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DESIGN QUALIFICATION FOR HVAC SYSTEM

PROJECT: NEW EXPANSION OPERATING THEATRE &
SUPPORTING CLEAN ROOM FOR EXISTING EYE CENTRE
IN NEXUS, BANGSAR SOUTH FOR OASISEYE
SPECIALISTS SDN. BHD.

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 Lufter Sdn. Bhd.			
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Wong Peng Peng	Validation Executive		23-May-2023
Reviewed by: Ahmad Aslam	Design Assistant Manager		23-May-2023
Reviewed by: Shawn Eng	Assistance Project Manager		23-May-2023
By signing below, OasisEye Specialists Sdn. Bhd. 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:			
Reviewed by:		N/A	
Approved by:	GOO CHUI HOONG Operations Manager OasisEye Specialists		24-May-2023

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1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	L-POEBS01-OT&SCR-VD-URS-R01	User Requirement Specification for HVAC System - New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd.
2.	L-POEBS01-OT&SCR-VD-FSDS-R01	Functional Specification Design Specification for HVAC System - New Expansion Operating Theatre & Supporting Clean Room for Existing Eye Centre in Nexus, Bangsar South for OasisEye Specialists Sdn. Bhd.

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	17 FEB 2023	Peng Peng	New
01	24 MAY 2023	Peng Peng	Additional Heater Control and TRH

3.0 PURPOSE

The purpose of this document is to verify that the system has been designed in way that all measures in the User Requirement Specification have been taken into consideration.

4.0 SCOPE

This Design Qualification is applicable to the design of the New Operating Theater and Supporting Clean Room which will be operational within the Nexus, Bangsar South, OasisEye Specialist Sdn. Bhd.

5.0 REVIEW METHODOLOGY

Design Qualification is performed by scrutinizing technical data sheets such as engineering drawing, specifications and manuals provided by the equipment vendors. Careful attention is given to ensure that all user requirements have been considered and fulfilled whenever possible.

Under Section 8: Design Verification, a verification checklist is used to verify the design specification against the user requirements. The content of this checklist is extracted directly from the URS (reference no **L-POEBS01-OT&SCR-VD-URS-R01**). The availability of supporting documents and their locations must be indicated in the checklist.

For every deviation between the design specification and URS, assessment shall be performed and corrective action will be taken.

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6.0 ROLES & RESPONSIBILITY

The following personnel have been designated to prepare, execute, review and approve the protocol.

Company	Job Title	Responsibility
OasisEye Specialist Sdn. Bhd.	Client Representative	To review the DQ protocol/report. To provide approval to the submitted DQ protocol/report. To review vendor's specification against the URS To provide approval to the submitted documents. To ensure all relevant technical specifications in vendor's documents are correct.
Lufter Sdn. Bhd.	Project Manager Project Engineer Validation Executive	To prepare the DQ protocol. To evaluate vendor's design against the URS.

7.0 ABBREVIATION

No.	Term/Abbreviation	Definition
1.	AHU	Air Handling Unit
2.	AHRI	Air-Conditioning, Heating and Refrigeration Institute
3.	ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
4.	CFU	Colony-Forming Unit
5.	CPP	Critical Process Parameter
6.	CQA	Critical Quality Attributes
7.	DPG	Differential Pressure Gauge
8.	DX	Direct Expansion
9.	FSDS	Functional Specification Design Specification
10.	HEPA	High-Efficiency Particulate Air
11.	HVAC	Heating, Ventilation and Air Conditioning
12.	ISO	International Standardization for Organization
13.	NEBB	National Environmental Balancing Bureau
14.	No	Number
15.	OT	Operation Theatre
16.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
17.	PU	Polyurethane
18.	Ref	Reference
19.	RH	Relative Humidity
20.	TRH	Temperature and Relative Humidity
21.	URS	User Requirement Specification

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8.0 SYSTEM DESCRIPTION

8.1 Heating, Ventilation & Air Conditioning System (HVAC)

The HVAC System designed for the classified cleanroom consists of one (1) units of new AHU which are designed to supply condition air to the cleanroom of the Operation Theatre 3, Operation Theatre 4, Scrub 2, Scrub 3 and Packing & Autoclave Room 2 as per Table 1 under Section 8.2.

