

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 1 of 33     |

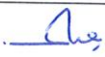
## INSTALLATION QUALIFICATION FOR HVAC SYSTEM (QUALITY CONTROL LABORATORY)

PROJECT: ESTABLISHMENT OF PHARMANIAGA HALAL VACCINE  
MANUFACTURING FACILITY, QUALITY CONTROL LABORATORY,  
ADMINISTRATIVE BUILDING AND INSULIN MANUFACTURING FACILITY FOR  
MESSRS PHARMANIAGA LIFESCIENCE SDN. BHD. (PUCHONG)

### 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) |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------------------------------------------------|--------------------|
| <b>Authored by:</b><br>Siti Norhana Fatehah                                                                                                     | Validation cum QA Executive               |   | 4-Jul-2022         |
| <b>Reviewed by:</b><br>Mohd Fahmi Abd Majid                                                                                                     | Design, Quality & Special Project Manager |   | 4-Jul-2022         |
| <b>Reviewed by:</b><br>Mohd Suhaimi Ishak                                                                                                       | Senior Project Manager                    |  | 4-Jul-2022         |
| By signing below, Pharmaniaga LifeScience 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) |
| <b>Reviewed by:</b><br>Mohd Fadhti Bin Jaafar                                                                                                   | Head of Technical Service                 |  | 05-Jul-2022        |
| <b>Reviewed by:</b><br>Nurul Sa'adiqah Abdul Multalib                                                                                           | Head of Engineering                       |   | 05-Jul-2022        |
| <b>Reviewed by:</b><br>Noor Zurqahy Mohamed Noor                                                                                                | Head of Project                           |  | 05-Jul-2022        |
| <b>Reviewed by:</b><br>Zuraiclah Abd Wahab                                                                                                      | Head of Quality Control                   |  | 05-Jul-2022        |
| <b>Approved by:</b><br>Abkariah Azhari                                                                                                          | Head of Quality Assurance                 |  | 06-Jul-2022        |

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 2 of 33     |

## Table of Contents

|      |                                                            |    |
|------|------------------------------------------------------------|----|
| 1.0  | Reference Documents.....                                   | 3  |
| 2.0  | Version History .....                                      | 3  |
| 3.0  | Introduction and Scope .....                               | 3  |
| 4.0  | Purpose.....                                               | 3  |
| 5.0  | Roles & Responsibility.....                                | 4  |
| 6.0  | System Description .....                                   | 5  |
| 6.1  | Heating, Ventilation & Air Conditioning System (HVAC)..... | 5  |
| 6.2  | Cleanrooms Operating Conditions.....                       | 6  |
| 7.0  | System Boundaries .....                                    | 7  |
| 8.0  | Test Sheets .....                                          | 7  |
| 9.0  | Testing Rationale .....                                    | 8  |
| 10.0 | Summary of Test.....                                       | 27 |
| 11.0 | Test Instrument Record .....                               | 28 |
| 12.0 | Signature Record .....                                     | 28 |
| 13.0 | Interim Approval .....                                     | 29 |
| 14.0 | Post-Execution Approval .....                              | 30 |
| 15.0 | Deviation List.....                                        | 31 |
| 16.0 | List of Attachments.....                                   | 33 |

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 3 of 33     |

## 1.0 Reference Documents

| No. | Document No.                  | Document Title                                                                                    |
|-----|-------------------------------|---------------------------------------------------------------------------------------------------|
| 1.  | URS-083-R02 (160322)          | User Requirement Specification<br>(HVAC System for Quality Control Laboratory)                    |
| 2.  | L-PLS03-VP&IF-VD-FSDS-HVAC-01 | Functional Specification and Design Specification for HVAC<br>System (Quality Control Laboratory) |
| 3.  | L-PLS03-VP&IF-VD-DQ-HVAC-01   | Design Qualification for HVAC System (Quality Control<br>Laboratory)                              |

## 2.0 Version History

| Revision No. | Date        | Revised By           | Reason for Revision |
|--------------|-------------|----------------------|---------------------|
| 00           | 06 JUL 2022 | Siti Norhana Fatehah | New                 |

## 3.0 Introduction and Scope

This document qualifies the new HVAC system installation for the Pharmaniaga Halal Vaccine Manufacturing Facility, Quality Control Laboratory, Administrative Building and Insulin Manufacturing Facility at Pharmaniaga LifeScience Sdn. Bhd. Cleanrooms is to be in compliance with the principle of Good Manufacturing Practices (cGMP) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), ISO clean room guidelines, and World Health Organization (WHO) guidelines on GMP. The HVAC is designed with reference to the HVAC standard for Air-Conditioning and Refrigeration Institute (ARI), American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), American Society for Testing and Materials (ASTM), The American Society of Mechanical Engineers (ASME) and Sheet Metal and Air Conditioning Contractors' National Association, Inc. (SMACNA) and Good Engineering Practices (GEP). The system has been assessed and categorized as "Direct Impact".

## 4.0 Purpose

This document is created to justify that the critical components have been installed as per the requirements in the design qualification and all necessary supporting documents are in place.

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 4 of 33     |

## 5.0 Roles & Responsibility

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

| Company                           | Job Title                                                   | Responsibility                                                                              |
|-----------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Pharmaniaga LifeScience Sdn. Bhd. | Client Representative                                       | To review/ approved the qualification protocol.                                             |
|                                   |                                                             | To assist in the execution of the qualification protocol.                                   |
|                                   |                                                             | To provide approval to the executed qualification protocol.                                 |
| Lufter Sdn. Bhd.                  | Project Manager<br>Project Engineer<br>Validation Executive | To review and approve the qualification protocol.                                           |
|                                   |                                                             | To prepare and ensure the qualification protocol is reviewed and approved before execution. |
|                                   |                                                             | To perform testing and compile analysis data during execution of the protocol.              |

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2021 |
|                            | Rev. No. | 00                          | Total Page(s)  | 5 of 33     |

## 6.0 System Description

### 6.1 Heating, Ventilation & Air Conditioning System (HVAC)

The HVAC System designed to serve the Grade D area consists of one (1) unit of AHU which is AHU-F3a.

