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INSTALLATION QUALIFICATION FOR ACTIVE 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 Lufiter 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 Hwe	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.

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 active passbox installation for the New Hotlab within the Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan. Active 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 justify that the critical components in the active passbox have been installed as per the requirements in the design qualification and all necessary supporting documents are in place.

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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 review the IQ protocol/report. To provide approval to the submitted IQ protocol/ report. To review vendor's specification against the approved quotation. To provide approval to the submitted documents. To ensure all relevant technical specifications in vendor's documents are correct. To verify and approve all results of the IQ report.
Lufter Sdn. Bhd.	Validation Executive Project Manager Project Engineer	To prepare the IQ protocol. To execute qualification according to approved protocol.

6.0 ABBREVIATIONS

No.	Term/Abbreviation	Definition
1.	A/C	Acceptance Criteria
2.	AHU	Air Handling Unit
3.	APB	Active Passbox
4.	ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
5.	Cert	Certificate
6.	C/W	Come With
7.	D	Depth
8.	DQ	Design Qualification
9.	H	Height
10.	HEPA	High-Efficiency Particulate Air
11.	IQ	Installation Qualification
12.	ISO	International Standardization for Organization
13.	NC	Not Controlled
14.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
15.	Ref	Reference
16.	t	Thickness
17.	URS	User Requirement Specification
18.	W	Width

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7.0 SYSTEM DESCRIPTION

7.1 Active Passbox

Three (3) units of active passbox are installed between two different classified areas for material pass through. This function is to protect the controlled environment from being polluted while the transfer of a material is taking place. The active passbox is fitted with primary G2 filters (washable) at the side return and bottom return, whereas HEPA filter grade H13 come with housing are to prevent cross contamination.

In addition, the active 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 active passbox to indicate if any door is open. When the active 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 active passbox also equipped with electrical buzzer for communication purposes in between two areas. The external casing of active passbox is constructed of electro-galvanised come with epoxy powder coated.

7.2 Active Passbox (APB) Specification

Description	Specification
Location	APB1: Clean Corridor adjacent to Decay Room APB2: Component Prep. Room adjacent to Med Prep Area APB3: Clean Corridor adjacent to QC Room
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: 400mm(W) x 500mm(D) x 450mm(H) 2. External size: 850mm(W) x 590mm(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. H13 HEPA Filter c/w housing - 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

Table 1: Specification for Active Passbox



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7.3 Active Passbox (APB) Operating Conditions

Table **Error! Reference source not found.** below shows the active passbox parameters designed to meet the design parameters required as stated in the URS document (L-SJMC02-HTL-VD-URS-R00; under section 8.2).

AHU	Equipment Description	Equipment No.	Room ISO Classification	Pressure (Pa) (ref. atmosphere)	Relative Humidity (%)	Temperature (°C)
AHU-1	Active Passbox 1	APB1	ISO 7	35	50 – 60	18 - 22
	Active Passbox 2	APB2	ISO 8	25	50 – 60	18 - 22
	Active Passbox 3	APB3	ISO 7	35	50 – 60	18 - 22

8.0 SYSTEM BOUNDARIES

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

- Active Passbox



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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	Design - Design Documentation Record (General)	IQ-01
2	Active Passbox Features Verification	IQ-02
3	Documentation Verification - Calibration Verification Record	IQ-03
4	Documentation Verification - Filter Grade Certification	IQ-04
5	Installation Verification - HEPA Filter Installation	IQ-05
6	Installation Verification (System) - Installation Against Drawing	IQ-06
7	Installation Verification – Active Passbox Installation	IQ-07
8	Support - Change Control Record	IQ-08

