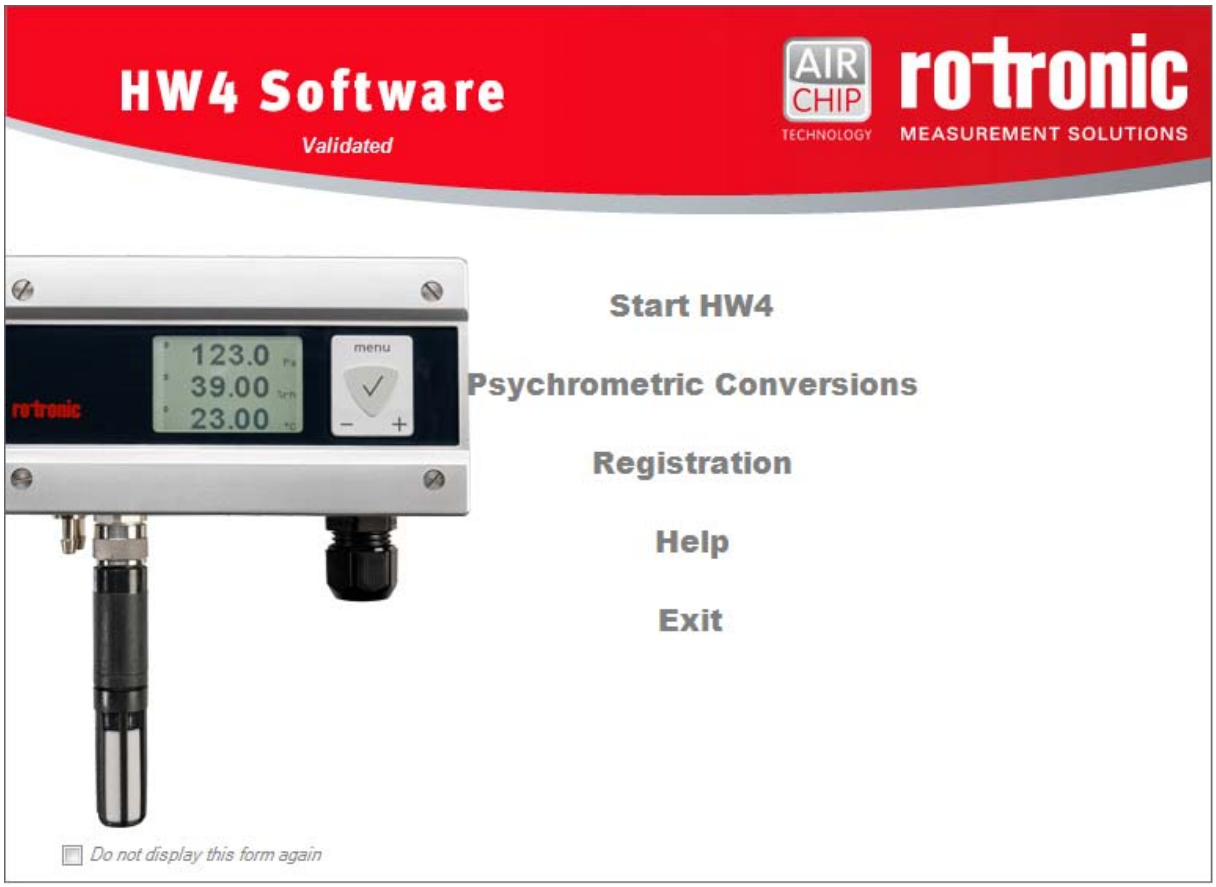
ROTRONIC HW4 Software

Version 3.9.0.19099

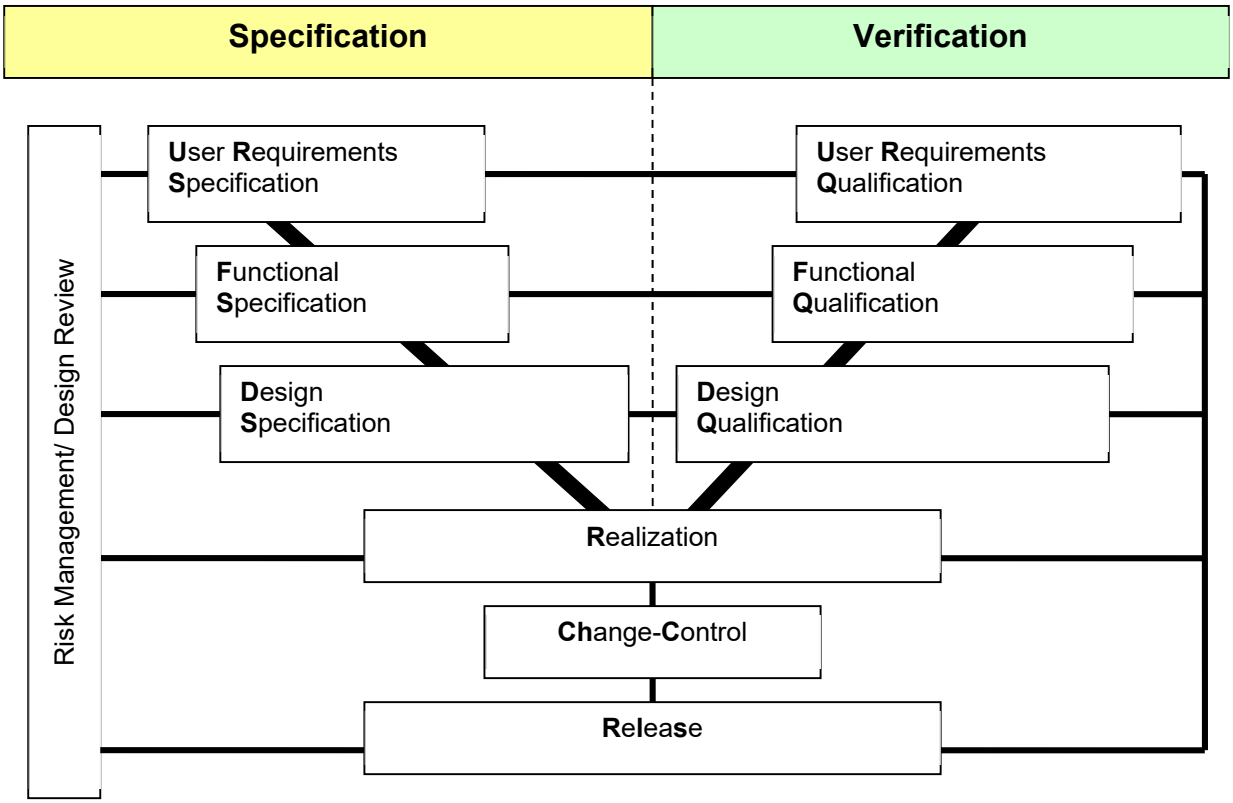
Validation and Compliance Declaration



Document: Validation and Compliance Declaration	**Date**
DV04-30.HW4-370	May, 2019

Table of contents

General Validation Process



The document *ROTRONIC HW4 Software, Validation and Compliance Declaration DV04-30.HW4-390* gives an overview 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. These documents can be reviewed by customer during a site audit.

eCompliance White Paper

The current compliance status of HW4-based systems is described and documented in the document *eCompliance White Paper*, *ROTRONIC HW4 System – ERES-WP-0300*.
This White Paper presents the current interpretation of Rotronic AG concerning regulatory requirements to computerized system validation, electronic record, and electronic signature as applicable for the healthcare, food and beverage industry as well as for medical devices manufacturing and distribution.

