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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. 17 17 12 77312 028

Manufacturer: **Advanced Bionics AG**
Laubisrütistr. 28
8712 Stäfa
SWITZERLAND



Product: **External components for Cochlear Implant 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.: 713114185

Valid from: 2018-03-12
Valid until: 2023-03-11



Date, 2018-02-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



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. 17 17 12 77312 028**Model(s):** see attachment**Parameters:** ./.**Facility(ies):**
Advanced Bionics, LLC
12740 San Fernando Road, Sylmar CA 91342, USA

Advanced Bionics, LLC
28515 Westinghouse Place, Valencia CA 91355, USA

Advanced Bionics AG
Laubisrütistr. 28, 8712 Stäfa, SWITZERLAND**Design Facility(ies):**
Advanced Bionics, LLC
28515 Westinghouse Place, Valencia CA 91355, USA



**Attachment for Certificate no I7 17 12 77312 028
dated 2018-02-16**

Products: External components for Cochlear Implant Systems

Test Report No.: 713018009 / 713114185

Model:	Model no:
Naída CI Q70	CI-5245-xxx; xxx denotes color
Earhook	CI-5710-xxx; xxx denotes size and/or grip
T-Mic™ 2	CI-5835-xxx; xxx denotes size
RF Cable	CI-5415-xxx; xxx denotes color and length
Zn-Air Battery Pak	CI-5500-xxx; xxx denotes color and type
PowerCel™ 110	CI-5511-xxx; xxx denotes color
PowerCel™ 170	CI-5517-xxx; xxx denotes color
PowerCel™ 230	CI-5523-xxx; xxx denotes color
Naída CI PowerCel™ Charger	CI-5605
AB myPilot	CI-5900-100
Naída CI Power Adapter	CI-7455-100
AAA PowerPak™ Accessory	CI-7403
Power Adapter Cable	CI-7405-xxx; xxx denotes color and length

Test Report No.: 713033363

Model:	Model no:
Naída CI AquaCase™	CI-7431



Product Service

Attachment for Certificate no I7 17 12 77312 028
dated 2018-02-16

Test Report No.: 713054313

Model:

Model no:

Naída CI Q90 Acoustic Earhook

CI-5850-xxx; xxx denotes side and length

Test Report No.: 713065129

Model:

Model no:

Naída CI Q30

CI-5260-xxx; xxx denotes color

Naída CI Q90

CI-5280-xxx; xxx denotes color

Test Report No.: 713074798

Model:

Model no:

PowerCel™ 110 Mini

CI-5521-xxx; xxx denotes color

PowerCel™ 170 Mini

CI-5527-xxx; xxx denotes color

Munich, MHS-CRT, 2018-02-16

Stefan Preiß
Certification Medical Technology



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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 077312 0019 Rev. 01

Manufacturer: **Advanced Bionics AG**
Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product: **Accessories for Cochlear Implant 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.: 713164632

Valid from: 2020-05-07

Valid until: 2024-05-26

Date, 2020-05-07

Christoph Dicks
Head of Certification/Notified Body

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EC Certificate

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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 077312 0019 Rev. 01

Model(s): see below

Product: Accessories for Cochlear Implant Systems

Test Report No.: 71371174

Model:	Model no.:
HiRes 90K™ Magnet Insert Dummy	CI-1410
HiRes 90K™ Replacement Magnet	CI-1412
Recess Gauge for HiRes 90K™	CI-4330
Coil Gauge for HiRes 90K™	CI-4340
BTE-ICS Template for HiRes 90K™	CI-4420
HiRes 90K™ Mock Up	CI-4425
Recess Marking Template for HiRes 90K™	CI-4430
HiRes 90K™ Surgical Tool Kit	CI-4500
HiRes 90K™ Surgeon's Kit	CI-8160

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Bến Nghé, Quận 1, Thành Phố Hồ
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EC Certificate

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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 077312 0020 Rev. 01

Manufacturer: **Advanced Bionics AG**
Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product: **External components for Cochlear Implant 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.: 713165123

Valid from: 2020-05-13

Valid until: 2024-05-26

Date, 2020-05-13

Christoph Dicks
Head of Certification/Notified Body

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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 077312 0020 Rev. 01

Model(s):	see below
Product:	External components for Cochlear Implant Systems
Test Report No.:	70106513
Model:	Model No.:
Auria™ iConnect	CI-5751-xxx
	xxx denotes color
Test Report No.:	70121027
Model:	Model No.:
Auria™ Harmony™ Processor	CI-5235-xxx
	xxx denotes color

