Declaration of Conformity

Gerätebau GmbH

Dr. Müller Gerätebau GmbH
Burgker Strasse 133
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 product.

Name of the product:

Hemolysis-Systems-Solution, System glucose / lactate / hemoglobin
Glucocapil taking system, 1.5 ml / 500 µl without capillaries
Glucocapil taking system, 1.5 ml / 500 µl with open-end capillaries

Applied norms / guidelines

DIN EN 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
98/79/EG	In vitro diagnostic medical devices

The CE mark was fixed to the product.

Freital, 20.03.2013

Ralf Günther
General Manager