By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 667866**

Issued To: **Cochlear Bone Anchored Solutions AB**
Konstruktionsvägen 14
Mölnlycke
SE-435 33
Sweden

In respect of:

Design and manufacture of hearing aids and implants for rehabilitation of hearing, craniofacial implants and accessories.

Those aspects of Annex II related to securing and maintaining sterility in the design and manufacture of healing caps.

Those aspects of Annex II related to metrology in the design and manufacture of rulers for abutment selection and magnet implantation.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-08-11** Date: **2020-01-31** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 667866

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Product listing:

NBOG code(s)	Device description	Intended Purpose
Class Is		
MD 0303	Healing Caps	N/A for Class Is
Class Im		
MD 0104	Ruler	N/A for Class Im
Class IIa		
MD 1108	Sound Processors, long term use, non-invasive, active	N/A for Class IIa
MD 1111	Standalone software used to support the Sound Processor	N/A for Class IIa
MD 0106	Instruments used for implant surgery	N/A for Class IIa
MD 1104	Drill unit	N/A for Class IIa
MD 0103	Prosthetic components	N/A for Class IIa
Class IIb		
MD 0203	Abutments, Implants and Screws	Implanted devices for long term use, placed in skull and craniofacial bone as a bone anchorage

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