DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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; 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: 2021-09-09

Date, 2020-01-28

Christoph Dicks
Head of Certification/Notified Body

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17