The new AHU-OT-02 unit consists of only one (1) section. The fresh air passes through a filter box equip with filter grade G4(B) to filter any dust before going into heat recovery wheel where energy from the exhaust air is recovered for conditioning of the air. Then, the air passing through the AHU shall then be forced through another set of grades F9 filters for filtration before it is conditioned in the direct expansion (DX) post coil to reduce its temperature and moisture content.

After exiting the AHU unit, the post-cooled air will flow through three (3) heaters to be heated to the required temperature as per the URS. The supply air is then further filtrated by H14 HEPA filters at the HEPA Filter Terminal before being released into respective rooms.

For AHU-OT-02, the supply air enters the cleanroom via a network of ducting/branch ducts and flexible duct. Air control devices like aluminum blade volume control dampers are strategically installed along the main duct and branch duct to throttle the supply, and exhaust air. Manual dampers will be installed at each of the supply air diffusers and exhaust air grilles for fine adjustment.

Air exiting from all cleanrooms served by AHU-OT-02 will then pass through the same heat recovery wheel for energy recovery before being exhausted out.

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8.2 Cleanrooms Operating Conditions

In order to meet the user requirement specification, Lufter has designed the room parameters as below:

AHU	Room Description	Room No.	Room ISO Class	Pressure (Pa) (ref. atmosphere)	Relative Humidity (RH) (%)	Temperature (°C)	Air Change
AHU-OT-02	Operation Theatre 3	001	ISO 7	20	50-60	18-22	≥ 25
	Operation Theatre 4	002	ISO 7	20	50-60	18-22	≥ 25
	Scrub 2	003	ISO 7	10	50-60	18-22	≥ 25
	Janitor 3	004	ISO 8	10	50-60	18-22	≥ 20
	Packing & Autoclave Room 2	005	ISO 8	10	50-60	18-22	≥ 20

Table 1: Cleanroom parameters

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9.0 Design Verification

URS Clause	Design Requirement	Design Ref.	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)												
8.1 Premises																
8.1.1	The cleanroom premises of this existing facility shall include rooms as listed below: <table><tr><th>No.</th><th>Room(s)</th></tr><tr><td>1</td><td>Operation Theatre 3</td></tr><tr><td>2</td><td>Operation Theatre 4</td></tr><tr><td>3</td><td>Scrub 2</td></tr><tr><td>4</td><td>Janitor 3</td></tr><tr><td>5</td><td>Packing & Autoclave Room 2</td></tr></table> Table 1: Classified Cleanrooms in New Operating Theatre & Supporting Clean Room at Nexus, Bangsar South, OasisEye Specialist Sdn. Bhd.	No.	Room(s)	1	Operation Theatre 3	2	Operation Theatre 4	3	Scrub 2	4	Janitor 3	5	Packing & Autoclave Room 2	Attachment 1: Construction Drawing - Room Grade Classification (L/POEBS01/OT & SCR/OC/HWC/02/K01)	✓	N/A
No.	Room(s)															
1	Operation Theatre 3															
2	Operation Theatre 4															
3	Scrub 2															
4	Janitor 3															
5	Packing & Autoclave Room 2															
8.1.2	The new wall partition and ceiling panel shall be of Polyurethane (PU) panel with a thickness of 75mm.	Attachment 2: Construction Drawing - Wall & Door Layout (L/POEBS01/OT & SCR/OC/IF0/01/K01) Attachment 3: Construction Drawing - Ceiling Layout (L/POEBS01/OT & SCR/OC/IF0/02/K01) Attachment 4: Sample Identification Tag for PU panel (L-POEBS01-SIT-IF0-01)	✓	N/A												

