



Declaration of Conformity

We herewith declare, in exclusive responsibility, that the instruments

Tissue Processor MTP
Paraffin Wax Embedding Centre MPS/P1, MPS/P2, MPS/P, MPS/W, MPS/C, MPS/CX
Rotary Microtome CUT4062, CUT5062, CUT6062
Fast cooling unit for microtomes MTR
Aquatec
Sledge Microtome Cuttec S
Cryostat MTC, MEV, MEV plus, MNT
Staining Machine MSM
Linear Stainer Cromatec I & II
Floating Bath / Slide Warmer: Slidetec WATER, Slidetec HEAT, Slidetec WATER/HEAT, Slidetec WATER s

are developed, designed and manufactured in compliance with the applicable directives

- **Council Directive 2014/35/EU, (Low Voltage) and**
- **Council Directive 2014/30/EU (Electromagnetic Compatibility)**
- **Risk Management ISO 14971:2019**
- **IVDR (EU) 2017/746 – Class “Risk class “A” / Annex VIII – Rule V – Classification.**
These are instruments specifically intended for use in in vitro diagnostic procedures.
laboratory supplies without critical features intended to make the products usable for in vitro
diagnostic procedures in connection with a specific investigation’s medical devices
Technical documentation Annex II & Post-Market Surveillance Annex III
- **Directive 2011/65/EU (restriction of the use of certain hazardous substances in electrical and electronic equipment)**

including their amendments up to the date mentioned below.

The following harmonized standards were applied:

• **EN 61010-1:2020**

Safety requirements for electrical equipment for measurement, control and laboratory use -
Part 1: General requirements

• **EN 61326-1:2013**

Electrical equipment for measurement, control and laboratory use -
EMC requirements -
Part 1: General requirements

• **EN 61000-3-2:2019**

Electromagnetic compatibility (EMC)
Part 3-2: Limits - Limits for harmonic current emissions

• **EN 61000-3-3:2020**

Electromagnetic compatibility (EMC)
Part 3: Limits -
Section 3: Limitation of voltage fluctuations and flicker in low-voltage
supply systems for equipment with rated current ≤ 16 A
IEC 62366-1:2021
Suitability for use

In addition, the following in-house standards were applied: **ISO 9001:2015; ISO 13485:2016**

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