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America

CERTIFICATE

No. QS6 17 07 78611 064

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

Certification Mark:



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

Standard(s): ISO 13485:2016

Regulatory Authority: TGA, ANVISA, Health Canada, FDA, MHLW / PMDA.
See attached for listing of specific
regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website

<http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder>

TÜV SÜD America Inc. is an MDSAP Authorized Auditing Organization.

DUNS No: 75-055-1194
Effective Date: 2017-07-18
Expiry Date: 2020-07-17

Earl Buckmiller
Director, Quality Systems & MS Cert. Body





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CERTIFICATE

No. QS6 17 07 78611 064

Cochlear Limited
1 University Avenue
Macquarie University NSW 2109
AUSTRALIA
DUNS No: 75-055-1194

**Design and Development, Manufacture 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
DUNS No: 74-429-9690

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

Cochlear Limited
12 Helen Street
4006 Newstead QLD
AUSTRALIA
DUNS No: 74-429-9689

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

Effective Date: 2017-07-18
Expiry Date: 2020-07-17

Earl Buckmiller
Director, Quality Systems & MS Cert. Body



CERTIFICATE

No. QS6 17 07 78611 064

Cochlear Technology Centre Belgium
Schaliënhoevedreef 20, Building I
B-2800 Mechelen
BELGIUM
DUNS No: 37-349-4868

Design, Development, Manufacture, Distribution, and Service 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, 59200 Kuala Lumpur
MALAYSIA
DUNS No: 53-441-6553

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

Effective Date: 2017-07-18
Expiry Date: 2020-07-17

A handwritten signature in black ink, reading 'Earl Buckmiller'.

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

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Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1
- Schedule 3, Part 4

Brazil

- Federal Law n. 6360/76
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009
- RDC ANVISA n. 56/2001

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Japan

- MHLW Ministerial Ordinance No.169, 2004

Effective Date:

2017-07-18

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