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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 014553 0042 Rev. 03

Holder of Certificate: **Biegler GmbH**
Allhangstrasse 18a
3001 Mauerbach
AUSTRIA

Certification Mark:

Scope of Certificate:

Design and development, production and service of active Blood and/or Infusion Warmers, sterile non-active accessories and Blood/Infusion Lines, and active Automatic Pressure Infusors
Importer of accessories for Automatic Pressure Infusors
The provision of design and development services for general active medical devices and general non-active medical devices
The provision of production services for general active medical devices, general non-active non-implantable medical devices, non-active soft tissue implants and accessories

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 014553 0042 Rev. 03

Report No.: 713353666

Valid from: 2025-07-01
Valid until: 2028-06-30

Date, 2025-05-08

Christoph Dicks
Head of Certification/Notified Body

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

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

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No. Q5 014553 0042 Rev. 03

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): **Biegler GmbH**
Allhangstrasse 18a, 3001 Mauerbach, AUSTRIA

See Scope of Certificate

Parameters: ./.

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