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OPERATIONAL QUALIFICATION FOR DYNAMIC PASSBOX

PROJECT: NEW HOTLAB AT SUBANG JAYA MEDICAL CENTRE,
SUBANG JAYA, SELANGOR DARUL EHSAN.

APPROVAL OF PROTOCOL			
Signatures below signify that both vendor and client have read, understand, and agree with the content of this document. Approval of protocol must be granted by both parties before its execution.			
This document was prepared and approved by the below representatives from Lufter Sdn. Bhd.			
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Wong Peng Peng	Validation Executive		17-Oct-2022
Reviewed by: Ahmad Aslam	Assistant Manager		17-Oct-2022
Reviewed by: Koh Soon Yong	Project Manager		17-Oct-2022
By signing below, Subang Jaya Medical Centre confirms that all their requirements for this project have been reflected in this document.			
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by: Quek Kiat Hoe	Deputy Chief Pharmacist		11 NOV 2022
Reviewed by:		N/A	
Approved by: Steven	Manager		21 Nov 2022

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1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	L-SJMC02-HTL-VD-URS-R00	User Requirement Specification - New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.
2.	L-SJMC02-HTL-VD-DQ-R00	Design Qualification, New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.
3.	L-SJMC02-HTL-VD-IQ-DPB-01-R00	Installation Qualification for Dynamic Passbox, New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	21 NOV 2022	Peng Peng	New

3.0 INTRODUCTION AND SCOPE

This document qualifies the new dynamic passbox operation at the New Hotlab within the Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan. Dynamic passbox to be in compliance with the principle of American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), PIC/S Guide to Good Manufacturing Practice for Medicinal Products, PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments. The system has been assessed and categorized as "Direct Impact".

4.0 PURPOSE

This document is created to verify the ability of all the critical components in the dynamic pass box system to operate as per the measures in the approved design and specifications.



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5.0 ROLES & RESPONSIBILITY

The following personnel have been designated to prepare, execute, review and approve the protocol.

Company	Job Title	Responsibility
Subang Jaya Medical Centre	Client Representative	To provide approval to the submitted protocol/ report. To ensure all relevant technical specifications in vendor's documents are correct. To review the validation protocol/ report.
Lufter Sdn. Bhd.	Project Manager Project Engineer Validation Executive	To evaluate vendor's design against the URS. To execute the approved validation protocol. To prepare and ensure the validation protocol is reviewed and approved before execution.
TecnicAire Services Sdn. Bhd.	3 rd Party NEBB Tester	To conduct cleanroom performance testing in accordance to NEBB standards. To provide cleanroom performance testing report and certification.



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6.0 ABBREVIATIONS

No.	Term/Abbreviation	Definition
1.	A/C	Acceptance Criteria
2.	ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
3.	CFU	Colony-Forming Unit
4.	Cert	Certificate
5.	c/w	Come With
6.	D	Depth
7.	DQ	Design Qualification
8.	DPB	Dynamic Passbox
9.	H	Height
10.	HEPA	High-Efficiency Particulate Air
11.	IQ	Installation Qualification
12.	ISO	International Standardization for Organization
13.	m/s	Meter Per Second
14.	NC	Not Controlled
15.	No	Number
16.	NEBB	National Environmental Balancing Bureau
17.	OQ	Operational Qualification
18.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
19.	Ref	Reference
20.	t	Thickness
21.	URS	User Requirement Specification
22.	W	Width

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7.0 SYSTEM DESCRIPTION

7.1 Dynamic Passbox

Three (3) units of dynamic passbox are installed to protect the controlled environment from being polluted while the transfer of a material take place. The dynamic passbox is fitted with primary G2 filters (washable) at the side return and bottom return, whereas one (1) unit of fan filter unit is fitted with HEPA filter grade H13 to prevent cross contamination.

In addition, the dynamic passbox has an electromagnetic interlocking system to prevent both doors to be opened at the same time and also to prevent the cross contamination. Indicator lamp is installed at both side of the dynamic passbox to indicate if any door is open. When the dynamic passbox is locked, the red color indicator lamp will appear. In another condition, the green color indicator lamp will appear while the door is opened. The dynamic passbox also equipped with electrical buzzer for communication purposes in between two areas. The external casing of dynamic passbox is constructed of electro-galvanised come with epoxy powder coated.

Dynamic passbox located at Radioiodine adjacent to NM-202 Inject 1 equipped with additional 2mm(t) lead sheet laminated at one side of the dynamic passbox.

