



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)

(Other devices than custom made or intended for clinical investigation)

No. I7 017853 0137 Rev. 02

Manufacturer:

MED-EL

Elektromedizinische Geräte GmbH

Fürstenweg 77A

6020 Innsbruck

AUSTRIA

Product:

Implantable Hearing Prosthesis Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713169200

Valid from:

2020-05-08

Valid until:

2024-05-26

Date,

2020-05-08

Christoph Dicks

Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 017853 0137 Rev. 02

Model(s): Bonebridge

Product: Implantable Hearing Prosthesis Systems

Test Report No.: 71395793

Model:

Bone Conduction Implant Kit

Model no.:

BCI 601 Kit

Test Report No.: 713034823

Model:

BCI Lifts

BCI Lifts

BCI Lifts

BCI Lifts

BCI Sizer Kit

Model no.:

BCI Lifts 1 mm

BCI Lifts 2 mm

BCI Lifts 3 mm

BCI Lifts 4 mm

Test Report No.: 713048872

Model:

Audio Processor

Model no.:

SAMBA BB



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 017853 0137 Rev. 02

Test Report No.: 713148751_1, 713148751_2

Model:

Bone Conduction Implant Kit

BCI 602 Sizer Kit

BCI Lifts

Model no.:

BCI 602 Kit

BCI 602 Lifts (1mm)

Test Report No.: 713160251

Model:

Audio Processor

Model no.:

SAMBA 2 BB