

Declaration of Conformity

Medical Device: Baha® System & Vistafix™ System

Manufacturer Name: Cochlear Bone Anchored Solutions AB

Manufacturer Address: Konstruktionsvägen 14
SE-435 33 Mölnlycke
SWEDEN

Classification: I, I Sterile, I Measuring, IIa & IIb

Classification Rule Applied: 1, 2, 4, 5, 6, 7, 8 & 9

Conformity Assessment: Annex II (with the exemption of section 4)
Annex VII (for class I devices)

Notified Body: BSI, identification no. 2797

Certificate Number: CE 667866

I hereby declare that the products concerned conform to the requirements of LVFS 2003:11 & LVFS 2009:18 which is the Swedish implementation of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC.



Name: Marie Skoglund

Title: Regulatory Affairs Manager

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

Declaration of Conformity - All products

Article #	Article name	MDD Class	GMDN Code
90065	Audio adapter for head worn devices	I	33993
90067	Audio adapter Cordelle II	I	33993
90068	Bilateral connection cord	I	33993
90095	Fixture mount standard Unigrip	I	44758
90138	Headband	I	41212
90139	Surgical organizer Ti	I	12143
90171	Testband	I	41212
90185	Telecoil black	I	33993
90238	Fixture mount short Unigrip	I	44758
90377	Impression coping tapered	I	44758
90379	Impression coping squared	I	44758
90380	Machine Screwdriver 20mm UniGrip	I	33968
90381	Machine Screwdriver 25mm UniGrip	I	33968
90397	Machine Screwdriver abutment	I	33968
90408	Screwdriver for hexagon	I	33968
90453	Screwdriver for internal hexagon 20mm	I	33968
90456	Screwdriver for hexagon 17mm	I	33968
90459	Screwdriver Unigrip 20mm	I	33968
90469	Screwdriver UniGrip 95mm	I	33968
90474	Abutment inserter	I	44758
90478	Connection to handpiece	I	44758
90623	Audio cord beige 75 cm	I	33993
90625	Audio cord beige 150 cm	I	33993
90627	Audio cord black 75 cm	I	33993
90629	Audio cord black 150 cm	I	33993
90794	Guide pin 10mm	I	44758
90796	Guide Pin 20mm	I	44758
90941	Abutment Clamp	I	44758
90942	Forceps Ti	I	44758
90943	Dissector	I	44758
90944	Raspatorium	I	44758
91040	Abutment Cleaning Brush	I	33993
91086	Counter Torque Wrench	I	44758
91095	Indicator for Baha	I	44758
91116	Drill Indicator for WS-75 and Osscora	I	44758
91180	Cochlear Baha Audio adapter Short Cable	I	33993
91181	Cochlear Baha Telecoil	I	33993
91868	Cochlear Baha Audio adapter Long Cable	I	33993
92142	Implant inserter	I	44758
92143	Multi wrench with ISO adapter	I	44758
92145	Component tray	I	12143
92146	Baha instrument organiser	I	12143
92290	Square adapter for Multi wrench	I	44758
92353	ISO adapter for Surgical wrench	I	44758

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Article #	Article name	MDD Class	GMDN Code
92776	Baha Softband unilat, Champagne blonde	I	41212
93183	Counter torque wrench for Vistafix® VXA300	I	44758
93185	Abutment replica for Vistafix® VXA300	I	44758
93192	Impression coping squared for Vistafix® VXA300	I	44758
93571	Indicator for Baha Attract	I	44758
93572	Bone bed indicator	I	44758
93581	Demo SP Magnet 5 Black	I	44758
94071	Implant magnet template	I	44758
94760	Cochlear Wireless TV Streamer, EU	I	57886
94761	Cochlear Wireless TV Streamer, US	I	57886
94762	Cochlear Wireless TV Streamer, GB	I	57886
94763	Cochlear Wireless TV Streamer, AUS	I	57886
94765	Cochlear Baha Remote Control	I	57885
94770	Cochlear Wireless Phone Clip, EU	I	57886
94771	Cochlear Wireless Phone Clip, US	I	57886
94772	Cochlear Wireless Phone Clip, GB	I	57886
94773	Cochlear Wireless Phone Clip, AUS	I	57886
94781	Cochlear Wireless Mini Microphone, US	I	57886
94783	Cochlear Wireless Mini Microphone, AUS	I	57886
94790	Cochlear Baha Remote Control 2, EU	I	57885
94791	Cochlear Baha Remote Control 2, US	I	57885
94792	Cochlear Baha Remote Control 2, GB	I	57885
94793	Cochlear Baha Remote Control 2, AUS	I	57885
95070	Soft tissue gauge 6 mm	I	44758
95180	Bone bed indicator	I	44758
95331	Baha 5 Sound Processor Tamper-proof battery door	I	34180
95750	Baha Softband unilateral, Pink	I	41212
95751	Baha Softband unilateral, Light blue	I	41212
95752	Baha Softband unilateral, Dark blue	I	41212
95753	Baha Softband unilateral, Brown	I	41212
95754	Baha Softband unilateral, Black	I	41212
95755	Baha Softband unilateral, Blonde	I	41212
95756	Baha Softband unilateral, Red	I	41212
95757	Baha Softband unilateral, Jungle	I	41212
95760	Baha Softband bilateral, Pink	I	41212
95761	Baha Softband bilateral, Light blue	I	41212
95762	Baha Softband bilateral, Dark blue	I	41212
95763	Baha Softband bilateral, Brown	I	41212
95764	Baha Softband bilateral, Black	I	41212
95765	Baha Softband bilateral, Blonde	I	41212
95766	Baha Softband bilateral, Red	I	41212
95767	Baha Softband bilateral, Jungle	I	41212
95771	SP Magnet 1	I	47286
95772	SP Magnet 2	I	47286