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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 077312 0030 Rev. 00

Manufacturer: Advanced Bionics AG

Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product: External components for Cochlear Implant 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.: 713143861

Valid from: 2019-04-10

Valid until: 2024-04-09

Date, 2019-04-10

Stefan Preiß

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No. I7 077312 0030 Rev. 00

Model(s):	see below
Facility(ies):	Advanced Bionics AG Laubisrütistr. 28, 8712 Stäfa, SWITZERLAND Advanced Bionics, LLC 12740 San Fernando Road, Sylmar CA 91342, USA Advanced Bionics, LLC 28515 Westinghouse Place, Valencia CA 91355, USA
Design Facility(ies) Parameters:	Advanced Bionics, LLC 28515 Westinghouse Place, Valencia CA 91355, USA /.

Product: External Components for Cochlear Implant Systems

Test Report No.: 713143861

Model:	Model no.:
Chorus™ Sound Processor	CI-5292
Chorus™ Battery	CI-5550
Chorus™ Battery Charger	CI-5606
Chorus™ Programming Cable	CI-6516
Chorus™ Protective Case	CI-7432



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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 077312 0032 Rev. 01

Manufacturer: **Advanced Bionics AG**
Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product: **External components for Cochlear Implant 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.: 713173626

Valid from: 2020-05-22
Valid until: 2024-05-26

Date, 2020-05-22

Christoph Dicks
Head of Certification/Notified Body

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 (Other devices than custom made or intended for clinical investigation)
No. I7 077312 0032 Rev. 01

Model(s): see below
Product: External Components for Cochlear Implant Systems

Test Report No.: 713152046

Model:	Model No.:
AIM™ System	CI-6126
AIM™ Sterile Inserts	CI-6120
AIM™ Programming Cable	CI-6125
AIM™ Insert Earphone	CI-6129

Test Report No.: 713173626

Model:	Model No.:
AIM™ Sound Tubes	CI-6121

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Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
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No. I7 077312 0033 Rev. 00

Manufacturer:

Advanced Bionics AG

Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product:

**External components for Cochlear Implant
Systems**

**Accessories and Application SW for Cochlear
Implant 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.:

713159035

Valid from:

2019-09-04

Valid until:

2024-05-26

Date,

2019-09-04

Stefan Preiß

Head of Certification/Notified Body

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Nam**

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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 077312 0033 Rev. 00

Model(s): see below

Facility(ies): Advanced Bionics, LLC
28515 Westinghouse Place, Valencia CA 91355, USA

Advanced Bionics, LLC
12740 San Fernando Road, Sylmar CA 91342, USA

Advanced Bionics AG
Laubisrütistr. 28, 8712 Stäfa, SWITZERLAND

Design Facility(ies): Advanced Bionics LLC
28515 Westinghouse Place, Valencia CA 91355, USA

Product: External Components and Accessories
for Cochlear Implant Systems

Test Report No.: 71361447

Model:
Auria™ PowerCel™ Charger

Model no.:
CI-5600-003

Auria™ Standard Earhook

CI-5730-xxx
xxx denotes color and size

Auria™ PowerCel™ Plus

CI-5540-xxx
xxx denotes color

PowerCel™

CI-55cc-ddd
cc denotes capacity,
ddd denotes color

Auria™ T-Mic™

CI-5830-xxx
xxx denotes color

Auria™ Direct Connect

CI-5840-xxx
xxx denotes color

Auria™ Direct Connect Cable

CI-5841-xxx
xxx denotes cable length

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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 077312 0033 Rev. 00

Product: Application Software for Cochlear Implant Systems

Test Report No.: 71371174

Model:
SoundWave™ Professional Suite Software

Model no.:
CI-6055-xxx
xxx denotes version

**Product: External Components and Accessories
for Cochlear Implant Systems**

Test Report No.: 71383105

Model:
UHP Cable BTE

Model no.:
CI-5410-xxx
xxx denotes color and length

UHP Cable PSP

CI-5412-xxx
xxx denotes color and length

UHP Color Cap

CI-7125-xxx
xxx denotes color

UHP Magnet

CI-7511

Model:
UHP Bottom Cover Patch

Model no.:
CI-7513

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No. I7 077312 0033 Rev. 00

Test Report No.: 713006620

Model:
T-Comm

Model no.:
CI-5845-XXX

Test Report No.: 713018009

Model:
CPI-3 Clinical Programming Interface

Model no.:
CI-6101

Test Report No.: 713037317

Model:
Concave UHP

Model no.:
CI-5307

Test Report No.: 713117498

Model:
Universal Headpiece UHP 2.0

Model no.:
CI-5315

UHP 2.0 Color Cap

CI-7128-xxx
xxx denotes color

N52 Magnet

CI-7522

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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 077312 0034 Rev. 00

