FAT
Factory Acceptance Test

PROTOCOL FOR

FLEX-SAS

SERIAL NUMBER

Prepared by	Company	Job Title	Signature	Date

The objective and scope for the proposed Factory Acceptance testing described in this Factory Acceptance Test Protocol have been reviewed and approved for execution by the appropriate project team members.

Approved by	Company	Job Title	Signature	Date

The execution and summary of the executed testing recorded in this Factory Acceptance Test Protocol have been reviewed and approved by the undersigned.

Approved by	Company	Job Title	Signature	Date

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Document Revision History

Rev. #	Type of Revision	Data
00	First Release	

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1. INTRODUCTION

1.1. PURPOSE

The purpose of this protocol is to define the procedures and acceptance criteria for the activities to be performed at Tema Sinergie facilities. Every single test will be performed first by Tema Sinergie's Technician (Performer) and reviewed by the Customer/End User Witness (Witness).

This protocol will be prepared by Tema Sinergie's Product Specialist Department, approved by Quality Assurance Manager and Head of Product Specialist.

The FAT protocol will be forwarded in electronic copy to the Customer by Sales Manager / Project Manager / or Tema person in charge about 2 weeks before the agreed test date for his knowledge and approval.

If the customer doesn't send back to Tema Sinergie the scan copy of the first page for the contents approval, the protocol will be anyway considered as accepted and the customer representative must sign at the beginning of the FAT.

If the Customer expresses requests concerning the FAT protocol content, Tema Sinergie's Quality Dept. will evaluate the possibility to apply the proposed modifications, accordingly.

In case the request to modify the FAT protocol content would be so extensive as to generate excessive costs in comparison to the standard protocol, Tema Sinergie reserves the right to modify the quoted pricing, accordingly.

Once the protocol has been approved by both parties (Tema Sinergie and Customer) through the signatures in the appropriate section of the protocol cover page (second table: Review and Approval of Content for Execution) the protocol cannot be changed substantially (e.g. additional tests) unless approval of Tema Sinergie with eventual economic quotation.

The FAT takes place at Tema Sinergie Factory site. The Customer's responsible person must be present during the test performances.

Minor corrections (e.g. typos, misspellings, revisions of documents) can be managed directly on the printed document with the date and signature of both Tema Sinergie representatives and Customer representatives for validation.

Any major deviation or abnormality found during the execution of the protocol has to be managed with the Deviation Report Section, where the corrective action and result will be defined and reported.

Every page of this protocol with manual hand written entries must be signed by both Tema Sinergie's Technician (filling the space Performed by) and the assigned Customer person (filling the space Witnessed by).

After the positive conclusion of all the tests, the protocol will be approved by both parties (Tema Sinergie and Customer) through the signatures in the proper section of the protocol cover page (third table: Execution and Summary of the Executed Testing).

In the "Summary" chapter any note will be defined and the decisions agreed accordingly with Customer in case of deviation will be reported. Minor problems (e.g. missing documents) should be solved without additional return of Customer to Tema Sinergie facilities.

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

General Notes:

1. If the Customer will not be present during the FAT execution for force majeure, the designated person for validation of Tema Sinergie will perform the protocol and will sign in the sections of his competence ("Performed by"). After the positive conclusion of all sections of the protocol, Tema Sinergie's Quality Department will verify the correct filling of the protocol and attachments. This is demonstrated by: 1) filling the name of QA person in the Annex working group; 2) putting the signature of QA person for the approval of execution in the cover page and in the Summary; 3) checking with signature in the section "Witnessed By".
2. Once concluded, the original paper copy of the completed protocol with the related attachments will be delivered to the customer representative, except otherwise agreed with Customer. Tema Sinergie will keep a scan copy of the completed protocol and related attachments.
3. If two weeks before the agreed period the Customer wishes a change in execution dates of FAT, Tema Sinergie will reserve the right to assess availability. In case of postponement requested by the Customer, Tema Sinergie will not respond to penalty clauses or delays in the FAT. In all other cases, dates previously agreed will be kept.

The acceptance of this fulfilled protocol will permit the emission of the invoice only in case a part of the payment is contractually linked to the positive conclusion of this protocol.

1.2. System Description

The Production Line described in this document is designed to produce a shielded dispensing isolator and transfer hatch in agreement with Good Manufacturing Practice (GMP) regulations; production line's hot cell should assure:

- quality and integrity of final product;
- radioprotection of operators;
-

These two fundamental conditions are guaranteed by various sensors that are involved in the following features:

- Internal pressure and under pressure control;
- Internal radioactivity levels monitor;
- Ventilation and air purity, with laminar flow control;
- Isolation of air inside hot cells with surrounding environment;

1.3. Working Group

Enter every person involved in the execution of this validation protocol. For each of them record:

- Name and Last Name
- Professional Role
- Company
- Signature
- Initials

1.4. System Identification

Collect primary information about the system that is going to be tested, such as:

- Serial Number
- Customer
- End User

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

1.5. TEST INSTRUMENT DATA

1.5.1. Test Work

Identify and attach a copy of the calibration certificate of all the instruments that will be used during the execution of this protocol. Record the serial number and model number of the instruments used.

1.5.2. Acceptance Criteria

The instruments used during the execution of this protocol have been identified and are within their calibration period (Yearly validity with a tolerance of +/- 15 days from the expiry date).

Calibration certificates, at least in electronic copy, are traceable to instruments.

Unless otherwise agreed, if the following equipment is used along this protocol, these minimum technical requirements must be met:

- Precision Scale: accuracy of 1%, down to 0,05 g or better
- Dose Calibrator: accuracy ≤ 5%, linearity ≤2%; readability down to 1 MBq or better

1.6. SYSTEM AND TECHNICAL DOCUMENTATION VERIFICATION

1.6.1. Test Work

Verify that the documentation required for this equipment is present, as listed in the chapter.

1.6.2. Acceptance Criteria

The documentation required listed in chapter is present, at least in electronic copy. Certificates and schemes are traceable.

1.7. CONSTRUCTION DESIGN VERIFICATION

1.7.1. Test Work

Where applicable:

- Trace the installed system and compare it to the construction designs.
- Verify that type and location of instruments/equipment are in accordance to the drawings.
- Verify the overall dimensions and the position of the connection points of all the utilities.
- Verify finishes as specified, ergonomics, crack and crevice free, internal joins must be smooth, radiused and sealed.
- Verify that shielding is as specified (wall, doors, glass windows and pincers kneecap if present).
- Attach the updated drawings to the final report.

1.7.2. Acceptance Criteria

The type and location of installed instruments/equipment and overall dimensions are in accordance to the drawings. The drawings relevant to this system have been verified and updated to reflect field installation "AS BUILT". Drawings are traceable.

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

1.8. GENERAL VERIFICATION

1.8.1. Test Work

A preliminary verification should be performed on the equipment to proceed with the following validation; identify the major components of the equipment and verify the correct installation and check the absence of any mechanical interference or problem.

