INSTALLATION QUALIFICATION PROTOCOL FOR GARMENT STORAGE CABINET

Pre - Execution Approval

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

1.0 Objective:

The purpose of installation qualification is as follows

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

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**Garment storage Cabinet**
ID Number	**…….**
Location	**Change Room**

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3.0 Equipment / System Description:

Klenz Change™ recirculatory Garment Storage cabinet is designed to provide controlled micro - environment for storage of sterile garments or other clean room for accessories.

This recirculatory unit is designed with a horizontal side to side air flow in the work area with pick up from the opposite side through the return plenum which has a fresh intake pre filter to replace any loss of air through opening of the cabinet door. The cabinet is suitable for storing & sets of sterilized packed garments.

The storage cabined is equipped with:

- Single door with polycarbonate glass panel.
- Shelves for storage.

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 Garment Storage Cabinet 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:

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……
……
……

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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 : Summary Report of Installation Qualification.

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.	KlenzChange ™		
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, 855 x 570 x 75 mm (Antimicrobial)		
5.	Pre filters	Should beEU – 6, 855 x 570 x 45 mm (Biocidal)		
		Should beEU - 6, 180 x 180 x 25 mm (Biocidal)		
6.	DOP Port	100 % DOP test port Should be provided		
7.	Electrical construction	a) Illumination : U.V light: 1.5'L; 15Watts. 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.	UV lamp	UV lamp with hour meter and interlocking arrange for put OFF UV light Should be provided		
9.	IR Heater	IR Heater wither thermister controlled set point Should be provided		
10.	Relay / Switchgear	Should be provided		
11.	Indicators	➢ Power ON ➢ Blower ON ➢ UV ON ➢ Light switch Should be provided		
12.	Differential pressure gauge	Should be 0 to 25 mm WC		
13.	Special features	Soft touch ON -OFF switch Should be provided		
		Adjustable floor aligner Should be provided		
14.	Motor	Should be 0.5 HP; 1440 RPM;		
15.	Blower (Impeller)	Should be 235 x 117 mm		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
16.	Overall Dimensions (W x D x H)	Should be 960 x 640 x 1555 mm		
17.	Work Space Dimensions (W x D x H)	Should be 610 x 610 x 610 mm		
B.	**Location suitability**			
1.	Location	Should be place in Change Room		
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		
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 Garment Storage Cabinet	…….		

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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:

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Summary Report Prepared By:

Date & Sign