DoC Baha 5 Power R&TTE



DECLARATION OF CONFORMITY

Medical Device: Baha® 5 Power

We, Cochlear Bone Anchored Solutions AB, located in Konstruktionsvägen 14, SE-435 33 Mölnlycke, Sweden, declare under sole responsibility that the product:

Type of equipment: Bone Anchored Sound Processor

Trade name: Baha[®] 5 Power Model: Baha[®] 5 Power

to which this declaration relates is in conformity with the essential requirements of the R&TTE Directive (1999/5/EC)

The product is in conformance with the following standards:

HEALTH & SAFETY (Art. 3(1)(a)): EN 60601-1 2005 + CORR. 1:2006 + CORR. 2:2007 +

AM1:2012 EN 62479:2010

EMC (Art. 3(1)(b)): EN 301 489-1 V1.9.2

EN 301 489-17 V2.2.1

SPECTRUM (Art. 3(2)): EN 300 328 V1.8.1

I hereby declare that the products concerned, as per listed below, conform to the requirements of the R&TTE Directive 1999/5/EC.

Jon Callerfjord

Director of Quality & Regulatory

Cochlear Bone Anchored Solutions AB
Konstruktionsvägen 14
SE-435 33 Mölnlycke
SWEDEN

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Approved By: Marie Skoglund (maskoglund)

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Article# 95470	Article name Baha 5 Power Soundprocessor, B	Blonde
95471	Baha 5 Power Soundprocessor, B	Black
95472	Baha 5 Power Soundprocessor, S	Silver
95473	Baha 5 Power Soundprocessor, B	Brown
95474	Baha 5 Power Soundprocessor, C	opper
95475	Baha 5 Power Demo, Black	

Revision	Changes

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