Rotronic AG
Grindelstrasse 6
CH-8303 Bassersdorf

HygroLab System
V2.7.0.0

Compliance Declaration

1 Approval

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2 Change Control

Document Version	Description	Responsible	Date
V1.0	Initial Compliance Declaration	Rotronic AG	26.10.2022
V1.1	Adding the verification documents in Chapter 9.1	Rotronic AG	30.01.2023

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4 Introduction

4.1 Purpose:

The purpose of the compliance declaration is to explain how and why the HygroLab System is complaint to existing regulations.

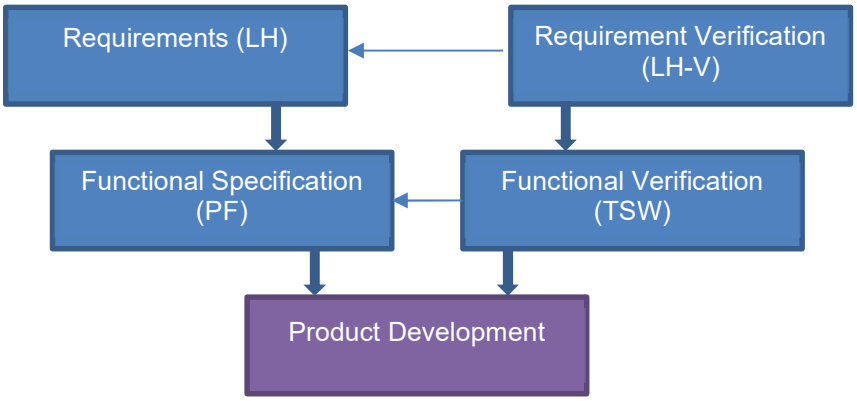
4.2 Scope:

This document is limited to the process carried out by Rotronic AG based upon the GAMP®5 recommendations and FDA 21 CFR Part 11 and EU Annex 11 regulations.

5 Validation Process

This chapter describes the Rotronic internal validation process of the HygroLab System and the corresponding measurement devices.

5.1 Validation Process



5.2 Validation Results

The document *HygroLab_TSW_V270* gives a full overview and report of the performed validation and test process which includes:

- Functionality check of the software and associated devices,
- Data validation,
- Accuracy and completeness of protocols and event files
- Data integrity and protection.

The traceability of the tests as well as the traceability concerning the test environment is provided. The test evidence provided in the following documents is listed in the Validation Test and Reports.

These documents can be reviewed by customers during a site audit.

6 Compliance White Paper

The current compliance status of HygroLab-based systems with the activated FDA Mode is described and documented in the document eCompliance White Paper, *HYGROLAB-WP-V270-EN_V1.0*.

This White Paper presents the current interpretation of Rotronic AG concerning regulatory requirements for computerized system validation, electronic record, and electronic signature as applicable for the healthcare, food and beverage industries as well as for medical device manufacturing and distribution.

7 Validated Products

This document – ROTRONIC HYGROLAB, Validation and Compliance declaration HYGROLAB-CD-V270-EN_V1.0 attests that the HygroLab with compliant devices (see the corresponding Compliance Assessment) and HygroLab-based software performs as it is supposed to and that it can be considered as qualified and fit for purpose according to the meaning of GAMP®5 as well as of FDA 21 CFR Part 11, and EU Annex 11 to the EU Guidelines of Good Manufacturing Practice for Medicinal Products.

Product name	Order code	Version
HygroLab (FDA Mode activated)	HYGROLAB	2.7.0.0
Water activity probes:	HC2-AW HC2A-AW	3.2 3.2
Humidity probe	HC2A-S	1.2

8 Validation Reports

Release Documents

Description	Document name	Version
Validation and Compliance Declaration	This document	1.0
eCompliance White Paper (WP)	HYGROLAB-WP-V270-EN_V1.0.pdf	1.0
Release Notes	HygroLab_Release_Note.pdf	1.0

9 Validation Documents

Available documents for an HygroLab validation:

9.1 Verification Documents

Description	Document name	Version
Operation Qualification (OQ)	HygroLab_IQOQ_V270-EN_V1.0.docx	1.0
Installation Qualification (IQ)	HygroLab_IQOQ_V270-EN_V1.0.docx	1.0

10 Manuals

Description	Document name
HygroLab	https://service.rotronic.com/products-manual/hygrolab.html

11 Compliance Declaration

Rotronic AG attest that the validated version of the Rotronic HygroLab and associated devices (Chapter 6) fulfil the requirements defined in the Rotronic eCompliance White Paper, based on the following references:

- GAMP®5.
- FDA 21 CFR Part 11.
- EU Annex 11: Computerised Systems.
- EU Annex 15: Qualification and Validation.
- FDA 21 CFR Part 210 and 211.
- ISO 14644-1 and ISO 14644-2.

Validated by ROTRONIC AG.

The ROTRONIC HYGROLAB and devices have been reviewed against the specifications and the eCompliance White Paper, HYGROLAB-WP-V270-EN_V1.0, in order to provide evidence that the above-mentioned regulations and guide are fulfilled accordingly.

The measuring devices and the software have been validated and verified against the specifications provided by the manufacturer.