



DESIGN QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX

Pre - Execution Approval

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



DESIGN QUALIFICATION PROTOCOL FOR DYNAMIC PASS BOX

1.0 Objective:

The purpose of Design Qualification of the Dynamic pass box is to ensure that all the critical aspects including safety, effective cleaning, maintenance, utility requirement, working space, have been considered while designing the equipment and they are properly documented.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Dynamic Pass Box
ID Number
Location	Sterile Corridor to MLT Room

3.0 Equipment / System Description:

KlenzPort™ 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.

4.0 Checklist for design verification:

Design of Dynamic pass box shall be verified for the compliance with the critical parameters mentioned in the URS/ executed tender.



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Construction			
Cabinet	SS 304	SS 304	
Door	SS 304	SS 304	
HEPA filter Screen	SS 304	SS 304	
HEPA filters	Not Mentioned	EU – 13, 457x457x75 mm (Antimicrobial)	
Pre filters	Not Mentioned	EU – 6, 407x202x45 mm (Biocidal)	
DOP Port	Should be provided	100 % DOP test port	
Electrical construction	a) 300 lux along with one number of 5/15 amp, each switch socket (combined) b) Independent controls for lighting, blowers & sockets.	a) Illumination : 36-Watts Lamp. b) Independent controls for lighting, blowers & Sockets.	
Acceptable Tolerance for Control Parameter			
Air velocity	Between 0.50 m/sec to 0.45 m/sec	0.45 ± 0.05 m/sec	
Noise (Decibels)	Less than 65	Not Mentioned	
Differential pressure	Should be between 7 to 12 mm WC	Not Mentioned	
Particle count	As per ISO 14644 - 1	Complies	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Type of Control System			
Relay / Switchgear	Should be provided	Provided	
Indicators	<ul style="list-style-type: none"> ➤ Power ON ➤ Blower ON ➤ Light switch 	Provided	
Differential pressure gauge	0 to 25 mm WC	0 to 25 mm WC	
Accuracy of gauge	± 3 %	± 3 %	
Electrical power supply	440 - 3 phase 50 Hz / 220 1 phase 50 Hz	230 V; AC; 50 Hz	
Special features	Not Mentioned	Soft touch key pad switch	
Safety			
Alarm	Audiovisual alarm for motor blower trip	Audiovisual alarm for motor blower trip	
	False door opening alarm	Provided	
MCB	Make Hager / Merlin gerlin / Legrand	Provided	
Motor	Not Mentioned	0.16 HP; 2880 RPM;	
Blower (Impeller)	Not Mentioned	112 x 85 mm	



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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Type of Control System			
Overall Dimensions (WxDxH)	28 x 27 x 40 inch (711x686x1016 mm)	760 x 680 x 1210 mm	
Work Space Dimensions (WxDxH)	24 x 24 x 24 inch (610 x 610 x 610 mm)	610 x 610 x 610 mm	

5.0 Any Changes identified towards equipment design / lay out.

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6.0 Recommendations and Conclusions:

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7.0 References:

- User requirement specification.
- Copy of purchase order.
- Risk assessment.
- Document submitted by the supplier / vendor

8.0 Documents Attached

Document Title	Annexure No.
List of changes / deviation	I
User requirement specification.	II
Copy of purchase order	III
Risk assessment	IV
Document submitted by the supplier / vendor	V

9.0 Abbreviations:

- URS : User requirement specification
- SS : Stainless Steel
- mm : millimeter
- WC : water content
- % : Percentage
- m/sec : Meter per second



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Annexure - I

List of changes / Deviations

S.No.	Description of Change / Deviations	Justification

Verified By:

Approved By:



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Post execution approval:

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