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

Product Service

Certificate

No. Q5 061585 0030 Rev. 00

Holder of Certificate: **B. Braun Medical AG**
Seesatz 17
6204 Sempach
SWITZERLAND

Certification Mark:

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

Scope of Certificate: **Design and development, production and distribution of sterile disposables (syringes, cannula, diagnostic disposables and accessories), disinfection and hygiene products, medical devices for wound bed preparation, physically acting medical devices for multi-drug-resistant-organism decolonization for topical and oral application, irrigation solutions, organ preservation solutions, procedure packs**

Contract manufacturing of sterile priming solutions for Heart Lung Machine

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). See also notes overleaf.

Report No.: 713154272

Valid from: 2019-08-01
Valid until: 2022-07-31

Date, 2019-07-26

Stefan Preiß
Head of Certification/Notified Body

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

A4 / 07.17

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TÜV SÜD
Product Service

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No. Q5 061585 0030 Rev. 00

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 AG
Route de Sorge 9, 1023 Crissier, SWITZERLAND

B. Braun Medical AG
Seesatz 17, 6204 Sempach, SWITZERLAND

B. Braun Medical AG
Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

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