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Article #	Article name	MDD Class	GMDN Code
95773	SP Magnet 3	I	47286
95774	SP Magnet 4	I	47286
95775	SP Magnet 5	I	47286
95776	SP Magnet 6	I	47286
95809	Baha Softband soft pad	I	41212
95934	Indicator for Baha 5 SuperPower, Baha Connect System	I	44758
95948	Baha 5 SuperPower Fitting Adaptor	I	40888
96048	Indicator for Baha 5 SuperPower, Baha Attract System	I	44758
HCB 089	Audio cord beige 22.5 cm	I	33993
HCB 527-0	Telecoil Classic 300 black	I	33993
HIA 009-0	Counter torque wrench	I	44758
HIB 002-0	Open end wrench Baha	I	44758
HIB 003-0	Screwdriver Baha	I	33968
P771900	Baha 5 SuperPower Earhook+ (Medium, Carbon)	I	34180
P771901	Baha 5 SuperPower Earhook+ (Medium, Smoke)	I	34180
P771902	Baha 5 SuperPower Earhook+ (Medium, Mocha)	I	34180
P771903	Baha 5 SuperPower Earhook+ (Medium, Maize)	I	34180
P771904	Baha 5 SuperPower Earhook+ (Large, Carbon)	I	34180
P771905	Baha 5 SuperPower Earhook+ (Large, Smoke)	I	34180
P771906	Baha 5 SuperPower Earhook+ (Large, Mocha)	I	34180
P771907	Baha 5 SuperPower Earhook+ (Large, Maize)	I	34180
P770841	Cochlear Wireless Mini Microphone 2 GB	I	57886
P770842	Cochlear Wireless Mini Microphone 2 EU	I	57886
P770843	Cochlear Wireless Mini Microphone 2 AUS	I	57886
P770844	Cochlear Wireless Mini Microphone 2 US	I	57886
P770845	Cochlear Wireless Mini Microphone 2+ GB	I	57886
P770846	Cochlear Wireless Mini Microphone 2+ EU	I	57886
P770847	Cochlear Wireless Mini Microphone 2+ AUS	I	57886
P770848	Cochlear Wireless Mini Microphone 2+ US	I	57886
P1129017	Baha 5 Sound Processor Tamper-proof battery door 3 pcs	I	34180
P807175	Baha SoundArc, Small	I	47286
P807176	Baha SoundArc, Medium	I	47286
P807177	Baha SoundArc, Large	I	47286
P807178	Baha SoundArc, Extra Large	I	47286
P807179	Baha SoundArc Colour Kit	I	47286
P807181	Baha SoundArc, Connector disc	I	47286
P1324401	Baha SoundArc Extra Small	I	47286
P1572994	Baha SoundArc Hair Matching Colour Kit	I	47286
P1573011	Baha SoundArc Fun Colour Kit	I	47286
P1668404	Cochlear™ Baha® 6 Max Battery Door – Tamper Resistant	I	34180
90329	Baha Blade Dermatome	Ila	35134
90338	Gold screw Unigrip for gold cylinder	Ila	16101
90416	Drill countersink 3mm	Ila	44758

