INSTALLATION QUALIFICATION PROTOCOL FOR STATIC PASS BOX

Pre - Execution Approval

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

INSTALLATION QUALIFICATION PROTOCOL FOR STATIC PASS BOX

1.0 Objective:

The purpose of installation qualification is as follows

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

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**Static Pass Box**
ID Number	**…….**
Location	**Cooling Zone to Sterility Testing Room**

3.0 Equipment / System Description:

KlenzPort™ Static pass box is designed for material transfer between two areas under same classification.

The system is equipped with:

- Two SS doors with view panels of glass flush mounted.
- Electro magnetic interlocking arrangement.
- UV. Hour Meter

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 Static 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:

Copy of Purchase order

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

Annexure - VII : Copy of Purchase order

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	…….		
3.	Instrument Make	Klenzaids		
4.	Instrument Model No.	Klenz Port ™		
5.	Design qualification Reference	Design qualification submitted by the vendor		
6.	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.	Overall Dimensions (W x D x H)	Should be 710 x 680 x 785 mm		
4.	Internal Dimensions (W x D x H)	Should be 610 x 610 x 610 mm		
5.	Illumination	U.V. Light 15 w; 1.5' L should be provided		
6.	Interlock	Electromagnetic Interlocking should be provided		
7.	Special features	Hour meter, SS Door with tough end glass should be provided		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
B.	**Location suitability**			
1.	Location	Should be place between Cooling Zone to Sterility Testing Room		
C.	**Utilities**			
1.	Electrical power supply	Should be 230 V; AC; 50 Hz		
D.	**Safety**			
1.	Not Applicable	Not Applicable		
E.	**MOC Certificates**			
1.	Not Applicable	Not Applicable		
F.	**Calibration Certificates**			
1.	Not Applicable	Not Applicable		
G.	**Testing Certificates**			
1.	Not Applicable	Not Applicable		
H.	**Drawing Details**	**Drawing No.**		
1.	Drawing of Static 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:

INSTALLATION QUALIFICATION PROTOCOL FOR STATIC PASS BOX

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