



Declaration of Conformity

1. **Legal Manufacturer:** **Advanced Bionics, LLC**
28515 Westinghouse Place
Valencia, CA 91355
USA
2. **Manufacturing Sites:**

Advanced Bionics, LLC 12740 San Fernando Road. Sylmar, CA 91342 USA	Advanced Bionics, LLC 28515 Westinghouse Place Valencia, CA 91355 USA
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3. **Authorized Representative:** **Advanced Bionics GmbH**
Feodor-Lynen-Strasse 35
DE-30625 Hannover
Germany
4. **Object of the Declaration:** **HiResolution™ Bionic Ear System**
5. **Single Registration Number (SRN):**
6. **The legal manufacturer maintains a Quality System in compliance with the EN ISO 13485:**

Certificate QMS:	<i>Q5 077725 0004 Rev. 00</i>	<i>Valid Until: 2022-04-24</i>
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7. **The legal manufacturer declares under their sole responsibility that the object of the declaration is in conformity with the Medical Device Regulation (EU) 2017/745 and certified according to its Annex II and III**
8. **Medical device risk class:** **Class I Annex II +III of the Regulation (EU) 2017/745**
9. **Valid from:** **2021-02-09**



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According to EU Regulation 2017/745

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10. Products covered by this Declaration of Conformity

Product Scope: External Components for Cochlear Implant Systems

Model No.	Model Name	Basic UDI-DI
CI-5551-280	M Battery Small (lava red)	08400944CI5551YD
CI-5551-260	M Battery Small (blue ocean)	08400944CI5551YD
CI-5551-270	M Battery Small (majesty purple)	08400944CI5551YD
CI-5551-130	M Battery Small (chestnut)	08400944CI5551YD
CI-5551-140	M Battery Small (silver gray)	08400944CI5551YD
CI-5551-150	M Battery Small (velvet black)	08400944CI5551YD
CI-5551-190	M Battery Small (caribbean pirate)	08400944CI5551YD
CI-5551-250	M Battery Small (precious pink)	08400944CI5551YD
CI-5551-110	M Battery Small (alpine white)	08400944CI5551YD
CI-5551-240	M Battery Small (resin beige)	08400944CI5551YD
CI-5551-120	M Battery Small (sand beige)	08400944CI5551YD
CI-5552-280	M Battery Medium lava red	08400944CI5552YF
CI-5552-260	M Battery Medium blue ocean	08400944CI5552YF
CI-5552-270	M Battery Medium majesty purple	08400944CI5552YF
CI-5552-130	M Battery Medium chestnut	08400944CI5552YF
CI-5552-140	M Battery Medium silver gray	08400944CI5552YF
CI-5552-150	M Battery Medium velvet black	08400944CI5552YF
CI-5552-190	M Battery Medium caribbean pirate	08400944CI5552YF
CI-5552-250	M Battery Medium precious pink	08400944CI5552YF
CI-5552-110	M Battery Medium alpine white	08400944CI5552YF
CI-5552-240	M Battery Medium resin beige	08400944CI5552YF
CI-5552-120	M Battery Medium sand beige	08400944CI5552YF
CI-5553-280	M Battery Large lava red	08400944CI5553YH
CI-5553-260	M Battery Large blue ocean	08400944CI5553YH
CI-5553-270	M Battery Large majesty purple	08400944CI5553YH



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CI-5553-130	M Battery Large chestnut	08400944CI5553YH
CI-5553-140	M Battery Large silver gray	08400944CI5553YH
CI-5553-150	M Battery Large velvet black	08400944CI5553YH
CI-5553-190	M Battery Large caribbean pirate	08400944CI5553YH
CI-5553-250	M Battery Large precious pink	08400944CI5553YH
CI-5553-110	M Battery Large alpine white	08400944CI5553YH
CI-5553-240	M Battery Large resin beige	08400944CI5553YH
CI-5553-120	M Battery Large sand beige	08400944CI5553YH
CI-5555-130	M Standard Battery chestnut	08400944CI5555YM
CI-5555-140	M Standard Battery silver gray	08400944CI5555YM
CI-5555-150	M Standard Battery velvet black	08400944CI5555YM
CI-5555-120	M Standard Battery sand beige	08400944CI5555YM
CI-5555-240	M Standard Battery resin beige	08400944CI5555YM
CI-5607	M Battery Charger	08400944CI5607YF