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10.0 TESTING RATIONALE

Ref.	Acceptance Criteria	Rationale
1	Approved system design documentation is available.	To provide documented evidence that all required design documentation(s) is complete and has been approved by the relevant parties.
2	The data on all features of active passbox is consistent with the design specification.	To provide documented evidence that the data on features requirements conforms to the design specification.
3	A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.	To provide documented evidence that all critical instruments have been calibrated.
4	Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.	To provide documented evidence that all HEPA filters conforms to their target efficiency and are able to satisfy the design requirements.
5	HEPA filters of the correct grade have been installed and are their efficiencies are not compromised during the installation process.	To provide documented evidence that all HEPA filters are able to perform as per the design requirement upon installation.
6	The installation of all mechanical work is as per the approved design layout.	To provide documented evidence that the mechanical work has been installed according to the approved design layout.
7	The construction of active passbox installation complies with the safety standard.	To provide documented evidence to proof the safety of active passbox installation.
8	Records for all changes made to the system throughout the execution of this checking procedure are available 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:	Design – Design Documentation Record (General)	Test No: IQ-01
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Objective:
To provide documented evidence that all required design documentation(s) are available and has been approved by the relevant parties.

Pre-requisites:
All documents should be reviewed and approved.

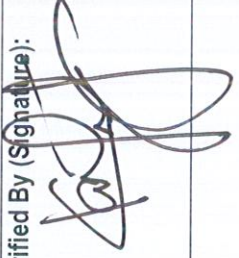
Method:
Record details of the design documentation; include the document reference, title, version, and status and approval date.

Acceptance Criteria:
Approved system design documentation is available.

Results:

Document Type	Document Ref.	Document Title	Document Version	Document Status	Approval Date	Verified By (Initial & Date)
Validation	L-SJMC02-HTL-VD-DQ	Design Qualification	00	Approved	24-Aug-2022	10-Feb-2023
		N/A				
		13-Feb-2023				

Comments/Deviations/Supporting Documentation:
NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Feb-2023
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Installation Qualification	Doc. No. Rev. No.	L-SJMC02-HTL-VD-IQ-APB-01 00	Effective Date Total Page(s)	21 NOV 2022 10 of 35

Title: Active Passbox Features Verification		Test No: IQ-02
Objective: To provide documented evidence that the data on features requirements conforms to the design specification.		
Method: Check the active passbox and compare against the design specification.		
Acceptance Criteria: The data on all features of active passbox is consistent with the design specification.		

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Title:	Active Passbox Features Verification	Test No: IQ-02
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Results:

Equipment Name	Design Specification	Acceptance Criteria	Actual	Conformity (Yes/No)	Verified By (Initial & Date)
Active Passbox 1 (APB1)	Material (External)	Electroplated c/w Epoxy Powder Coated	Electroplated c/w Epoxy Powder Coated	Yes/No	HA 13-Feb-2023
	Material (Internal)	Stainless Steel 304 4B finished	Stainless Steel 304 4B finished	Yes/No	HA 13-Feb-2023
	HEPA Filter Grade	H13	H13	Yes/No	HA 13-Feb-2023
	Primary Filter Grade	G2	G2	Yes/No	HA 13-Feb-2023
	PAO Test Port	Available	Available	Yes/No	HA 13-Feb-2023
	Differential Pressure Model for HEPA Filter	Minihelic Differential Pressure Gauge	Minihelic Differential Pressure Gauge	Yes/No	HA 13-Feb-2023
	Differential Pressure Model for Active Passbox	Magnehelic Differential Pressure Gauge	Magnehelic Differential Pressure Gauge	Yes/No	HA 13-Feb-2023
	Light Indicator	Green, Red	Green, Red	Yes/No	HA 13-Feb-2023
	Power Source (v/p/f)	230/1/50	230/1/50	Yes/No	HA 13-Feb-2023
	Internal	Width = 400 mm	400 mm	Yes/No	HA 13-Feb-2023
		Depth = 500 mm	500 mm	Yes/No	HA 13-Feb-2023
		Height = 450 mm	450 mm	Yes/No	HA 13-Feb-2023
	External	Width = 850 mm	850 mm	Yes/No	HA 13-Feb-2023
		Depth = 590 mm	590 mm	Yes/No	HA 13-Feb-2023
		Height = 1250 mm	1250 mm	Yes/No	HA 13-Feb-2023