All AHUs supply recirculated air to the rooms as listed in Table 2.

AHU-F3a consists of two separate sections. The first section draws in fresh air and forces it through the primary (grade G4-washable) filter for the first stage of filtration. The fresh air is then conditioned in the chilled-water pre-cooling coil to reduce its temperature and moisture content. In the second section of the AHU unit, the conditioned air is allowed to mix with the return air before passing through a set secondary (grade G4 (washable) and F9) filter. Following the second stage of filtration, the mixed air will then be further cooled down at the chilled-water post-cooling coil section. After that, the post-cooled air will flow through an electrical heater to be heated to the required before exiting the AHU unit.

The supply air enters the grade D cleanrooms via a network of ducting/branch ducts and flexible duct then further filtrated by HEPA (grade H14) (efficiency of >99.995%) filters at the HEPA Filter Terminal before being released into the rooms.

For AHU, air control devices like aluminum blade volume control dampers are strategically installed along the main duct and branch duct to throttle the supply, return air as well as the exhaust air. Manual dampers are installed at each of the supply air diffusers and return air grilles for fine adjustment.

Air exiting from all rooms served by these AHUs will return to the AHU to be recirculated except for the rooms listed below where the air will be exhausted out either via room exhaust.

| No. | AHU     | Room Exhaust                    |
|-----|---------|---------------------------------|
| 1.  | AHU-F3a | Personnel Airlock In/Out (L217) |

Table 1: Rooms with air being exhausted out

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 6 of 33     |

## 6.2 Cleanrooms Operating Conditions

Table 2 below shows the cleanroom parameters designed to meet the design parameters required for Grade D areas as stated in the URS document (URS-083-R02; under section 4.3) and as per existing condition with latest room name given by Pharmaniaga LifeScience Sdn. Bhd.

| AHU     | Room/Area                | Room No. | Room Grade | Pressure (Pa) (reference atmosphere) | Relative Humidity (%) | Temperature (°C) | Minimum Air Change Required | Design Air Change (As Per Consultant Approval) |
|---------|--------------------------|----------|------------|--------------------------------------|-----------------------|------------------|-----------------------------|------------------------------------------------|
| AHU-F3a | Personnel Airlock In/Out | L217     | D          | 20                                   | 50-60                 | 18-24            | ≥ 20                        | 20                                             |
|         | Sterility                | L218     | D          | 25                                   | 50-60                 | 18-24            | ≥ 20                        | 25                                             |

Table 2: Cleanroom parameter

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 7 of 33     |

## 7.0 System Boundaries

The airflow schematic diagram (L-PLS03-VP&IF-AF-02-R02) illustrates the components which comprise the HVAC System and the airflow direction.

The installation qualification covers at the minimum the following equipment/components:

- Air Handling Unit (AHU) System
- High Efficiency Particulate Air (HEPA) Filter
- Ducting System
- Room Differential Pressure Gauge
- Exhaust Air Fan (EAF)
- Control System

## 8.0 Test Sheets

This section details the checks to be carried out in support of the system.

| A/C Ref. | Test Sheet Title                                                        | Test No. |
|----------|-------------------------------------------------------------------------|----------|
| 1        | Design - Design Documentation Record (General)                          | IQ-01    |
| 2        | Nameplate Verification                                                  | IQ-02    |
| 3        | Documentation - Calibration Verification Record (General)               | IQ-03    |
| 4        | Documentation Verification - Filter Grade Certification                 | IQ-04    |
| 5        | Installation Qualification - Pre-Operational Check (Ducting System)     | IQ-05    |
| 6        | Installation Verification - HEPA Filter Installation                    | IQ-06    |
| 7        | Installation Verification (System) - Installation Against Drawing       | IQ-07    |
| 8        | Installation Verification (System) - Electrical Control Panel (General) | IQ-08    |
| 9        | Support - Change Control Record                                         | IQ-09    |

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 8 of 33     |

## 9.0 Testing Rationale

| A/C Ref. | Acceptance Criteria (A/C)                                                                                                                                                                     | Rationale                                                                                                                                      |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| 1        | System design documentation has been reviewed and approved.                                                                                                                                   | To provide documented evidence that all required design documentation(s) is available and has been approved by the relevant parties.           |
| 2        | The data on equipment nameplates is consistent with the design specification.                                                                                                                 | To provide documented evidence that the data on all equipment nameplates conforms to the design specification.                                 |
| 3        | A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.                                                               | To provide documented evidence that all critical instruments have been calibrated.                                                             |
| 4        | Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.                                                              | To provide documented evidence that all HEPA filters conforms to their target efficiency and are able to satisfy the design requirements.      |
| 5        | The installation of the ducting system complies with the specification of ductwork Installation and all mechanical works are as per the latest layout drawing.                                | To provide documented evidence that all ducting has been installed according to the general specification of ductwork installation.            |
| 6        | HEPA filters of the correct grade are installed and are in good condition with valid filter efficiency certification available to prove their efficiencies are up to the design requirements. | To provide documented evidence that all HEPA filters have been installed correctly, in good condition and conforms to their target efficiency. |
| 7        | The installation of all mechanical work is as per the approved design layout.                                                                                                                 | To provide documented evidence that the mechanical work has been installed according to the approved design layout.                            |
| 8        | The construction of control panels and other electrical installations complies with the safety standard.                                                                                      | To provide documented evidence to proof the safety of the control panels and other electrical installations.                                   |
| 9        | Records are available for all changes made to the system throughout the execution of this checking procedure.                                                                                 | To provide documented records of all changes made to the system upon installation.                                                             |



| Design – Design Documentation Record (General) |  |
|------------------------------------------------|--|
| Title:                                         |  |

Test No: IQ-01

**Objective:**

To provide documented evidence that all required design documentation(s) are available and has been approved by the relevant parties.

