



Product Service

Certificate

No. Q8 074070 0006 Rev. 00

Holder of Certificate: **NewTec GmbH**
Buchenweg 3
89284 Pfaffenhofen a. d. Roth
GERMANY

Facility(ies): **NewTec GmbH**
Buchenweg 3, 89284 Pfaffenhofen a. d. Roth, GERMANY

See Scope of Certificate

Certification Mark:



Scope of Certificate: **The provision of design and development services for general active medical devices for electronic- and software components, as well as training services in the field of medical technology**

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:Q8_074070_0006_Rev.00

Report No.: 713349195

Valid from: 2025-03-31

Valid until: 2028-03-30

Date, 2025-03-17

Christoph Dicks
Head of Certification/Notified Body