



Product Service

Certificate

No. Q5 014553 0042 Rev. 02

Holder of Certificate:

**Biegler GmbH**Allhangstrasse 18a
3001 Mauerbach
AUSTRIA

Facility(ies):

Biegler GmbH

Allhangstrasse 18a, 3001 Mauerbach, AUSTRIA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

**Design and development, production and service of Blood and Infusion Warmer including sterile accessories and Automatic Pressure Infusors
Importer of accessories for Automatic Pressure Infusors****The provision of design and development and production services for active and non-active medical devices and accessories**

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

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.02

Report No.: 713350480

Valid from: 2024-12-17

Valid until: 2025-06-30

Date, 2024-12-17

Christoph Dicks

Head of Certification/Notified Body