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

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

TÜV SÜD Product Service

Certificate

No. Q6 012974 0596 Rev. 00

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

Facility(ies): B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

Certification Mark:

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

Scope of Certificate: **Production of tubing sets and assemblies for sterile medical devices for fluid, blood and gas management, including moulding, extrusion, welding, heat forming, gluing, printing and packing under controlled conditions.**
Products include: blood lines, suction and drainage, urology, catheterization, ventilation, nutrition, transfusion/infusion/rinsing and configured customised sets.

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713147669

Valid from: 2019-03-28
Valid until: 2021-12-17

Date, 2019-03-28

I. Preuß

Stefan Preiß

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

TÜV®

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