DAkkS
Deutsche
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D-ZM-11321-01-00

Product Service

Certificate

No. Q5 017853 0129 Rev. 04

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

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, 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), Hearing assessment software and application.**
Servicing of External Components for Cochlear Implant Systems, Implantable Neurostimulator Systems, Implantable Hearing Prosthesis Systems and Bone Conduction Hearing Systems

Digitally signed by Timuş Andrei
Date: 2026.02.27 11:44:58 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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:Q5 017853 0129 Rev. 04

Report No.: 713308225

Valid from: 2024-09-10
Valid until: 2027-09-09

Date, 2024-07-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICAT ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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

Design and Development, Production, 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), Hearing assessment software and application.
Servicing of External Components for Cochlear Implant Systems, Implantable Neurostimulator Systems, Implantable Hearing Prosthesis Systems and Bone Conduction Hearing Systems.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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