



Certificate

No. Q5 099528 0004 Rev. 02

Holder of Certificate: **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

Certification Mark:



Scope of Certificate:

Design, development, manufacture, sales and distribution of lines, sets and accessories for extracorporeal treatments, lines, sets for intravascular administration and accessories, intravascular fluids containers, sterile and not sterile. Design, development, manufacture and contract manufacture, sales and distribution of components, semi-finished products for extracorporeal treatments. Design, development, manufacture and contract manufacture, sales and distribution of components, semi-finished products and bags for parenteral administration. Contract manufacturing of plastic sets/systems and disposable bags.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_099528_0004_Rev_02

Report No.: ITA1545327

Valid from: 2020-10-20

Valid until: 2023-10-19

Date, 2020-09-14

Christoph Dicks
Head of Certification/Notified Body