



America

CERTIFICATE

No. QS6 099528 0006 Rev. 00

Certificate Holder:

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

Certification Mark:



Scope of Certificate:

Design, Development, and Manufacture of Blood Lines Set / Kit for the area of Intensive Care, Nephrology and Cardiology; Design, Development, and Manufacture of Intravascular Infusion Sets and Bags for Parenteral Administration for the area of General Medical Care

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F005581

Effective Date:

2022-05-26

Expiry Date:

2025-05-25

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Date of Issue: 2022-06-06

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

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

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Facility Scopes:

Haemotronic S.p.A.

Via Carreri 16, 41037 Mirandola (MO), ITALY

Design and Development of Blood Lines Set / Kit, Intravascular
Infusion Sets and Bags for Parenteral Administration;
Manufacture of Bags for Parenteral Administration
REPs Facility ID: F005581

Haemotronic S.p.A.

Via Ugo Roncada, 83/E, Località Carbonara di PO, 46021
Borgocarbonara (MN), ITALY

Manufacture of Blood Lines Set / Kit, Intravascular Infusion
Sets and Bags for Parenteral Administration
REPs Facility ID: F005581

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