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Active Passbox Features Verification				Test No: IQ-02	
Equipment Name	Design Specification	Acceptance Criteria	Actual	Conformity (Yes/No)	Verified By (Initial & Date)
Active Passbox 2 (APB2)	Material (External)	Electrogalvanized c/w Epoxy Powder Coated	Electrogalvanized c/w Epoxy Powder Coated	Yes/No	13-Feb-2023
	Material (Internal)	Stainless Steel 304 4B finished	Stainless Steel 304 4B finished	Yes/No	13-Feb-2023
	HEPA Filter Grade	H13	H13	Yes/No	13-Feb-2023
	Primary Filter Grade	G2	G2	Yes/No	13-Feb-2023
	PAO Test Port	Available	Available	Yes/No	13-Feb-2023
	Differential Pressure Model for HEPA Filter	Minihelic Differential Pressure Gauge	Minihelic Differential Pressure Gauge	Yes/No	13-Feb-2023
	Differential Pressure Model for Active Passbox	Magnehelic Differential Pressure Gauge	Magnehelic Differential Pressure Gauge	Yes/No	13-Feb-2023
	Light Indicator	Green, Red	Green, Red	Yes/No	13-Feb-2023
	Power Source (v/p/f)	230/1/50	230/1/50	Yes/No	13-Feb-2023
	Internal	Width = 400 mm	400 mm	Yes/No	13-Feb-2023
		Depth = 500 mm	500 mm	Yes/No	13-Feb-2023
	Dimension	Height = 450 mm	450 mm	Yes/No	13-Feb-2023
		Width = 850 mm	850 mm	Yes/No	13-Feb-2023
		Depth = 590 mm	590 mm	Yes/No	13-Feb-2023
		Height = 1250 mm	1250 mm	Yes/No	13-Feb-2023



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Title:		Active Passbox Features Verification			Test No: IQ-02	
Equipment Name	Design Specification	Acceptance Criteria	Actual	Conformity (Yes/No)	Verified By (Initial & Date)	
Active Passbox 3 (APB3)	Material (External)	Electrogalvanized c/w Epoxy Powder Coated	Electrogalvanized c/w Epoxy Powder Coated	Yes/No	13-Feb-2023	
	Material (Internal)	Stainless Steel 304 4B finished	Stainless Steel 304 4B finished	Yes/No	13-Feb-2023	
	HEPA Filter Grade	H13	H13	Yes/No	13-Feb-2023	
	Primary Filter Grade	G2	G2	Yes/No	13-Feb-2023	
	PAO Test Port	Available	Available	Yes/No	13-Feb-2023	
	Differential Pressure Model for HEPA Filter	Minihelic Differential Pressure Gauge	Minihelic Differential Pressure Gauge	Yes/No	13-Feb-2023	
	Differential Pressure Model for Active Passbox	Magnehelic Differential Pressure Gauge	Magnehelic Differential Pressure Gauge	Yes/No	13-Feb-2023	
	Light Indicator	Green, Red	Green, Red	Yes/No	13-Feb-2023	
	Power Source (v/p/f)	230/1/50	230/1/50	Yes/No	13-Feb-2023	
	Internal	Width = 400 mm	400 mm	Yes/No	13-Feb-2023	
		Depth = 500 mm	500 mm	Yes/No	13-Feb-2023	
		Height = 450 mm	450 mm	Yes/No	13-Feb-2023	
	Dimension	Width = 850 mm	850 mm	Yes/No	13-Feb-2023	
		Depth = 590 mm	590 mm	Yes/No	13-Feb-2023	
		Height = 1250 mm	1250 mm	Yes/No	13-Feb-2023	

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Title:		Test No: IQ-02			
Active Passbox Features Verification					
Comments/Deviations/Supporting Documentation: NIL					
Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13 - Feb - 2023.			

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Title: Documentation Verification – Calibration Verification Record **Test No: IQ-03**

Objective:
 To provide documented evidence that all critical instruments have been calibrated.

