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

02 May 2024

Notified Body Confirmation Letter
Reference: EU2023-607/716405

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number: SE-MF-000012413

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
92130 BA300 abutment 6mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92131 BA300 abutment 9mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92132 BA210 abutment 5.5mm for flange fixture	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92133 BA210 abutment 8.5mm for flange fixture	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93333 BA400 Abutment 6mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93334 BA400 Abutment 8mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93335 BA400 Abutment 10mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93336 BA400 Abutment 12mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93337 BA400 Abutment 14 mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93357 BA300 Abutment 12 mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340894 BA310 Abutment 6mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340895 BA310 Abutment 8mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340896 BA310 Abutment 10mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
P1340897 BA310 Abutment 12mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340898 BA310 Abutment 14mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92136 Cover screw conical (Baha)	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92126 BIA300 implant 3mm w abutment 6mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92127 BIA300 implant 4mm w abutment 6mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92128 BI300 implant 3mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92129 BI300 implant 4 mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92346 BIA300 implant 4mm w Abutment 9mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93329 BIA400 Implant 4mm w Abutment 6mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93330 BIA400 Implant 4mm w Abutment 8mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93331 BIA400 Implant 4mm w Abutment 10mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93332 BIA400 Implant 4mm w Abutment 12mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93338 BIA400 Implant 4 mm w Abutment 14 mm	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340888 BIA310 Implant 4mm with 6mm abutment	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340889 BIA310 Implant 4mm with 8mm abutment	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
P1340890 BIA310 Implant 4mm with 10mm abutment	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340891 BIA310 Implant 4mm with 12mm abutment	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
P1340893 BIA310 Implant 4mm with 14mm abutment	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
93550 BIM400 Implant Magnet	Class IIb implantable non-WET	N/A	Certificate CE 667866; NB 2797
92140 Widening drill 3mm w countersink	Class IIa	N/A	Certificate CE 667866; NB 2797
92141 Widening drill 4mm w countersink	Class IIa	N/A	Certificate CE 667866; NB 2797
93363 Conical guide drill 3+4mm	Class IIa	N/A	Certificate CE 667866; NB 2797
95083 Healing cap with plug 20 mm	Class I device placed on the market in sterile condition	N/A	Certificate CE 667866; NB 2797
95084 Healing cap with plug 30 mm	Class I device placed on the market in sterile condition	N/A	Certificate CE 667866; NB 2797
Baha X	Class IIa	95461 Baha 5 SuperPower Actuator Unit	Certificate CE 667866; NB 2797
Baha X	Class IIa	95462 Baha 5 SuperPower Actuator Unit	Certificate CE 667866; NB 2797
Baha X	Class IIa	95463 Baha 5 SuperPower Actuator Unit	Certificate CE 667866; NB 2797
Baha X	Class IIa	95464 Baha 5 SuperPower Actuator Unit	Certificate CE 667866; NB 2797
Baha X	Class IIa	95936 Baha 5 SuperPower Bodyworn Cable	Certificate CE 667866; NB 2797
Baha X	Class IIa	95937 Baha 5 SuperPower Bodyworn Cable	Certificate CE 667866; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Baha X	Class IIa	95938 Baha 5 SuperPower Bodyworn Cable	Certificate CE 667866; NB 2797
Baha X	Class IIa	95939 Baha 5 SuperPower Bodyworn Cable	Certificate CE 667866; NB 2797
Baha X	Class IIa	96000 Baha 5 SuperPower Processing Unit, Demo	Certificate CE 667866; NB 2797
Baha X	Class IIa	96001 Baha 5 SuperPower Processing Unit	Certificate CE 667866; NB 2797
Baha X	Class IIa	96002 Baha 5 SuperPower Processing Unit	Certificate CE 667866; NB 2797
Baha X	Class IIa	96003 Baha 5 SuperPower Processing Unit	Certificate CE 667866; NB 2797
Baha X	Class IIa	96004 Baha 5 SuperPower Processing Unit	Certificate CE 667866; NB 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/10/30	Initial issue
2023/11/30	Amended device classification
2024/04/15	Addition, to table 1, of Baha 5 SuperPower and its substitute device.
2024/04/22	Specification of all SKUs of Baha 5 SuperPower.
2024/05/02	Update of Baha 5 SuperPower substitute device's name to Baha X.