1.8.2. Acceptance Criteria

Verify that there is no mechanical problem and equipment is correctly installed.

1.9. AUTOMATION VERIFICATION

1.9.1. Test Work

- Verify the functionality of the mechanical items and required interlocks.
- Besides verify also the correct sequences required by the Operator Manual/Operating Specification of the automated device.
- Verify the correct functionality of the alarm system.

1.9.2. Acceptance Criteria

The controlled system works as per Operating Manual/ Operating Specification

1.10. AIR FLOW VERIFICATION WITH SMOKE TRACER

1.10.1. Test Work

This test is performed in conformity with ISO 14644-3: TEST METHODS Annex B.7 Airflow direction Test.

In case of LAF requirements perform the following test:

- Start the ventilation in the cell and verify the unidirectional air flow by means smoke direction.

In case of turbulent air flow perform the following test:

- Fill the chamber with smoke and start the ventilation and verify that the system is able to deplete smoke from any spot and corner of the enclosure.

1.10.2. Acceptance Criteria

- For LAF chamber, the flow of the smoke generated inside the LAF from the ceiling level is unidirectional. Inside the cell/isolator the flow of air must be straight line towards the surface, without dead zones or refluxes, and without going out of the cell itself. There must be no penetrations towards the outside. In the frontal grids or openings, the air flow must go to the inside, without external refluxes and without penetrations inside of the box.
- For turbulent flows, system is able to vent uniformly and deplete smoke from any spot and corner of the enclosure.

1.11. AIR FLOW VERIFICATION WITH SMOKE TRACER

1.11.1. Test Work

This test is performed in conformity with ISO 14644-3: TEST METHODS Annex B.7 Airflow direction Test.

In case of LAF requirements perform the following test:

- Start the ventilation in the cell and verify the unidirectional air flow by means smoke direction.

In case of turbulent air flow perform the following test:

- Fill the chamber with smoke and start the ventilation and verify that the system is able to deplete smoke from any spot and corner of the enclosure.

1.11.2. Acceptance Criteria

- For LAF chamber, the flow of the smoke generated inside the LAF from the ceiling level is unidirectional. Inside the cell/isolator the flow of air must be straight line towards the surface, without dead zones or refluxes, and without going out of the cell itself. There must be no penetrations towards the outside. In the frontal grids or openings, the air flow must go to the inside, without external refluxes and without penetrations inside of the box.
- For turbulent flows, system is able to vent uniformly and deplete smoke from any spot and corner of the enclosure.

1.12. LEAK TIGHTNESS TEST

Containment enclosure acceptance test, according to the pressure change method (5.2) ISO 10648-2:1994(E) - Method taking into account corrections due to variations temperature and atmospheric pressure

1.12.1. Definitions

Containment enclosure: Enclosure designed to prevent the leakage of the products contained in the environment concerned into the external environment, or the penetration of substances of external environment into the internal environment, or both at the same time.

Hourly leak rate, Tf: Ratio between the hourly leakage F of the containment enclosure under normal working conditions (pressure and temperature) and the volume V of the said containment enclosure.

$T_f = \frac{F}{V}$	$T_f = \frac{60}{t} \cdot \left(\frac{P_n \cdot T_1}{P_1 \cdot T_n} - 1 \right)$
Hourly leak rate	**Hourly leak rate**

It is expressed in reciprocal hours.

Where:

t is the duration of the test, in minutes;

P1 is the absolute pressure (ambient pressure minus under pressure) at the first reading, in Pa;

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Pn is the absolute pressure at the last reading, in Pa;

T1 is the temperature at the first reading, in Kelvin (°C+273=K);

Tn is the temperature at the last reading, in Kelvin;

60 represents the 60 minutes in an hour.

1.12.2. Test Work

The room temperature and barometric pressure shall be measured during the test with the thermometer and barometer set up close to the containment enclosure. The containment enclosure thermometer shall be suspended in the middle of the enclosure before the final sealing of the openings. Before starting the leak test the temperature and pressure in the containment enclosure to be tested and the test room shall be allowed to stabilize. Set up the containment enclosure negative pressure to 3 times usage vacuum value and then close the extract valve.

Before starting the test, the box could be exposed to some complete pressurization and under-pressurization cycles, so as to allow the settling of the walls, of bolted joints, connections and bags passages.

When the pressure and the temperature are stabilized, isolate the containment enclosure by shutting the valves, and measure the temperature and negative pressure in the containment enclosure for 60 min at 15-minute intervals, together with the ambient pressure. The first and last readings are used for the evaluation; the intermediate readings are used to control the test conditions.

In case of test failure, find and repair the leakage using tracer gas test or bubble test.

1.12.3. Validity Range

During the test (max duration 1 h) the following conditions should be fulfilled:

- internal temperature variations shall be lower than 0,5 °C;
- atmospheric pressure variations shall be lower than 100 Pa (during the test we assume that the atmospheric pressure doesn't change);
- if possible, temperature variations of the test room should be lower than 1 °C.

If these conditions are not entirely satisfied, the test shall be repeated or an alternative method used.

Note: The influence of temperature and pressure may be summarized as: a change of 1 °C in internal temperature corresponds to a change in internal pressure of 350 Pa.

1.12.4. Acceptance Criteria

The leak tightness of the containment enclosure must comply with the rate of leakage of containment enclosure of the class it has been classified, in accordance with ISO 10648-2 when all the internal machines and interfaces are installed:

LEAK RATES:	
Class 2	$T_f < 2,5 \times 10^{-3}\ h^{-1}$
Class 3	$T_f < 1,0 \times 10^{-2}\ h^{-1}$

Note: The relevant containment enclosure class is specified in the specific test report section.

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Note: This form should be completed only if executed test has been reported.

1.13. NON-VIABLE PARTICLE COUNT

1.13.1. Test Work

This test is performed to determinate that the completed at-rest clean-air device can meet the EC GMP –The Rules Governing Medicinal Products in the European Union. Vol 4 Good Manufacturing Practice - Medicinal Products for Human and Veterinary Use – Annex 1 "Manufacture of Sterile Medicinal Products" current edition air cleanliness class specified.

This test is performed in conformity with:

ISO 14644 – Clean rooms and associated controlled environments

Part 1: Classification of air cleanliness by particle concentration Ed.2015

Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration Ed.2015

Part 3: Test methods –Annex B1 Ed.2015

A test point grid at the working level that will satisfy user requirements and be compatible with the type and operational mode of the clean air device should be established.

Note for the cleaning room: the sampling should be made placing the isokinetic probe at maximum height of 30 cm over the normal working level and at minimum height of 1 mt on the floor.

Determination of the number, locations, and grid configurations of sampling points should be based on the specified cleanliness class and the number of critical locations, present in order to obtain the desired confidence level for verification of the specified air cleanliness class.

The number of sampling point it's estimated with the following table in accordance to the ISO 14644 Part 1 Table A.1 Sampling locations related to clean room area.

