



Product Service

Certificate

No. Q5 078611 0062 Rev. 03

Holder of Certificate: **Cochlear Limited**
1 University Avenue
Macquarie University NSW 2109
AUSTRALIA

Certification Mark:



Scope of Certificate: **Design, Development, Production, Service, and Distribution of Implantable Hearing Prosthesis Systems including Ancillary Medical Devices (External Components and Accessories) for Implantable Hearing Prosthesis Systems**

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 078611 0062 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_078611_0062_Rev.03)

Report No.: 713180472

Valid from: 2021-03-12

Valid until: 2023-07-14

Date, 2021-03-12

Christoph Dicks
Head of Certification/Notified Body

Certificate

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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):	<p>Cochlear Limited 1 University Avenue, Macquarie University NSW 2109, AUSTRALIA</p> <p>Design, Development, Production and Distribution of Implantable Hearing Prosthesis Systems including Ancillary Medical Devices (External Components and Accessories) for Implantable Hearing Prosthesis Systems</p> <p>Cochlear Limited 14 Mars Road, Lane Cove NSW 2066, AUSTRALIA</p> <p>Production and Distribution of Implantable Hearing Prosthesis Systems including Ancillary Medical Devices (External Components and Accessories) for Implantable Hearing Prosthesis Systems</p> <p>Cochlear Limited 12 Helen Street, Newstead QLD 4006, AUSTRALIA</p> <p>Production and Distribution of Implantable Hearing Prosthesis Systems including Ancillary Medical Devices (External Components and Accessories) for Implantable Hearing Prosthesis Systems</p> <p>Cochlear Technology Centre Belgium Schaliënhoevedreef 20 Build.I, 2800 Mechelen, BELGIUM</p> <p>Design, Development, Production and Distribution of Implantable Hearing Prosthesis Systems including Ancillary Medical Devices (External Components and Accessories) for Implantable Hearing Prosthesis Systems</p> <p>Cochlear Malaysia Sdn Bhd Unit UG-1, Upper Ground Floor, Vertical Podium, The Vertical, Avenue 3, Bangsar South, No. 8 Jalan Kerinchi, 59200 Kuala Lumpur, MALAYSIA</p> <p>Production, Service and Distribution of Implantable Hearing Prosthesis Systems including Ancillary Medical Devices (External Components and Accessories) for Implantable Hearing Prosthesis Systems</p>