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Article #	Article name	MDD Class	GMDN Code
90417	Drill countersink 4mm	Ila	44758
90446	Gold bar Ø2 x 50 mm	Ila	16101
90448	Gold bar Ø2 x 100 mm	Ila	16101
90772	Gold Cylinder 4mm	Ila	16101
90842	Clip attachment Ø2mm	Ila	44758
91051	Osscora Surgical Set	Ila	37251
91052	Osscora Surgical Set	Ila	37251
92140	Widening drill 3mm w countersink	Ila	44758
92141	Widening drill 4mm w countersink	Ila	44758
92840	Baha BP110 Power, Champagne Blonde	Ila	33993
92841	Baha BP110 Power, Soft Black	Ila	33993
92842	Baha BP110 Power, Slate Grey	Ila	33993
92843	Baha BP110 Power, Chestnut Brown	Ila	33993
92844	Baha BP110 Power, Glacier White	Ila	33993
92845	Baha BP110 Power, Piano Black	Ila	33993
92846	Baha BP110 Power, Demo	Ila	33993
93184	Gold cylinder 4mm for Vistafix® VXA300 Abutment	Ila	16101
93363	Conical guide drill 3+4mm	Ila	44758
94223	Baha Fiting Software 4.0	Ila	40888
94227	Baha Fitting Software 4.0 – CSDS	Ila	40888
95201	Baha 5 Soundprocessor, Blonde	Ila	34180
95202	Baha 5 Soundprocessor, Black	Ila	34180
95203	Baha 5 Soundprocessor, Silver	Ila	34180
95204	Baha 5 Soundprocessor, Brown	Ila	34180
95205	Baha 5 Soundprocessor, Copper	Ila	34180
95207	Baha 5 Demo, Black	Ila	34180
95430	Baha Fitting Software	Ila	40888
95431	Baha Fitting Software CSDS	Ila	40888
95448	Baha 5 Smart App	Ila	57885
95459	Cochlear Baha Control App for iOS	Ila	57885
95460	Cochlear Baha Control App for Android	Ila	57885
95461	Baha 5 SuperPower Actuator unit	Ila	34180
95462	Baha 5 SuperPower Actuator unit	Ila	34180
95463	Baha 5 SuperPower Actuator unit	Ila	34180
95464	Baha 5 SuperPower Actuator unit	Ila	34180
95936	Baha 5 SuperPower Bodyworn Cable	Ila	34180
95937	Baha 5 SuperPower Bodyworn Cable	Ila	34180
95938	Baha 5 SuperPower Bodyworn Cable	Ila	34180
95939	Baha 5 SuperPower Bodyworn Cable	Ila	34180
96000	Baha 5 SuperPower Processing unit, Demo	Ila	34180
96001	Baha 5 SuperPower Processing unit	Ila	34180
96002	Baha 5 SuperPower Processing unit	Ila	34180
96003	Baha 5 SuperPower Processing unit	Ila	34180
96004	Baha 5 SuperPower Processing unit	Ila	34180