Area of Zone 2]	**Nr. of Samples (ISO 14644-1:2015)2]**
2	1
4	2
6	3
8	4
10	5
24	6
28	7
32	8
36	9
52	10
56	11
64	12
68	13
72	14
76	15
104	16
108	17
116	18
148	19
156	20
192	21

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232	22
276	23
352	24
436	25
636	26
1000	27
>1000	See Formula A.1

$$N_L = 27 \times \left(\frac{A\,m^2}{1000}\right)$$

Formula A.1: Formula used to determinate the number of sampling locations

The determination of each sampling location will be based on a semi-random sampling technique, based on a "hypergeometric" distribution, which is the statistical model for sampling without replacement

Note: All measurements are made under ambient conditions; there is no induced challenge aerosol.

Non-viable particle counts (0.5 µm and larger) at rest condition has to be performed according to the EU-GMP and ISO 14644-1.

Document results in the relevant table.

The following data should be recorded:

- Particle size range,
- Volume of air sampled,
- Particle counts,
- Time,
- Sampling point locations.

Particle count data should be normalized to the number of particles per cubic meter (or cubic foot) of air. Remember to make a zero background test of the instrument at the start and at the end of the measurement.

1.13.2. Acceptance Criteria

Class	Condition	Criteria	
Class A	At rest	≤ 3.520	particles/m³ for particle size > 0.5 µm
		≤ 20	particles/m³ for particle size > 5.0 µm
		≤ 100	particles/ft³ for particle size > 0.5 µm
	In operation	≤ 3.520	particles/m³ for particle size > 0.5 µm
		≤ 20	particles/m³ for particle size > 5.0 µm
		≤ 100	particles/ft³ for particle size > 0.5 µm
Class B	At rest	≤ 3.520	particles/m³ for particle size > 0.5 µm
		≤ 29	particles/m³ for particle size > 5.0 µm
		≤ 100	particles/ft³ for particle size > 0.5 µm
	In operation	≤ 352.000	particles/m³ for particle size > 0.5 µm

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Note: This form should be completed only if executed test has been reported.

		≤ 2.900	particles/m^3 for particle size > 5.0 µm
		≤ 10.000	particles/ft^3 for particle size > 0.5 µm
		≤ 82	particles/ft^3 for particle size > 5.0 µm
Class C	At rest	≤ 352.000	particles/m^3 for particle size > 0.5 µm
		≤ 2.900	particles/m^3 for particle size > 5.0 µm
		≤ 10.000	particles/ft^3 for particle size > 0.5 µm
		≤ 82	particles/ft^3 for particle size > 5.0 µm
	In operation	≤ 3.520.000	particles/m^3 for particle size > 0.5 µm
		≤ 29.000	particles/m^3 for particle size > 5.0 µm
		≤ 100.000	particles/ft^3 for particle size > 0.5 µm
		≤ 821	particles/ft^3 for particle size > 5.0 µm
Class D	At rest	≤ 3.520.000	particles/m^3 for particle size > 0.5 µm
		≤ 29.000	particles/m^3 for particle size > 5.0 µm
		≤ 100.000	particles/ft^3 for particle size > 0.5 µm
		≤ 821	particles/ft^3 for particle size > 5.0 µm

EC GMP –The Rules Governing Medicinal Products in the European Union. Vol 4 Good Manufacturing Practice - Medicinal Products for Human and Veterinary Use – Annex 1 "Manufacture of Sterile Medicinal Products" current edition

1.14. FILTER LEAKAGE

1.14.1. Test Work

This is performed in conformity with ISO 14644 part 3: TEST METHODS Annex B.6 Installed filter leakage Test.

This test is performed to confirm that the HEPA filter system is properly installed by verifying the absence of bypass leakage in the installation, and that the filters are free of damage and small leaks. These tests are particularly important for clean-air devices intended to create clean areas classified at Class A and cleaner (according to ISO 14644).

The test is performed by introducing a challenge aerosol upstream of the filters and scanning immediately downstream of the filters and support frame. These procedures detect small holes and other damage in the filter medium and frame seal, bypass leaks in the filter frame and gasket seal, and leaks in the filter mounting.

This test must be performed both for the laminar filter and for IN and OUT filters. If a Charcoal filter is present beside the OUT filter, the test cannot be performed on the OUT filter as the charcoal dust can nullify the results.

Using a photometer, follow this method:

Record the filter identification and the filter efficiency certification number.

Measure the leakage of the filters.

FOR MAIN FILTERS: Start the fan, send the aerosol in the suction section of filter. Measure the aerosol concentration in the upstream section of the filter and verify the 100 % of solution concentration. Downstream the filter section perform the leakage test, scanning with the photometer probe the entire surface of the filter and the junction between filter and filter mounting frame.

FOR DUCTED FILTERS: Start the fan, send the aerosol in the suction section of filter. Measure the aerosol concentration in the upstream section of the filter and verify the 100 % of solution concentration. Downstream the

filter section perform the leakage test, verifying the integrity of the filter by connecting the photometer probe to the dedicated inlet, placed downstream the filter in the duct at a reasonable position.

1.14.2. Acceptance Criteria

The filter leak penetration is less than or equal to 0,05 % for H13 and 0,01 % for H14 and U15.

1.15. Air Changes per Hour Verification

1.15.1. Test Work

This test is performed in conformity with ISO 14644-3: TEST METHODS Annex B.4 Airflow Test

This test is performed to determinate the number of air changes of the Hot Cell/Isolator per hour of fan work.

Switch on the fans of the Hot Cell/Isolator and set the extraction fan. Take measurements for a minimum of 5 sec with a vane / hot wire anemometer probe on the outlet or inlet of the fan; the test is carried out with a dedicated cone pipe, which allows the introduction of the TESTO probe.

Record:

- Average air speed just outside the extraction fan
- Area of the extraction fan outlet surface
- Total volume of the Hot Cell/Isolator box

Calculate the n° of air changes per hour of the Hot Cell/Isolator, by calculating the air supply of the extraction system and dividing the obtained value to the volume of the box.

1.15.2. Acceptance Criteria

The n° of air changes per hour should be greater than 20.

1.16. Deviation Report

Describe on Attachment any deviation or anomaly found during the execution of this protocol. Define and report the corrective actions and results.

The Corrective action, when signed and dated, will give documented evidence that the system is installed and/or operates correctly. Any deviation must be closed before SAT.

1.17. Summary

Describe the summary and the conclusion of the execution of protocol.

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Note: This form should be completed only if executed test has been reported.

2. WORKING GROUP

Enter every person involved in the execution of this protocol. For each of them record:

- Name and Last Name
- Function (Professional Role)
- Company
- Role in this protocol (P = Performer; W = Witness)
- Signature
- Initials

Name	Function	Company	Role in this protocol	Signature	Initials
		Tema Sinergie	P		

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

3. SYSTEM IDENTIFICATION

Information	
Serial Number [1]:	
Installation Site:	
Customer:	
Tema Sinergie Job Order:	

([1]) Serial Number is shown on unit's identification plate or firmware. Refer to user manual for plate positioning details.