Pre-requisites:
 Device Catalogues should be provided at the attachment section.

Method:
 Review calibration certification available for each of the critical instruments; note the calibration certificate reference, calibration frequency and calibration due date.

Acceptance Criteria:
 A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.

Results:

Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)
DPG-APB-01	Dwyer Minihelic Differential Pressure Gauge: 0-500 Pa Model: 2-5000-500PA	Active Passbox 1 (APB1)	Yearly	17-Jan-2023	17-Jan-2024	CTP 1237-23	13-Feb-2023
DPG-APB-02	Dwyer Minihelic Differential Pressure Gauge: 0-500 Pa Model: 2-5000-500PA	Active Passbox 2 (APB2)	Yearly	17-Jan-2023	17-Jan-2024	CTP 1233-23	13-Feb-2023
DPG-APB-03	Dwyer Minihelic Differential Pressure Gauge: 0-500 Pa Model: 2-5000-500PA	Active Passbox 3 (APB3)	Yearly	17-Jan-2023	17-Jan-2024	CTP 1234-23	13-Feb-2023

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Title: Documentation Verification – Calibration Verification Record						Test No: IQ-03	
Instrument Ref.	Instrument Description	Room/Location	Calibration Frequency	Calibration Date	Calibration Due Date	Calibration Ref./Serial No.	Verified By (Initial & Date)
DPG-APB-04	Dwyer Magnehelic Differential Pressure Gauge: 0-60 Pa Model: 2000-60PA	Active Passbox 1 (APB1)	Yearly	09-Feb-2023	09-Feb-2024	CTP 1608-23	HA 13-Feb-2023
DPG-APB-05	Dwyer Magnehelic Differential Pressure Gauge: 0-60 Pa Model: 2000-60PA	Active Passbox 2 (APB2)	Yearly	17-Jan-2023	17-Jan-2024	CTP 1230-23	HA 13-Feb-2023
DPG-APB-06	Dwyer Magnehelic Differential Pressure Gauge: 0-60 Pa Model: 2000-60PA	Active Passbox 3 (APB3)	Yearly	09-Feb-2023	09-Feb-2024	CTP 1609-23	HA 13-Feb-2023
DPG-APB-07	Dwyer Magnehelic Differential Pressure Gauge: 0-60 Pa Model: 2000-60PA	Active Passbox 1 (APB1)	Yearly	17-Feb-2023	17-Feb-2024	CTP 1231-23	HA 13-Feb-2023
DPG-APB-08	Dwyer Magnehelic Differential Pressure Gauge: 0-60 Pa Model: 2000-60PA	Active Passbox 2 (APB2)	Yearly	09-Feb-2023	09-Feb-2024	CTP 1607-23	HA 13-Feb-2023
DPG-APB-09	Dwyer Magnehelic Differential Pressure Gauge: 0-60 Pa Model: 2000-60PA	Active Passbox 3 (APB3)	Yearly	17-Jan-2023	17-Jan-2024	CTP 1229-23	HA 13-Feb-2023

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Title: Documentation Verification – Calibration Verification Record					
Comments/Deviations/Supporting Documentation: Refr to Calibration Certificate (Hardware Documents)					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature): 		Date: 13 - Feb - 2023	

Test No: IQ-03



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Title:	Documentation Verification – Filter Grade Certification	Test No: IQ-04
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Objective/Purpose:

To provide documented evidence that all HEPA filters conforms to their target efficiency and are able to satisfy the design requirements.

Pre-requisites:

System design reviews have been completed.

Method:

For each filter referenced below, ensure a fully valid filter efficiency certificate is available.

Acceptance Criteria:

Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.

