Declaration of Conformity

Gerätebau GmbH

Dr. Müller Gerätebau GmbH
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DE-01705 Freital

Herewith we declare on our own responsibility that the medical device meets all applicable requirements of the Directive 98/79/EC and applied standards and guidelines.

We do not guarantee the fulfilment of these norms and guidelines after unauthorized modification of the device.

Name of the product:
SUPER ID clinchem
(incl. accessories)

Applied norms / guidelines

DIN EN 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
98/79/EG	In vitro diagnostic medical devices
DIN EN 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements
DIN EN 61010-2-081	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment and other purposes
DIN EN 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
DIN EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC-requirements – Part 1: General requirements
DIN EN 61326-2-6	Electrical equipment for measurement, control and laboratory use – EMC-requirements – Part 2-6: Particular requirements – In-vitro-diagnostic (IVD) medical equipment

The CE mark was fixed to the device.

Freital, 20.03.2013

Ralf Günther
General Manager

Stand: 03/2013

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