4. TEST INSTRUMENT DATA

Description	Manufacturer / Model	Serial Number	Calibration Date	Due Date	Certificate Appended [Y/N]	Att.Ref
						INST01
						INST02
						INST03
						INST04
						INST05
						INST06
						INST07
						INST08
						INST09
						INST10
						INST11
						INST12
						INST13
						INST14

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Note: This form should be completed only if executed test has been reported.

5. SYSTEM AND TECHNICAL DOCUMENTATION VERIFICATION - FLEX

5.1. GENERAL DOCUMENTATION

Document Type	Document Nr	Rev	Available [Y/N]	Att. Reference
Layout				DOC01
General Construction Drawing	120000118	02		DOC02
Electrical scheme				DOC03
Pneumatic Scheme	307010009	03		DOC04
Ventilation Scheme	305200005	06		DOC05
Manometers / Manostats Scheme	305200140	00		DOC06
Filter Integrity Test Schematic	305200290	00		DOC07
Declaration of conformity	sn DeclarationOfConformity	-		DOC08
User Manual	SYNT2 Lang. EN	1.0		DOC09
Spare Parts List	Spare Parts List			DOC10
Test on grounding system				DOC11
Hot cell cleaning	Hot Cell cleaning	2		DOC12

5.2. FILTERS DOCUMENTATION

Document Type	Filter SN	Available [Y/N]
LAF filter certificate		

Document Type	Filter SN	Available [Y/N]
Inlet filter certificate		

Document Type	Filter SN	Available [Y/N]
Outlet filter certificate		

Document Type	Filter SN	Available [Y/N]
Frontal Pre-chamber Inlet Filter certificate		
Frontal Pre-chamber Outlet Filter certificate		

Document Type	Filter SN	Available [Y/N]
Delivery Duct Inlet Filter certificate		

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

5.3. ENVIRONMENTAL SENSORS DOCUMENTATION

Document Type	Sensor SN	Sensor is present? [Y/N]	Available [Y/N]
Internal Manometer Certificate			

Document Type	Sensor SN	Sensor is present? [Y/N]	Available [Y/N]
Unidirectional Flow Anemometer Certificate			

Document Type	Sensor SN	Sensor is present? [Y/N]	Available [Y/N]
Air-renewal Anemometer Certificate			

Document Type	Sensor SN	Sensor is present? [Y/N]	Available [Y/N]
Internal Thermometer Certificate			

Document Type	Sensor SN	Sensor is present? [Y/N]	Available [Y/N]
Internal Hygrometer Certificate			

5.4. RADIATION SENSORS DOCUMENTATION

Document Type	Sensor SN	Available [Y/N]
GM Cell certificate		
GM Fumes certificate		

Acceptance Criteria:	Compliance[Y/N]
The technical documentation required is present. Certificates and schemes are traceable.	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

6. SYSTEM AND TECHNICAL DOCUMENTATION VERIFICATION - SAS

6.1. FILTERS DOCUMENTATION

Document Type	Filter SN	Attachment Reference	Available [Y/N]
Inlet filter certificate			

Document Type	Filter SN	Attachment Reference	Available [Y/N]
Outlet filter certificate			

6.2. ENVIRONMENTAL SENSORS DOCUMENTATION

Document Type	Sensor SN	Sensor is present? [Y/N]	Available [Y/N]
Internal Manometer Certificate			

Document Type	Sensor SN	Sensor is present? [Y/N]	Available [Y/N]
Air-renewal Anemometer Certificate			

6.3. ACCEPTANCE

Comments:

Acceptance Criteria:	Compliance [Y/N]
The technical documentation required is present. Certificates and schemes are traceable.	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

7. CONSTRUCTION DESIGN VERIFICATION

FLEX-SAS

Document Type	Document Number	Rev.	Available [Y/N]	Verified [Y/N]
General Construction Drawing	120000118	02		
Electrical scheme				
Pneumatic Scheme	307010009	03		
Ventilation Scheme	305200005	06		
Filter integrity test Schematic	305200290	00		

Comments:

Acceptance Criteria:	Compliance[Y/N]
The type and location of installed instruments/equipment and overall dimensions are in accordance to the drawings. The drawings relevant to this system has been verified and updated to reflect field installation "AS BUILT". Drawings are traceable.	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

8. GENERAL VERIFICATION

FLEX

Mechanical installation	**Compliance [Y/N]**
Frames	
Polycarbonate Doors and Panels	
Finishes	
Ventilation Components (connections, tubes, pipe fittings, pressure switches, etc)	

Check Mechanical interferences:	**Compliance [Y/N]**
Frontal polycarbonate door	
Pre-Chamber Drawer (if present)	
Pre-Chamber Internal Door (if present)	
Gloves (if present)	
Internal sliding doors (if present)	

Comments:

Acceptance Criteria:	**Compliance [Y/N]**
No mechanical problem has been found and equipment is correctly installed.	

SAS

Mechanical installation	**Compliance [Y/N]**
Frames	
Polycarbonate Doors and Panels	
Finishes	
Ventilation Components (connections, tubes, pipe fittings, pressure switches, etc)	

Check Mechanical interferences:	**Compliance [Y/N]**
Frontal polycarbonate door	
Pre-Chamber Drawer (if present)	
Pre-Chamber Internal Door (if present)	
Gloves (if present)	
Internal sliding doors (if present)	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Comments:

Acceptance Criteria:	**Compliance [Y/N]**
No mechanical problem has been found and equipment is correctly installed.	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9. AUTOMATION VERIFICATION

9.1. TOUCH-SCREEN DISPLAY

Activity Description	Verified [Y/N]
Check the correct functioning of display, touch-screen interface	
Check the correct functioning of the buzzer	

Comments:

9.2. DOORS

9.2.1. Interlocks

9.2.1.1 FLEX Main Chamber

Activity description	Condition	Verified [Y/N]
Opening of main shielded frontal door	No radioactivity inside --> Radioactivity probe not over threshold	

Activity description	Condition	Verified [Y/N]
Opening of main polycarbonate window	Main shielded frontal door open	
	Internal GM counter OK	
	Pre-Chamber internal port closed (door in position and gasket inflated)	
	Sliding door to SAS closed	

Comments:

9.2.1.2 FLEX Pre-Chamber

Activity description	Condition	Verified [Y/N]
Opening of Pre-Chamber Frontal Shielded Door	Internal GM counter OK	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Activity description	Condition	Verified [Y/N]
Opening of Pre-Chamber Frontal Polycarbonate Door	Pre-Chamber Frontal Shielded Door opened	
	Pre-Chamber Internal Port closed	

Activity description	Condition	Verified [Y/N]
Opening of Pre-Chamber Internal Port	Pre-Chamber clean	
	Main Chamber Clean	
	Pre-Chamber Frontal Polycarbonate Door closed	
	Main Chamber Polycarbonate Window closed	

Comments:

9.2.1.3 SAS Chamber

Activity description	Conditions	Verified [Y/N]
Opening of SAS polycarbonate window	Both Internal sliding doors closed (Door in position and gasket inflated)	
	SAS pressure set-point reached = - 200 Pa	

