



Product Service

# Certificate

No. Q5 017853 0129 Rev. 02

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

**Facility(ies):** 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; Implant Programming Systems, Passive Middle Ear Implants

**Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
 DIN EN ISO 13485:2016

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). See also notes overleaf.

**Report No.:** 713167665  
**Valid from:** 2020-01-28  
**Valid until:** 2022-01-28

**Date,** 2020-01-28  
 Christoph Dicks  
 Head of Certification/Notified Body