

Nucleus 7 Processing Unit (CP1000) Declaration of Conformity D1581264

Version: 3

State: Approved (T+B)

Approver: Nils Bown (nbown)

Date : 11 Aug 2021

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Hear now. And always



EU Declaration of Conformity


Manufacturer:	Cochlear Limited 1 University Avenue Macquarie University NSW 2109 Australia
Single Registration Number (SRN):	AU-MF-000009890
Authorised Representative:	Cochlear Deutschland GmbH & Co. KG Karl-Wiechert-Allee 76A 30625 Hannover Germany
Scope of Products:	See attached Schedule of Products
Conformity Assessment Procedure:	ANNEX IX – All Chapters Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation.
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München Germany Notified Body Identification No.: 0123
CE Certificate(s):	QMS Certificate issued under Annex IX, Chapter I: G12 078611 0117 Rev. 00 Technical Assessment Certificate issued under Annex IX, Chapter II: G70 078611 0123 Rev. 01
Common Specifications (CS):	None

The products covered by this declaration are in conformity with the following European Union legislation:

- Regulation (EU) 2017/745 on medical devices.

I hereby confirm that this EU declaration of conformity is issued under the sole responsibility of the manufacturer, Cochlear Limited.

Authorised Signatory on behalf of Cochlear Limited and for the Person Responsible for Regulatory Compliance:

DocuSigned by:

0AC55D29F40942D...

Steven Kennedy

Date: 09-08-2021

VP Global Regulatory Affairs

Place: Sydney, Australia

Schedule of Products

Cochlear Part Number	Product Name	Model Number	Option	Basic UDI-DI	Risk Class	CND Code	GMDN Code
Z482005	Nucleus® 7 Processing Unit	CP1000	Black, Platinum Detail	9321502CP1000PU3T	Class III	J0380	47374
Z482006	Nucleus® 7 Processing Unit	CP1000	Brown	9321502CP1000PU3T	Class III	J0380	47374
Z482007	Nucleus® 7 Processing Unit	CP1000	Grey	9321502CP1000PU3T	Class III	J0380	47374
Z482008	Nucleus® 7 Processing Unit	CP1000	Sand	9321502CP1000PU3T	Class III	J0380	47374
Z482009	Nucleus® 7 Processing Unit	CP1000	Black, Golden Detail	9321502CP1000PU3T	Class III	J0380	47374
Z544559	Nucleus® 7 Processing Unit	CP1000	White	9321502CP1000PU3T	Class III	J0380	47374

Change History

Version	Date	Change	Author
1	22 Jan 2021	Initial Introduction	Natalie Dubs
2	20 May 2021	Approval of N7R5 (CN20-04), certificate change to Rev. 1	Rick Rosa
3	9 Aug 2021	Added SRN and QMS certificate numbers	Natalie Dubs