Activity description	Conditions	Verified [Y/N]
Opening of internal shielded sliding door (to FLEX)	SAS polycarbonate windows closed	
	FLEX Polycarbonate window closed	
	internal shielded sliding door (toFLEX) closed (door in position and inflated gasket)	
	FLEX internal GM is OK	
	SAS pressure set-point reached = - 200 Pa	
	FLEX pressure set-point reached = - 100 Pa	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Activity description	Conditions	Verified [Y/N]
Opening of internal shielded sliding door (to SAS)	SAS polycarbonate windows closed	
	FLEX Polycarbonate window closed	
	Shielded door to FLEX closed (door in position and inflated gasket)	
	FLEX internal GM is OK	
	SAS pressure set-point reached = - 200 Pa	
	FLEX pressure set-point reached = - 100 Pa	

Comments:

9.2.2. Alarms

9.2.2.1 FLEX Chamber

Event	Active alarm	Verified [Y/N]
Main polycarbonate door inflatable gasket failure	INFL. MAIN GASKET FAIL. + NOT SUFF. UNDERPRESSURE	
Pre-chamber External Door Inflatable Gasket Failure	INFL. PR. EXT. GASKET FAIL.	
Pre-chamber Internal Door Inflatable Gasket Failure	INFL. PR. INT. GASKET FAIL.	

9.2.2.2 SAS Chamber

Event	Active alarm	Verified [Y/N]
Main polycarbonate door inflatable gasket failure	INFL. MAIN GASKET FAIL. + NOT SUFF. UNDERPRESSURE	
Pre-chamber External Door Inflatable Gasket Failure	INFL. PR. EXT. GASKET FAIL.	
Pre-chamber Internal Door Inflatable Gasket Failure	INFL. PR. INT. GASKET FAIL.	
Left Internal sliding door inflatable gasket failure	ALARM INFL. LEFT GASKET.	
Right Internal sliding door inflatable gasket failure	ALARM INFL. RIGHT GASKET.	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.3. VIAL DELIVERY

Activity description	Interlock	Action	Condition	Verified [Y/N]
Stand-by - ready to accept vial			Ventilation active	
			Main shielded Door closed	
			Container in position	
			No vial in the transfer system	
			Valves close	

Activity description	Interlock	Action	Condition	Verified [Y/N]
Transferring Vial to middle position		Push button to start delivery (present in the FLEX control panel)	Door closed	
			Container in position	
			Upper valve open	
			Lower valve close	
			No Vial in down position	

Activity description	Interlock	Action	Condition	Verified [Y/N]
Transferring Vial to down position	Transferring Vial to middle position phase successful		Container in position	
			Upper valve close	
			Lower valve open	

Activity description	Interlock	Action	Condition	Verified [Y/N]
Vial in container	Transferring Vial to down position phase successful		Container in position	
			Valves close	
			Vial present in container	

Activity description	Interlock	Action	Condition	Verified [Y/N]
Get the shielded vial	Drawer automatically unlocked by successful delivery	Extract the vial by pulling the drawer		

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Comments:

9.4. INTERNAL RADIOACTIVITY PROBE

9.4.1. FLEX Interlocks

Test Description	Verified [Y/N]
Check the correct functioning and the correct positioning of the probe by approaching one test source:	
Check that value on the display increases	
When value exceeds pre-alarm threshold, check visual signals on display	
When value exceeds pre-alarm threshold, check that door opening is forbidden	
When value exceeds alarm threshold, check visual signals on display	
When value exceeds alarm threshold, check that door opening is forbidden	

Comments:

9.4.2. Alarms

	Verified [Y/N]
Disconnect probe and check alarm	
If a "GM Cell fail" alarm is present, check that door opening is forbidden	

Comments:

9.5. EXHAUST DUCT RADIOACTIVITY PROBE

This testing paragraph should be executed only in case this system is equipped with a fumes radioactivity probe in the outlet ventilation duct

	YES	NO

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Is fumes radioactivity probe present?	Proceed in this section	Skip to next section

9.5.1. Interlocks

Check the correct functioning and the correct positioning of the Radioactivity Probe by approaching one test source	**Verified [Y/N]**
Check that value on the display increases	
When value exceeds alarm threshold, check visual signals on display	
When value exceeds threshold, check that system turns off ventilation, closes inlet and outlet valve and isolates the cell for a pre-configured period of decontamination	

Comments:

9.5.2. Alarms

	Verified [Y/N]
Disconnect Radioactivity Probe counter and check alarm	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.6. LIGHTING

9.6.1. FLEX Lights

	Verified [Y/N]
Turn ON and OFF lights and check correct functioning	
Check that lights buttons change state on the display	

Comments:

9.6.2. SAS Lights

	Verified [Y/N]
Turn ON and OFF lights and check correct functioning	
Check that lights buttons change state on the display	

Comments:

9.7. U.V. LAMP

Test description	Verified [Y/N]
Turn ON and OFF U.V. lamp and check correct functioning	
Check that U.V. button change state on the display	
Check that U.V. lamp has priority on normal lights: if operator turns ON U.V., light is automatically turned OFF. If U.V. lamp is ON, operator cannot turn ON normal lights.	
Check that if shielded frontal door is open, operator cannot turn ON U.V. lamp (on display this condition is showed)	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.8. VENTILATION VERIFICATION

9.8.1. FLEX Ventilation Verification

Check that Ventilation states are automatically activated when required conditions are satisfied

9.8.1.1 Normal Working Conditions

Event	Vent Status	Verified [Y/N]
System normal working conditions	VENT_ON	
Operator stops ventilation	VENT_OFF	
Cell polycarbonate window opening	VENT_ON1	
Internal sliding door opening	VENT_ON	

Acceptance Criteria:	Compliance [Y/N]
Ventilation System works as specified	

Comments:

9.8.1.2 Alarms List

Event	Active alarm	Ventilation state	Verified [Y/N]
Inlet filter clogged (if this feature is not present, please go to the next section)	INLET FILTER CLOGGED	VENT_ON	
Outlet filter clogged (if this feature is not present, please go to the next section)	OUTLET FILTER CLOGGED	VENT_ON	
Laminar filter clogged	LAM. FILTER CLOGGED	VENT_ON	
Small leaks inside cell	NONE	VENT_ON	
Large leaks inside cell	NOT SUFF UNDERPRESSURE	VENTM1_OVERP	

Acceptance Criteria:	Compliance [Y/N]
Alarms can be simulated and messages are consistent	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.8.1.3 Internal Pressure Verification

Record the time to reach the working pressure value, once pushed the Vent button with all seals inflated.