Validated Products

This document – *ROTRONIC HW4 Software, Validation and Compliance Declaration DV04-30.HW4-390* – attests that the ROTRONIC HW4 Software building together with compliant devices (see the corresponding Compliance Assessment) a HW4-based system performs as it is supposed to and that it can be considered as fit for purpose according to the meaning of GAMP® 5 as well as of 21 CFR Part 11, 21 CFR 110, 21 CFR 111, 21 CFR 210, 21 CFR 211, and EU Annex 11 to the EU Guidelines of Good Manufacturing Practice for Medicinal Products.

Product	Article	Instruction manuals:	Reviewed
HW4 V3.9.0.19099	HW4 Validated (ID12)	General instructions and functions common to all devices **E-M-HW4v3-Main_20**	√
		List of Manuals **E-M-HW4v3-DR-001_17**	√
		Data Recording Function AirChip 3000 Devices **E-M-HW4v3-DIR_17**	√
		HW4 Software Device Manager and further function HP32 **E-M-HW4v3-F2-027_00**	√
		HW4 Software version 3 Device Manager and Data Logging HygroGen **E-M-HW4v3-F2-026_00**	√
		HW4 Software version 3 Device Manager and AW function Aw Therm **E-M-HW4v3-F2-025_00**	√
		HW4 Software Device Manager and Probe Adjustment HS5 **E-M-HW4v3-F2-024_01**	√
		HW4 Software Device Manager HygroMet4 heated meteo transmitter **E-M-HW4v3-F2-023_11**	√
		Device Manager and Data Logging HL1 and TL1 Data Loggers **E-M-HW4v3-F2-022_15**	√
		Device Manager and Data Logging LOG-RC Series Data Loggers **E-M-HW4v3-F2-021_19**	√
		Device Manager HC2-AW-USB Water Activity Probe **E-M-HW4v3-F2-020_16**	√
		Device Manager HygroLab C1 Humidity Temperature Indicator **E-M-HW4v3-F2-019_16**	√

		Device Manager and Data Logging HL20 and HL21 Data Loggers **E-M-HW4v3-F2-018_19**	√
		Device Manager TF5 Temperature Transmitter **E-M-HW4v3-F2-017_17**	√
		Device Manager HFM53 Humidity Temperature Transmitter **E-M-HW4v3-F2-016_17**	√
		Device Manager and Data Recording HF8 Humidity Temperature Transmitter **E-M-HW4v3-F2-015_18**	√
		Device Manager HygroMet MP Humidity Temperature Probe **E-M-HW4v3-F2-014_17**	√
		HygroLog HL-NT functions **E-M-HW4v3-F2-013_17**	√
		Device Manager and Data Recording HP23 Humidity Temperature Indicator **E-M-HW4v3-F2-012_18**	√
		Device Manager EWHS310 Humidity Temperature Transmitter **E-M-HW4v3-F2-011_17**	√
		Device Manager XA Humidity Temperature Probe **E-M-HW4v3-F2-010_17**	√
		Device Manager XB Humidity Temperature Transmitter **E-M-HW4v3-F2-009_17**	√
		Device Manager HF6 Humidity Temperature Transmitters **E-M-HW4v3-F2-008_17**	√
		Device Manager HF7 Humidity Temperature Transmitters **E-M-HW4v3-F2-007_17**	√
		Device Manager HP22 Humidity Temperature Indicator **E-M-HW4v3-F2-006_17**	√

		Device Manager HF5 Humidity Temperature Transmitter **E-M-HW4v3-F2-005_17**	√
		Device Manager HP21 Temperature Humidity Indicator **E-M-HW4v3-F2-004_17**	√
		Device Manager HF4 Humidity Temperature Transmitter **E-M-HW4v3-F2-003_17**	√
		Device Manager HF3 Transmitters and Thermo-Hygrostats **E-M-HW4v3-F2-002_17**	√
		Device Manager HC2 probe series **E-M-HW4v3-F2-001_17**	√
		HW4 Software Device Manager HygroStat MB **E-M-HW4v3-F1-005_16**	√
		HW4 Software Device Manager HygroClip Alarm (HCA) **E-M-HW4v3-F1-004_16**	√
		HW4 Software Device Manager HygroClip DI **E-M-HW4v3-F1-003_16**	√
		Device Manager Legacy Transmitters and Indicators **E-M-HW4v3-F1-002_16**	√
		HygroLog NT function **E-M-HW4v3-F1-001_17**	√
		Humidity and Temperature Adjustment AirChip 3000 devices **E-M-HW4v3-A2-001_16**	√
		Probe Adjustment function Legacy devices **E-M-HW4v3-A1-001_16**	√
		Device Manager and Probe Adjustment PF4 Differential Pressure Transmitter **E-M-HW4v3-P-001_13**	√
		Device Manager and Data Recording CRP Clean Room Panel **E-M-HW4v3-P-002_12**	√

