



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q8 068923 0009 Rev. 01

Holder of Certificate: **ITK Engineering GmbH**

Im Speyerer Tal 6-8
76761 Rülzheim
GERMANY

Certification Mark:



Scope of Certificate: **The provision of design and development and software services for general active medical devices.**

The provision of design and development services for electronic and mechatronic components for general active 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:Q8 068923 0009 Rev. 01

Report No.: 713378262

Valid from: 2026-03-03

Valid until: 2029-03-02

Date, 2025-12-11

Christoph Dicks
Head of Certification/Notified
Body



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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): **ITK Engineering GmbH**
Im Speyerer Tal 6-8, 76761 Rülzheim, GERMANY

See Scope of Certificate

ITK Systems Engineering S.L.U.
Carrer de Sancho de Ávila 80, 08018 Barcelona, SPAIN

The provision of design and development and software services for
general active medical devices.

Parameters: ./.