Pressure setpoint to reach	Time to reach set point
-100	

Acceptance Criteria:	Compliance [Y/N]
System reaches internal pressure setpoints within 5 minutes	

Check if the machine can maintain the right setpoint pressure with ventilation on, doors closed and gaskets inflated:

Time	0'	5'	10'	15'	Average	Standard Deviation
Pressure (Pa)						

Acceptance Criteria:	Compliance [Y/N]
Average of recorded pressure values must be within -100 +/- 25 Pa	

Comments:

9.8.2. SAS Ventilation Verification

Check that Ventilation states are automatically activated when required conditions are satisfied

9.8.2.1 Normal Working Conditions

Event	Vent Status	Verified [Y/N]
System normal working conditions	VENT_ON	
Operator stops ventilation	VENT_OFF	
Main polycarbonate window opening	VENT_REC	
Internal sliding doors opening → FLEX	VENT_ON	

Acceptance Criteria:	Compliance [Y/N]
Ventilation System works as specified	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.8.2.2 Alarms List

Event	Active alarm	Ventilation state	Verified [Y/N]
Inlet filter clogged (if this feature is not present, please go to the next section)	INLET FILTER CLOGGED	VENT_ON	
Outlet filter clogged (if this feature is not present, please go to the next section)	OUTLET FILTER CLOGGED	VENT_ON	
Small leaks inside cell	NONE	VENT_ON	
Large leaks	NOT SUFF. UNDERPRESSURE	VENTM1_OVERP	

Comments:

9.8.2.3 Internal Pressure Verification

Record the time to reach the working pressure value, once pushed the Vent button with all seals inflated.

Pressure setpoint to reach	Time to reach setpoint

Acceptance Criteria:	Compliance [Y/N]
System reaches internal pressure setpoints within 5 minutes	

Check if the machine can maintain the right setpoint pressure with ventilation on, doors closed and gaskets inflated. The standard deviation must be < 10.

Time	0'	5'	10'	15'	Average	Standard Deviation
Pressure (Pa)						

Acceptance Criteria:	Compliance [Y/N]
Average of recorded pressure values must be within -100 +/- 15 Pa	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.9. AUTOMATIC VALVES ISOLATING SYSTEM

This testing paragraph should be executed only in case this system is equipped with an automatic valves system for inlet and outlet ventilation.

	YES	NO
Is automatic valves system present?	Proceed in this section	Skip to next section

9.9.1. Interlocks

Initial state	Event	Final state	Verified [Y/N]
Vent OFF, Vin= CLOSE, Vout= CLOSE	Start vent	Vent ON, Vin = OPENVout = OPEN	
Vent ON, Vin= OPEN, Vout= OPEN	Stop vent	Vent OFF, Vin = CLOSEVout = CLOSE	
Vent ON, Vin= OPEN, Vout= OPEN	Fumes radioactivity probe over threshold	Vin = CLOSE → after T_Delay_Vout: Vent OFF, Vout = CLOSE	

Note: GM Fumes Activity is the condition in which GM Fumes Value exceeds prealarm threshold if by-pass "GM Fumes TH" is disable, or the condition in which GM Fumes Value exceeds alarm threshold if by-pass "GM Fumes TH" is enable; when GM Fumes Activity goes ON a Decay Timer starts its count

Comments:

9.9.2. Alarms

Test description	Verified [Y/N]
Disconnect fumes radioactivity probe and check alarm "GM Fumes no signal" once IDLE TIME elapsed	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.10. COMPRESSED AIR FAILURE

9.10.1. Actions

In case of compressed air failure, check that every seal stays frozen in the state it was before failure		**Verified [Y/N]**
Polycarbonate main door inflatable seal remains inflated	FLEX	
	SAS	
Pre-chamber external door inflatable seal remains inflated	FLEX	
	SAS	
Pre-chamber internal door inflatable seal remains inflated	FLEX	
	SAS	
SAS internal sliding inflatable seal remains inflated	TO FLEX	

Comments:

9.10.2. Alarms

Event	**Active alarm**	**Verified [Y/N]**
General Compressed Air failure	GEN. COMPRESSED AIR FAIL.	

Comments:

9.11. MAIN POWER FAILURE

In case of compressed air failure, check that every seal stays frozen in the state it was before failure		**Verified [Y/N]**
Polycarbonate main door inflatable seal remains inflated	FLEX	
	SAS	
Pre-chamber external door inflatable seal remains inflated	FLEX	
	SAS	
Pre-chamber internal door inflatable seal remains inflated	FLEX	
	SAS	
SAS internal sliding inflatable seal remains inflated	TO FLEX	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Comments:

After power failure recovery, check that:	**Verified [Y/N]**
Ventilation re-starts working automatically	
Display's software is automatically reloaded	
Display visualizes a message of recently reloaded software	

Comments:

9.12. I/O BOX SIGNALS

9.12.1. Input Signals

Vent-enable:	**Verified [Y/N]**
If NOT ACTIVE (electrical contact OPEN) a visual signal "supervisor stop" on display is present	
When Vent ON, if Vent-enable goes NOT ACTIVE → Vent OFF	
When Vent-enable OFF, if Vent-enable goes ACTIVE → Vent ON	

Comments:

Active-dispensing:	**Verified [Y/N]**
If ACTIVE (electrical contact open) a visual signal "dispensing in progress" on display is present	
If activity-dispensing goes ACTIVE → Vent ON	
If activity-dispensing is ACTIVE → turn OFF the ventilation is not possible (only keep pushed the button Vent for few seconds)	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Active-delivery:	**Verified [Y/N]**
If ACTIVE (electrical contact open) a visual signal "delivery in progress" on display is present	
If ACTIVE → frontal door and frontal drawer cannot be open	

Comments:

9.12.2. Output Signals

Ventilation-status: contact normally open, that means if Vent is OFF, the contact is open, if Vent is ON contact is closed.	**Verified [Y/N]**
Pressure-status: contact normally open, that means if pressure value is not correct, the contact is open, if pressure value is correct the contact is closed.	
MAIN door-status: contact normally open, that means if frontal door is open contact is open, if frontal door is closed contact is closed.	
PRE-CHAMBER door-status: contact normally open, that means if door is open contact is open, if door is closed contact is closed.	
Cell-status: normally open, that means if there is a ventilation alarm, or a seal alarm, or a device alarm (calibrator), or a GM alarm the contact is open, if there is no alarm contact is closed.	
GMCell-status: contact normally open, that means if there is a GM Cell alarm or broken, the contact is open, if there is no alarm contact is closed.	
GMFumes-status: contact is normally open, that means if there is a GM Fumes alarm or broken, the contact is open, if there is no alarm contact is closed.	

Comments:

9.13. PROBES VERIFICATION

In this section probes installed on the equipment which are involved in the maintainment of the GMP class of the enclosure will be verified.

Check the correct functionality of the probes installed inside the cell by comparing the displayed values with the values of certificated instruments used for the test (Acceptance criteria: +/-10 %)

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

9.13.1. Internal Pressure Manometer

Probes	Value on internal probe	Value on reference instrument	S/N of reference instrument	Delta %	Compliance [Y/N]
Internal Pressure Manometer FLEX					
Internal Pressure Manometer SAS					

Acceptance Criteria:	Compliance [Y/N]
Deviation between probe reading and certified reference read value must be less than 10%	

Comments:

9.13.2. Laminar Air Flow Anemometer

This testing paragraph should be executed only in case this system is equipped with specific anemometer to monitor the laminar air flow speed.

