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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies): Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, single use Right heart pulmonary artery catheters, Monitoring sets for invasive physiological pressure measurement, Introducer sheaths and sets, Arterial puncture cannulae, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713168177

Valid from:

2020-05-06

Valid until:

2024-05-26

Date,

2020-05-14

Christoph Dicks
Head of Certification/Notified Body



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