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URS Clause	Design Requirement	Design Ref.	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.1.3	All doors shall be insulated PU panel single and double leaf swing door.	Attachment 2: Construction Drawing - Wall & Door Layout (L/POEBS01/OT&SCR/DC/IFD/01/R01) Attachment 4: Sample Identification Tag for PU panel (L-POEBS01-SZT-IFD-01)	✓	N/A
8.1.4	Three (3) units of passive passbox shall be provided for the transfer of materials.	Attachment 2: Construction Drawing - Wall & Door Layout (L/POEBS01/OT&SCR/DC/IFD/01/R01)	✓	N/A
8.1.5	The flooring system in the classified cleanroom shall be completed with self-levelling epoxy with coving.	Attachment 5: Construction Drawing - Floor Finish Layout (L/POEBS01/OT&SCR/DC/IFD/03/R01)	✓	N/A

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URS Clause	Design Requirement	Design Ref.	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)																																						
8.2	Heating Ventilation Air Conditioning (HVAC) System																																									
8.2.1	Critical Process Parameter (CPP) The cleanroom design shall meet the following operating conditions: <table><thead><tr><th>AHU</th><th>Room Description</th><th>Room No.</th><th>Room ISO Class</th><th>Pressure (Pa) (ref. atmosphere)</th><th>Relative Humidity (RH) (%)</th><th>Temperature (°C)</th></tr></thead><tbody><tr><td rowspan="5">AHU -OT-02</td><td>Operation Theatre 3</td><td>001</td><td>ISO 7</td><td>20</td><td>50-60</td><td>18-22</td></tr><tr><td>Operation Theatre 4</td><td>002</td><td>ISO 7</td><td>20</td><td>50-60</td><td>18-22</td></tr><tr><td>Scrub 2</td><td>003</td><td>ISO 7</td><td>10</td><td>50-60</td><td>18-22</td></tr><tr><td>Janitor 3</td><td>004</td><td>ISO 8</td><td>10</td><td>50-60</td><td>18-22</td></tr><tr><td>Packing & Autoclave Room 2</td><td>005</td><td>ISO 8</td><td>10</td><td>50-60</td><td>18-22</td></tr></tbody></table>	AHU	Room Description	Room No.	Room ISO Class	Pressure (Pa) (ref. atmosphere)	Relative Humidity (RH) (%)	Temperature (°C)	AHU -OT-02	Operation Theatre 3	001	ISO 7	20	50-60	18-22	Operation Theatre 4	002	ISO 7	20	50-60	18-22	Scrub 2	003	ISO 7	10	50-60	18-22	Janitor 3	004	ISO 8	10	50-60	18-22	Packing & Autoclave Room 2	005	ISO 8	10	50-60	18-22	Attachment 6: Design Table for AHU-OT-02 (L-POEBS01-OT&SCR-07-01-01-R01 (095533)) Attachment 7: Construction Drawing - Airflow Schematic (L/POEBS01/07&SCR/DC/HVAC/05/R02)	✓	Cleanroom Parameters will be tested during Cleanroom Performance Test (CPT) by NIEBS Tester.
AHU	Room Description	Room No.	Room ISO Class	Pressure (Pa) (ref. atmosphere)	Relative Humidity (RH) (%)	Temperature (°C)																																				
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URS Clause	Design Requirement	Design Ref.	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)																																																																																				
8.2.2	Critical Quality Attributes (CQA) The HVAC system shall produce required cleanroom condition as follows: <table><tr><th>Room Classification</th><th>Attributes</th><th>Maximum permitted number</th></tr><tr><td rowspan="2">ISO 7 & ISO 8</td><td>Non-viable count</td><td>Refer Table 6 below</td></tr><tr><td>Viable count</td><td>Refer Table 7 below</td></tr></table> Table 3: Critical Quality Attributes <table><tr><th rowspan="2">ISO Class No.</th><th colspan="6">Maximum Allowable Concentration (particles/m³) for Particles Equal to and Greater Than the Considered Sizes, Shown Below</th></tr><tr><th>0.1 µm</th><th>0.2 µm</th><th>0.3 µm</th><th>0.5 µm</th><th>1.0 µm</th><th>5 µm</th></tr><tr><td>1</td><td>10</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>2</td><td>100</td><td>24</td><td>10</td><td></td><td></td><td></td></tr><tr><td>3</td><td>1,000</td><td>237</td><td>102</td><td>35</td><td></td><td></td></tr><tr><td>4</td><td>10,000</td><td>2,370</td><td>1,020</td><td>352</td><td>83</td><td></td></tr><tr><td>5</td><td>100,000</td><td>23,700</td><td>10,200</td><td>3,520</td><td>832</td><td></td></tr><tr><td>6</td><td>1,000,000</td><td>237,000</td><td>102,000</td><td>35,200</td><td>8,320</td><td>293</td></tr><tr><td>7</td><td></td><td></td><td></td><td>352,000</td><td>83,200</td><td>2,930</td></tr><tr><td>8</td><td></td><td></td><td></td><td>3,520,000</td><td>832,000</td><td>29,300</td></tr><tr><td>9</td><td></td><td></td><td></td><td>35,200,000</td><td>8,320,000</td><td>293,000</td></tr></table> Table 4: ISO allowable number of airborne particles of cleanrooms (Non-viable)	Room Classification	Attributes	Maximum permitted number	ISO 7 & ISO 8	Non-viable count	Refer Table 6 below	Viable count	Refer Table 7 below	ISO Class No.	