



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 077725 0019 Rev. 00

Manufacturer:

Advanced Bionics, LLC

28515 Westinghouse Place
Valencia CA 91355
USA

**Authorized
Representative:**

Advanced Bionics GmbH
Feodor-Lynen-Str. 35, 30625 Hannover, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 077725 0019 Rev. 00

Report No.:

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Valid from:

2021-02-10

Valid until:

2026-01-25

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-02-10



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No. G70 077725 0019 Rev. 00

Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	08400944CI5293YE
Intended Purpose:	<p>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.</p> <p>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.</p>
Device(s):	<p>Naída™CI M90 Sound Processor (alpine white) CI-5293-110 Naída™CI M90 Sound Processor (sand beige) CI-5293-120 Naída™CI M90 Sound Processor (chestnut) CI-5293-130 Naída™CI M90 Sound Processor (silver gray) CI-5293-140 Naída™CI M90 Sound Processor (velvet black) CI-5293-150 Naída™CI M90 Sound Processor (resin beige) CI-5293-240</p>



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Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	08400944CI5294YG
Intended Purpose:	<p>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 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.</p>
Device(s):	<p>Naída™CI M30 Sound Processor (sand beige) CI-5294-120 Naída™CI M30 Sound Processor (chestnut) CI-5294-130 Naída™CI M30 Sound Processor (silver gray) CI-5294-140 Naída™CI M30 Sound Processor (velvet black) CI-5294-150 Naída™CI M30 Sound Processor (resin beige) CI-5294-240</p>



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Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	08400944CI5295YJ
Intended Purpose:	<p>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.</p>
Device(s):	<p>Sky CI™ M90 Sound processor alpine white, CI-5295-110; sand beige, CI-5295-120; chestnut, CI-5295-130; silver gray, CI-5295-140; velvet black, CI-5295-150; caribbean pirate, CI-5295-190; resin beige, CI-5295-240; precious pink, CI-5295-250; blue ocean, CI-5295-260; majesty purple, CI-5295-270; lava red, CI-5295-280</p>
The validity of this certificate depends on conditions and/or is limited to the following:	-None-