



## COMPLIANCE DECLARATION

DV04-30.787.03-1\_11

for

Software

HW4 VERSION 2.0.1.15990

Physical devices

HYGROLOGNT: FIRMWARE RELEASE 1.2

DOCKING STATIONS FOR THE HYGROLOG NT:

DS-NT4, DS-NT4-WL, DS-U1; DS-U2, DS-U4, DS-U4-4-4-20, DS-U4-WL: v 1.4

DS-PT2, DS-PT4, DS-PT4-WL: v1.1

DS-R1 : v1.0

DS-U4WEB : v1.0

HYGROFLEX, HYGROFLEX M, HYGROLAB, HYGROPALM, M23, M33: FIRMWARE RELEASE 4.0

HYGROCLIP DI FIRMWARE VERSION 1

HYGROCLIP ALARM FIRMWARE VERSION 2

HYGROSTAT MB FIRMWARE VERSION 1

We attest that the validated version of the Rotronic HW4 software and associated devices fulfil the requirements defined in the Rotronic ERES White Paper, version 2.0, based on the following paragraphs:

21 CFR PART 11

21 CFR 110

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.  
Inspected by Kereon AG,  
August 2007

The HW4 software and devices have been reviewed against the specifications and the ERES White Paper, version 1.0, in order to provide evidence that the above mentioned regulations are fulfilled accordingly.

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

Inspected by Yves Samson  
Kereon AG

Accepted by the manufacturer  
ROTRONIC AG