IPac

Standard Qualification

SmartCheck

Model	*SLS1010S*
Serial Number	*C442893113*
Asset Number	*GELP 043*

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IPac

Initial Qualification Package

Description

This IPac is intended to ensure compliance with standards, norms and regulations applicable to equipment in regulated environments and to verify that the equipment performs as required in quality-critical applications. Completion of the qualification process using IPac ensures a professional installation with initial verification, producing documentation ideally suited for integration into a quality management system. IPac is designed to meet Installation Qualification (IQ), Operational Qualification (OQ) requirements. Monitoring of equipment during routine operation section details the procedures for the ongoing process of demonstrating the consistent performance of the equipment through its lifetime and a Maintenance Plan section details maintenance and re-qualification activities after equipment has been released for routine operation.

Procedure Statement

The IPac equipment qualification will be performed by a trained and authorized METTLER TOLEDO Service technician. The equipment referenced in this document has been installed in accordance with the METTLER TOLEDO Work Instruction Installation of SmartCheck instrument. Note: The abbreviation N/A in this entire document means "Not Applicable."

Qualification Process

Initial qualification of the SmartCheck is performed in accordance with the METTLER TOLEDO Work Instruction Installation of SmartCheck instrument. Forms may be completed by either adding handwritten information or by completing electronic forms on a computer. In any case, the signed hard copy is the original document.

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1 Installation Qualification

1.1 Purpose of Qualification

The purpose of Installation Qualification is to demonstrate installation conditions are appropriate, equipment has been received as ordered, all documentation, site requirements are appropriate, and equipment can be installed and put into operation successfully.

1.2 Reason for Qualification

The installation and qualification of equipment is a/an:

☒ Installation of a new instrument

☐ Relocation

☐ Qualification of existing instrument

1.3 Installation of Equipment

Equipment Identification

Device type:	*SmartCheck*
Manufacturer:	*Mettler-Toledo*
Model:	*SLS1010S*
Serial Number:	*C442893113*

Peripheral equipment

Device type:	*COMPUTADOR DE MESA*
Manufacturer:	*DELL*
Model:	*OPTIPLEZ 7780*
Serial Number:	*4J003L3*

Customer Information

Company Name:	*INSTITUTO NACIONAL DE SALUD*
Address:	*AVENIDA CALLE 26 No. 51 - 20*
City:	*COLOMBIA*
Zip Code:	*N/A*

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1.4 Receiving and Unpacking

The delivered equipment is complete compared with the customer order and with the defined standard delivery in the operation instructions.

Equipment

	Complete	Incomplete	N/A
SmartCheck	☒	☐	
Accessories	☒	☐	☐

1.5 Visual Inspection

All equipment including power cable(s), external power adaptor(s), peripheral(s) or accessories are free of visible physical damage.

☒ Satisfactory ☐ Not satisfactory

1.6 Documentation

The delivered equipment documentation is correct and complete, as defined in the standard delivery section in the corresponding operation instructions.

	Complete	Incomplete	N/A	Document No.	Location
Operating Instructions	☒	☐	☐	*30491817A*	*VIRTUAL*
Declaration of Conformity	☐	☐	☒	*N/A*	*N/A*
N/A	☐	☐	☒	*N/A*	*N/A*
N/A	☐	☐	☒	*N/A*	*N/A*

Missing items and Documents

List all missing items and documents and the agreed action with the customer. If no items and documents are missing this section can be skipped.

N/A Agreed action *N/A*

N/A Agreed action *N/A*

1.7 Instrument Location

Identify details of the location the device is installed.

Company name:	*INSTITUTO NACIONAL DE SALUD*
Address:	*AVENIDA CALLE 26 No. 51 - 20*
Department:	*TALLER GELP*
Building:	*BLOQUE A*
Room:	*TALLER GELP*
Location notes:	*N/A*

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1.8 Environmental conditions

The installation site and environmental condition is in accordance with METTLER TOLEDO specification

☒ Yes ☐ No

1.9 Equipment Configuration

Document connection relation for devices connected to the SmartCheck directly.