Results:

Equipment Name	HEPA Filter ID Tag No.	Acceptance Criteria		As Found		Verified By (Initial & Date)
		Grade & Type		Serial No.	Cert. Ref.	
Active Passbox 1 (APB1)	HF-APB-01	JAF 295 X 395 X 69 mm Grade H13	JAF 295 X 395 X 69 mm Grade H13	J0596156	JVU2-AH3- 29539569-N22-P2	<i>[Signature]</i> 10-Feb-2023
Active Passbox 2 (APB2)	HF-APB-02	JAF 295 X 395 X 69 mm Grade H13	JAF 295 X 395 X 69 mm Grade H13	J0596154	JVU2-AH3- 29539569-N22-P2	<i>[Signature]</i> 10-Feb-2023
Active Passbox 3 (APB3)	HF-APB-03	JAF 295 X 395 X 69 mm Grade H13	JAF 295 X 395 X 69 mm Grade H13	J0596155	JVU2-AH3- 29539569-N22-P2	<i>[Signature]</i> 10-Feb-2023

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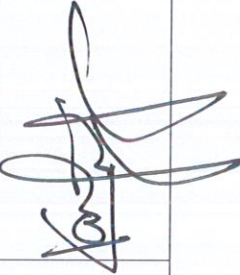
Title:	Documentation Verification – Filter Grade Certification	Test No: IQ-04
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Comments/Deviations/Supporting Documentation:

Refer to Filter Inspection Report (Handover Documents)

Overall Test Outcome (PASS/FAIL)

Verified By (Signature):



Date:

13 - Feb - 2023

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Title: Installation Verification – HEPA Filter Installation					
Objective/Purpose: To provide documented evidence that all HEPA filters are able to perform as per the design requirement upon installation.					
Pre-requisites: Certificates of conformity for HEPA filters indicate compliance with design specification.					
Method: 1. Technical cleaning should be conducted before HEPA installation. 2. During HEPA installation proper PPE must be worn, i.e., powder-free glove, jumpsuit, hairnet, and shoes cover. 3. Initiate the system shutdown procedure and confirm electrical isolation. Identify HEPA filter(s) to be installed. Clean grille, casing, base plate and filter housing with alcohol taking care to remove all dust and dirt. Allow to dry. 4. To install a new filter, invert box so filter falls from box, minimizing physical contact. Record unique reference number and visually inspect filter for any damage. If a test certificate is included, attach this to report. Take filter to housing, remove from bag and carefully smear a thin layer of grease around it to assist insertion. Taking care not to touch the filter media, only hold or press on gasket or frame whenever required, insert into housing and tighten into place. When screwing on the HEPA casing, avoid to over screw as it might damage the casing. 5. Repeat steps 3 and 4 for subsequent HEPA filters. Once all HEPA filters have been installed, start-up system and record clean filter pressure drops for information (do this after the air flow design has been achieved).					
Acceptance Criteria: HEPA filters of the correct grade have been installed and their efficiencies are not compromised during the installation process.					

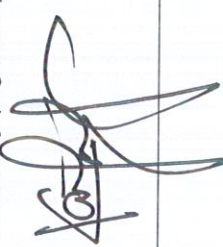
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Title: Installation Verification – HEPA Filter Installation

Test No: IQ-05

Results:

Equipment Name	HEPA Filter Ref.	Acceptance Criteria HEPA Filter Grade	Actual Result		Verified By (Initial & Date)
			HEPA Filter Grade	Visual Inspection Satisfactory (Yes/No)	
Active Passbox 1 (APB1)	HF-APB-01	JAF 295 X 395 X 69 mm Grade H13	JAF 295 x 395 x 69 mm Grade H13	(Yes) No	JAF 10-Feb-2023
Active Passbox 2 (APB2)	HF-APB-02	JAF 295 X 395 X 69 mm Grade H13	JAF 295 x 395 x 69 mm Grade H13	(Yes) No	JAF 10-Feb-2023
Active Passbox 3 (APB3)	HF-APB-03	JAF 295 X 395 X 69 mm Grade H13	JAF 295 x 395 x 69 mm Grade H13	(Yes) No	JAF 10-Feb-2023

Installation Qualification		Doc. No. Rev. No.	L-SJMC02-HTL-VD-IQ-APB-01 00	Effective Date Total Page(s)	21 NOV 2022 22 of 33
Title: Installation Verification – HEPA Filter Installation					
Comments/Deviations/Supporting Documentation: Refer to Filter Inspection Report (Handover Documents)					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature):		Date:	
				13 - Feb - 2023	

Test No: IQ-05

Installation Qualification		Doc. No.	L-SJMC02-HTL-VD-IQ-APB-01	Effective Date	21 NOV 2022
		Rev. No.	00	Total Page(s)	23 of 35

Title:	Installation Verification (System) – Installation Against Drawing	Test No: IQ-06
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Objective:

To provide documented evidence that the mechanical work has been installed according to the approved design layout.

