



DECLARATION OF CONFORMITY

DoC-2021-04

According to EU Regulation 2017/745

Declaration of Conformity

1. **Legal Manufacturer:** **Advanced Bionics, LLC**
28515 Westinghouse Place
Valencia, CA 91355
USA
2. **Manufacturing Sites:** **Advanced Bionics, LLC** **Advanced Bionics, LLC**
12740 San Fernando Road. 28515 Westinghouse Place
Sylmar, CA 91342 Valencia, CA 91355
USA USA
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. **Notified Body:** **TÜV SÜD Product Service GmbH**
Address: Ridlerstrasse 65, 80339 München, Germany
ID Number: NB 0123
Scope Expression: MDA 0101
Conformity Assessment Route: Annex IX of the Regulation (EU) 2017/745
7. **The legal manufacturer maintains a Quality System in compliance with the EN ISO 13485:**

Certificate QMS: Q5 077725 0004 Rev. 00 *Valid Until:* 2022-04-24
8. **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 IX for the Complete Quality Assurance System.**

Certificate EU Quality Management System G12 077725 0021 Rev.01 *Valid Until:* 2026-01-27
Certificate DE, Annex IX listed below
9. **Medical device risk class:** **Class III Annex IX of the Regulation (EU) 2017/745**
10. **Valid from:** 2021-04-20



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11. Products covered by this Declaration of Conformity

EC DE Certificate: G70 077725 0022 Rev. 00

Valid Until:2026-04-14

Product Scope: Cochlear Implants

Model No.	Model Name	Basic UDI-DI
CI-1600-04	HiRes™ Ultra CI HiFocus™ MS Electrode	08400944CI160004PV
INTENDED PURPOSE The HiRes™ Ultra CI HiFocus™ MS Electrode cochlear implant is an auditory active implantable device in 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 HiRes™ Ultra CI HiFocus™ MS Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the pre-curved electrode array to enable hearing.		
CI-1600-05	HiRes™ Ultra CI HiFocus™ SlimJ Electrode	08400944CI160005PX
INTENDED PURPOSE The HiRes™ Ultra CI HiFocus™ SlimJ Electrode cochlear implant is an auditory active implantable device in 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 HiRes™ Ultra CI HiFocus™ SlimJ Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the lateral wall electrode array to enable hearing.		
CI-1601-04	HiRes™ Ultra 3D CI HiFocus™ MS Electrode	08400944CI160104Q2
INTENDED PURPOSE The HiRes™ Ultra 3D HiFocus™ MS Electrode cochlear implant is an auditory active implantable device in 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 HiRes™ Ultra CI HiFocus™ MS Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the pre-curved electrode array to enable hearing. A self-aligning internal magnet allows the cochlear implant to be scanned at 1.5T and 3.0T at any orientation within the MRI scanner without bandaging and without magnet removal.		
CI-1601-05	HiRes™ Ultra 3D CI HiFocus™ SlimJ Electrode	08400944CI160105Q4
INTENDED PURPOSE The HiRes™ Ultra 3D HiFocus™ SlimJ Electrode cochlear implant is an auditory active implantable device in 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		



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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 HiRes™ Ultra CI HiFocus™ SlimJ Electrode cochlear implant receives power and sound data over an inductively coupled link from the external sound processor system and converts the sound data into electrical stimulation which is delivered to the auditory nerve via the lateral wall electrode array to enable hearing. A self-aligning internal magnet allows the cochlear implant to be scanned at 1.5T and 3.0T at any orientation within the MRI scanner without bandaging and without magnet removal.

EC DE Certificate:

G70 077725 0019 Rev. 00

Valid Until:2026-01-25

Product Scope:

External Components for Cochlear Implant Systems

Model No.	Model Name	Basic UDI-DI
CI-5293-110	Naída™ CI M90 Sound Processor alpine white	08400944CI5293YE
CI-5293-120	Naída™ CI M90 Sound Processor sand beige	08400944CI5293YE
CI-5293-130	Naída™ CI M90 Sound Processor chestnut	08400944CI5293YE
CI-5293-140	Naída™ CI M90 Sound Processor silver gray	08400944CI5293YE
CI-5293-150	Naída™ CI M90 Sound Processor velvet black	08400944CI5293YE
CI-5293-240	Naída™ CI M90 Sound Processor resin beige	08400944CI5293YE

INTENDED PURPOSE

The Naída™ CI M90 sound processor 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 Naída™ CI M90 sound processor is a behind the ear (BTE) sound processor which works together with the implant to bypass the damaged part of the inner ear and converts 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 Naída™ CI M90 is the premium version with full access to multiple automatic programs and features including bimodal and bilateral and supports compatibility with acoustic amplification.

