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

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

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 012974 0609 Rev. 00

Manufacturer

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

Accessories for Angiography, Surgery, Angiography / Atherectomy and Haemodynamic Monitoring
(class I sterile)
Procedure Kits, Monitoring sets for invasive physiological pressure measurement
(article 12 systems and procedure packs)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713160243+713160242

Valid from: 2019-10-08
Valid until: 2024-05-26

Date, 2019-10-08

Stefan Preiß
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

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Facility(ies):

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

AESCULAP CHIFA Sp. z o.o.
ul. Tysiaclecia 14, 64-300 Nowy Tomysl, POLAND

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