



Product Service

# Certificate

No. Q6 012974 0596 Rev. 02



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

**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.**

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). 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:Q6\\_012974\\_0596\\_Rev.02](http://www.tuvsud.com/ps-cert?q=cert:Q6_012974_0596_Rev.02)



**Report No.:** 713196561

**Valid from:** 2021-06-29  
**Valid until:** 2024-06-28

**Date,** 2021-06-29

Christoph Dicks  
 Head of Certification/Notified Body



Product Service

# Certificate

No. Q6 012974 0596 Rev. 02

**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 Medical Kft Production Division  
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

See Scope of Certificate

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

See Scope of Certificate

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Product Service

# Certificate

No. Q5 022239 0095 Rev. 02

**Holder of Certificate:** **B. BRAUN MEDICAL SAS**  
 26 Rue Armengaud  
 92210 Saint-Cloud  
 FRANCE



**Facility(ies):** B. BRAUN MEDICAL SAS  
 13 rue Croix la Comtesse, 28400 Nogent-le-Rotrou, FRANCE

*TRƯỞNG PHÒNG DĂNG KÝ  
 Trịnh Thị Linh*

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** Design, development and production of non-sterile and sterile medical devices for urology, incontinence, irrigation, urine sampling, drainage and surgical applications.  
 Design and production of irrigation sets.  
 Production of non-sterile and sterile administration and transfer medical devices for infusion and enteral nutrition.  
 Production of non-sterile and sterile medical devices for biopsy.  
 Production of ostomy collection bags.

**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, 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\\_022239\\_0095\\_Rev\\_02](http://www.tuvsud.com/ps-cert?q=cert:Q5_022239_0095_Rev_02)

**Report No.:** 713197131  
**Valid from:** 2021-09-27  
**Valid until:** 2023-12-31

**Date,** 2021-09-27

Christoph Dicks  
 Head of Certification/Notified Body