Pre-requisites:

Approved as-built drawing should be attached.

Method:

1. Take a copy of the required drawings to be verified and record the revision numbers in the results table.
2. Compare the drawing against the installation and mark the drawing to clearly indicate areas or items that are correct, that are incorrect and items that could not be verified.
3. Identify the marked-up copy of the drawing with the protocol and test reference then sign and date.

Acceptance Criteria:

The installation of all mechanical work is as per the approved design layout.

Results:

Drawing Title	Ref. No.	Revision No.	Conformity (Yes/No)	Verified By (Initial & Date)
Furniture Layout	L/SJMC02/HTL/DA/IFA/06	00	Yes/No	AT 10-Feb-2023
			Yes/No	
	N/A		Yes/No	
			Yes/No	
			Yes/No	
			Yes/No	

Installation Qualification		Doc. No.	L-SJMC02-HTL-VD-IQ-APB-01	Effective Date	21 NOV 2022
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Title:	Installation Verification (System) – Installation Against Drawing	Test No: IQ-06
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Comments/Deviations/Supporting Documentation:
Refer to attachments

Overall Test Outcome (PASS/FAIL)		Verified By (Signature):	Date:
			13 - Feb - 2023

Installation Qualification	Doc. No.	L-SJMC02-HTL-VD-IQ-APB-01	Effective Date
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Title:	Installation Verification – Active Passbox Installation	Test No: IQ-07
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Objective:

To provide documented evidence to proof the safety of active passbox installation.

Pre-requisites:

None

Method/Acceptance Criteria/Results:

The construction of passbox installation complies with the safety standard.

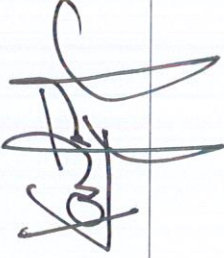
Equipment Name	Test Method	Acceptance Criteria	Conformity (Yes/No)	Verified By (Initial & Date)
Active Passbox 1 (APB1)	Verify power supplies of active passbox.	Power supplies of the active passbox are connected.	Yes/No	13-12-2023
	Verify the condition of the active passbox.	Ensure that no material is present in the active passbox and both the doors of active passbox are closed.	Yes/No	13-12-2023
	Verify the condition of the interlocking door.	Interlocking of door is properly working.	Yes/No	13-12-2023
	Verify that condition of the buzzer and indicator light.	Buzzer and indicator light are properly working.	Yes/No	13-12-2023
Active Passbox 2 (APB2)	Verify power supplies of active passbox.	Power supplies of the active passbox are connected.	Yes/No	13-12-2023
	Verify the condition of the active passbox.	Ensure that no material is present in the active passbox and both the doors of active passbox are closed.	Yes/No	13-12-2023
	Verify the condition of the interlocking door.	Interlocking of door is properly working.	Yes/No	13-12-2023
	Verify that condition of the buzzer and indicator light.	Buzzer and indicator light are properly working.	Yes/No	13-12-2023

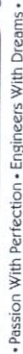
Installation Qualification		Doc. No.	L-SJMC02-HTL-VD-IQ-APB-01	Effective Date	21 NOV 2022
		Rev. No.	00	Total Page(s)	26 of 35