CI-5294-120	Naída™ CI M30 Sound Processor sand beige	08400944CI5294YG
CI-5294-130	Naída™ CI M30 Sound Processor chestnut	08400944CI5294YG
CI-5294-140	Naída™ CI M30 Sound Processor silver gray	08400944CI5294YG
CI-5294-150	Naída™ CI M30 Sound Processor velvet black	08400944CI5294YG
CI-5294-240	Naída™ CI M30 Sound Processor resin beige	08400944CI5294YG

INTENDED PURPOSE

The Naída™ CI M30 sound processor is an accessory of an auditory active implantable system, the HiResolution Bionic Ear system. The HiResolution Bionic Ear system is intended to provide auditory



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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 Naída™ CI M30 sound processor is a behind-the-ear (BTE) sound processor which works together with the implant to bypass the damaged part of the inner ear and converts 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 Naída™ CI M30 is the essential version with basic automatic programs and features.

CI-5295-110	Sky CI™ M90 Sound Processor alpine white	08400944CI5295YJ
CI-5295-120	Sky CI™ M90 Sound Processor sand beige	08400944CI5295YJ
CI-5295-130	Sky CI™ M90 Sound Processor chestnut	08400944CI5295YJ
CI-5295-140	Sky CI™ M90 Sound Processor silver gray	08400944CI5295YJ
CI-5295-150	Sky CI™ M90 Sound Processor velvet black	08400944CI5295YJ
CI-5295-190	Sky CI™ M90 Sound Processor caribbean pirate	08400944CI5295YJ
CI-5295-240	Sky CI™ M90 Sound processor resin beige	08400944CI5295YJ
CI-5295-250	Sky CI™ M90 Sound Processor precious pink	08400944CI5295YJ
CI-5295-260	Sky CI™ M90 Sound processor blue ocean	08400944CI5295YJ
CI-5295-270	Sky CI™ M90 Sound processor majesty purple	08400944CI5295YJ
CI-5295-280	Sky CI™ M90 Sound processor lava red	08400944CI5295YJ

INTENDED PURPOSE

The Sky CI™ M90 sound processor 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 Sky CI™ M90 sound processor is a behind-the-ear (BTE) sound processor which works together with the implant to bypass the damaged part of the inner ear and converts 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 Sky CI™ M90 sound processor can be used by both adults and children, and provides dedicated pediatric hearing solution (multiple color options, and adjustable program for individual pediatric users). The Sky CI™ M90 provides full access to multiple automatic programs and features including bimodal and bilateral and supports compatibility with acoustic amplification.



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EC DE Certificate:
Product Scope:

G70 077725 0020 Rev.00
Application Software for Cochlear Implant Systems

Valid Until:2026-01-26

Model No.	Model Name	Basic UDI-DI
CI-6057-001	Target CI	08400944CI6057Y7
INTENDED PURPOSE The Target CI fitting software 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 of the HiResolution Bionic Ear System 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 Target CI fitting software from Advanced Bionics is intended to be used by qualified hearing care professionals to configure, program, and fit compatible sound processors to patient-specific requirements. It is not worn by the recipient and there is no minimum or maximum limit on the time that the software can be used.		
CI-6058-001	AB Remote	08400944CI6058Y9
INTENDED PURPOSE: The AB Remote app 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 of the HiResolution Bionic Ear system 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 AB Remote app is designed to be used with Advanced Bionics' Naída CI M and Sky CI M sound processors to allow the user to control volume related and program settings, as well as accessing additional helpful information.		



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EC DE Certificate:

G70 077725 0018 Rev.00

Valid Until:2026-01-26

Product Scope:

External Components for Cochlear Implant Systems

Model No.	Model Name	Basic UDI-DI
CI-5320-001	Slim HP 3.5" beige	08400944CI5320XQ
CI-5320-002	Slim HP 3.5" black	08400944CI5320XQ
CI-5320-003	Slim HP 3.5" brown	08400944CI5320XQ
CI-5320-004	Slim HP 3.5" gray	08400944CI5320XQ
CI-5320-005	Slim HP 3.5" white	08400944CI5320XQ
CI-5320-006	Slim HP 4.25" beige	08400944CI5320XQ
CI-5320-007	Slim HP 4.25" black	08400944CI5320XQ
CI-5320-008	Slim HP 4.25" brown	08400944CI5320XQ
CI-5320-009	Slim HP 4.25" gray	08400944CI5320XQ
CI-5320-010	Slim HP 4.25" white	08400944CI5320XQ
CI-5320-011	Slim HP 5.5" beige	08400944CI5320XQ
CI-5320-012	Slim HP 5.5" black	08400944CI5320XQ

INTENDED PURPOSE

The Slim HP headpieces 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 is a headpiece with an integrated cable designed for use with a sound processor on the ear and is intended to transfer sound signals and power between Advanced Bionics' cochlear implant and sound processor.