Manufacturer: **Advanced Bionics AG**
Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product: **Accessories for Cochlear Implant Systems**

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Report no.: 713164628

Valid from: 2020-05-14
Valid until: 2024-05-26

Date, 2020-05-14

Christoph Dicks
Head of Certification/Notified Body

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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 077312 0034 Rev. 00

Model(s): see below

Product: Accessories for Cochlear Implant Systems

Test Report No.: 713069130

Model:	Model no.:
HiRes™ Ultra Mock Up	CI-4426
HiRes™ Ultra Temporary Non Magnetic Plug	CI-1411
HiRes™ Ultra Replacement Magnet	CI-1413

Test Report No.: 713087343

Model:	Model no.:
HiRes™ Ultra Reusable Surgical Tool Kit	CI-4509
HiRes™ Ultra Recess Gauge	CI-4331
HiRes™ Ultra Coil Gauge	CI-4341
HiRes™ Ultra BTE Template	CI-4421
HiRes™ Ultra Magnet Tool Kit	CI-1418
HiRes™ Ultra Magnet Insertion Tool	CI-4348
HiRes™ Ultra Magnet Pusher Tool	CI-4349

Test Report No.: 713108826

Model:	Model no.:
HiFocus™ SlimJ Electrode Depth Gauge	CI-1605
HiFocus™ Electrode Forceps Kit	CI-4350-02

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

No. I7 077312 0034 Rev. 00

Test Report No.: 713130816

Model:

UHP 3D

AquaMic™ 3D

UHP 3D Color Cap

AquaMic™ 3D Color Cap

3D Magnet

3D Headpiece Magnet Kit

3D Headpiece Foam Spacer

Model no.:

CI-5316

CI-5317

CI-7129-xxx (xxx denotes color)

CI-7130-xxx (xx denotes color)

CI-7523-xxx (xxx denotes size)

CI-7527

CI-7524

Test report No. 713154736

Model:

HiRes™ Ultra 3D Replacement Magnet

HiRes™ Ultra 3D Temporary Non-Magnetic Plug

Model no.:

CI-1419

CI-1420

Test Report No.: 713160193

Model:

UHP 3D Plus

3D Magnet Plus

Model no.:

CI-5318

CI-7523-006

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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 077312 0035 Rev. 00

Manufacturer: **Advanced Bionics AG**
Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product: **External components for Cochlear Implant 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.: 713164630

Valid from: 2020-04-09

Valid until: 2024-05-26

Date, 2020-04-09

Christoph Dicks
Head of Certification/Notified Body

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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 077312 0035 Rev. 00

Model(s):	see below
Product:	External components for Cochlear Implant Systems
Test Report No.:	71389519
Model:	Model no.:
Neptune™ Sound Processor	CI-5240-XXX XXX denotes color
Neptune™ Connect	CI-5241-XXX XXX denotes color
Neptune™ Covers	CI-7126-XXX XXX denotes color
Neptune™ Cable for UHP	CI-5413-XXX XXX denotes color and cable length
Neptune™ Cable for AquaMic™	CI-5414-XXX XXX denotes color and cable length
Thin Magnet	CI-7518
Foam Spacer	CI-7517
AquaMic™	CI-5306
AquaMic™ Color Caps	CI-7127-XXX XXX denotes color

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Product Service

EC Certificate

Full Quality Assurance System

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

No. I1 077312 0036 Rev. 00

Manufacturer: Advanced Bionics AG

Laubisrütistr. 28
8712 Stäfa
SWITZERLAND

Product: Cochlear Implant Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report no.: 713164170

Valid from: 2019-11-12

Valid until: 2024-05-26

Date, 2019-11-12

Christoph Dicks
Head of Certification/Notified Body

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Product Service

EC Certificate

Full Quality Assurance System

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

No. I1 077312 0036 Rev. 00

Facility(ies): Advanced Bionics, LLC
 28515 Westinghouse Place, Valencia CA 91355, USA

Advanced Bionics, LLC
 12740 San Fernando Road, Sylmar CA 91342, USA

Advanced Bionics AG
 Laubisrütistr. 28, 8712 Stäfa, SWITZERLAND

Design Facility(ies): Advanced Bionics, LLC
 28515 Westinghouse Place, Valencia CA 91355, USA

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 Việt Nam

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