

## 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     |

## Declaration of Conformity - All products

| 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.<br>Products 90418, 90420, 90422 and 90424 removed due to obsolescence.<br>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.<br>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<br>Products 92142, 92143, 92145, 92126, 92290 & 92353 added   |        |
| 12      |      | Products 92840-92846 added.<br>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.<br>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:<br>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 |        |

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| 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<br>Removed product due to harmonization of classification for Product keys: 96072 |                |
| 52      |            | Added: SoundArc Connector disc (P807181)<br>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:<br>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.<br>Added Baha 6 Max 2 mm (P1809177, P1809178, P1809179, P1809180, P1809221, P1809222, P1809223)   | Marie Skoglund |