Control module (cabinet + HMI)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Main materials:	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
- Vessel: AISI316L, borosilicate glass	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
- Internal parts (baffles, sparger, etc.): AISI316L	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
- O-rings: silicone	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A

Control module – GENESIS 1	Quantity	Actual
Pt100 vessel temperature sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Pt100 jacket temperature sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
pH digital sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
DO2 digital sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
ORP digital sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
CO2 digital sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Antifoam/Level sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
TCD digital sensor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
TMFC for Air	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
TMFC for O ₂	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
TMFC for N ₂	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
TMFC for CO ₂	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Electrical heaters for heating	3	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Peristaltic pumps variable speed	4	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Pressure Transmitter	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Agitation group with brushless motor	1	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A


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Acceptance status			
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Comments			
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Performed by	Name: MATEO <i>BRIGGI</i>	date: <i>06/10/25</i>	Signature: <i>Mateo Brighi</i>
Approved by	Name: ANDREA <i>CACCIARI</i>	date: <i>6/10/25</i>	Signature: <i>Andrea Cacciari</i>


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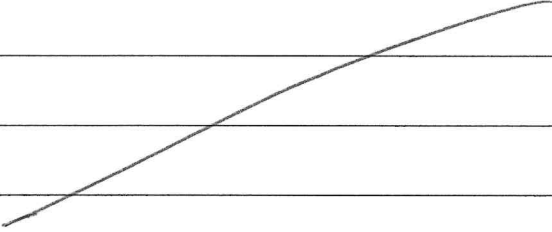
13 SUPPLIER DOCUMENTATION CHECK


Test ID	Test title
TT-IQ-03	Documentation check
Objective	
Identify the documentation required for the installation and the functioning of the fermenter	
Test preparation	
N/A	
Test protocol	
Check the list of CE conformity, certificates and any other type of documentation provided by the manufacturer or installer of the fermenter. Note the presence or absence of the drawings, plans, certificates, or documents that match the requirements indicated in the following table. Attach all the documentation to this IQ protocol	
Acceptance criteria	
<ul style="list-style-type: none"> - Each item on the configurator list must be present. - The test is compliant when all the criteria are met. In case of non-compliance with criteria, a deviation form must be filled.	
ASME vessel certification	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
CE certificate	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Bronkhorst certificates (Thermal Mass Flow Controller)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Hamilton sensors (pH, DO2, ORP, CO2, TCD sensors)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Pall Quality Assurance certificates (filters)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Nuova General Instruments certificates (jacket and vessel safety valves)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Watson Marlow certificate (peristaltic pump)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
User manual	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A

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Warranty	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Manometer certificate (tool)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Tachymeter certificate (tool)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Thermometer certificate (tool)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Wiring diagram	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Power supply data sheet (Mean Well)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Temperature sensor data sheet (Easytech)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
pH, DO2, ORP, CO2, TCD sensors data sheet (Hamilton)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Motor, Servodrive data sheets (Lovato)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Thermal Mass Flow Controller data sheet (Bronkhorst)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Mechanical seal data sheet (Roten)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Cooling fans data sheet (9GA0924P4J03, Sanyo Denki)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Filtered power switch data sheet (FN9289-10-06, Schaffner)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Electrical valve data sheet (VX215MGAXB, SMC)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Programmable controller data sheet (Siemens)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Peristaltic pumps data sheets (Watson Marlow)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Levels amplifiers data sheet (Lovato)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Diaphragm valves data sheet (Gemu)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Steam Trap data sheet (Spirax Sarco)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Plate Exchangers data sheet (Techno System)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Circulation Pump data sheet (Wilo)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Chiller data sheet (Lauda)	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Spare Parts list	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Test protocol	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
P&ID	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A

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Acceptance status			
<input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev _____			
Comments			
			
Number of pages attached			
Performed by	Name: <i>MATTEO PALOSCHI</i>	date: <i>06/10/25</i>	Signature: <i>Matteo Paloschi</i>
Approved by	Name: <i>ANDREA CACCIANALI</i>	date: <i>06/10/25</i>	Signature: <i>Andrea Caccianali</i>

Project:	124532	IQ Protocol		
Equipment:	Genesis 20.0	IQ Protocol_C-L-25-006_G20.0_ Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna "Bruno Ubertini"_R00	Page:	21 of 34
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Test ID	Test title
TT-IQ-04	User manual
Objective	
Verify the presence of the User and maintenance manual of the system	
Test preparation	
N/A	
Test protocol	
Check the configurator, with blue pen, mark the present item. Item missing should be listed into the comment section	
Acceptance criteria	
- The user and maintenance manual must be provided by the manufacturer of the equipment and contains at least the following things	
Solaris Manual for the fermenter contains:	
Utilities required for fermenter operations	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Residual risks	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Procedure for the correct sequence of the operation and control for equipment start-up	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Maintenance instructions	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Software manual	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A


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Acceptance status			
<input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev _____			
Comments			
Number of pages attached			
Performed by	Name: <i>MATEO PALESCHI</i>	date: <i>06/10/25</i>	Signature: <i>Mateo Paleschi</i>
Approved by	Name: <i>ANDREA CACCIARI</i>	date: <i>06/10/25</i>	Signature: <i>Andrea Cacciari</i>


