



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 077725 0009 Rev. 00

Manufacturer:

Advanced Bionics, LLC

28515 Westinghouse Place
Valencia CA 91355
USA

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.:

713172098_7

Valid from:

2020-07-31

Valid until:

2023-03-11

Date,

2020-07-31

Christoph Dicks

Head of Certification/Notified Body



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No. I7 077725 0009 Rev. 00

Model(s): see below

Test Report No.: 713018009 / 71311418

Model

Model No:

Product: External Components for Cochlear Implant Systems

Model:

Model No.:

Naida 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

Power Cel™ 110

CI-5511-xxx; xxx denotes color

Power Cel™ 170

CI-5517-xxx; xxx denotes color

Power Cel™ 230

CI-5523-xxx; xxx denotes color

Naida CI PowerCel™ Charger

CI-5605

AB myPilot

CI-5900-100

Naida 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

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

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TÜV®

ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFICAT ♦ CERTIFIKAT ♦ 認證證書 ♦



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Model:

Naída CI AquaCase™

Test Report No.: 713054313

Model:

Naída CI Q90 Acoustic Earhook

Test Report No.: 713065129

Model:

Naída CI Q30

Naída CI Q90

Test Report No.: 713074798

Model:

PowerCel™ 110 Mini

PowerCel™ 170 Mini

Model no:

CI-7431

Model no:

CI-5850-xxx; xxx denotes side and length

Model no:

CI-5260-xxx; xxx denotes color

CI-5280-xxx; xxx denotes color

Model no:

CI-5521-xxx; xxx denotes color

CI-5527-xxx; xxx denotes color