**Pre-requisites:**

All documents should be reviewed and approved.

**Method:**

Record details of the design documentation; include the document reference, title, version, and status and approval date.

**Acceptance Criteria:**

Approved system design documentation is available.

**Results:**

| Document Type | Document Reference          | Document Title                                                   | Document Version | Document Status | Approval Date | Verified By<br>(Initial & Date) |
|---------------|-----------------------------|------------------------------------------------------------------|------------------|-----------------|---------------|---------------------------------|
| Validation    | L-PLS03-VP&IF-VD-DQ-HVAC-OI | Design Qualification for HVAC System Quality Control Laboratory) | R00              | Approved        | 7-Jul-2022    | Han 15-Jul-2022                 |
|               |                             |                                                                  |                  |                 |               |                                 |
|               |                             |                                                                  |                  |                 |               |                                 |
|               |                             |                                                                  |                  |                 |               |                                 |
|               |                             | N/A                                                              |                  |                 |               |                                 |
|               |                             | Han 15-Jul-2022                                                  |                  |                 |               |                                 |
|               |                             |                                                                  |                  |                 |               |                                 |
|               |                             |                                                                  |                  |                 |               |                                 |



|                            |                      |                                   |                                 |                         |
|----------------------------|----------------------|-----------------------------------|---------------------------------|-------------------------|
| Installation Qualification | Doc. No.<br>Rev. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01<br>00 | Effective Date<br>Total Page(s) | 06 JUL 2022<br>10 of 33 |
|----------------------------|----------------------|-----------------------------------|---------------------------------|-------------------------|

|                                                       |  |                |  |
|-------------------------------------------------------|--|----------------|--|
| Title: Design - Design Documentation Record (General) |  | Test No: IQ-01 |  |
|-------------------------------------------------------|--|----------------|--|

Comments/Deviations/Supporting Documentation:

N/A

|                                          |                                 |                      |
|------------------------------------------|---------------------------------|----------------------|
| Overall Test Outcome (PASS/FAIL)<br>Pass | Verified By (Signature):<br>Ham | Date:<br>15-JUL-2022 |
|------------------------------------------|---------------------------------|----------------------|



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|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 11 of 33    |

|               |                               |                       |
|---------------|-------------------------------|-----------------------|
| <b>Title:</b> | <b>Nameplate Verification</b> | <b>Test No: IQ-02</b> |
|---------------|-------------------------------|-----------------------|

**Objective:**

To provide documented evidence that the data on all equipment nameplates conforms to the design specification.

**Method:**

Document the name, model, and other information found on the nameplate and compare against the design specification. Serial number shall be recorded in the test sheet as found at site. Other information not available on the name plate should be verified against the documents supplied by contractor. (Picture of the nameplate should be attach at the attachment section).

**Acceptance Criteria:**

The data on all equipment nameplates is consistent with the design specification.

**Results:**

| Equipment Reference | Description                    | As Specified     | As Found         | Conformity (Yes/No) | Verified By (Initial & Date) |
|---------------------|--------------------------------|------------------|------------------|---------------------|------------------------------|
| AHU-F3a             | Model                          | A1(M)0985H-0985W | A1CM)0985H-0985W | Yes/No              | than 15-JUL-2022             |
|                     | Serial Number                  | * Record at site | M186915          | Yes/No              | than 15-JUL-2022             |
|                     | Manufacturer                   | Salver           | Salver           | Yes/No              | than 15-JUL-2022             |
|                     | Total Supply Air Quantity, CFM | 1123             | 1440             | Yes/No              | than 15-JUL-2022             |
|                     | External Static Pressure, Pa   | 1079             | 875              | Yes/No              | than 15-JUL-2022             |
|                     | Fan Brand                      | Kruger           | Kruger           | Yes/No              | than 15-JUL-2022             |
|                     | Fan Model                      | BNC-R315/DI(I)   | BNC-R315/DI(CI)  | Yes/No              | than 15-JUL-2022             |
|                     | Fan Motor Serial Number        | * Record at site | HY210901036      | Yes/No              | than 15-JUL-2022             |
|                     | Fan Motor, KW                  | 1.5              | 1.5              | Yes/No              | than 15-JUL-2022             |
|                     | Volts/Poles / Hz               | 415/2/50         | 415/2/50         | Yes/No              | than 15-JUL-2022             |

|                            |  |          |                             |                |             |
|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 12 of 33    |

| Title: |  | Test No: IQ-02 |  |  |  |
|--------|--|----------------|--|--|--|
|--------|--|----------------|--|--|--|

**Comments/Deviations/Supporting Documentation:**

Refer to Attachment 1 : Picture of AHU Nameplate and Fan Motor Serial Number  
 Refer to Attachment 2 : AHU-F3a Data Sheet  
 Refer to Attachment 3 : AHU-F3a Shop Drawing

|                                          |  |                                         |                                  |
|------------------------------------------|--|-----------------------------------------|----------------------------------|
| Overall Test Outcome (PASS/FAIL)<br>Pass |  | Verified By (Signature):<br>[Signature] | Date:<br>15-JUL-2022 15-JUL-2022 |
|------------------------------------------|--|-----------------------------------------|----------------------------------|

06 JUL 2022

|                            |  |          |                             |                |
|----------------------------|--|----------|-----------------------------|----------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date |
|                            |  | Rev. No. | 00                          | Total Page(s)  |
|                            |  | 13 of 33 |                             |                |

**Title: Documentation - Calibration Verification Record (General)**

Test No: IQ-03

**Objective:**

To provide documented evidence that all critical instruments have been calibrated.