Model: *SLS1010S*

Serial number: *C442893113*

Asset number: *GELP 043*

Settings

Pipette tolerance [%] *10*

Connection

☐ EasyScan USB ☒ EasyScan Flex Reader ☐ N/A

Model: *N/A*

Serial Number: *N/A*

☐ PipetteX Standalone ☒ PIpetteX Distributed ☐ N/A

PC Id (Standalone): *MARCA: DELL CODIGO INTERNO:37653 S/N: 4J003L3*

Version Number: *v4.1.0.20 (PIPETTEX)*

Firmware Number: *2.0.3.20200811 (SMARTCHECK)*

License Key: *2D2A2-2GJJJ-23832-2LPJW-2GCJT*

☐ Silex Gateway ☒ N/A

Model:

Firmware Number:

Serial Number:

Power up

Connect instrument to the power cable and ensure the startup functionality is as described in the operating instructions.

☒ Yes ☐ No

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1.10 Completion of Installation Qualification

Installation Qualification was completed and documented according to the METTLER TOLEDO Work Instruction Installation of SmartCheck instrument.

Performed by:

Name: *WILMER DOMINGUEZ*

Function: *ASESOR TECNICO*

Date: *2025-08-01*

Signature: Initials: *WD*

Reviewed and approved by:

Name:

Job title:

Date: *2025-08-01*

Signature: Initials:

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2 Operational Qualification

2.1 Operational Readiness

The instrument is acclimatized and ready for the operational qualification.

☒ Yes ☐ No

Instrument

Setup and configuration of device is appropriate; pipette tolerance, draft shield and weighing pan are installed and functioning.

☒ Yes ☐ No ☐ N/A

Peripheral

The peripheral equipment has been configured and functions according to customer requirements.

☒ Yes ☐ No ☐ N/A

2.2 Performance Tests

Repeatability Test

Perform repeatability test according to WI Maintenance SmartCheck:

Weight Used

Nominal Volume:	*1 g*
Weight Class:	*E2*
Calibration Date:	*2024-08-05*
Cert No.:	*CAP-859-24*

Sensitivity Test

Perform sensitivity test according to WI Maintenance SmartCheck:

Weight Used

Nominal Volume:	*10 g*
Weight Class:	*E2*
Calibration Date:	*2024-08-05*
Cert No.:	*CAP-859-24*

Test Report

Report name:	*SMARTCHECK REPORT*
Report ID:	*VI8623-004-080125-SMARTCHECK REPORT*
Creation date:	*2025-08-01*

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3 Equipment familiarization for users

3.1 Purpose

This section ensures that users get appropriate equipment familiarization to allow productive work procedures and safe processes with the device referred to in this document. Equipment familiarization covers instruction on basic operations, functionality and features of the device, cleaning procedures, and use of the METTLER TOLEDO operating instructions.

Equipment familiarization of users was performed according to the METTLER TOLEDO Work Instruction Installation of SmartCheck instrument.

The participants listed in Annex 1, section A have received equipment familiarization.

Equipment familiarization performed by:

Name: *WILMER DOMINGUEZ* Function: *ASESOR TECNICO*

Date: *2025-08-01* Initials: *WD*

Remarks ☒ N/A *N/A*

N/A

3.2 Completion of Operation and Performance Qualification

Operation Qualification was completed and documented according to the METTLER TOLEDO Work Instruction Installation of SmartCheck instrument.

Performed by:

Name: *WILMER DOMINGUEZ*

Function: *ASESOR TECNICO*

Date: *2025-08-01*

Signature: Initials: *WD*

Reviewed and approved by:

Name:

Job Title:

Date: *2025-03-27*

Signature: Initials:

Remarks: ☒ N/A *N/A*

N/A

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4 Monitoring of equipment during routine operation (Reference Annex2)

4.1 Purpose

This section details the procedures for the ongoing process of demonstrating the consistent performance of the equipment through its lifetime. To ensure accuracy and traceability of results, METTLER TOLEDO recommends periodical routine tests performed by the user.