INTENDED PURPOSE:

The M Batteries and M Battery Charger are accessories of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

M Batteries are intended to power the Advanced Bionics Naída CI M and Sky CI M Sound Processors. The M Battery Charger is intended to recharge only the M Batteries. Placing a charged M Battery on the sound processor will power on the sound processor. Removing the M Battery will power off the sound processor.

CI-5068	M Waterproof Battery	08400944CI5068Y5
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INTENDED PURPOSE:

The M Waterproof Battery is an accessory of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The M Waterproof Battery is intended to power the Advanced Bionics Naída CI M and Sky CI M



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Sound Processors and protect the sound processor for moisture and debris. Connecting the sound processor to the connector within the M Waterproof Battery will power on the sound processor. Removing the sound processor from the M Waterproof Battery will power off the sound processor.

CI-5501-120	M Zn-Air Battery Pak sand beige	08400944CI5501XW
CI-5501-280	M Zn-Air Battery Pak lava red	08400944CI5501XW
CI-5501-260	M Zn-Air Battery Pak blue ocean	08400944CI5501XW
CI-5501-270	M Zn-Air Battery Pak majesty purple	08400944CI5501XW
CI-5501-130	M Zn-Air Battery Pak chestnut	08400944CI5501XW
CI-5501-140	M Zn-Air Battery Pak silver gray	08400944CI5501XW
CI-5501-150	M Zn-Air Battery Pak velvet black	08400944CI5501XW
CI-5501-190	M Zn-Air Battery Pak caribbean pirate	08400944CI5501XW
CI-5501-250	M Zn-Air Battery Pak precious pink	08400944CI5501XW
CI-5501-110	M Zn-Air Battery Pak alpine white	08400944CI5501XW
CI-5501-240	M Zn-Air Battery Pak resin beige	08400944CI5501XW

INTENDED PURPOSE:

The M Zn-Air Battery Pak is an accessory of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The M Zn-Air Battery Pak is intended to power the Advanced Bionics Naída CI M and Sky CI M Sound Processors.

CI-7131-001	Slim HP Color Cap lava red	08400944CI7131XZ
CI-7131-002	Slim HP Color Cap blue ocean	08400944CI7131XZ
CI-7131-003	Slim HP Color Cap majesty purple	08400944CI7131XZ
CI-7131-004	Slim HP Color Cap sand beige	08400944CI7131XZ
CI-7131-005	Slim HP Color Cap chestnut	08400944CI7131XZ
CI-7131-006	Slim HP Color Cap silver gray	08400944CI7131XZ
CI-7131-007	Slim HP Color Cap velvet black	08400944CI7131XZ
CI-7131-008	Slim HP Color Cap Caribbean pirate	08400944CI7131XZ
CI-7131-009	Slim HP Color Cap precious pink	08400944CI7131XZ



