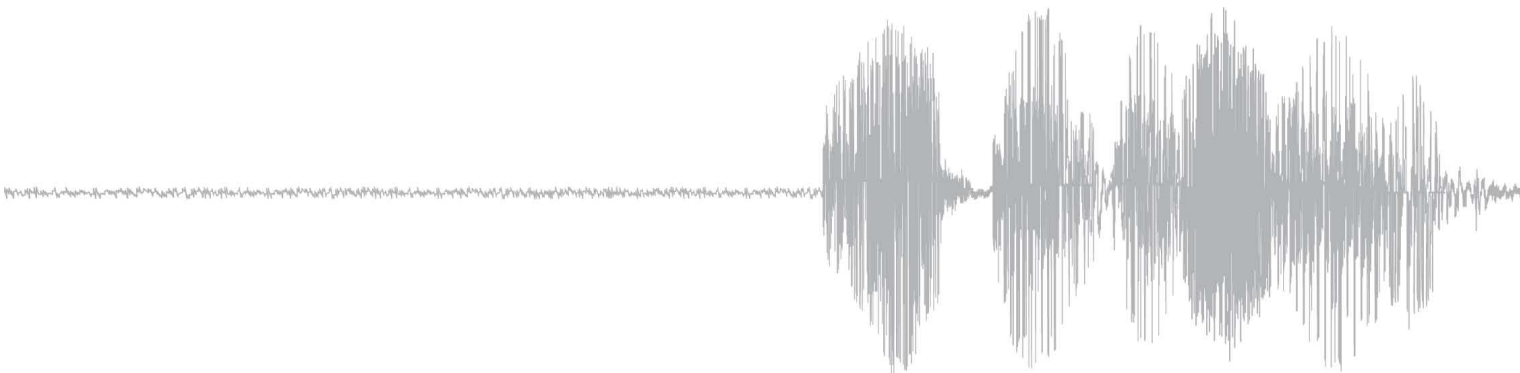




EU MDR Declaration of Conformity - Baha Sound Processors

D2295383

Version: 2
State: Released

Representations of electronic signatures applied to this document

Approved by: Jenny Dahlberg (jdahlberg)
Date: 2025-06-18 06:58:10 GMT
Reviewed by: Dan-Olof Alnehill (dalnehill)
Date: 2025-06-17 08:56:58 GMT

Hear now. And always





EU MDR Declaration of Conformity - Baha Sound Processors

EU MDR Declaration of Conformity

Manufacturer:	Cochlear Bone Anchored Solutions AB Konstruktionsvägen 14 SE-435 33 Mölnlycke SWEDEN Single Registration Number (SRN): SE-MF-000012413
Risk Class:	Class IIa
EMDN Code & Term:	Y214599, HEARING AIDS – OTHERS
Product(s):	See attached Schedule of Products.
Intended Purpose	See attached Table of Intended Purpose.
Conformity Assessment Procedure:	ANNEX IX – Chapter I and Chapter III Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation (sampled as required).
Notified Body:	BSI The Netherlands Notified Body Identification No.: 2797
CE Certificate(s):	QMS Certificate issued under Annex IX, Chapters I and III: Certificate No.: MDR 716803 R001
Common Specifications (CS):	None
Relevant Standards or other technical specifications required to be listed by regulation:	Directive 2014/53/EU, Article 3: 1(a): Health and Safety of the User – IEC 60601-1:2005+A1:2012 1(b): Electromagnetic Compatibility – EN/(IEC) 62479:2010, EN 301 489-17 V3.2.0, EN 301 489-1 V2.1.1 2: Effective use of spectrum allocated – EN 300 328 V2.2.2



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

- Regulation (EU) 2017/745 on medical devices.
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and the conformity assessment route of Annex II. All essential radio test suites have been carried out and all products covered by the scope of this declaration are in conformity with all essential requirements of Directive 2014/53/EU.
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The technical documentation relevant to the products covered by this declaration are kept at the manufacturer's address listed above.

I hereby confirm that this EU declaration of conformity is issued under the sole responsibility of the manufacturer, Cochlear Bone Anchored Solutions AB.

Authorised Signatory on behalf of Cochlear Bone Anchored Solutions AB and for the Person Responsible for Regulatory Compliance:

Signed by:

CDAA053BC9234D1...

Jenny Dahlberg

Quality Manager

Date: 17-06-2025

Place: Mölnlycke, Sweden



EU MDR Declaration of Conformity - Baha Sound Processors

1 SCHEDULE OF PRODUCTS

Cochlear Part (Catalogue) Number	Product Name	Option / Variant	Basic UDI-DI	GMDN code
95470	Baha 5 Power, Blonde	N/A	9321502Baha5Power6B	62209
95471	Baha 5 Power, Black	N/A	9321502Baha5Power6B	62209
95472	Baha 5 Power, Silver	N/A	9321502Baha5Power6B	62209
95473	Baha 5 Power, Brown	N/A	9321502Baha5Power6B	62209
95474	Baha 5 Power, Copper	N/A	9321502Baha5Power6B	62209
95475	Baha 5 Power Demo, Black	N/A	9321502Baha5Power6B	62209
P1668389	Cochlear Baha 6 Max, Blonde	N/A	9321502Baha6MaxM3	62209
P1668390	Cochlear Baha 6 Max, Black	N/A	9321502Baha6MaxM3	62209
P1668391	Cochlear Baha 6 Max, Silver	N/A	9321502Baha6MaxM3	62209
P1668392	Cochlear Baha 6 Max, Brown	N/A	9321502Baha6MaxM3	62209
P1668393	Cochlear Baha 6 Max, Copper	N/A	9321502Baha6MaxM3	62209
P1668394	Cochlear Baha 6 Max, Mint	N/A	9321502Baha6MaxM3	62209
P1668395	Cochlear Baha 6 Max Demo, Black	N/A	9321502Baha6MaxM3	62209
P1809177	Cochlear Baha 6 Max, Blonde, 2mm	N/A	9321502Baha6MaxM3	62209
P1809178	Cochlear Baha 6 Max, Black, 2mm	N/A	9321502Baha6MaxM3	62209
P1809179	Cochlear Baha 6 Max, Silver, 2mm	N/A	9321502Baha6MaxM3	62209