**Pre-requisites:**

Device Assessment (Catalogues) should be provided at the attachment section.

**Method:**

Review calibration certification available for each of the critical instruments; verify the accuracy and range, against design requirements and note the calibration certificate reference, calibration frequency and calibration due date.

**Acceptance Criteria:**

A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated.

**Results:**

| Instrument Reference | Instrument Description                                       | Room/ Location              | Calibration Frequency | Calibration Date | Calibration Due Date | Calibration Reference | Initial & Date |
|----------------------|--------------------------------------------------------------|-----------------------------|-----------------------|------------------|----------------------|-----------------------|----------------|
| DPG-F3a-01           | Dwyer Magnehelic Pressure Gauge: 30-0-30 Pa Model: 2300-60Pa | Sterility Room              | Yearly                | 17-Jun-2022      | 17-Jun-2023          | CTP 5291-22           | Ha 15-Jul-2022 |
| DPG-F3a-02           | Dwyer Magnehelic Pressure Gauge: 30-0-30 Pa Model: 2300-60Pa | Personnel Airlock In/ Out 2 | Yearly                | 17-Jun-2022      | 17-Jun-2023          | CTP 5292-22           | Ha 15-Jul-2022 |
| DPG-F3a-03           | Dwyer Magnehelic Pressure Gauge: 30-0-30 Pa Model: 2300-60Pa | Personnel Airlock In/ Out 1 | Yearly                | 17-Jun-2022      | 17-Jun-2023          | CTP 5290-22           | Ha 15-Jul-2022 |

|                            |  |          |                             |                |             |
|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 14 of 33    |

| Title: Documentation – Calibration Verification Record (General)                                                                                                                                                                                                                                      |                          | Test No: IQ-03 |             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------|-------------|
| Comments/Deviations/Supporting Documentation:<br>Refer to Attachment 4 : Differential Pressure Gauge and HEPA Filter Layout (CIF)<br>Refer to Attachment 5 : Calibration Certificate for Differential Pressure Gauge<br>Refer to Attachment 6 : Differential Pressure Gauge Installation Verification |                          |                |             |
| Overall Test Outcome (PASS/FAIL)                                                                                                                                                                                                                                                                      | Verified By (Signature): | Date:          |             |
| Pass                                                                                                                                                                                                                                                                                                  | Ham                      | 15-JUL-2022    | 15-JUL-2022 |

|                            |  |          |                             |                |             |
|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 15 of 33    |

|               |                                                                |                       |
|---------------|----------------------------------------------------------------|-----------------------|
| <b>Title:</b> | <b>Documentation Verification – Filter Grade Certification</b> | <b>Test No: IQ-04</b> |
|---------------|----------------------------------------------------------------|-----------------------|

**Objective/Purpose:**

To provide documented evidence that all HEPA filters conforms to their target efficiency and are able to satisfy the design requirements.

**Pre-requisites:**

System design reviews have been completed.

**Method:**

For each filter referenced below, ensure a fully valid filter efficiency certificate is available.

**Acceptance Criteria:**

Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.

**Results:**

| Equipment Reference | HEPA Filter ID Tag No. | Acceptance Criteria                                         | As Found                                                    |                  |                       | Verified By (Initial & Date) |
|---------------------|------------------------|-------------------------------------------------------------|-------------------------------------------------------------|------------------|-----------------------|------------------------------|
|                     |                        | Grade & Type                                                | Grade & Type                                                | Serial Number    | Certificate Reference |                              |
| AHU-F3a             | THF-F3a-01             | Camfil<br>1210 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14 | Camfill<br>1210mm CW) X 600 mm CH) X 77 mm CD)<br>Grade H14 | 000001 - 3569598 | 15290008              | ttan<br>15-Jul-2022          |
|                     | THF-F3a-02             | Camfil<br>1210 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14 | Camfill<br>1210mm CW) X 600 mm CH) X 77 mm CD)<br>Grade H14 | 000002 - 3569598 | 15290008              | ttan<br>15-Jul-2022          |
|                     | THF-F3a-03             | Camfil<br>600 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14  | Camfill<br>600mm CW) X 600 mm CH) X 77 mm CD)<br>Grade H14  | 000001 - 3569618 | 15290013              | ttan<br>15-Jul-2022          |



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|----------------------------|----------------------|----------------------------------|---------------------------------|-------------------------|
| Installation Qualification | Doc. No.<br>Rev. No. | L-PLS03-VP&F-VD-IQ-HVAC-01<br>00 | Effective Date<br>Total Page(s) | 06 JUL 2022<br>16 of 33 |
|----------------------------|----------------------|----------------------------------|---------------------------------|-------------------------|

| Title:                                        |                          | Documentation Verification – Filter Grade Certification                                                                                    |             | Test No: IQ-04 |
|-----------------------------------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------------|
| Comments/Deviations/Supporting Documentation: |                          | Refer to Attachment 4: Differential Pressure Gauge and Terminal HEPA Filter Layout (CIF)<br>Refer to Attachment 7: HEPA Filter Certificate |             |                |
| Overall Test Outcome (PASS/FAIL)              | Verified By (Signature): | Date:                                                                                                                                      |             |                |
| PASS                                          | han                      | 15-Jul-2022                                                                                                                                | 15-Jul-2022 |                |



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|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 17 of 33    |

**Title:** Installation Qualification - Pre-Operational Check (Ducting System) **Test No: IQ-05**

**Objective/Purpose:**

To provide documented evidence that all ducting has been installed according to the general specification of ductwork installation.

