



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 061585 0030 Rev. 03

Holder of Certificate: **B. Braun Medical AG**

Seesatz 17
6204 Sempach
SWITZERLAND

Certification Mark:



Scope of Certificate:

Design and development, manufacturing and distribution of sterile and non-sterile, non-active, non-implantable medical devices for wound bed preparation, disinfectants, antiseptics, sterilizing agents and detergents for medical devices, clinical procedure kits, medical devices for channeling liquid and medical devices for multidrug-resistant organism decolonization and skin care.

Design and development, manufacturing and distribution of urinary-catheter-irrigation sterile solutions and medical devices for wound bed preparation.

The provision of marketing, distribution of medical devices for wound bed preparation, disinfectants, antiseptics, sterilizing agents and detergents for medical devices, urinary-catheter-irrigation sterile solutions, clinical procedure kits, medical devices for channeling liquid and medical devices for multidrug-resistant organism decolonization and skin care on the Swiss Market.

The provision of marketing, distribution and maintenance servicing services for sterile and non-sterile medical devices on the Swiss Market.

The provision of design and development, manufacturing, ETO and moist heat sterilization and distribution services for sterile general non-active, non-implantable medical devices.

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 061585 0030 Rev. 03

Report No.: 713369969



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Valid from:
Valid until:

2025-08-01
2028-07-31

Date, 2025-07-24


Christoph Dicks
Head of Certification/Notified Body

Deutschland, Hamburg, 2025-07-24
Hiermit wird bestätigt, dass die nachstehend aufgelisteten Produkte und Dienstleistungen nach den Vorschriften der entsprechenden Richtlinien und/oder Verordnungen der Europäischen Union sowie den einschlägigen nationalen Vorschriften hergestellt und/oder vertrieben werden. Die Produkte und Dienstleistungen sind in der Liste der zugelassenen Produkte und Dienstleistungen der Kommission der Europäischen Union (CE-Liste) vermerkt.

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

B. Braun Medical AG

Route de Sorge 9, 1023 Crissier, SWITZERLAND

Design and development, manufacturing and distribution of urinary-catheter-irrigation sterile solutions and medical devices for wound bed preparation.

The provision of design and development, manufacturing, moist heat sterilization and distribution services for sterile general non-active, non-implantable medical devices.

B. Braun Medical AG

Seesatz 17, 6204 Sempach, SWITZERLAND

Management

Design and development, manufacturing and distribution of sterile and non-sterile, non-active, non-implantable medical devices for wound bed preparation, disinfectants, antiseptics, sterilizing agents and detergents for medical devices, urinary-catheter-irrigation sterile solutions, clinical procedure kits, medical devices for channeling liquid, medical devices for multidrug-resistant organism decolonization and skin care.

The provision of marketing, distribution of medical devices for wound bed preparation, disinfectants, antiseptics, sterilizing agents and detergents for medical devices, urinary-catheter-irrigation sterile solutions, clinical procedure kits, medical devices for channeling liquid, medical devices for multidrug-resistant organism decolonization and skin care on the Swiss Market.

The provision of marketing, distribution and maintenance servicing services for sterile and non-sterile medical devices on the Swiss Market.

B. Braun Medical AG

Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

The provision of design and development, manufacturing, ETO sterilization and distribution services for sterile general non-active, non-implantable medical devices.