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Cochlear Part (Catalogue) Number	Product Name	Option / Variant	Basic UDI-DI	GMDN code
P1809180	Cochlear Baha 6 Max, Brown, 2mm	N/A	9321502Baha6MaxM3	62209
P1809221	Cochlear Baha 6 Max, Copper, 2mm	N/A	9321502Baha6MaxM3	62209
P1809222	Cochlear Baha 6 Max, Mint, 2mm	N/A	9321502Baha6MaxM3	62209
P1809223	Cochlear Baha 6 Max Demo, Black, 2mm	N/A	9321502Baha6MaxM3	62209
P2054744	Cochlear Baha 7 Sound Processor, Blonde	N/A	9321502Baha7ZH	62209
P2054745	Cochlear Baha 7 Sound Processor, Black	N/A	9321502Baha7ZH	62209
P2054746	Cochlear Baha 7 Sound Processor, Silver	N/A	9321502Baha7ZH	62209
P2054747	Cochlear Baha 7 Sound Processor, Brown	N/A	9321502Baha7ZH	62209
P2054748	Cochlear Baha 7 Sound Processor, Copper	N/A	9321502Baha7ZH	62209
P2054769	Cochlear Baha 7 Sound Processor, Mint	N/A	9321502Baha7ZH	62209
P2114094	Cochlear Baha 7 Sound Processor, Lavender	N/A	9321502Baha7ZH	62209
P2054770	Cochlear Baha 7 Demo Sound Processor, Black	N/A	9321502Baha7ZH	62209
P2054771	Cochlear Baha 7 Sound Processor, Blonde, 2mm	N/A	9321502Baha7ZH	62209
P2054772	Cochlear Baha 7 Sound Processor, Black, 2mm	N/A	9321502Baha7ZH	62209
P2054773	Cochlear Baha 7 Sound Processor, Silver, 2mm	N/A	9321502Baha7ZH	62209



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Cochlear Part (Catalogue) Number	Product Name	Option / Variant	Basic UDI-DI	GMDN code
P2054774	Cochlear Baha 7 Sound Processor, Brown, 2mm	N/A	9321502Baha7ZH	62209
P2054775	Cochlear Baha 7 Sound Processor, Copper, 2mm	N/A	9321502Baha7ZH	62209
P2054776	Cochlear Baha 7 Sound Processor, Mint, 2mm	N/A	9321502Baha7ZH	62209
P2114095	Cochlear Baha 7 Sound Processor, Lavender, 2mm	N/A	9321502Baha7ZH	62209
P2054777	Cochlear Baha 7 Demo Sound Processor, Black, 2mm	N/A	9321502Baha7ZH	62209



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2 TABLE OF INTENDED PURPOSE

Cochlear Part (Catalogue) Number	Intended Purpose
95470 95471 95472 95473 95474 95475	The Cochlear Baha System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Baha 5 Power Sound Processor is intended to be used as part of the Cochlear Baha System to pick up surrounding sound and transfer it to the skull bone via a Baha Implant, Baha Softband or Baha SoundArc and can be used unilaterally or bilaterally
P1668389 P1668390 P1668391 P1668392 P1668393 P1668394 P1668395 P1809177 P1809178 P1809179 P1809180 P1809221 P1809222 P1809223	The Cochlear Baha System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Baha 6 Max Sound Processor is intended to be used as part of the Cochlear Baha System to pick up surrounding sound and transfer it to the skull bone via a Baha Implant, Baha Softband or Baha SoundArc and can be used unilaterally or bilaterally.



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Cochlear Part (Catalogue) Number	Intended Purpose
P2054744 P2054745 P2054746 P2054747 P2054748 P2054769 P2114094 P2054770 P2054771 P2054772 P2054773 P2054774 P2054775 P2054776 P2114095 P2054777	The Cochlear Baha System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. The Baha 7 Sound Processor is intended to be used as part of the Cochlear Baha System to pick up surrounding sound and transfer it to the skull bone via a Baha Implant, Baha SoundBand, Baha Softband or Baha SoundArc and can be used unilaterally or bilaterally.



EU MDR Declaration of Conformity - Baha Sound Processors

3 CHANGE HISTORY

Version	Date	Change	Author
1	Jan-2025	Moved to new document template. This document replaces D2086271, Declaration of Conformity – Baha Sound Processors Added P2054744, P2054745, P2054746, P2054747, P2054748, P2054769, P2114094, P2054770, P2054771, P2054772, P2054773, P2054774, P2054775, P2054776, P2114095, P2054777	DA
2	June-2025	Renewal of MDR certificate, revision R001.	DA