**Pre-requisites:**

Ducting system installation have been completed.

**Method:**

Verify each aspect of the system installation, as detailed within the results section.

**Acceptance Criteria:**

The installation of the ducting system complies with the general specification of ductwork installation.

**Results:**

| Acceptance Criteria                                                                                                                                               | Conformity (Yes/No) | Verified By (Initial & Date) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|------------------------------|
| System installation has been completed according to the ducting layout drawing and all connections have been made.                                                | Yes/No              | Ha 15-JUL-2022               |
| Inspection for ducting is present and correctness of the tag number for the supply and return air grilles.                                                        | Yes/No              | Ha 15-JUL-2022               |
| Ductwork and bracket are mounted adequately.                                                                                                                      | Yes/No              | Ha 15-JUL-2022               |
| Ductwork insulation is correctly installed and properly finished with labels indicating air flow direction. Insulation for cleanliness of the ducting is present. | Yes/No              | Ha 15-JUL-2022               |
| Probes and pressure gauge are installed as specified.                                                                                                             | Yes/No              | Ha 15-JUL-2022               |
| Connections to equipment are correct in relation to design flow direction.                                                                                        | Yes/No              | Ha 15-JUL-2022               |
| Volume control damper are installed and free to operate.                                                                                                          | Yes/No              | Ha 15-JUL-2022               |
| All components are properly secured.                                                                                                                              | Yes/No              | Ha 15-JUL-2022               |
| Anti-vibration mountings have precise deflection and all shipping braces have been removed.                                                                       | Yes/No              | Ha 15-JUL-2022               |
| Flushing/ forced circulation cleaning has been completed.                                                                                                         | Yes/No              | Ha 15-JUL-2022               |
| External cleanliness of AHU.                                                                                                                                      | Yes/No              | Ha 15-JUL-2022               |

|                            |  |          |                             |                |             |
|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 18 of 33    |

|               |                                                                            |                       |
|---------------|----------------------------------------------------------------------------|-----------------------|
| <b>Title:</b> | <b>Installation Qualification - Pre-Operational Check (Ducting System)</b> | <b>Test No: IQ-05</b> |
|---------------|----------------------------------------------------------------------------|-----------------------|

**Comments/Deviations/Supporting Documentation:**

Refer to Attachment B : Picture of Ducting Installation  
 Refer to Attachment 9 : MicroLab Ductwork Layout AHU-F3 & AHU-F3a (First Floor)  
 Refer to Attachment 10 : Duct Flushing Report

**Overall Test Outcome (PASS/FAIL):**

Pass

**Verified By (Signature):**

han

**Date:**

15-JUL-2022 15-JUL-2022

|                            |  |          |                             |                |             |
|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 19 of 33    |

|               |                                                             |                 |              |
|---------------|-------------------------------------------------------------|-----------------|--------------|
| <b>Title:</b> | <b>Installation Verification – HEPA Filter Installation</b> | <b>Test No:</b> | <b>IQ-06</b> |
|---------------|-------------------------------------------------------------|-----------------|--------------|

**Objective/Purpose:**  
To provide documented evidence that all HEPA filters are able to perform as per the design requirement upon installation.

**Pre-requisites:**  
Certificates of conformity for HEPA filters indicate compliance with design specification.

**Method:**

1. Initiate the system shutdown procedure and confirm electrical isolation. Identify HEPA filter(s) to be installed. Clean filter housing with alcohol taking care to remove all dust and dirt. Allow to dry.
2. To install a new filter, invert box so filter falls from box, minimising physical contact. Record unique reference number and visually inspect filter for any damage. If a test certificate is included, attach this to report. Take filter to housing, remove from bag and carefully smear a thin layer of grease around it to assist insertion. Taking care not to touch the filter media, insert into housing and tighten into place.
3. Repeat steps 1 and 2 for subsequent HEPA filters. Once all HEPA filters have been installed, start-up system and record clean filter pressure drops for information (do this after the air flow design has been achieved).

**Acceptance Criteria:**  
HEPA filters of the correct grade have been installed and their efficiencies are not compromised during the installation process.

**Results:**

| AHU     | HEPA Filter Reference | As Specified                                                |  | As Found                                                    |  | Visual Inspection Satisfactory (Yes/No) | Verified By (Initial & Date) |
|---------|-----------------------|-------------------------------------------------------------|--|-------------------------------------------------------------|--|-----------------------------------------|------------------------------|
|         |                       | HEPA Filter Grade                                           |  | HEPA Filter Grade                                           |  |                                         |                              |
| AHU-F3a | THF-F3a-01            | Camfil<br>1210 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14 |  | Camfil<br>1210 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14 |  | Yes / No                                | 15-JUL-2022                  |
|         | THF-F3a-02            | Camfil<br>1210 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14 |  | Camfil<br>1210 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14 |  | Yes / No                                | 15-JUL-2022                  |
|         | THF-F3a-03            | Camfil<br>600 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14  |  | Camfil<br>600 mm (W) X 600 mm (H) X 77 mm (D)<br>Grade H14  |  | Yes / No                                | 15-JUL-2022                  |