Maximum Allowable Concentration (particles/m ³) for Particles Equal to and Greater Than the Considered Sizes, Shown Below						0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5 µm	1	10						2	100	24	10				3	1,000	237	102	35			4	10,000	2,370	1,020	352	83		5	100,000	23,700	10,200	3,520	832		6	1,000,000	237,000	102,000	35,200	8,320	293	7				352,000	83,200	2,930	8				3,520,000	832,000	29,300	9				35,200,000	8,320,000	293,000	Attachment 1: Construction Drawing - Room Grade Classification (4 POEBS01/OT&SOR/DC/HVAC/02/001) Attachment 2: Sample Identification Tag for H1V4 Terminal HEPA Filter (L-POEBS01-SIT-HVAC-10)	✓	Particle count and Total Microbial Test will be tested during Cleanroom Performance Test (CPT) by NBSB Tester.
Room Classification	Attributes	Maximum permitted number																																																																																						
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	<table><thead><tr><th rowspan="2">Grade</th><th colspan="2">Maximum Limits for Total Particle $\geq 0.5\mu\text{m}/\text{m}^3$</th><th colspan="2">Maximum Limits for Total Particle $\geq 5\mu\text{m}/\text{m}^3$</th></tr><tr><th>At Rest</th><th>In Operation</th><th>At Rest</th><th>In Operation</th></tr></thead><tbody><tr><td>A</td><td>3,520</td><td>3,520</td><td>Not Specified (a)</td><td>Not Specified (a)</td></tr><tr><td>B</td><td>3,520</td><td>352,000</td><td>Not Specified (a)</td><td>2,930</td></tr><tr><td>C</td><td>352,000</td><td>3,520,000</td><td>2,930</td><td>29,300</td></tr><tr><td>D</td><td>3,520,000</td><td>Not Predetermined (b)</td><td>29,300</td><td>Not Predetermined (b)</td></tr></tbody></table> Table 5: PIC/S maximum permitted total particle concentration for classification Notes: (a) Classification including $5\mu\text{m}$ particles may be considered where indicated by the CCS or historical trends. (b) For grade D, in operation limits are not predetermined. The manufacturer should establish in operation limits based on a risk assessment and routine data where applicable. <table><thead><tr><th rowspan="2">Grade</th><th colspan="3">Maximum Permitted Microbial Contamination Level</th></tr><tr><th>Air Sample (cfu/m³)</th><th>Settle Plates (diameter 90mm) (cfu/4 hours)</th><th>Contact Plates (diameter 55mm) (cfu/plate)</th></tr></thead><tbody><tr><td>A</td><td></td><td>No Growth</td><td></td></tr><tr><td>B</td><td>10</td><td>5</td><td>5</td></tr><tr><td>C</td><td>100</td><td>50</td><td>25</td></tr><tr><td>D</td><td>200</td><td>100</td><td>50</td></tr></tbody></table> Table 6: PIC/S maximum permitted microbial contamination level (Viable) Notes: (a) These are average values (b) Individual settle plates may be exposed for less than 4 hours (c) ISO 7 = Grade C; ISO 8 = Grade D	Grade	Maximum Limits for Total Particle $\geq 0.5\mu\text{m}/\text{m}^3$		Maximum Limits for Total Particle $\geq 5\mu\text{m}/\text{m}^3$		At Rest	In Operation	At Rest	In Operation	A	3,520	3,520	Not Specified (a)	Not Specified (a)	B	3,520	352,000	Not Specified (a)	2,930	C	352,000	3,520,000	2,930	29,300	D	3,520,000	Not Predetermined (b)	29,300	Not Predetermined (b)	Grade	Maximum Permitted Microbial Contamination Level			Air Sample (cfu/m ³)	Settle Plates (diameter 90mm) (cfu/4 hours)	Contact Plates (diameter 55mm) (cfu/plate)	A		No Growth		B	10	5	5	C	100	50	25	D	200	100	50	Attachment 1 : Construction Drawing - Room Grade Classification (L/POEBS01/07-SCR/DC/HVAC/03/100)	Attachment 8 : Sample Identification Tag for H14 Terminal HEPA Filter (L-POEBS01-SIT-HVAC-10)	✓	Particle count and Total Microbial Test will be tested during Cleanroom Performance Test (CPT) by NBBIS Tester.
Grade	Maximum Limits for Total Particle $\geq 0.5\mu\text{m}/\text{m}^3$		Maximum Limits for Total Particle $\geq 5\mu\text{m}/\text{m}^3$																																																						
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8.2.3	HVAC Requirements One (1) AHU shall be used to supply the required airflow to the respective cleanrooms to achieve the above required conditions.	Attachment 7: Construction Drawing - Airflow Schematics (L-POES01/OT & SCR/DC/HVAC/05/REV2)	✓	N/A
8.2.4	Design & Functional Constraints			
8.2.4.1	The AHU shall utilize direct expansion (DX) type for cooling and dehumidification.	Attachment 7: Construction Drawing - Airflow Schematics (L-POES01/OT & SCR/DC/HVAC/05/REV2)	✓	N/A
8.2.4.2	A heat recovery wheel shall be utilized to reduce the energy required for cooling and dehumidification.	Attachment 7: Construction Drawing - Airflow Schematics (L-POES01/OT & SCR/DC/HVAC/05/REV2) Attachment 9: Sample Identification Tag for Heat Recovery Wheel (L-POES01-SIT-HVAC-73)	✓	N/A

