INSTALLATION QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

INSTALLATION QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Dynamic Pass Box is installed as per design.
- To ensure that the Dynamic Pass Box installed confirms to purchase specifications and manufacturer literature, and to document the information that the Dynamic Pass Box meets the specification.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**Dynamic Pass Box**
ID Number	**……**
Location	**MLT Room to Incubation Room**

3.0 Equipment / System Description:

KlenzPort^{TM} recirculatory pass box is designed for material transfer between two areas under different classification.

The system is equipped with:

- Two SS doors with view panels of glass flush mounted.
- Electro magnetic interlocking arrangement.
- Magnehelic Gauge.

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4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

5.0 Checklist for Installation verification:

Installation of Dynamic Pass Box shall be verified for the compliance with the critical parameters mentioned in the Functional Design Specification.

The purpose of this checklist is to check and document the received material and installation at site with respect to drawings, details, and data sheets approved during DQ and GEP. GEP considers the basic engineering requirements for skilful maneuvering, means those methods and practices, which the administrator determines to be consistent with scientific and engineering principles.

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

8.0 References:

Purchase order (already available with Design Qualification)

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification

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10.0 Abbreviations:

IQ : Installation Qualification

DQ : Design Qualification

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

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Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.	…..		
2.	Vendor's Name	Klenzaids Bioclean		
3.	Instrument Make	Klenzaids		
4.	Instrument Model No.	……		
5.	Design qualification Reference	Design qualification submitted by the vendor		
6.	Factory Acceptance Test (FAT) Certificate	Should be provided		
7.	Instrument Manual	Instrument Manual submitted by the vendor		

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Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
1.	Cabinet (MOC)	Should be SS 304		
2.	Door (MOC)	Should be SS 304		
3.	HEPA filter Screen (MOC)	Should be SS 304		
4.	HEPA filters	Should be EU - 13, 457 x 457x 75 mm (Antimicrobial)		
5.	Pre filters	Should be EU - 6, 407 x 202 x 45 mm (Biocidal)		
6.	DOP Port	100 % DOP test port Should be provided		
7.	Electrical construction	a) Illumination: 36-Watts Lamp. b) Independent controls for lighting, blowers & Sockets.		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
8.	Relay / Switchgear	Should be provided		
9.	Indicators	➢ Power ON ➢ Blower ON ➢ Light switch Should be provided		
10.	Differential pressure gauge	Should be 0 to 25 mm WC		
11.	Special features	Soft touch key pad switch Should be provided		
12.	Motor	Should be 0.16 HP; 2880 RPM;		
13.	Blower (Impeller)	Should be 112 x 85 mm		
14.	Overall Dimensions (W x D x H)	Should be 760 x 680 x 1210 mm		
15.	Work Space Dimensions (W x D x H)	Should be 610 x 610 x 610 mm		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
B.	**Location suitability**			
1.	Location	Should be place between MLT Room to Incubation Room - I		
C.	**Utilities**			
1.	Electrical power supply	Should be 230 V; AC; 50 Hz		
D.	**Safety**			
1.	Alarm	Audiovisual alarm for motor blower trip Should be provided		
		False door opening alarm Should be provided		
E.	MOC Certificates	Should be provided		
F.	Calibration Certificates	Should be provided		
G.	Testing Certificates	Should be provided		
H.	Drawing Details	Drawing No.		
1.	Drawing of Dynamic Pass Box	……		

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Annexure - III

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By:

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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

_____

_____

_____

_____

_____

_____

Summary Report Prepared By:

Date & Sign