|                                                                                                                                                                           |                          |                      |                                   |                                 |                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|-----------------------------------|---------------------------------|-------------------------|
| Installation Qualification                                                                                                                                                |                          | Doc. No.<br>Rev. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01<br>00 | Effective Date<br>Total Page(s) | 06 JUL 2022<br>20 of 33 |
| <b>Title:</b> Installation Verification – HEPA Filter Installation<br><b>Test No:</b> IQ-06                                                                               |                          |                      |                                   |                                 |                         |
| <b>Comments/Deviations/Supporting Documentation:</b><br>Refer to Attachment 7 : HEPA Filter Certificate<br>Refer to Attachment II : HEPA Filter Installation Verification |                          |                      |                                   |                                 |                         |
| Overall Test Outcome (PASS/FAIL)                                                                                                                                          | Verified By (Signature): | Date:                |                                   |                                 |                         |
| Pass                                                                                                                                                                      | Han                      | 15-JUL-2022          |                                   | 15-JUL-2022                     |                         |

|                            |                      |                                   |                                 |                         |
|----------------------------|----------------------|-----------------------------------|---------------------------------|-------------------------|
| Installation Qualification | Doc. No.<br>Rev. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01<br>00 | Effective Date<br>Total Page(s) | 06 JUL 2022<br>21 of 33 |
|----------------------------|----------------------|-----------------------------------|---------------------------------|-------------------------|

| Title: | Installation Verification (System) – Installation Against Drawing | Test No: IQ-07 |
|--------|-------------------------------------------------------------------|----------------|
|--------|-------------------------------------------------------------------|----------------|

**Objective:**

To provide documented evidence that the mechanical work has been installed according to the approved design layout.

**Pre-requisites:**

Approved as-built drawing should be attached.

**Method:**

1. Take a copy of the required drawings to be verified and record the revision numbers in the results table.
2. Compare the drawing against the installation and mark the drawing to clearly indicate areas or items that are correct, that are incorrect and items that could not be verified.
3. Identify the marked-up copy of the drawing with the protocol and test reference then sign and date.

**Acceptance Criteria:**

The installation of all mechanical work is as per the approved design layout.

**Results:**

| Drawing Title                                                    | Reference No.                    | Revision No.    | Conformity (Yes/No) | Verified By (Initial & Date) |
|------------------------------------------------------------------|----------------------------------|-----------------|---------------------|------------------------------|
| Differential Pressure Gauge and Terminal HEPA Filter Layout C/F) | L/PLS03/VP&IF/SD/HVAC/HPG/01/ROO | ROO             | Yes/No              | Han 15-Jul-2022              |
| Microlab Ductwork Layout AHU-F3 & AHU-F3a (First Floor)          | L/PLS03/VP&IF/SD/HVAC/M1/05/RO3  | RO3             | Yes/No              | Han 15-Jul-2022              |
| Microlab Control Panel Layout CAHU-F3a)                          | L/PLS03/VP&IF/SD/HVAC/M1/20/ROO  | ROO             | Yes/No              | Han 15-Jul-2022              |
|                                                                  | N/A                              |                 | Yes/No              |                              |
|                                                                  |                                  | Han 15-Jul-2022 | Yes/No              |                              |

|                            |  |          |                             |                |             |
|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 22 of 33    |

|               |                                                                          |                       |
|---------------|--------------------------------------------------------------------------|-----------------------|
| <b>Title:</b> | <b>Installation Verification (System) - Installation Against Drawing</b> | <b>Test No: IQ-07</b> |
|---------------|--------------------------------------------------------------------------|-----------------------|

**Comments/Deviations/Supporting Documentation:**

Refer to Attachment 4 : Differential Pressure Gauge and Terminal HEPA Filter Layout (C/F)  
Refer to Attachment 9 : Microlab Ductwork Layout AHU-F3 & AHU-F3a (First Floor)  
Refer to Attachment 12 : Microlab Control Panel Layout CAHU-F3a)

|                                  |                          |             |
|----------------------------------|--------------------------|-------------|
| Overall Test Outcome (PASS/FAIL) | Verified By (Signature): | Date:       |
| PASS                             | <i>Hen</i>               | 15-JUL-2022 |
|                                  |                          | 15-JUL-2022 |

|                            |  |          |                             |                |             |
|----------------------------|--|----------|-----------------------------|----------------|-------------|
| Installation Qualification |  | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            |  | Rev. No. | 00                          | Total Page(s)  | 23 of 33    |

|               |                                                                                |  |  |  |                       |
|---------------|--------------------------------------------------------------------------------|--|--|--|-----------------------|
| <b>Title:</b> | <b>Installation Verification (System) – Electrical Control Panel (General)</b> |  |  |  | <b>Test No:</b> IQ-08 |
|---------------|--------------------------------------------------------------------------------|--|--|--|-----------------------|

**Objective:**

To provide documented evidence to proof the safety of the control panels and other electrical installations.

**Pre-requisites:**

Approved electrical control panel drawing should be attached.

