





Certificate No. Q8 068923 0009 Rev. 00

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 and manufacturing 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 and certification regulation of 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. 00

Report No.:

713265287

Valid from: Valid until: 2023-03-03 2026-03-02

Date, 2023-02-13

Christoph Dicks Head of Certification/Notified Body





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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):ITK Engineering GmbHIm 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: ./.