	YES	NO
Is the LAF anemometer system present?		
	Proceed in this section	Skip to next section

Probes	Value on internal probe	Value on reference instrument	S/N of reference instrument	Delta %	Compliance [Y/N]
LAF Anemometer FLEX					

Acceptance Criteria:	Compliance [Y/N]
Deviation between probe reading and certified reference read value must be less than 10%	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Comments:

9.14. GMP LINK

This testing paragraph should be executed only in case this system is connected to a central computer that records events which occur during normal operations and alarms

	YES	NO
Is this system connected with central computer for data recording?	Proceed in this section	Skip to next section

Test description	Verified [Y/N]
Check the correct traceability of alarms and events	

Comments:

9.15. ENVIRO LINK

This testing paragraph should be executed only in case radiation probes are connected to a central computer that records the values in a specific database

	YES	NO
Is this system connected with central computer for radiation data recording?	Proceed in this section	Skip to next section

Prepare the connection using the Serial-to-Ethernet converter and check the functionality	Verified [Y/N]
Verify the communication between system and central computer and check the recorded data	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

10. AVERAGE AIRFLOW VELOCITY AND UNIFORMITY FOR THE UNIDIRECTIONAL AIRFLOW VERIFICATION

FLEX

Test instruments:	S/N	Model	Producer
Anemometer			

General Information	
Filter Dimension (m):	
Recommended Airflow Velocity (m/s):	0,36 ↔ 0,54
Average Measured Airflow velocity (m/s):	A =
Actual Flowrate (m3/h):	A x x 3600 min =
Flowrate (m3/h) on LAF Fan Control Unit (K1):	
Flowrate (m3/h) on LAF Fan Control Unit (K2):	
Flowrate (m3/h) on LAF Fan Control Unit (K3):	
Differential Pressure Read Out on LAF Fan Control Unit:	

Max Deviation = 100 * (Max air velocity - Average Measured Airflow velocity) / Average Measured Airflow velocity

Min Deviation = 100 * (Min air velocity - Average Measured Airflow velocity) / Average Measured Airflow velocity

Data Spread			
Maximum air velocity[m/s]		Maximum Deviation [%]	
Minimum air velocity[m/s]		Minimum Deviation [%]	

Here a scheme with measurements point and air velocity measures

N°	Air velocity (m/s)	N°	Air velocity (m/s)	N°	Air velocity (m/s)
1		2		3	
4		5		6	
7		8		9	

Comments:

Acceptance Criteria:	Compliance[Y/N]
Average air velocity is between 0,36 m/s and 0,54 m/s	
Deviation from average velocity for each single point: ± 20%	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

11. AIR FLOW VERIFICATION WITH SMOKE TRACER

FLEX

See related video of the smoke flow patterns:

Comments:

Acceptance Criteria	Compliance[Y/N]
The flow of the smoke generated inside chamber is unidirectional without dead zones or refluxes, and without going out of the box itself. There are no penetrations towards the outside. In the frontal grids or openings, the airflow goes to the inside, without external refluxes.	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

12. LEAK TIGHTNESS TEST

12.1. FLEX

12.1.1. Instruments List

Test instruments:	S/N	Model	Producer
Thermometer 1:			
Thermometer 2:			
Manometer 1:			

12.1.2. Final Results

Reference Leak Rates	
Class 2	$T_f < 2,5 \times 10^{-3}\ h^{-1}$
Class 3	$T_f < 1,0 \times 10^{-2}\ h^{-1}$

Calculate Hourly Leak Rate (Tf) according to formula specified in chapter description.

Absolute temperature = certified instrument measured Celsius temperature + 273.15 (°K)

Absolute pressure = certified instrument measured relative pressure + 101325 (Pa)

	Description	Value
t	Leak Test Duration (min)	60
P1	Absolute initial pressure (Pa)	
Pn	Absolute final pressure (Pa)	
T1	Absolute initial temperature (K)	
Tn	Absolute final temperature (K)	

Enclosure Class	Hourly Leak Rate Tf
Class 2	

See attached sheet Mod (M060c) LEAK.1 for data details

Comments:

Acceptance Criteria	Compliance[Y/N]
The leak tightness of the containment enclosure complies with the rate of leakage of containment enclosure of the class it has been classified, in accordance with ISO 10648-2 when all the internal machines and interfaces are installed:	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

12.2. SAS

12.2.1. Instruments List

Test instruments:	S/N	Model	Producer
Thermometer 1:			
Thermometer 2:			
Manometer 1:			

12.2.2. Final Results

Reference Leak Rates	
Class 2	$T_f < 2,5 \times 10^{-3}\ h^{-1}$
Class 3	$T_f < 1,0 \times 10^{-2}\ h^{-1}$

Calculate Hourly Leak Rate (Tf) according to formula specified in chapter description.

Absolute temperature = certified instrument measured Celsius temperature + 273.15 (°K)

Absolute pressure = certified instrument measured relative pressure + 101325 (Pa)

	Description	Value
t	Leak Test Duration (min)	60
P1	Absolute initial pressure (Pa)	
Pn	Absolute final pressure (Pa)	
T1	Absolute initial temperature (K)	
Tn	Absolute final temperature (K)	

Enclosure Class	Hourly Leak Rate Tf
Class 2	

See attached sheet Mod (M060c) LEAK.1 for data details

Comments:

Acceptance Criteria	Compliance[Y/N]
The leak tightness of the containment enclosure complies with the rate of leakage of containment enclosure of the class it has been classified, in accordance with ISO 10648-2 when all the internal machines and interfaces are installed:	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

13. NON-VIABLE PARTICLES COUNT

13.1. FLEX

Test instruments:	S/N	Model	Producer
Particle Counter			

Airlock	Classified area	Occupancy State	Test Date	Report availability [YES/NO]
	B	At Rest		

Test Data	
Considered size of particles	0,5 µm and 5,0 µm
Number of sampling point location	
Volume of air sampled	36 ft^3 = 1,02 m^3

Scheme of sampling location coordinates:

ACCEPTANCE CRITERIA AND TEST RESULTS:

Acceptance Criteria	Particles Size	particles/m^3	particles/ft^3
Class A at rest	> 0.5 µm	< 3.520	100
	> 5.0 µm	< 20	
Class B at rest	> 0.5 µm	< 3.520	100
	> 5.0 µm	< 29	
Class C at rest	> 0.5 µm	< 352.000	10.000
	> 5.0 µm	< 2.900	82
Class D at rest	> 0.5 µm	< 3.520.000	100.000
	> 5.0 µm	< 29.000	821

Considered Particles Size	Average value	UoM	Compliance to Class B (Y/N)
0,5 µm		particles/m^3	
5,0 µm		particles/m^3	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Attach here the **Non-Viable Particle Count** test report:

