DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 019717 0030 Rev. 00

Holder of Certificate: **B. Braun Avitum Italy S.p.A.**
Via XXV Luglio, 11
41037 Mirandola (MO)
ITALY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Non-Active Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis); Design and Development, Production of Non-Active Medical Devices for Transfusion, Nutrition, Irrigation and Arthroscopy; Distribution and Servicing of Active Medical Devices for Extracorporeal Blood Treatment and Nutrition; Production and Distribution of Concentrates for Hemodialysis**

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.: 713124436

Valid from: 2018-10-24
Valid until: 2021-07-31

Date, 2018-10-24

Stefan Preiß

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 019717 0030 Rev. 00

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

Facility(ies): B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

Supplement to Quality System Certificate

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO), ITALY

for the facility

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO), ITALY

The quality system certified as stated above additionally fulfills the applicable requirements of **EN ISO 11135:2014 – Sterilization of health care products – Ethylene oxide** - as documented in the audit report no. 713124436.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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