CI-5321-001	Slim HP AquaMic 12" beige	08400944CI5321XS
CI-5321-002	Slim HP AquaMic 12" black	08400944CI5321XS
CI-5321-003	Slim HP AquaMic 12" brown	08400944CI5321XS
CI-5321-004	Slim HP AquaMic 12" gray	08400944CI5321XS
CI-5321-005	Slim HP AquaMic 18" beige	08400944CI5321XS
CI-5321-006	Slim HP AquaMic 18" black	08400944CI5321XS
CI-5321-007	Slim HP AquaMic 18" brown	08400944CI5321XS



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CI-5321-008	Slim HP AquaMic 18" gray	08400944CI5321XS
CI-5321-009	Slim HP AquaMic 24" beige	08400944CI5321XS
CI-5321-010	Slim HP AquaMic 24" black	08400944CI5321XS
CI-5321-011	Slim HP AquaMic 24" brown	08400944CI5321XS
CI-5321-012	Slim HP AquaMic 24" gray	08400944CI5321XS
CI-5321-013	Slim HP AquaMic 42" beige	08400944CI5321XS
CI-5321-014	Slim HP AquaMic 42" black	08400944CI5321XS
CI-5321-015	Slim HP AquaMic 42" brown	08400944CI5321XS
CI-5321-016	Slim HP AquaMic 42" gray	08400944CI5321XS

INTENDED PURPOSE

The Slim HP AquaMic™ headpieces 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 AquaMic™ is a headpiece with an integrated cable and a microphone designed for use in water environments. It is intended to transfer sound signals and power between Advanced Bionics' cochlear implant and sound processor. The embedded microphone, if enabled, allows the headpiece to also function as a sound input source.

CI-5322-001	Slim HP Mic 12" black	08400944CI5322XU
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INTENDED PURPOSE

The Slim HP Mic headpieces 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 Mic is a headpiece with an integrated cable and a microphone designed for use with a sound processor worn off the ear. It is intended to transfer sound signals and power between Advanced Bionics' cochlear implant and sound processor. The embedded microphone, if enabled, allows the headpiece to also function as a sound input source.

CI-5323	Slim HP Standard	08400944CI5323XW
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INTENDED PURPOSE: The Slim HP Standard is an external component 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



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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 Standard is a headpiece that uses separate cables and is designed to be worn on the ear. It is intended to transfer sound signals and power between your Advanced Bionics' cochlear implant and sound processor.

CI-5851-001	M Acoustic Earhook Right 00	08400944CI5851YU
CI-5851-002	M Acoustic Earhook Right 0	08400944CI5851YU
CI-5851-003	M Acoustic Earhook Right 1	08400944CI5851YU
CI-5851-004	M Acoustic Earhook Right 2	08400944CI5851YU
CI-5851-005	M Acoustic Earhook Right 3	08400944CI5851YU
CI-5851-006	M Acoustic Earhook Left 00	08400944CI5851YU
CI-5851-007	M Acoustic Earhook Left 0	08400944CI5851YU
CI-5851-008	M Acoustic Earhook Left 1	08400944CI5851YU
CI-5851-009	M Acoustic Earhook Left 2	08400944CI5851YU
CI-5851-010	M Acoustic Earhook Left 3	08400944CI5851YU

INTENDED PURPOSE:

The M Acoustic Earhook is an external component 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 Acoustic Earhook provides acoustic amplification for patients with aid able low frequency hearing.

The M Acoustic Earhook coupled with the Naída CI M90 or Sky CI M90 sound processor is intended to provide acoustic amplification and electrical stimulation to Advance Bionics cochlear implant recipients.



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12. Signed for and on behalf of: Advanced Bionics

Date of issue: 2021-04-20
Place of issue: Hannover, Germany

Author

2021-04-20

Aniko Bardi
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Date

Reviewer

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Date