7.2 Dynamic Passbox (DPB) Specification

Description	Specification
Location	DPB1: Radioiodine adjacent to Decay Room DPB2: Clean Corridor adjacent Component Prep. Room DPB3: Radioiodine adjacent to NM-202 Inject 1
Material of Construction	1. External casing: Electro-galvanised c/w Epoxy Powder Coated 2. Internal casing: Stainless Steel 304 – 4B Finished
Dimension	1. Internal size: 350mm(W) x 700mm(D) x 450mm(H) 2. External size: 650mm(W) x 790mm(D) x 1250mm(H)
Color	White SG
Window	5mm(t) Clear Acrylic Sheet
Filtration	1. G2 Primary Filter (Washable) - 2 pieces (Side Return & Bottom Return) 2. Fan Filter Unit (H13) - 1 unit
Locking System	Electromagnetic Interlocking System
Release Button	LED ring flat type push button (release door)
Communication	Electric buzzer c/w flat type stainless steel button
Indicating Light	Red – Locked Condition
	Green – Opened Condition

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8.0 SYSTEM BOUNDARIES

The operational qualification covers at the minimum the following equipment/components:

- a) Air Parameter for the Dynamic Passbox

9.0 TEST SHEETS

This section details the checks to be carried out in support of the system.

A/C Ref.	Test Sheet Title	Test No.
1	Documentation Verification– Protocol Review	OQ-01
2	Device Functionality – Filter Integrity Verification (HEPA Filter)	OQ-02
3	Performance Verification – Air Velocity Test	OQ-03
4	Performance Verification – Particle Count Verification	OQ-04
5	Performance Verification – Total Microbial Count Test	OQ-05
6	Support – Procedure Verification	OQ-06
7	Support - Change Control Record	OQ-07



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10.0 TESTING RATIONALE

Ref.	Acceptance Criteria	Rationale
1	The previous stages of commissioning & qualification have been completed; any unresolved snags/deviations must be documented and have no impact on the tests in this protocol.	To provide documented evidence that all necessary commissioning/qualification required prior to the operation of this system have been completed.
2	The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.	To provide documented evidence that the HEPA filters have pass the leak test and meet the design requirements.
3	The air velocity is within the acceptable range specified in the design requirements.	To provide documented evidence that the air velocity is within the acceptable range and meets the design requirements.
4	Air particle count in dynamic passbox is within the acceptable range specified in the design specification.	To provide documented evidence that the air particle count in dynamic passbox is within acceptable range and meets the design requirements.
5	Total microbial count (cfu/m ³) in dynamic passbox are within the recommended limits for microbiological monitoring of cleanrooms according to PIC/S_PE 009-16 Annexes 1.	To provide documented evidence that the total microbial count in dynamic passbox is within limits according to PIC/S_PE 009-16 Annexes 1 standards.
6	Operation, maintenance and cleaning documentations have been completed and available. Equipment logbooks are also available.	To provide documented evidence that all documentations required for operation, maintenance and cleaning of the system are complete and available.
7	Records are available for all changes made to the system throughout the execution of this checking procedure and further tests required after the changes made have been conducted.	To provide documented records of all changes made to the system upon installation.



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Title:		Documentation Verification- Protocol Review			Test No: OQ-01
Objective:		To provide documented evidence that all necessary commissioning/ qualification required prior to the operation of this system have been completed.			
Pre-requisites:		All documents should be reviewed and approved.			
Method:		1. Locate the completed system reports and executed protocol tests/ checks. 2. Confirm approval status and any conditions which may affect current test executions (conditionally approved or unconditionally approved) in the results table below.			
Acceptance Criteria:		1. The previous stages of commissioning & qualification have been completed. 2. Any unresolved deviations must be documented. 3. Unresolved deviation shall not have an impact on the test in this protocol.			
Results:					
Protocol Type	Protocol Title	Protocol Ref.	Protocol Version	Approval Date	Verified By (Initial & Date)
Validation	Installation Qualification for dynamic Passbox, New Hotlab at SJMC	L-SJMC02-H7L-VD-ID-DPB-01	R00	13-Feb-2023	H 13-Mar-2023



