Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**Cochlear Bone Anchored Solutions AB**
Manufacturer address and contact details	Konstruktionsvägen 14 Mölnlycke SE-435 33 Sweden regulatorysupport-cbas@cochlear.com
Single Registration Number (SRN) (if available)	SE-MF-000012413

Authorised Representative name (if applicable)	**N/A**
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.
  Choose applicable statements:
  ☐ Expired *before* 20 March 2023:
  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:
  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☒Expired/expires *after* 20 March 2023:
  Choose one applicable statement:
  ☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

  In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

  Choose one applicable statement:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  ☐A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ☒A QMS in accordance with Article 10(9) MDR is in place.

  ☒A notified body has issued a certificate for an MDR-compliant QMS, which can be made available upon request.

- **Device(s) as listed in the attached schedule**
  - The device(s) continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Authorised Signatory on behalf of Cochlear Bone Anchored Solutions AB and for the Person Responsible for Regulatory Compliance:

Ann Lundström

Director Regulatory Affairs

Date: 3 May 2024

Place: Mölnlycke, Gothenburg

Schedule I: Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
92130 BA300 abutment 6mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92131 BA300 abutment 9mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92132 BA210 abutment 5.5mm for flange fixture	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92133 BA210 abutment 8.5mm for flange fixture	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93333 BA400 Abutment 6mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93334 BA400 Abutment 8mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

93335 BA400 Abutment 10mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93336 BA400 Abutment 12mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93337 BA400 Abutment 14mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93357 BA300 Abutment 12 mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340894 BA310 Abutment 6mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340895 BA310 Abutment 8mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340896 BA310 Abutment 10mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340897 BA310 Abutment 12mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340898 BA310 Abutment 14mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92136 Cover screw conical	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92126 BIA300 implant 3mm w abutment 6mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92127 BIA300 implant 4mm w abutment 6mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A

92128 BI300 implant 3mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92129 BI300 implant 4mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92346 BIA300 implant 4mm w Abutment 9mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93329 BIA400 Implant 4mm w Abutment 6mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93330 BIA400 Implant 4mm w Abutment 8mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93331 BIA400 Implant 4mm w Abutment 10mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93332 BIA400 Implant 4mm w Abutment 12mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93338 BIA400 Implant 4mm w Abutment 14mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340888 BIA310 Implant 4mm with 6mm abutment	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340889 BIA310 Implant 4mm with 8mm abutment	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A

P1340890 BIA310 Implant 4mm with 10mm abutment	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340891 BIA310 Implant 4mm with 12mm abutment	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
P1340893 BIA310 Implant 4mm with 14mm abutment	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93550 BIM400 Implant Magnet	CE 667866	2024-05-26	BSI 2797	BSI 2797	2027-12-31	N/A
92140 Widening drill 3mm w countersink	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
92141 Widening drill 4mm w countersink	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
93363 Conical guide drill 3+4mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
95083 Healing cap with plug 20 mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
95084 Healing cap with plug 30 mm	CE 667866	2024-05-26	BSI 2797	BSI 2797	2028-12-31	N/A
95461 Baha 5 SuperPower Actuator unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
95462 Baha 5 SuperPower Actuator unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X

95463 Baha 5 SuperPower Actuator unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
95464 Baha 5 SuperPower Actuator unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
95936 Baha 5 SuperPower Bodyworn Cable	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
95937 Baha 5 SuperPower Bodyworn Cable	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
95938 Baha 5 SuperPower Bodyworn Cable	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
95939 Baha 5 SuperPower Bodyworn Cable	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
96000 Baha 5 SuperPower Processing unit, Demo	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
96001 Baha 5 SuperPower Processing unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
96002 Baha 5 SuperPower Processing unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X

96003 Baha 5 SuperPower Processing unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X
96004 Baha 5 SuperPower Processing unit	CE 667866	2024-05-26	BSI 2797	N/A	2025-10-31	Baha X