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CI-7131-010	Slim HP Color Cap alpine white	08400944CI7131XZ
CI-7131-011	Slim HP Color Cap resin black	08400944CI7131XZ
CI-7132-001	Slim HP Color Cap sand beige large	08400944CI7132Y3
CI-7132-002	Slim HP Color Cap chestnut large	08400944CI7132Y3
CI-7132-003	Slim HP Color Cap silver gray large	08400944CI7132Y3
CI-7132-004	Slim HP Color Cap velvet black large	08400944CI7132Y3
CI-7132-005	Slim HP Color Cap resin black large	08400944CI7132Y3
INTENDED PURPOSE: The Slim HP Color Caps are part of the external components of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing. The Slim HP Color Cap is designed for use with a headpiece connected to the sound processor on the ear and is intended to snap in place on top of the headpiece securely covering the magnet well and the microphone.		
CI-7524-001	Slim HP Standard Magnet 1	08400944CI7524YQ
CI-7524-002	Slim HP Standard Magnet 2	08400944CI7524YQ
CI-7524-003	Slim HP Standard Magnet 3	08400944CI7524YQ
CI-7524-004	Slim HP Standard Magnet 4	08400944CI7524YQ
CI-7524-005	Slim HP Standard Magnet 5	08400944CI7524YQ
CI-7524-006	Slim HP Standard Magnet 6	08400944CI7524YQ
CI-7524-007	Slim HP Standard Magnet 7	08400944CI7524YQ
CI-7525-001	Slim HP 3D Magnet 1	08400944CI7525YS
CI-7525-002	Slim HP 3D Magnet 2	08400944CI7525YS
CI-7525-003	Slim HP 3D Magnet 3	08400944CI7525YS
CI-7525-004	Slim HP 3D Magnet 4	08400944CI7525YS
CI-7525-005	Slim HP 3D Magnet 5	08400944CI7525YS
CI-7525-006	Slim HP 3D Magnet 6	08400944CI7525YS
CI-7525-007	Slim HP 3D Magnet 7	08400944CI7525YS



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INTENDED PURPOSE:

The Slim Headpiece Magnets are accessories of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The Slim HP Magnets are intended to be used with the Slim HP, Slim HP Mic, Slim HP AquaMic, and Slim HP Standard. The Slim HP Magnets are intended to secure the headpiece to the user's head.

CI-5711-100	M Earhook small	08400944CI5711YB
CI-5711-110	M Earhook standard	08400944CI5711YB
CI-5711-200	M Earhook small with grip	08400944CI5711YB
CI-5711-210	M Earhook standard with grip	08400944CI5711YB

INTENDED PURPOSE:

The M Earhooks are accessories of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The M Earhooks are intended for use with the Advanced Bionics Naída CI M and Sky CI M Sound Processors. The M Earhook is intended to hold the sound processor on the ear when the sound processor is worn in a behind-the-ear configuration.

CI-5826	M Programming Cable	08400944CI5826YV
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INTENDED PURPOSE:

The M Programming Cable is an accessory of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The M Programming Cable is intended to connect the Naída CI M or Sky CI M sound processor to the CPI-3 Clinical Programming Interface. This enables fitting of the Naída CI M or Sky CI M sound processor with Advanced Bionics Target CI.

CI-5837-100	M T-Mic small	08400944CI5837Z2
CI-5837-200	M T-Mic medium	08400944CI5837Z2
CI-5837-300	M T-Mic large	08400944CI5837Z2



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INTENDED PURPOSE:

The M T-Mic is an accessory of an auditory active-implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory sensation via electrical stimulation of the auditory nerve for individuals with severe to profound bilateral or unilateral sensorineural hearing loss. Severe hearing loss is defined as audiometric thresholds greater than or equal to 70 dB HL, but less than 90 dB HL. Profound hearing loss is defined as audiometric thresholds greater than or equal to 90 dB HL. The external components work together with the implant to bypass the damaged part of the inner ear and convert sound picked up by the microphone or streamed via wireless communication into electrical signals that are used by the cochlear implant to enable hearing.

The M T-Mic is intended for use with the Advanced Bionics Naída CI M and Sky CI M Sound Processors. The M T-Mic is intended to pick up sound at the natural opening of the ear canal when the sound processor is worn in a behind-the-ear configuration.

11. Signed for and on behalf of: **Advanced Bionics**

Date of issue: 2021-02-09
Place of issue: Hannover, Germany

Author

Aniko Bardi
Senior Regulatory Affairs Specialist
Advanced Bionics

2021-02-09

Date

Reviewer

Kemine Hale
Senior Manager Regulatory &
Clinical Affairs, PRRC-AR
Advanced Bionics

2021-02-09

Date