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Article #	Article name	MDD Class	GMDN Code
95470	Baha 5 Power Soundprocessor, Blonde	Ila	34180
95471	Baha 5 Power Soundprocessor, Black	Ila	34180
95472	Baha 5 Power Soundprocessor, Silver	Ila	34180
95473	Baha 5 Power Soundprocessor, Brown	Ila	34180
95474	Baha 5 Power Soundprocessor, Copper	Ila	34180
95475	Baha 5 Power Demo, Black	Ila	34180
P736025	Baha 5 Smart App	Ila	57885
P803254	Baha Fitting Software	Ila	40888
P803255	Baha Fitting Software	Ila	40888
P878155	Baha Fitting Software 5.2	Ila	40888
P878156	Baha Fitting Software 5.2	Ila	40888
P907535	Baha 5 Smart App i2.0	Ila	57885
P907536	Baha 5 Smart App A1.0	Ila	57885
P1287308	Baha Fitting Software 5 Basic	Ila	57884
P1287311	Baha Fitting Software 4 Basic	Ila	57884
P1682914	Cochlear™ Baha® Fitting Software 6	Ila	57884
P1701568	Cochlear™ Baha® Fitting Software 6 Basic	Ila	57884
P1668389	Cochlear™ Baha® 6 Max Sound Processor, Blonde	Ila	34180
P1668390	Cochlear™ Baha® 6 Max Sound Processor, Black	Ila	34180
P1668391	Cochlear™ Baha® 6 Max Sound Processor, Silver	Ila	34180
P1668392	Cochlear™ Baha® 6 Max Sound Processor, Brown	Ila	34180
P1668393	Cochlear™ Baha® 6 Max Sound Processor, Copper	Ila	34180
P1668394	Cochlear™ Baha® 6 Max Sound Processor, Mint	Ila	34180
P1668395	Cochlear™ Baha® 6 Max Demo Sound Processor, Black	Ila	34180
P1809177	Cochlear™ Baha® 6 Max Sound Processor, Blonde, 2mm	Ila	34180
P1809178	Cochlear™ Baha® 6 Max Sound Processor, Black, 2mm	Ila	34180
P1809179	Cochlear™ Baha® 6 Max Sound Processor, Silver, 2mm	Ila	34180
P1809180	Cochlear™ Baha® 6 Max Sound Processor, Brown, 2mm	Ila	34180
P1809221	Cochlear™ Baha® 6 Max Sound Processor, Copper, 2mm	Ila	34180
P1809222	Cochlear™ Baha® 6 Max Sound Processor, Mint, 2mm	Ila	34180
P1809223	Cochlear™ Baha® 6 Max Demo Sound Processor, Black, 2mm	Ila	34180
P1646054	Baha Smart App	Ila	57885
P1646035	Baha Smart App	Ila	57885
90360	Cover screw Unigrip	Ilb	16101
90362	Cover screw internal hexagon	Ilb	16101
90426	Console abutment 30° Unigrip	Ilb	16101
90427	Console abutment 60° Unigrip	Ilb	16101
90428	Console abutment 90° Unigrip	Ilb	16101
90429	Console abutment 110° Unigrip	Ilb	16101
90436	Healing abutment 7mm Unigrip	Ilb	16101
90438	Fixture ST 3mm	Ilb	16101
90440	Fixture ST 4mm	Ilb	16101
90620	Cover screw space w internal hexagon	Ilb	16101

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Article #	Article name	MDD Class	GMDN Code
90774	Standard Abutment 7mm	IIb	16101
90776	Standard Abutment 5,5mm	IIb	16101
90778	Standard Abutment 4mm	IIb	16101
90780	Standard Abutment 3mm	IIb	16101
91074	Abutment 6mm	IIb	16101
91075	Abutment 9mm	IIb	16101
92126	BIA300 implant 3mm w abutment 6mm	IIb	16101
92127	BIA300 implant 4mm w abutment 6mm	IIb	16101
92128	BI300 implant 3mm	IIb	16101
92129	BI300 implant 4 mm	IIb	16101
92130	BA300 abutment 6mm	IIb	16101
92131	BA300 abutment 9mm	IIb	16101
92132	BA210 abutment 5.5mm for flange fixture	IIb	16101
92133	BA210 abutment 8.5mm for flange fixture	IIb	16101
92136	Cover screw conical	IIb	16101
92346	BIA300 implant 4mm w Abutment 9mm	IIb	16101
92994	Cochlear™ Vistafix® VXA300 Abutment 3.5mm	IIb	16101
92995	Cochlear™ Vistafix® VXA300 Abutment 4.5mm	IIb	16101
92996	Cochlear™ Vistafix® VXA300 Abutment 6mm	IIb	16101
92997	Cochlear™ Vistafix® VXA300 Abutment 7.5mm	IIb	16101
92998	Cochlear™ Vistafix® VXA300 Healing abutment	IIb	16101
93100	Cochlear™ Vistafix® VXI300 Implant 3mm	IIb	16101
93101	Cochlear™ Vistafix® VXI300 Implant 4mm	IIb	16101
93102	Cover screw conical for Vistafix® VXI300 Implant	IIb	16101
93329	BIA400 Implant 4mm w Abutment 6mm	IIb	46638
93330	BIA400 Implant 4mm w Abutment 8mm	IIb	46638
93331	BIA400 Implant 4mm w Abutment 10mm	IIb	46638
93332	BIA400 Implant 4mm w Abutment 12mm	IIb	46638
93333	BA400 Abutment 6mm	IIb	46638
93334	BA400 Abutment 8mm	IIb	46638
93335	BA400 Abutment 10mm	IIb	46638
93336	BA400 Abutment 12mm	IIb	46638
93337	BA400 Abutment 14mm	IIb	46638
93338	BIA400 Implant 4mm w Abutment 14mm	IIb	46638
93357	BA300 Abutment 12mm	IIb	16101
93550	BIM400 Implant Magnet	IIb	46638
P1340894	BA310 Abutment 6mm	IIb	46638
P1340895	BA310 Abutment 8mm	IIb	46638
P1340896	BA310 Abutment 10mm	IIb	46638
P1340897	BA310 Abutment 12mm	IIb	46638
P1340898	BA310 Abutment 14mm	IIb	46638
P1340888	BIA310 Implant 4mm with 6mm abutment	IIb	46638
P1340889	BIA310 Implant 4mm with 8mm abutment	IIb	46638
P1340890	BIA310 Implant 4mm with 10mm abutment	IIb	46638