4.2 Decision for Periodic Routine Test Procedure

☒ N/A (No routine test procedure will be performed)

☐ User specified routine test procedure applies

Test procedure (SOP) identification: *N/A*

Version of SOP: *N/A*

Location SOP's: *N/A*

5 Release for Routine Operation

5.1 Purpose

Initial Qualification was performed and completed according to the METTLER TOLEDO Work Instruction Installation of SmartCheck instrument. This section details the release for routine operation, which is the official and formal release of equipment as an irreversible step. Release for routine operation is dependent on compliance with all technical specifications as well as quality and regulatory requirements. Equipment also must meet all additional customer requirements as identified in the purchase order.

Equipment released for routine operation by:

Name: *WILMER DOMINGUEZ*

Job Title: *ASESOR TECNICO*

Date: *2025-08-01*

Signature: Initials: *WD*

Equipment released for routine operation approved by:

Name: *N/A*

Function: *N/A*

Date: *N/A*

Signature: Initials: *N/A*

Remarks: ☒ N/A *N/A*

N/A

N/A

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6 Maintenance plan

6.1 Purpose

This section details maintenance and re-qualification activities after equipment has been released for routine operation. Regulatory requirements request that equipment is properly maintained and verified to ensure accuracy of results. It is the user's responsibility to define maintenance activities and frequency, and METTLER TOLEDO recommends taking care of this as part of the initial qualification process.

6.2 Maintenance provider

Company Name:	*LABZUL S.A.S.*
Address:	*AVENIDA CARRERA 30 No. 85A - 39*
Zip Code / City:	*BOGOTÁ D.C.*
Department:	*CUNDINAMARCA*
Phone:	*518 5031*
Email to Service Support:	*laura.lopez@labzul.com*

6.3 Maintenance plan

Maintenance activities

☒ Maintenance
☐ N/A

Frequency

☒ Yearly
☐ Semi-annual
☐ Monthly
☐ User defined *N/A*

☐ N/A

Date of first maintenance *2025-08-01*

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Annex 1

A) Equipment Familiarization for Users

The participants listed below are trained and qualified to work with the SmartCheck and corresponding peripheral equipment referred to in this document. Equipment familiarization for users was performed according to the METTLER TOLEDO Work Instruction Installation of SmartCheck instrument.

Device Model: *SLS1010S*

Remarks: ☒ N/A *N/A*

N/A

N/A

Trainer

Name: *WILMER DOMINGUEZ*

Date: *2025-08-01*

Signature:

Participant	Participant
Name: *JUAN PABLO PINEDA*	Name: *N/A*
Date: *2025-08-01*	Date: *N/A*
Signature:	Signature:
Signature of Trainer:	Signature of Trainer:
Participant	**Participant**
Name: *N/A*	Name: *N/A*
Date: *N/A*	Date: *N/A*
Signature:	Signature:
Signature of Trainer:	Signature of Trainer:
Participant	**Participant**
Name: *N/A*	Name: *N/A*
Date: *N/A*	Date: *N/A*
Signature:	Signature:
Signature of Trainer:	Signature of Trainer:

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Annex 2

B) Periodical Routine Test

Pre-Conditions

- The Test Kit order no. 30448961 for SmartCheck is needed to execute this routine test.
- SmartCheck shall be connected to the power for at least 2 hours
- The vessel shall be without water and dry
- The SmartCheck shall be placed on a stable, vibration free and draft free room
- Prepare to have the 1) special weighing 2) 1g test weight 3) Black high draft shield and 4) tweezer nearby

Procedure

1. Remove the draft shield from the SmartCheck and place the special draft shield on top of the vessel
2. After several seconds the 1000µL = 1g will start blinking; now place the 1g weight on the weighing pan
3. Place the black high draft shield over it and wait until the LED gets stable; a stable weight value has been taken
4. Take away the black draft shield to remove the 1 g weight and wait until the LED starts blinking again
5. Place the 1 on the weighing pan, repeat the step 2-4 another nine times until 10 repetitions have been done
6. After the final step SmartCheck will calculate the result by showing a Pass (green) or Fail (red)
7. After finishing the test, remove the special weighing pan and place back the standard draft shield
8. SmartCheck is now ready for usage

What if Fail

If the test fails, proceed as follows:

- Repeat the test.
- If it fails again, inform your supervisor and make sure the device is set aside and no longer used.
- If needed, call your local service provider to repair the device.

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