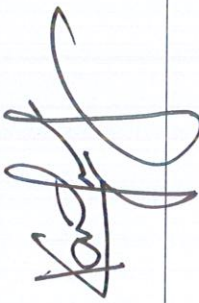
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Title:	Documentation Verification- Protocol Review	Test No: OQ-01
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Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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Title:	Device Functionality – Filter Integrity Verification (HEPA Filter)				
Objective:	To provide documented evidence that the HEPA filters have pass the leak test and meet the design requirements.				
Pre-requisites:	System commissioning and balancing has been completed.				
Method:	1. The filters' face velocities were determined to ensure that they were within the general design range. 2. The digital aerosol photometer and the aerosol generator were set-up according to the manufacturer's specification. 3. PAO-4 aerosol was generated with the aerosol generator and introduces at the upstream of the filters. 4. Measure the upstream concentration in $\mu\text{g}/\text{liter}$, immediately upstream of the filter being tested. Adjustment made, if necessary, to ensure concentration is within preferred range. 5. The digital aerosol photometer was setup for downstream penetration measurement once the upstream concentration was satisfied and set. 6. Scan the filter using a rectangular sampling probe by holding the probe approximately 25mm from frame and filter surface at a rate of approximately 50mm/s. 7. The upstream challenge concentration was sampled again to ensure consistency of the challenge throughout the test upon completion of the tests.				
Acceptance Criteria:	The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.				



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Title: Device Functionality – Filter Integrity Verification (HEPA Filter)			Test No: OQ-02		
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Results:

Equipment Ref.	Filter Ref.	Location	Acceptance Criteria	Actual Result		Verified By (Initial & Date)
				Upstream Challenge	Downstream Penetration %	
DPB1	HF-DPB-01	Radioiodine adjacent to Decay Room	Downstream penetration % is $\leq 0.1\%$ of upstream concentration	21	Media: 0.002 Gasket: 0.004	13-mar-2023
DPB2	HF-DPB-02	Clean Corridor adjacent Component Prep. Room	Downstream penetration % is $\leq 0.1\%$ of upstream concentration	23	Media: 0.001 Gasket: 0.005	13-mar-2023
DPB3	HF-DPB-03	Radioiodine adjacent to NM-202 Inject 1	Downstream penetration % is $\leq 0.1\%$ of upstream concentration	14	Media: 0.003 Gasket: 0.005	13-mar-2023

Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-mar-2023
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Title: Performance Verification – Air Velocity Test					
Objective: To provide documented evidence that air velocity is within acceptable range and meets the design requirements.					
Pre-requisites: None					
Method: 1. Filter(s) was divided into two test grids each for dynamic passbox. 2. The balometer was setup with the VelGrid attachment for automatic compensation of air density variation. 3. The VelGrid, having a dimension of 350 mm x 350 mm, was placed at the center of the grid, with the VelGrid's 150 mm standoff spacers just touching the outlet filter surface. The VelGrid's sides were to maintain parallel to the filter edges. 4. One reading was taken for each grid. 5. The airflow average of the dynamic passbox computed from these data.					
Acceptance Criteria: The air velocity is within the acceptable range specified in the design requirements.					
Results:					
Equipment Description	Location	Acceptance Criteria	Actual Result	Verified By (Initial & Date)	
Dynamic Passbox 1 (DPB1)	6 inches below from HEPA filter face	0.45 m/s $\pm$ 20%	0.53	HA 13-MAR-2023	
Dynamic Passbox 2 (DPB2)	6 inches below from HEPA filter face	0.45 m/s $\pm$ 20%	0.50	HA 13-MAR-2023	
Dynamic Passbox 3 (DPB3)	6 inches below from HEPA filter face	0.45 m/s $\pm$ 20%	0.49	HA 13-MAR-2023	



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Title: Performance Verification – Air Velocity Test

Test No: OQ-03

Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)

Verified By (Signature):

Date:

13 - Mar - 2023

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Title:	Performance Verification – Particle Count Verification	Test No: OQ-04
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Objective:

To provide documented evidence that the air particle count in dynamic passbox is within acceptable range and meets the design requirements.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. The dynamic passbox was purged for at least 1 hour before testing commences.
2. The number of the test grid is determined by working area in m² as per ISO 14644-1:2015(E) Table A.1.
3. The sample time was set to 1 minute (Solair 3100) for Grade D per sample with the counters' sample rate at 28.3 lpm under at rest condition.
4. The sample time was set with the counter sample rate under at rest condition.
5. A minimum of 1 sample was taken at the center of each grid, at a height of 1 meter above the floor for dynamic pass box at working level. When the count was greater than 75% of the allowable count limit, 3 samples was taken at that sample location.
6. When an obstruction was encountered, the sample was taken at 300 mm above the obstruction.
7. The average was computed from the collected data.

Acceptance Criteria:

Air particle count in dynamic passbox is within the acceptable range specified in the design specification.