Title: Installation Verification – Active Passbox Installation			Test No: IQ-07	
Equipment Name	Test Method	Acceptance Criteria	Conformity (Yes/No)	Verified By (Initial & Date)
Active Passbox 3 (APB3)	Verify power supplies of active passbox.	Power supplies of the active passbox are connected.	Yes/No	13-Feb-2023
	Verify the condition of the active passbox.	Ensure that no material is present in the active passbox and both the doors of active passbox are closed.	Yes/No	13-Feb-2023
	Verify the condition of the interlocking door.	Interlocking of door is properly working.	Yes/No	13-Feb-2023
	Verify that condition of the buzzer and indicator light.	Buzzer and indicator light are properly working.	Yes/No	13-Feb-2023

Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
		13-Feb-2023



Title:	Support – Change Control Record
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Objective:

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

Pre-requisites:

All approved change form must be attached.

Method:

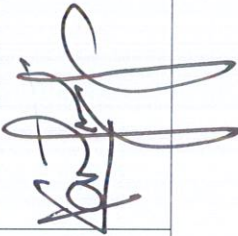
1. Record each change made to the system during the completion of the protocol. Record the change reference, a brief description of the change and the date of the change. Clearly and concisely outline what needs to be changed, so the impacted areas can review and analyze.
2. Review the changes made to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

Acceptance Criteria:

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

Results:

[illegible]

Installation Qualification		Doc. No. Rev. No.	L-SJMC02-HTL-VD-IQ-APB-01 00	Effective Date Total Page(s)	21 NOV 2022 28 of 35
Title:		Test No: IQ-08			
Support – Change Control Record					
Comments/Deviations/Supporting Documentation: NIL					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature): 		Date: 13 - Feb. 2023	

Installation Qualification	Doc. No.	L-SJMC02-HTL-VD-IQ-APB-01	Effective Date	21 NOV 2022
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11.0 SUMMARY OF TEST

This section, detailing system specific Acceptance Criteria (A/C), should be completed following a review of the test sheets, within Section 9, and supporting data, contained within the referenced project files.

Design

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
1	Approved system design documentation is available.	Yes	N/A	HA 16-Feb-2023
2	The data on all features of active passbox is consistent with the design specification.	Yes	N/A	HA 13-Feb-2023
3	A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.	Yes	N/A	HA 13-Feb-2023

Documentation

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
4	Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.	Yes	N/A	HA 10-Feb-2023
5	HEPA filters of the correct grade have been installed and are their efficiencies are not compromised during the installation process.	Yes	N/A	HA 10-Feb-2023

Installation

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
6	The installation of all mechanical work is as per the approved design layout.	Yes	N/A	HA 10-Feb-2023
7	The construction of active passbox installation complies with the safety standard.	Yes	N/A	HA 13-Feb-2023

Additional

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

21 NOV 2022

12.0 TEST INSTRUMENT RECORD

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

N/A ~~by~~
- 13-Feb-2013

13.0 SIGNATURE RECORD

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

N/A



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14.0 INTERIM APPROVAL

This section is only required when all discrepancies in the deviation list have been considered, the pass box may proceed for Operational Qualification pending resolution finalization. If there are no discrepancies or all discrepancies found have been suitably resolved, may proceed for Post-Execution Approval.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by:			
Reviewed by:		<i>[Signature]</i> 12-Feb-2023	
Approved by:			



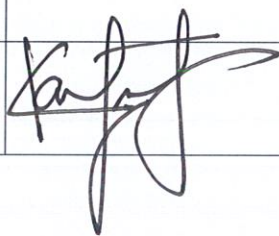
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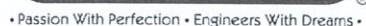
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15.0 POST-EXECUTION APPROVAL

CONDITIONAL ACCEPTANCE

The system operational checks have been reviewed. All testing associated during Installation 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		
Approved by: Steven	Manager		13 - Feb - 2023

[illegible]

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DEVIATION REPORT	Report no.:
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A. Description of Deviation:	
Documented By:	Date:

RESPONSE		
A. Reason of Deviation:		
B. Correction/preventive action to be taken:		
Evaluation by:	Signature	Date (dd-mmm-yyyy)
Reviewed By:		

N/A 11
13-Feb-2023

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]