



Product Service

## Certificate

No. Q5 017853 0129 Rev. 03

**Holder of Certificate:** **MED-EL**  
**Elektromedizinische Geräte GmbH**  
Fürstenweg 77A  
6020 Innsbruck  
AUSTRIA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Cochlear Implant Systems including related external components, Implantable Neurostimulator Systems including related external components, Implantable Hearing Prosthesis Systems including related external components, Bone Conduction Hearing Systems and Accessories, Surgical Instruments; Passive Middle Ear Implants, Muscle-/ Neurostimulation Systems (external), Sterile Cables for Muscle-/ Neurostimulation Systems (external)

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:Q5 017853 0129 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5 017853 0129 Rev. 03)

**Report No.:** 713204776

**Valid from:** 2021-09-10  
**Valid until:** 2024-09-09

**Date,** 2021-09-07

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):** MED-EL Elektromedizinische Geräte GmbH  
Fürstenweg 77A, 6020 Innsbruck, AUSTRIA

Design and Development, Production and Distribution of Cochlear Implant Systems including related external components, Implantable Neurostimulator Systems including related external components, Implantable Hearing Prosthesis Systems including related external components, Bone Conduction Hearing Systems and Accessories, Surgical Instruments; Passive Middle Ear Implants, Muscle-/ Neurostimulation Systems (external), Sterile Cables for Muscle-/ Neurostimulation Systems (external)