



Certificate

No. Q5 099528 0004 Rev. 00

Holder of Certificate: **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

Certification Mark:



Scope of Certificate:

Design and development, manufacture, sales and distribution of sterile and non-sterile disposable haemodialysis sets and accessories, intravascular administration sets and accessories, irrigation, urologic sets and accessories, intravascular fluid containers. Design and development, manufacture and contract manufacture, sales and distribution of components, semi-finished products, bags for dialysis, intravascular administration, irrigation and urology. 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). See also notes overleaf.

Report No.: ITA9408141S

Valid from: 2018-10-10

Valid until: 2020-10-19

Date, 2018-10-10

Stefan Preiß

ZERTIFIKAT • CERTIFICATE • 認證證書 • CERTIFICADO • CERTIFICAT

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