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8.2.5	AHU-OT-02			
8.2.5.1	The HVAC system supplies single pass air to all the cleanrooms, including Operation Theatre 3, Operation Theatre 4, Scrub 2, Janitor 3, and Packing & Autoclave Room 2. The exhausted air from all the cleanrooms shall be flowing towards heat recovery wheel before discharged to the atmosphere by exhaust fan instead of being recirculated. This is to prevent the cleanrooms from being contaminated by infectious particles.	Attachment 7: Construction Drawing - Airflow Schematic (L/POEBS01/OT & SCR/OC/HVAC/05/R02)	✓	N/A
8.2.6	Filtration System			
8.2.6.1	Fresh air shall be filtered by primary filter grade G4(B) equip inside filter box located before heat recovery wheel.	Attachment 7: Construction Drawing - Airflow Schematic (L/POEBS01/OT & SCR/OC/HVAC/05/R02) Attachment 10: Sample Identification Tag for G4 Filter (L-POEBS01-SIT-HVAC-11)	✓	N/A
8.2.6.2	Air filters used in the air handling system shall be secondary filter grade F9.	Attachment 7: Construction Drawing - Airflow Schematic (L/POEBS01/OT & SCR/OC/HVAC/05/R02) Attachment 11: Sample Identification Tag for F9 Filter (L-POEBS01-SIT-HVAC-12)	✓	N/A