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Title:	Performance Verification – Particle Count Verification	Test No: OQ-04
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Results:

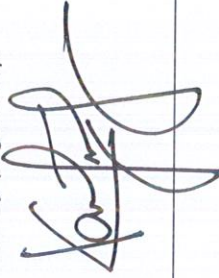
Equipment Description	Design Classification	Condition of Dynamic Passbox	Mean Particle Count/m ³ (particle size ≥0.5 µm)		Mean Particle Count/m ³ (particle size ≥5 µm)		Verified By (Initial & Date)
			Acceptance Criteria	Actual Result	Acceptance Criteria	Actual Result	
Dynamic Passbox 1 (DPB1)	ISO 8	At Rest	≤3,520,000	0	≤29,300	0	13-Mar-2023
Dynamic Passbox 2 (DPB2)	ISO 5	At Rest	≤3,520	0	Not specified	0	13-Mar-2023
Dynamic Passbox 3 (DPB3)	ISO 8	At Rest	≤3,520,000	0	≤29,300	0	13-Mar-2023

Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)

Verified By (Signature):



Date:

13-Mar-2023



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Title: Performance Verification – Total Microbial Count Test

Test No: OQ-05

Objective:

To provide documented evidence that the total microbial count in dynamic passbox is within limits according to PIC/S_PE 009-16 Annexes 1 standards.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. The airborne viable micro-organism monitoring is conducted by using impaction technique (air sampling) followed by laboratory incubation on sampled test media for micro-organism growth if any.
2. Total bacteria count is enumerated by using Tryptic Soy Agar (TSA) incubated at 35°C for 5 days.
3. Total fungal count is enumerated by using Sabouraud Dextrose Agar (SDA) incubated at 25°C for 7 days.
4. A pre-set sampler volumetric impact flow of 100 liters/min is used to expose the media and the respective plates incubated at the specific condition above.
5. At the end of the incubation cycle, the number of colony form unit (cfu) present on the media plate is counted and expressed in cfu/m³ using Feller's Statistical Correction formula.
6. The results obtained are compared against the prevailing standard adopted from PIC/S_PE 009-16 Annexes 1 for Total Viable Micro-organism (cfu/m³).
7. The microbial certificates of analysis will be out on the 9 days of both bacterial and fungal counts result obtained.

Acceptance Criteria:

Total microbial count (cfu/m³) in dynamic passbox are within the recommended limits for microbiological monitoring of cleanrooms according to PIC/S_PE 009-16 Annexes 1.



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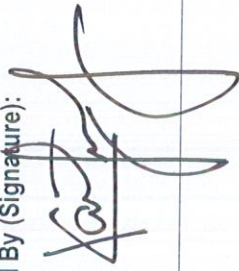
Title: Performance Verification – Total Microbial Count Test			Test No: OQ-05
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Results:

Equipment Description	Design Classification	Condition of Dynamic Passbox	Total Microorganism Count (cfu/m ³)		Verified By (Initial & Date)
			Acceptance Criteria	Actual Result	
Dynamic Passbox 1 (DPB1)	ISO 8	At Rest	≤ 200	3	HA 13-Mar-2023
Dynamic Passbox 2 (DPB2)	ISO 5	At Rest	≤ 10	1	HA 13-Mar-2023
Dynamic Passbox 3 (DPB3)	ISO 8	At Rest	≤ 200	6	HA 13-Mar-2023

Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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Title:	Support – Procedure Verification				Test No: OQ-06
Objective:	To provide documented evidence that all documentations required for operation, maintenance and cleaning of the system are complete and available.				
Pre-requisites:	Operation & Maintenance Manual should be available.				
Method:	Review the Operation, Maintenance and Cleaning procedures and equipment logbooks available for the system. Record the document title, document reference and issue date.				
Acceptance Criteria:	1. Operation, maintenance and cleaning documentations have been completed and available. 2. Equipment logbooks are also available.				
Results:					
Document Title	Document Ref.	Issue Date	Verified by (Initial & Date)		
Operation and Maintenance Manual.	L-SJMC02 - HTL-VD - OQm-Rev N/A	01-Nov-2023	AA 13-Nov-2023		



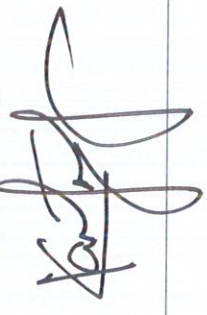
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Title:	Support – Procedure Verification	Test No: OQ-06
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Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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Title:	Support – Change Control Record	Test No: OQ-07
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Test No: QQ-07

To provide documented records of all changes made to the system upon installation.

All approved change form must be attached.

1. Record each change made to the system during the completion of the protocol. Record the change reference, a brief description of the change and the date of the change. Clearly and concisely outline what needs to be changed, so the impacted areas can review and analyze.
2. Review the changes made to the system and determine whether further testing is required. If further testing is required determine whether this has been completed satisfactorily.

