




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-R00-25-02 |
| Revision: | 00 |
| Manufacturer: | Donaldson Italia Srl |
| Supplier: | Astori Tecnica S.r.l. |
| Customer: | Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna "Bruno Ubertini" |

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| 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 |  |
| Approved By | Quality Manager | Olga Raschi | 18/03/2025 |  |
| Approved by | Customer (Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna "Bruno Ubertini") Quality Assurance Coordinator | ANDREA CACCIAVALLE | 18/03/25 |  |


1 REVISION TABLE

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

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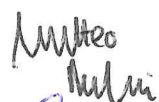
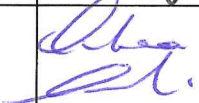
2 RESPONSIBILITIES


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 |
|---------|----------|--------------------|----------|---|
| IESLER | BIOLOGO | ANDREA CACCIAFALCI | 07/03/25 |  |
| | | | | |

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 |
|---------|----------|--------------------|----------|---|----------|
| SOLARIS | APP ENG | MATEO DALOSCH | 21/03/25 |  | MD |
| IESLER | BIOLOGO | ANDREA CACCIAFALCI | 7/03/25 |  | AC |
| | | | | | |
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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 |
|---------|------------|----------------|------------|---|
| SOLARIS | APP - ENG. | MATEO PALOSCHI | 21/03/2025 |  |
| | | | | |
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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 |
|------|----------------|-----------|----------|
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|--------------|-------------------------------|-----------------------|-----------------------------------|
| Performed by | Name: <i>MATEO ALONSI</i> | date: <i>21/03/25</i> | Signature: <i>Mateo Alonzi</i> |
| Approved by | Name: <i>ANOLEA CRISTIANI</i> | date: <i>07/03/25</i> | Signature: <i>Anolea Crisiani</i> |


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6 INSTALLATION LOCATION

The system is installed in the following location:


| | |
|-----------------------|---|
| Company | IZSLER |
| Address | VIA A. BIANCHI, 9 BRESCIA |
| System | GENESIS 20.0 2 |
| Department | LABORATORIO PRODUZIONE VACCINI E REAGENTI |
| Room | PALAZZO 12, 2° PIANO |
| Contact person | ANDREA CACCIANALI |

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-R00-25-02 |

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: | |
| | |
| | |
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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 PALOSCHI</i> | date: <i>21/03/25</i> | Signature: <i>Mateo Paloschi</i> |
| Approved by | Name: <i>ANDREA ORCIAI</i> | date: <i>07/03/25</i> | Signature: <i>Andrea Orciai</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: <u>MATEO PALOSCHI</u> | date: <u>21/03/25</u> | Signature: <u>Mateo Paloschi</u> |
| Approved by | Name: <u>ANDREA CACCIANALI</u> | date: <u>07/03/25</u> | Signature: <u>Andrea Caccianali</u> |

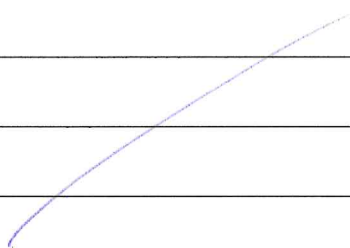
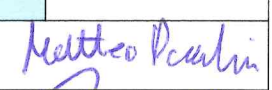

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11.1 Critical utilities:

| 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 checked="" 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 checked="" type="checkbox"/> | YES <input type="checkbox"/> NO <input 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 |
| C-STEAM (clean steam) | Pressure 2-3.0 bar(g) | <input checked="" type="checkbox"/> | YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |

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| | | |
|------------------------------|------------|--|
| 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 checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input 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: 7/10/2025 | Signature:  |
| Approved by | Name: ANDREA ACCIARICI | date: 07/10/25 | 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> | |

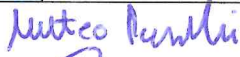
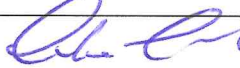
| | |
|----------------------------|--|
| Vessel – GENESIS 1 | Actual |
| Equipment type: bioreactor | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |


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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 | | | |
|---|--|--|------------------------|
| <input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev_____ | | | |
| Comments | | | |
| <div style="text-align: center; font-size: 2em; color: blue;">/</div> | | | |
| Performed by | | Name: MATEO PAIOSCHI | date: 7/10/2025 |
| Approved by | | Name: ANNEA CICCIAZZI | date: 07/10/25 |
| | | Signature:  | |
| | | Signature:  | |