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Article #	Article name	MDD Class	GMDN Code
P1340891	BIA310 Implant 4mm with 12mm abutment	IIb	46638
P1340893	BIA310 Implant 4mm with 14mm abutment	IIb	46638
93339	Baha ruler	Im	44758
90801	Healing Cap Ø 6,5mm	Is	16101
90802	Healing Cap Ø 14mm	Is	16101
95083	Healing cap with plug 20 mm	Is	46638
95084	Healing cap with plug 30 mm	Is	46638

Version	Date	Change	Author
01		Update with new products. Obsolete products are removed	
02		Osscora Surgical Set and Dermatome for Osscora are added	
03		Updated with correct address	
04		New name on products 90065, 91065 and 91116. Products 90418, 90420, 90422 and 90424 removed due to obsolescence. Corrected with 90450	
05		Products 91075 & 91068 added	
06		Baha BP100 & Fitting System added	
07		91310 Baha BP100 Demo added	
08		91074, 92132-92135 & 92137 added. 91180, 91181, 91868 & 92275 added	
09		92126-92131, 92346 & 92136 added	
10		New template according to 2007/47/EC	
11		Products 92138, 92139, 92140, 92141, 92148 & 92352 added Products 92142, 92143, 92145, 92126, 92290 & 92353 added	
12		Products 92840-92846 added. 90442, 90444, 90251, 90334, 90668, 90491, 90493, 90611 & 90613 removed due to obsolescence	
13		Products 92500, 92600, 93001-93004 added.	
14		Products 90312, HIA 007 & 90400 removed due to obsolescence	
15		Products for New Vistafix system added 92994-8, 93101-2, 93183-5, 93192	
16		New Softbands added 92771-78, 92781-88. 91040 Cleaning brush – new name	
17		New revision of template	
18		New devices 93329-93336 added	
19		New device 93339 added	
20		Products 90364, 90366 90140, 90141, 90142, 90544, 90545, 90655, 90851 removed due to obsolescence. New GMDN-code for BA&BIA 400 as the old has been obsolete.	
21		New devices 93363, 93550, 93561, 93562, 93563, 93564, 93565, 93570, 93571, 93572, 93581 & 94071 added	
22		New devices: 94770, 94771, 94772, 94773, 94780, 94781, 94782, 94783 & 94765 added	
23		New devices: 93630, 93631, 93632, 93633, 93634, 94230, 94223, 94224, 94227 & 94228 added.	
24		New devices 93566 & 95070 added	
25		Added new devices 94760-63 and 94790-93	

