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

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. 01

Manufacturer:

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

Facility(ies):

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

Haemotronic S.p.A.
Via Ugo Roncada, 83/E, Località Carbonara di PO, 46021
Borgocarbonara (MN), ITALY

Product Category(ies):

Disposable medical devices-sets and systems for parenteral administration and blood treatment: Lines, sets and accessories for extracorporeal treatments (Hemodialysis, Hemofiltration, Hemodiafiltration, Hemoperfusion, Plasmapheresis, Ultrafiltration, Plasma-absorption and filtration); Lines, sets and accessories for intravascular administration; Bags, lines and accessories for parenteral administration.

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.

Report No.: ITA1345607

Valid from: 2019-12-17
Valid until: 2023-10-18

Date, 2019-12-17

Christoph Dicks
Head of Certification/Notified Body

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

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