



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

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):

Cochlear Limited
1 University Avenue, Macquarie University NSW 2109,
AUSTRALIA

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

Cochlear Limited
14 Mars Road, Lane Cove NSW 2066, AUSTRALIA

Production and Distribution of Implantable Hearing Prosthesis
Systems including Ancillary Medical Devices (External
Components and Accessories) for Implantable Hearing Prosthesis
Systems

Cochlear Limited
12 Helen Street, Newstead QLD 4006, AUSTRALIA

Production and Distribution of Implantable Hearing Prosthesis
Systems including Ancillary Medical Devices (External
Components and Accessories) for Implantable Hearing Prosthesis
Systems

Cochlear Technology Centre Belgium
Schaliënhoevedreef 20 Build.I, 2800 Mechelen, BELGIUM

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

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

Production, Service and Distribution of Implantable Hearing
Prosthesis Systems including Ancillary Medical Devices (External
Components and Accessories) for Implantable Hearing Prosthesis
Systems