Acceptance Criteria	Compliance [Y/N]
The Chamber is classified as specified	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

13.2. SAS

Test instruments:	S/N	Model	Producer
Particle Counter			

Airlock	Classified area	Occupancy State	Test Date	Report availability [YES/NO]
	B	At Rest		

Test Data	
Considered size of particles	0,5 µm and 5,0 µm
Number of sampling point location	
Volume of air sampled	36 ft^3 = 1,02 m^3

Scheme of sampling location coordinates:

ACCEPTANCE CRITERIA AND TEST RESULTS:

Acceptance Criteria	Particles Size	particles/m^3	particles/ft^3
Class A at rest	> 0.5 µm	< 3.520	100
	> 5.0 µm	< 20	
Class B at rest	> 0.5 µm	< 3.520	100
	> 5.0 µm	< 29	
Class C at rest	> 0.5 µm	< 352.000	10.000
	> 5.0 µm	< 2.900	82
Class D at rest	> 0.5 µm	< 3.520.000	100.000
	> 5.0 µm	< 29.000	821

Considered Particles Size	Average value	UoM	Compliance to Class B (Y/N)
0,5 µm		particles/m^3	
5,0 µm		particles/m^3	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Attach here the **Non-Viable Particle Count** test report:

Acceptance Criteria	**Compliance [Y/N]**
The Chamber is classified as specified	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

14. FILTER LEAKAGE

14.1. FLEX

Test instruments:	S/N	Model	Producer
Photometer			
Aerosol Generator			

Acceptance Criteria:

The filter leak penetration is less than or equal to 0,05 % for H13 and 0,01 % for H14 and U15

14.1.1. Laminar Air Flow Filter

Filter Classification	Filter Identification S/N	Upstream Aerosol Concentration(20-100 µg/l)	Leakage Read-out [re%]	100 % Read-out [Cc]

Acceptance Criteria	Compliance[Y/N]
Filter performance is as specified	

Acceptance Criteria	Compliance [Y/N]
Filter Leak penetration less or equal to relevant compliance value	

Comments:

14.1.2. Inlet Filter

Filter Classification	Filter Identification S/N	Upstream Aerosol Concentration(20-100 µg/l)	Leakage Read-out [re%]	100 % Read-out [Cc]

Acceptance Criteria	Compliance[Y/N]
Filter performance is as specified	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

Acceptance Criteria	Compliance [Y/N]
Filter Leak penetration less or equal to relevant compliance value	

Comments:

14.1.3. Outlet Filter

Filter Classification	Filter Identification S/N	Upstream Aerosol Concentration(20-100 µg/l)	Leakage Read-out [re%]	100 % Read-out [Cc]

Comments:

Note: If a Charcoal filter is present beside the OUT filter, the test cannot be performed on the OUT filter as the charcoal dust can nullify the results.

Acceptance Criteria	Compliance[Y/N]
Filter performance is as specified	

14.2. SAS

Test instruments:	S/N	Model	Producer
Photometer			
Aerosol Generator			

Acceptance Criteria:

The filter leak penetration is less than or equal to 0,05 % for H13 and 0,01 % for H14 and U15

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

14.2.1. Inlet Filter

Filter Classification	Filter Identification S/N	Upstream Aerosol Concentration(20-100 µg/l)	Leakage Read-out [re%]	100 % Read-out [Cc]

Acceptance Criteria	Compliance[Y/N]
Filter performance is as specified	

Comments:

14.2.2. Outlet Filter

Filter Classification	Filter Identification S/N	Upstream Aerosol Concentration(20-100 µg/l)	Leakage Read-out [re%]	100 % Read-out [Cc]

Note: If a Charcoal filter is present beside the OUT filter, the test cannot be performed on the OUT filter as the charcoal dust can nullify the results.

Acceptance Criteria	Compliance[Y/N]
Filter performance is as specified	

Comments:

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

15. AIR CHANGES

15.1. FLEX

Test Instruments:	S/N	Model	Producer
Anemometer			

Is a Funnel for measuring volume flow present?

- If PRESENT please proceed with relative paragraph
- If NOT PRESENT please proceed with relative paragraph

15.1.1. Calculation Method with Funnel

Volume Flow is measured by means of particular funnel model: Testovent-410. See attachment AIRCH-01.

Variables	Calculation
A: Testovent Funnel factor:	22
B: Total Volume of the box (m^3)	0,298
C: Air velocity (m/s)	
D: Flow rate (m^3/h) (A x C)	
N° of air changes per hour = D / B	

15.1.2. Calculation Method without Funnel

Without funnel, the measurement of air velocity is directly taken on extraction conduit

Variables	Calculation
r: Conduit internal radius (m)	
A: Conduit internal section	A = π r^2 = 3,14 x ..... = ... m^2
B: Total Volume of the box (m^3)	0,298
C: Measured air velocity (m/s)	
D: Resulting flow rate (m^3/h)	A x C = ... (m^2) x ..... (m/s]) = ... x 3600 = ... m^3/h
N° of air changes per hour	D / B = ... (m^3/h) / ..... (m^3) = ... Air changes per hour

Comments:

Acceptance Criteria	Compliance [Y/N]
The Air Change Rate meets Acceptance Criteria (≥ 20 air changes per hour)	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

15.2. SAS

Test Instruments:	S/N	Model	Producer
Anemometer			

Is a Funnel for measuring volume flow present?

- If PRESENT please proceed with relative paragraph
- If NOT PRESENT please proceed with relative paragraph

15.2.1. Calculation Method with Funnel

Volume Flow is measured by means of particular funnel model: Testovent-410. See attachment AIRCH-01.

Variables	Calculation
A: Testovent Funnel factor:	22
B: Total Volume of the box (m^3)	
C: Air velocity (m/s)	
D: Flow rate (m^3/h) (A x C)	
N° of air changes per hour = D / B	

15.2.2. Calculation Method without Funnel

Without funnel, the measurement of air velocity is directly taken on extraction conduit

Variables	Calculation
r: Conduit internal radius (m)	
A: Conduit internal section	A = π r^2 = 3,14 x ..... = ... m^2
B: Total Volume of the box (m^3)	
C: Measured air velocity (m/s)	
D: Resulting flow rate (m^3/h)	A x C = ... (m^2) x ..... (m/s]) = ... x 3600 = ... m^3/h
N° of air changes per hour	D / B = ... (m^3/h) / ..... (m^3) = ... Air changes per hour

Comments:

Acceptance Criteria	Compliance [Y/N]
The Air Change Rate meets Acceptance Criteria (≥ 20 air changes per hour)	

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

16. DEVIATION REPORT

Section Reference:

Name	Signature	Company	Date

Corrective Action:

Name	Signature	Company	Date

Corrective Action Results:

Conclusions:		
Did the corrective action solved the deviation?	YES	NO

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.

17. SUMMARY

	[Y/N]
Was the protocol fully performed and passed?	

Comments:

END OF PROTOCOL

Performed By:	Date	Witnessed By:	Date

Note: This form should be completed only if executed test has been reported.