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URS Clause	Design Requirement	Design Ref.	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.2.6.3	HEPA Filters grade H14 shall be fitted at the HEPA Filter Terminal before air is discharged into all the classified cleanrooms.	Attachment 7: Construction Drawing - Airflow Schematic (L-POEBS01-OT & SCR/DC/HVAC/ISS/RO2) Attachment 8: Sample Identification Tag for H14 Terminal HEPA Filter (L-POEBS01-SIT-HVAC-10)	✓	N/A
8.2.7	Ducting System			
8.2.7.1	Material sheet used in ducting shall be Zincalume sheet, insulated to prevent any condensation externally. Ducting shall be constructed based on international standard.	Attachment 12: Sample Identification Tag for Ducting Material (Zincalume) (L-POEBS01-SIT-HVAC-04) Attachment 13: Sample Identification Tag for Duct Insulation (K-Flex) (L-POEBS01-SIT-HVAC-05)	✓	N/A
8.2.7.2	Duct work must have undergone and passed the duct leakage testing. The test report shall be submitted as part of handover documents.	Attachment 14: Sample of Duct leak Test Report (PRO-F-96-R01)	✓	Duct Leakage Test will be conducted during testing and commissioning

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URS Clause	Design Requirement	Design Ref.	Complied with URS? (✓, ✗ or NA)	Remarks (including evidence from other documents if any)
8.2.8	Differential Pressure Gauge (DPG)			
8.2.8.1	Calibrated pressure gauge ranging 0 to 60 Pa shall be installed at rooms for measuring room differential pressure.	Attachment 15: Sample Identification Tag for Differential Pressure Gauge (L-POEBS01-517-1P0-05)	✓	N/A
8.2.8.2	Calibrated pressure gauge ranging 0 to 500 Pa shall also be installed for monitoring of terminal HEPA filter conditions.	Attachment 15: Sample Identification Tag for Differential Pressure Gauge (L-POEBS01-517-1P0-05)	✓	N/A
8.2.9	Temperature and Relative Humidity Sensor (TRH)			
8.2.9.1	There shall be three (3) units of TRH located at the exhaust ducts.	Attachment 7: Construction Drawing - Airflow Schematic (L-POEBS01-07-1SCR/DC/HVAC/05/202) Attachment 16: Sample Identification Tag for Duct Sensor (L-POEBS01-517-ELEC-04)	✓	N/A



24 MAY 2023

10.0 POST-EXECUTION APPROVAL

This approval indicates that the design has been reviewed and meets all the requirements specified in the User Requirement Specification (URS). All discrepancies found have been suitably resolved.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by:			
Reviewed by:		N/A	
Approved by:	GOO CHUI HOONG Operations Manager OasisEye Specialists		24-May-2023-

11.0 DEVIATION LIST

Summary of all the deviations documented throughout the execution of the Design Qualification.

[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:		
N/A		
23-May-2023		
Evaluation by:	Signature	Date (dd-mmm-yyyy)
Reviewed By:		

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

24 MAY 2025

12.0 LIST OF ATTACHMENTS

List of attachments should include all the supporting evidence and deviation reports.

N/A
~~11~~
23-may-2013