		HW4 Software Device Manager and further function PF4/5 Differential Pressure Transmitter (sec. generation) **E-M-HW4v3-P-003_00**	√
		Device Manager and Probe Adjustment LoDp probe series **E-M-HW4v3-LDP-001_13**	√

ROTRONIC Validation Test and Reports

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

Specification		Verification		Reviewed
URS	DV04-31.HW4_V3.9.0.LH.1.2 DV04-31.HW4_V3.9.0.LH.1.3	**URQ**	DV32.10787.390.2.PF(LHV1.3)-V	√
FS	DV32.10787.390.2.PF(LHV1.3)	**FQ**	DV32.10787.390.2.PF(LHV1.3)-V	√
DS	DV32.10787.390.1.DS DV32.10787.390.2.DS	**DQ**	DV32.10787.390.1.TSW-V DV32.10787.390.2.TSW-V	√
ChC	DV04-32.10787.01.CHC			√
RIs	10787.Meilensteinfreigabe.390.1			√

Performance Qualification		Inspected
Compliance Declaration	DV04-30.HW4-370	√
eCompliance White Paper	ERES-WP-0300.pdf	√
ISO 9001	rag_zertifikat_iso9001_2014	√
Validation Report	DV04-30.HW4-370 Release_Kereon_V310_001	√

COMPLIANCE DECLARATION

for

Software

HW4 version 3.9.0.19099

We attest that the validated version of the Rotronic HW4 software and associated devices fulfill the requirements defined in the Rotronic *eCompliance White Paper*, version 3.00, based on the following references:

GAMP® 5
21 CFR Part 11
21 CFR 110, 21 CFR 111
21 CFR 210, 21 CFR 211
EU Annex 11 to the
EU Guidelines of Good Manufacturing Practice for Medicinal Products

validated by ROTRONIC Instrument Corp.
May 2019

The HW4 software and devices have been reviewed against the specifications and the eCompliance White Paper, version 3.00 regarding compliance.

Inspected by i. A. Clemens Duzy ROTRONIC AG
Date / Signature

Accepted by the manufacturer ppa. Andreas Gähwiler, ROTRONIC AG
Date / Signature

Release Confirmation

Manufacturer:	All physical devices and the HW4 software are manufactured by: ROTRONIC AG Grindelstrasse 6 CH – 8306 Bassersdorf, Switzerland http://www.rotronic.ch
Inspected by	Clemens Duzy ROTRONIC AG Grindelstrasse 6 CH – 8306 Bassersdorf, Switzerland http://www.rotronic.ch Date / Signature
Reviewed by	Ralph Stössel ROTRONIC AG Grindelstrasse 6 CH – 8306 Bassersdorf, Switzerland http://www.rotronic.ch Date / Signature
Quality Management	Susanne Hollmayer ROTRONIC AG Grindelstrasse 6 CH – 8306 Bassersdorf, Switzerland http://www.rotronic.ch Date / Signature
ISO 9001 Certified by	SQS Schweizerische Vereinigung für Qualitäts- und Management-Systeme Bernstrasse 103, CH – 3052 Zollikofen, Switzerland https://www.sqs.ch/
GAMP Committee	Supervisor: Yves Samson Kereon AG Mühlhauserstrasse 113 CH – 4056 Basel, Switzerland http://www.kereon.ch