**Method/Acceptance Criteria/Results:**

The construction of control panels and other electrical installations complies with the safety standard.

| No. | Test Method                                                                           | As Specified                                                                  | Conformity (Yes/No) | Verified By (Initial & Date) |
|-----|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|---------------------|------------------------------|
| 1   | Verify isolator provided.                                                             | Isolator provided.                                                            | Yes/No              | Ha 15-JUL-2022               |
| 2   | Verify the voltage present and supply references are label.                           | Voltage present and supply reference labelled.                                | Yes/No              | Ha 15-JUL-2022               |
| 3   | Verify that the electrical devices are identified.                                    | Electrical devices identified.                                                | Yes/No              | Ha 15-JUL-2022               |
| 4   | Verify that an earth strap is fit in the switchboard.                                 | Earth strap is fitted to the switchboard.                                     | Yes/No              | Ha 15-JUL-2022               |
| 5   | Verify that main live terminals are adequately shroud and label with voltage present. | Main live terminals are adequately shrouded and labeled with voltage present. | Yes/No              | Ha 15-JUL-2022               |
| 6   | Verify that components and wiring are segregate.                                      | Components and wiring are segregated.                                         | Yes/No              | Ha 15-JUL-2022               |
| 7   | Verify that the emergency stop button is provided.                                    | Emergency stop button provided which located at the AHU.                      | Yes/No              | Ha 15-JUL-2022               |



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|                                                                                                                   |                                 |                      |                             |                |                |
|-------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|-----------------------------|----------------|----------------|
| Installation Qualification                                                                                        |                                 | Doc. No.             | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022    |
|                                                                                                                   |                                 | Rev. No.             | 00                          | Total Page(s)  | 24 of 33       |
| Title: Installation Verification (System) – Electrical Control Panel (General)                                    |                                 |                      |                             |                | Test No: IQ-08 |
| Comments/Deviations/Supporting Documentation:<br>Refer to Attachment 12 : MicroLab Control Panel Layout CA#4-F3a) |                                 |                      |                             |                |                |
| Overall Test Outcome (PASS/FAIL)<br>Pass                                                                          | Verified By (Signature):<br>han | Date:<br>15-JUL-2022 | 15-JUL-2022                 |                |                |



|                            |          |                              |                |             |
|----------------------------|----------|------------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-V/P&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                           | Total Page(s)  | 25 of 33    |

## Support - Change Control Record

Test No: IQ-09

To provide documented records for all changes made to the system upon installation.

**Pre-requisites:**

All approved change form must be attached.

**Method:**

1. Record each change made to the system during the completion of the protocol. Record the change reference, a brief description of the change and the date of the change. Clearly and concisely outline what needs to be changed, so the impacted areas can review and analyze.

### Acceptance Criteria:

1. Records for all changes made to the system throughout the execution of this checking procedure are available.
2. Further tests required after the changes made have been conducted.

**Results:**

| Change Reference | Description of Change | Date of Change (dd/mm/yyyy) | Further Testing Required (Yes/No) | Further Testing Complete (Yes/No) | Verified By (Initial & Date) |
|------------------|-----------------------|-----------------------------|-----------------------------------|-----------------------------------|------------------------------|
|                  |                       |                             |                                   |                                   |                              |
|                  |                       |                             |                                   |                                   |                              |
|                  |                       |                             |                                   |                                   |                              |
|                  |                       | N/A                         |                                   |                                   |                              |
|                  |                       | 15-Jul-2022                 |                                   |                                   |                              |
|                  |                       |                             |                                   |                                   |                              |
|                  |                       |                             |                                   |                                   |                              |
|                  |                       |                             |                                   |                                   |                              |
|                  |                       |                             |                                   |                                   |                              |



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|----------------------------|----------------------|-----------------------------------|---------------------------------|-------------------------|
| Installation Qualification | Doc. No.<br>Rev. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01<br>00 | Effective Date<br>Total Page(s) | 06 JUL 2022<br>26 of 33 |
|----------------------------|----------------------|-----------------------------------|---------------------------------|-------------------------|

**Title:** Support - Change Control Record **Test No:** IQ-09

Comments/Deviations/Supporting Documentation:

N/A

|                                          |                                 |                      |
|------------------------------------------|---------------------------------|----------------------|
| Overall Test Outcome (PASS/FAIL)<br>Pass | Verified By (Signature):<br>Han | Date:<br>15-JUL-2022 |
|------------------------------------------|---------------------------------|----------------------|

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 27 of 33    |

## 10.0 Summary of Test

This section, detailing system specific Acceptance Criteria (A/C), should be completed following a review of the test sheets, within Section 8, and supporting data, contained within the referenced project files.

### Design

| Ref. No. | Acceptance Criteria                                                           | A/C Met? (Yes/No) | Deviation Ref. | Initial & Date    |
|----------|-------------------------------------------------------------------------------|-------------------|----------------|-------------------|
| 1        | Approved system design documentation(s) has been completed and approved.      | Yes               | N/A            | Ha<br>15-Jul-2022 |
| 2        | The data on equipment nameplates is consistent with the design specification. | Yes               | N/A            | Ha<br>15-Jul-2022 |

### Documentation

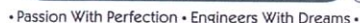
| Ref. No. | Acceptance Criteria                                                                                                                                                | A/C Met? (Yes/No) | Deviation Ref. | Initial & Date    |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|-------------------|
| 3        | A valid calibration certificate is available for all critical instruments to prove that these instruments have been calibrated according to the Device Assessment. | Yes               | N/A            | Ha<br>15-Jul-2022 |
| 4        | Filter efficiency certification is available for all HEPA filters to prove their efficiencies are up to the design requirements.                                   | Yes               | N/A            | Ha<br>15-Jul-2022 |

### Installation

| Ref. No. | Acceptance Criteria                                                                                                               | A/C Met? (Yes/No) | Deviation Ref. | Initial & Date    |
|----------|-----------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------|-------------------|
| 5        | The installation of the ducting system complies with the General Specification of Ductwork Installation.                          | Yes               | N/A            | Ha<br>15-Jul-2022 |
| 6        | HEPA filters of the correct grade have been installed and their efficiencies are not compromised during the installation process. | Yes               | N/A            | Ha<br>15-Jul-2022 |
| 7        | The installation of all mechanical work is as per the approved design layout.                                                     | Yes               | N/A            | Ha<br>15-Jul-2022 |
| 8        | The construction of control panels and other electrical installations complies with the safety standard.                          | Yes               | N/A            | Ha<br>15-Jul-2022 |