Project:	124532	IQ Protocol		
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14 PIPING MATCHING

Test ID	Test title
TT-IQ-05	Piping matching
Objective	
Verify the match of the piping system with what outlined in the P&ID approved	
Test preparation	
Take the P&ID provided by the manufacturer of the system	
Test protocol	
Verify the conformity of the piping system through comparing it with the P&ID approved	
Acceptance criteria	
Verify if the piping system is in accordance with what stylized in the P&ID. Document any discrepancies from the approved P&ID on a copy of the same, therefore, date and sign the copy "as built" and attach it to this document. Use the following Worksheet to document the comments and the result of the test execution.	
The system is compliant to the design criteria reported in the P&ID	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A

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Acceptance status			
<input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev _____			
Comments			
/			
Number of pages attached			
Performed by	Name: MATTEO PALOSCHI	date: 06/10/25	Signature: <i>Matteo Paloschi</i>
Approved by	Name: ANDEA CACCIARI	date: 06/10/25	Signature: <i>Andrea Cacciari</i>

Project:	124532	IQ Protocol		
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15 SOFTWARE INSTALLATION


Test ID	Test title
TT-IQ-06	Software installation
Objective	
Verify that the software is properly installed	
Test preparation	
N/A	
Test protocol	
Turn on the cabinet and the PC clicking on the button. The software should start automatically and show the Login page	
Acceptance criteria	
After login the software will show the main page	
The software Leonardo is installed.	
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	

Acceptance status			
<input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev _____			
Comments			
Number of pages attached			
Performed by	Name: <i>MATTEO PULOSCHI</i>	date: <i>06/10/25</i>	Signature: <i>Matteo Puloschi</i>
Approved by	Name: <i>ANOREA CACCIARALI</i>	date: <i>06/10/25</i>	Signature: <i>Anorea Cacciari</i>


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16 HARDWARE INSTALLATION

Test ID	Test title
TT-IQ-07	Hardware installation
Objective	
Verify that the system is properly installed and connected to the utilities	
Test preparation	
Get the User manual on the paragraph "Installation procedure"	
Test protocol	
Follow the procedure for the installation of the system, place the HMI on the cabinet, place the sensors in the bioreactor and connect the cables as described into the manual and according with the labels on the cables. Connect all the utilities to the rack piping., then connect all the transfer lines.	
Acceptance criteria	
Once turned on, the system is connected and ready to use.	
The system is completely installed	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A

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Acceptance status			
<input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev _____			
Comments			
<div style="text-align: right; color: lightblue; opacity: 0.5; font-size: small;"> IQ final report deviation report: to receive actions and </div>			
Number of pages attached			
Performed by	Name: MATTEO PALOSCHI	date: 06/10/25	Signature: <i>Matteo Paloschi</i>
Approved by	Name: ANDREA CACCIAVALI	date: 06/10/25	Signature: <i>Andrea Cacciavali</i>

Project:	124532	IQ Protocol		
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17 DOCUMENTATION


17.1 IQ final report

At the end of the review of audits prepare a Final Report of IQ protocol that reflects the information gathered during the execution of this document. On it should be indicated and described the results of experiments performed in succession.

When the results of the tests do not meet the acceptance criteria, should be highlighted deviation reports, corrective actions and results of those actions. At the end of the report, it will display the final judgment that shows the correct installation of the equipment.

17.2 Data preparation

The chapters in this document should be brought together in an orderly manner, including all the original data collected during the inspections / tests and any other document of great importance for a complete characterization of the device or system under test.


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18. ANNEX

Annex 1: Data Collection


Annex 2: Report of Deviations and Corrections

Annex 3: Acceptance


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ANNEX N° 2.
(Report of Deviations and Corrections)

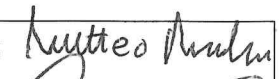
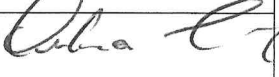
Deviation n°1
Deviation description:
Corrective action for deviation n°1
Describe the corrective action to perform:
Results after the corrective action n°1:
Result:


Project:	124532	IQ Protocol		
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Deviation n°2
Deviation description:
Corrective action for deviation n°2
Describe the corrective action to perform:
Results after the corrective action n°2:
Result:

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Deviation n°3
Deviation description:
Corrective action for deviation n°3
Describe the corrective action to perform:
Results after the corrective action n°3:
Result:

Performed by	Name: <u>MATEO PALOSCHI</u>	date: <u>06/10/25</u>	Signature: 
Approved by	Name: <u>ANDREA CACCIAVALLO</u>	date: <u>06/10/25</u>	Signature: 

Project:	124532	IQ Protocol		
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ACCEPTANCE

This is to confirm the acceptance of the equipment within the limits of the test performed during the IQ.

	NEGATIVE	POSITIVE	CONDITIONALLY APPROVED
IQ result		X	

Conditions for approval:

Performed by	Name: <i>Mattia PAVIOLIN</i>	date: <i>06/10/25</i>	Signature: <i>Mattia Paviolin</i>
Approved by	Name: <i>ANDREA CACCIARI</i>	date: <i>06/10/25</i>	Signature: <i>[Signature]</i>