Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 099528 0003 Rev. 00

Manufacturer:

Haemotronic S.p.A.
Via Carreri 16
41037 Mirandola (MO)
ITALY

Facility(ies):

Haemotronic S.p.A.
Via Ugo Roncada, 83/E, 46020 Carbonara di Po (MN), ITALY

Haemotronic S.p.A.
Via Carreri 16, 41037 Mirandola (MO), ITALY

Product Category(ies): **Disposable medical devices-sets and systems for infusion, transfusion and dialysis: Haemodialysis blood lines and sets; Infusion sets; Transfusion sets; Parenteral administration sets and bags; Urology sets; Irrigation sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Valid from: 2018-08-19
Valid until: 2023-08-18

Date, 2018-07-23

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany