

Wireless Accessories

Medical Device: Baha® System
Single Registration Number (SRN) SE-MF-000012413

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

Manufacturer Name: Cochlear Bone Anchored Solutions AB
Manufacturer Address: Konstruktionsvägen 14
SE-435 33 Mölnlycke
SWEDEN
Risk Class: In accordance with Annex VIII of EU MDR 2017/745
(see below)
Conformity Assessment: Article 52.7 of EU MDR 2017/745 (Remote control 2,
TV streamer, Phone Clip, Mini Microphone 2+)

Annex II of Radio Equipment Directive (RED)
2014/53/EU (Remote control 2)

Annex III of Radio Equipment Directive (RED)
2014/53/EU (TV streamer, Phone Clip, Mini
Microphone 2+)

Notified Body: According to EU MDR 2017/745: N/A
According to Annex II of Radio Equipment Directive
(RED) 2014/53/EU: N/A
According to Annex III of Radio Equipment Directive
(RED) 2014/53/EU:
Notified Body EC Code No. 1588 (TV streamer,
Phone Clip, Mini Microphone 2+)

American Certification Body Inc. 6731 Whittier Ave,
Suite C110, McLean, VA 22101, USA

Certificate Number: According to MDR 2017/745: N/A
According to Annex II of Radio Equipment Directive
(RED) 2014/53/EU: N/A
According to Annex III of Radio Equipment Directive
(RED) 2014/53/EU:
ACB Certificate No. ATCB029785 (TV streamer)
ACB Certificate No. ATCB029784 (Phone Clip)
ACB Certificate No. ATCB029786 (Mini Microphone
2+)

I hereby declare that the products concerned conform to the requirements of the EU Medical Devices Regulations 2017/745 and, when applicable, any other relevant Union legislation that provides for the issuing of an EU declaration of conformity:

1. Radio Equipment Directive (RED) 2014/53/EU

RED: Health & Safety: EN 60950-1:2006 + A2:2013, EN/IEC 62479: 2010;

EMC: EN 301 489-17 V3.2.0, EN 301 489-1 V2.2.0;

Spectrum: EN 300 328 V2.2.2



Name: Martin Arvidsson

Title: Person Responsible for Regulatory Compliance

For, and on behalf of:

Cochlear Bone Anchored Solutions AB

Konstruktionsvägen 14

SE-435 33 Mölnlycke

SWEDEN

1 WIRELESS ACCESSORIES

Risk class: In accordance with the rules set out in MDR 2017/745 Annex VIII: class I

Intended Use: The Cochlear Wireless Mini Microphone 2+ is intended to be a wireless remote microphone or connection to an audio device for a compatible Cochlear sound processor.

The Cochlear Wireless Phone Clip is intended to transfer signals between a Bluetooth® enabled mobile phone and a compatible Cochlear sound processor.

The Cochlear Wireless TV Streamer is intended to be a wireless connection to a television or other audio device for a compatible Cochlear sound processor.

The Cochlear Baha Remote Control 2 is intended to be a wireless remote control for a compatible Cochlear sound processor.

EMDN: Y214599, HEARING AIDS - OTHERS

GMDN: 57886, Hearing aid enhanced audio device, telecommunication/multimedia

Article #	Article name	Basic UDI-DI
94760	Cochlear Wireless TV Streamer, EU	9321502TVStreamerA8
94761	Cochlear Wireless TV Streamer, US	9321502TVStreamerA8
94762	Cochlear Wireless TV Streamer, GB	9321502TVStreamerA8
94763	Cochlear Wireless TV Streamer, AUS	9321502TVStreamerA8
94770	Cochlear Wireless Phone Clip, EU	9321502PhoneClipAK
94771	Cochlear Wireless Phone Clip, US	9321502PhoneClipAK
94772	Cochlear Wireless Phone Clip, GB	9321502PhoneClipAK
94773	Cochlear Wireless Phone Clip, AUS	9321502PhoneClipAK
94790	Cochlear Baha Remote Control 2, EU	9321502BRemoteControl2QQ
94791	Cochlear Baha Remote Control 2, US	9321502BRemoteControl2QQ
94792	Cochlear Baha Remote Control 2, GB	9321502BRemoteControl2QQ
94793	Cochlear Baha Remote Control 2, AUS	9321502BRemoteControl2QQ
P770845	Cochlear Wireless Mini Microphone 2+ GB	9321502MiniMic2+V4
P770846	Cochlear Wireless Mini Microphone 2+ EU	9321502MiniMic2+V4
P770847	Cochlear Wireless Mini Microphone 2+ AUS	9321502MiniMic2+V4
P770848	Cochlear Wireless Mini Microphone 2+ US	9321502MiniMic2+V4

2 CHANGE HISTORY

Version	Date	Change	Author
1	2021-06-23	First version of document. Declaration of Conformity according to EU MDR 2017/745 and Radio Equipment Directive (RED) 2014/53/EU.	Åsa Sundström
2	2021-09-02	SRN-Number added to document.	Johanna Ejesson
3	2023-04-05	Updated standard EN 300 328 (v.2.1.1) --> (v.2.2.2) Electronic signature added to document. GMDN Code 57886 added. Changed from CND to EMDN, but the code remains.	Ann Lundström/ Caroline Olsson