1. Records are available for all changes made to the system throughout the execution of this checking procedure.
2. Further tests required after the changes made have been conducted.

Change Ref.	Description of Change	Date of Change (dd-mm-yyyy)	Further Testing Required (Yes/No)	Further Testing Complete (Yes/No)	Verified By (Initial & Date)
	N/A	13-Mar-2023			



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Title:	Support – Change Control Record	Test No: OQ-07
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Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13 - Mar - 2023
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11.0 ACCEPTANCE CRITERIA SUMMARY

This section, detailing system specific Acceptance Criteria (A/C), should be completed following a review of the test sheets, within Section 8, and supporting data, contained within the referenced project files.

Pre-requisite

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
1	The previous stages of commissioning & qualification have been completed; any unresolved snags/deviations must be documented and have no impact on the tests in this protocol.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023

Operational

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
2	The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
3	The air velocity is within the acceptable range specified in the design requirements.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
4	Air particle count in dynamic passbox is within the acceptable range specified in the design specification.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
5	Total microbial count (cfu/m ³) in dynamic passbox are within the recommended limits for microbiological monitoring of cleanrooms according to PIC/S_PE 009-16 Annexes 1.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023

Support

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
6	Operation, maintenance and cleaning documentations have been completed and available. Equipment logbooks are also available.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023

Additional

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
7	Records are available for all changes made to the system throughout the execution of this checking procedure and further tests required after the changes made have been conducted.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023

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12.0 TRAINING VERIFICATION

Training attendance record of end-user and/or other relevant personnel(s) who underwent training by Lufter Sdn. Bhd. on the system operations, maintenance and brief troubleshooting methods.

Name of Trainee	Description of Training Provided	Date of Training	Training Cert. Ref.
	Refer to Training Attendance List		

13.0 TEST INSTRUMENT RECORD

A record of all test instruments used during Operational Qualification, ensuring all instruments have valid calibration certificates.

Test Instrument Description	Instrument Serial No.	Calibration Date	Calibration Frequency	Calibration Cert. No.	Calibration Cert. Location	Initial & Date
Digital Aerosol Photometer	23084	26-Apr-2022	Yearly	CPSG-A7KAL-21-22-025	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	14-Dec-2022	Yearly	PSYN-22081570	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	13-Jan-2023	Yearly	PSYN-23003342	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	07-Dec-2022	Yearly	PSYP-22081575	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	30-Jan-2023	Yearly	PSYP-23003340	Refer to CPT report	13-Mar-2023
Airborne Particle Counter	120804004	11-Aug-2022	Yearly	CR-220811-0633MA	Refer to CPT report	13-Mar-2023
Anemometer	2203130024	29-Mar-2022	Yearly	44649220330021	Refer to CPT report	13-Mar-2023
		N/A				13-Mar-2023

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14.0 SIGNATURE RECORD

A record of all key personnel(s) involved in the completion of the Operational Qualification.

Name	Company	Signature	Date (dd-mmm-yyyy)
Wanin Pavin Pavin	Lufter Soln Bhd		13-Mar-2023
	N/A		13-Mar-2023



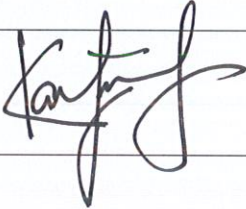
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15.0 POST-EXECUTION APPROVAL

CONDITIONAL ACCEPTANCE

The system operational checks have been reviewed. All testing associated during Operational Qualification are completed with all criteria being met. Any deviations that were noted (if any) have been resolved and closed out.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by:			
Reviewed by:		N/A 13-Mar-2023	
Approved by: Steven	Manager		13-Mar-2023



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16.0 DEVIATION LIST

Summary of all the deviations documented throughout the execution of the Operational Qualification.

NIA
11
13-mar-2023



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DEVIATION REPORT

Report no.:

A. Description of Deviation:

Documented By:

Date:

RESPONSE

A. Reason of Deviation:

B. Correction/preventive action to be taken:

N/A
13-Nov-2022

Evaluation by:

Signature

Date (dd-mmm-yyyy)

Reviewed By:

ACCEPTANCE

C. Corrective/preventive action taken:

Performed by:

Signature

Date (dd-mmm-yyyy)

Performed By:

Reviewed By:

Approved By:

Note: This page to be re-printed as required



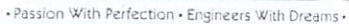
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17.0 LIST OF ATTACHMENTS

List of attachments should include all the supporting evidence and deviation reports.

[illegible]

[illegible]