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Version	Date	Change	Author
26		Correct GMDN code for 93561-93566	
27		Correct number for Soft tissue gauge 93570	
28		Correct number for Soft tissue gauge 93570	
29		Added new device 95185	
30		Removed products 90450 + 90665	
31		Introduction of Baha 4 Control Apps	
32		Added new device 95084	
33		Added Baha 5 Soundprocessors and Baha Fitting Software	
34		Added Notified Body and Certificate no. Revised change description for revision 30.	
35		Added SP Magnets 95771-76 and Baha 5 Smart App 95448	
36		Added Bone bed indicator 95180	
37		Added Softband 3.0 (ref 95750-95767) and Softband Soft pad 95809	
38		Updated certificate number, added 93337, 93338, 93357 long abutments (Dougong)	
39		Added 95331, Baha 5 Sound Processor Tamper-proof battery door	
40		New Windchill template. Added 95083, Healing cap with plug 20 mm	
41		Healing caps 95083 and 95084 updated with correct GMDN code (46638)	
42		Baha 5 SuperPower Processing unit (96000-96004), Baha 5 SuperPower Actuator unit (95461-95464), Baha 5 SuperPower Bodyworn Cable (95936-95939), Baha Fitting Software (96070-96071), Product Key 96072 and Earhook+ (P771900-P771907)	
43		95934 and 96048 (Indicator Baha 5 SuperPower), 95948 (Fitting Adaptor) added.	
44		Added: Cochlear Wireless Mini Microphone 2 (P770841-P770844) and Cochlear Wireless Mini Microphone 2+ (P770845-P770848).	
45		Added: Baha 5 Power (95470-95475) and Baha Fitting Software (P803254-P803255)	
46		Added: Baha 5 Smart App (P736025), moved Cochlear Baha Control Apps in order to be placed according to article number.	
47		First page updated. Added separate information about Manufacturer name and address. Added information about Annex VII for class I products. Corrected typo in revision history 44 from P770884 to P770844.	
48		Added: Baha Fitting Software 5.2 (P878155, P878156), Baha 5 Smart App i2.0 (P907535), Baha 5 Smart App A1.0 (P907536). (China specific articles.)	
49		Added: P1129017, Baha 5 Sound Processor Tamper-proof battery door 3 pcs	
50		Added: SoundArc (ref P807175- P807178)	
51		Removed products due to obsolescence: 90762, 90945, 91122, 91125, 92771, 92772, 92773, 92774, 92775, 92778, 92784, 92786, 92787, 94782, 93570, 94780, 90740, 92777, 92781, 92782, 92783, 92785, 92788, 91121, 90500, 90502, 90503, 90510, 90513, 90676, 90733, 90335, HCB 039-0, 90512, 90732, 91120, 91065, 91500, 93004, HCB 410-0, HCB 411-0, HCB 412-0, 90215, 91068, 92134, 92135, 95185, 91062, 92148, 90016, 90017, 90286, 90287, 90640, 91060, HCB	

Version	Date	Change	Author
		576-0, 91126, 91127, HCB 520-0, 91123, 91124, HCB 578-0, HCB 703-0, 93561, 93562, 93563, 93564, 93565, 93566, 91300, 91301, 91302, 91303, 91304, 91305, 91310, 90730, 90731, 90900, 90501, 90511, 90684, 90685, HCB 400-0, HCB 401-0, HCB 402-0, 90015, 94228, 94224, 96070, 96071, 91600, 92500, 92600 Removed product due to harmonization of classification for Product keys: 96072	
52		Added: SoundArc Connector disc (P807181) Corrected: Classification for 90436 Healing abutment 7mm Unigrip from IIa to IIb.	
53	20170825	Changed information about Notified Body on page 1. Changed from Intertek to BSI. New template implemented with version history table updated.	Marie Skoglund
54	20170904	Updated to latest version of document template.	Marie Skoglund
55	2017-10-25	Added: SoundArc Colour Kit (P807179)	Gunilla Landin
56	2018-01-10	Added: Baha Fitting Software 5 Basic (P1287308), Baha Fitting Software 4 Basic (P1287311)	Gunilla Landin
57	2018-02-08	Removed products due to obsolescence: 90430, 90432, 90434, 90480, 90305, 90410, 93630, 93631, 93632, 93633, 93634, 94230, 90415, 92139, 92352, 93003, 91109, 90385, 90840, 92137, 92138, 93001, 93002	Marie Skoglund
58	2018-04-11	Added: Baha SoundArc Extra Small (P1324401)	Gunilla Landin
59	2018-06-14	Added: BA and BIA 310 in sizes 8-12 mm (P1340895, P1340896, P1340897, P1340889, P1340890, P1340891)	Marie Skoglund
60	2018-12-12	Changed NB number from 0086 to 2797 (BSI UK to BSI NL)	Marie Skoglund
61	2019-02-18	Added: BA and BIA 310 in sizes 6 and 14 mm	Marie Skoglund
62	2019-09-12	Added: P1572994 Baha SoundArc Hair Matching Colour Kit and P1573011 Baha SoundArc Fun Colour Kit	Sofia Hjortmo
63	2020-05-05	Renewal of EC certificate (CE 667866, Date 2020-01-31).	Sofia Hjortmo
64	2020-08-31	CE marking of BFS6 (P1682914 and P1701568)	Marie Skoglund
65	2020-09-02	CE marking of Baha 6 devices (P1668389, P1668390, P1668391, P1668392, P1668393, P1668394, P1668395, P1646054, P1646035, P1668421, P1668404)	Marie Skoglund
66	2020-09-03	Corrected typo on name, P1668404	Marie Skoglund
67	2021-01-25	Removed P1668421, Cochlear Baha Snap Coupling Extender Kit. Added Baha 6 Max 2 mm (P1809177, P1809178, P1809179, P1809180, P1809221, P1809222, P1809223)	Marie Skoglund