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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 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 type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |
| Pall Quality Assurance certificates (filters) | <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |
| Nuova General Instruments certificates (jacket and vessel safety valves) | <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |
| Watson Marlow certificate (peristaltic pump) | <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |
| User manual | <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A |


| | | | | |
|------------|------------------|--|---|----------|
| 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: | 19 of 34 |
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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 |

| | | | | |
|------------|------------------|---|---|----------|
| 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: | 20 of 34 |
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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: MATEO PALOSCHI | date: 21/03/25 | Signature: <i>Matteo Paloschi</i> |
| Approved by | Name: ANDREA CACCIAVACCI | date: 21/03/25 | Signature: <i>Andrea Cacciavacci</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 |


| | | | | |
|------------|------------------|--|---|----------|
| 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: | 22 of 34 |
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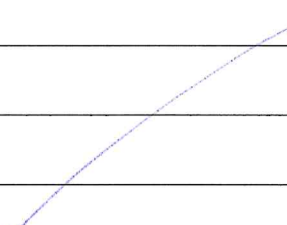
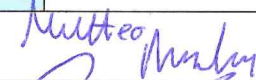
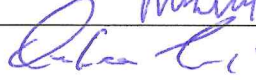
| Acceptance status | | | |
|--|-------------------------------|-------------------------|-------------------------------------|
| <input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev _____ | | | |
| Comments | | | |
| / | | | |
| Number of pages attached | | | |
| Performed by | Name: MATTEO PALOSCHI | date: 07/10/2025 | Signature: <i>Matteo Paloschi</i> |
| Approved by | Name: ANDEA ACCIARUCCI | date: 07/10/25 | Signature: <i>Andrea Acciarucci</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: | 23 of 34 |
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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 |

| | | | | |
|------------|------------------|--|---|----------|
| 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: | 24 of 34 |
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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: 7/10/2025 | Signature:  |
| Approved by | Name: ANDREA CACCIARINI | date: 07/10/25 | Signature:  |

| | | | | |
|------------|------------------|--|---|----------|
| 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: | 25 of 34 |
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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 | |

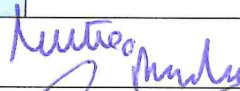
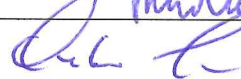
| Acceptance status | | | |
|---|---------------------------------|-------------------------|--|
| <input checked="" type="checkbox"/> conform <input type="checkbox"/> Not conform <input type="checkbox"/> deviation report: TDev_____ | | | |
| Comments | | | |
| / | | | |
| Number of pages attached | | | |
| Performed by | Name: <i>MATEO PALOSCHI</i> | date: <i>21/01/2025</i> | Signature: <i>Matteo Paloschi</i> |
| Approved by | Name: <i>ANDREA CACCIAVALLE</i> | date: <i>07/02/25</i> | Signature: <i>Andrea Caccialavalle</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: | 26 of 34 |
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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 |

| | | | | |
|------------|------------------|--|---|----------|
| 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: | 27 of 34 |
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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 PAIOSCHI | date: 21/03/2025 | Signature:  |
| Approved by | Name: ANDREA ACCIARI | date: 07/03/25 | Signature:  |

| | | | | |
|------------|------------------|--|---|----------|
| 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: | 28 of 34 |
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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.


| | | | | |
|------------|------------------|--|---|----------|
| 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: | 29 of 34 |
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18. ANNEX

Annex 1: Data Collection


Annex 2: Report of Deviations and Corrections

Annex 3: Acceptance


| | | | | |
|------------|------------------|--|---|------------|
| 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: | 31 of 34 |
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ANNEX N° 2.
(Report of Deviations and Corrections)

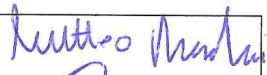

| |
|---|
| Deviation n°1 |
| Deviation description: |
| |
| |
| |
| |
| Corrective action for deviation n°1 |
| Describe the corrective action to perform: |
| |
| |
| |
| |
| Results after the corrective action n°1: |
| Result: |
| |
| |
| |


| | | | | |
|------------|------------------|--|---|------------|
| Project: | 124532 | IQ Protocol |  | |
| 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: | 32 of 34 |
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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: |
| |
| |
| |

| | | | | |
|------------|------------------|--|---|------------|
| 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: | 33 of 34 |
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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>MATTEO PALOSCHI</u> | date: <u>21/03/2025</u> | Signature:  |
| Approved by | Name: <u>ANDREA CACCIARINI</u> | date: <u>07/03/25</u> | Signature:  |

| | | | | |
|------------|------------------|--|---|------------|
| 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: | 34 of 34 |
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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>MATEO PALOSCHI</i> | date: <i>7/10/2025</i> | Signature: <i>Matteo</i> |
| Approved by | Name: <i>ANDREA CACCIAPIRELLI</i> | date: <i>07/10/25</i> | Signature: <i>Andrea</i> |