



Certificate

No. Q5 012974 0606 Rev. 01

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Certification Mark:



Scope of Certificate: Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial puncture cannula, arterial catheter sets

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 012974 0606 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_012974_0606_Rev._01)

Report No.: 713263785

Valid from: 2022-10-07

Valid until: 2025-09-30

Date, 2022-10-07



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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 Melsungen AG Vascular Systems**
Sieversufer 8, 12359 Berlin, GERMANY

Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial puncture cannula, arterial catheter sets

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

Production (extrusion) of non-sterile tubing for catheter production

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