



Product Service

# CERTIFICATE

No. Q2N 17 11 12974 447

**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:**


**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 13485:2012 + AC:2012  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2003 + Cor. 1:2009)  
 DIN EN ISO 13485:2012  
 Upgrade required until 2019-03-31

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.:** 713120812

**Valid from:** 2018-02-28

**Valid until:** 2021-02-27

**Date,** 2018-01-17

Stefan Preiß



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