### Additional

| Ref. No. | Acceptance Criteria                                                                                           | A/C Met? (Yes/No) | Deviation Ref. | Initial & Date    |
|----------|---------------------------------------------------------------------------------------------------------------|-------------------|----------------|-------------------|
| 9        | Records are available for all changes made to the system throughout the execution of this checking procedure. | Yes               | N/A            | Ha<br>15-Jul-2022 |

06 JUL 2022

## 11.0 Test Instrument Record

A record of all test instruments used during Installation Qualification, ensuring all instruments have valid calibration certificates.

|     |             |
|-----|-------------|
| N/A |             |
| Ha  | 15-Jul-2023 |

## 12.0 Signature Record

A record of all key personnel(s) involved in the completion of the Installation Qualification.

|                 |  |
|-----------------|--|
| N/A             |  |
| for 15-JUL-2022 |  |



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|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 29 of 33    |

### 13.0 Interim Approval

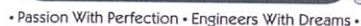
This section is only required when all discrepancies in the deviation list have been considered, the HVAC System may proceed for Operational Qualification pending resolution finalization. If there are no discrepancies or all discrepancies found have been suitably resolved, may proceed for Post-Execution Approval.

| Name         | Job Title or Role | Signature                 | Date (dd-mm-yyyy) |
|--------------|-------------------|---------------------------|-------------------|
| Reviewed by: |                   |                           |                   |
| Reviewed by: |                   |                           |                   |
| Reviewed by: |                   | N/A<br>Hem<br>15-JUL-2022 |                   |
| Reviewed by: |                   |                           |                   |
| Approved by: |                   |                           |                   |

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 30 of 33    |

## 14.0 Post-Execution Approval

| CONDITIONAL ACCEPTANCE                                                                                                                                                                                                           |                              |                                                                                      |                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------------------------------------------------------------------------|--------------------|
| The system operational checks have been reviewed. All testing associated during Installation Qualification are completed with all criteria being met. Any deviations that were noted (if any) have been resolved and closed out. |                              |                                                                                      |                    |
| Name                                                                                                                                                                                                                             | Job Title or Role            | Signature                                                                            | Date (dd-mmm-yyyy) |
| Reviewed by:<br>Mohd Fadhli Bin Jaafar                                                                                                                                                                                           | Head of Technical Service    |    | 18-Jul-2022        |
| Reviewed by:<br>Husni Sa'adiah Abdul Mutalib                                                                                                                                                                                     | Head of Engineering          |    | 18-Jul-2022        |
| Reviewed by:<br>Noor Zuraihan<br>Mohamed Noor                                                                                                                                                                                    | Head of Project              |    | 18-Jul-2022        |
| Reviewed by:<br>Zuraidah Abd<br>Wahab                                                                                                                                                                                            | Head of Quality<br>Control   |   | 18-Jul-2022        |
| Approved by:<br>Abkaniah Azhari                                                                                                                                                                                                  | Head of Quality<br>Assurance |  | 18-Jul-2022        |



06 JUL 2022

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

[illegible]

|                            |          |                             |                |             |
|----------------------------|----------|-----------------------------|----------------|-------------|
| Installation Qualification | Doc. No. | L-PLS03-VP&IF-VD-IQ-HVAC-01 | Effective Date | 06 JUL 2022 |
|                            | Rev. No. | 00                          | Total Page(s)  | 32 of 33    |

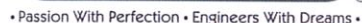
|                         |                    |
|-------------------------|--------------------|
| <b>DEVIATION REPORT</b> | <b>Report no.:</b> |
|-------------------------|--------------------|

|                                     |              |
|-------------------------------------|--------------|
| <b>A. Description of Deviation:</b> |              |
|                                     |              |
|                                     |              |
|                                     |              |
|                                     |              |
| <b>Documented By:</b>               | <b>Date:</b> |

|                                                     |                  |                           |
|-----------------------------------------------------|------------------|---------------------------|
| <b>RESPONSE</b>                                     |                  |                           |
| <b>A. Reason of Deviation</b>                       |                  |                           |
|                                                     |                  |                           |
|                                                     |                  |                           |
|                                                     |                  |                           |
|                                                     |                  |                           |
| <b>B. Correction/ preventive action to be taken</b> |                  | N/A                       |
|                                                     |                  | Ha 15-Jul-2022            |
|                                                     |                  |                           |
|                                                     |                  |                           |
| <b>Evaluation by:</b>                               | <b>Signature</b> | <b>Date (dd-mmm-yyyy)</b> |
| Reviewed By:                                        |                  |                           |

|                                                |                  |                           |
|------------------------------------------------|------------------|---------------------------|
| <b>ACCEPTANCE</b>                              |                  |                           |
| <b>C. Corrective/ preventive action taken:</b> |                  |                           |
|                                                |                  |                           |
|                                                |                  |                           |
|                                                |                  |                           |
|                                                |                  |                           |
| <b>Performed by:</b>                           | <b>Signature</b> | <b>Date (dd-mmm-yyyy)</b> |
| Reviewed By:                                   |                  |                           |
| Reviewed By:                                   |                  |                           |
| Reviewed By:                                   |                  |                           |
| Reviewed By:                                   |                  |                           |
| Approved By:                                   |                  |                           |

Note: This page to be re-printed as required

06 JUL 2022

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

[illegible]