



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 0022 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 0022 Rev. 00

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Valid from:

2021-04-15

Valid until:

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Christoph Dicks

Head of Certification/Notified Body

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Classification:	III
Device Group:	J0301 - AUDITORY ACTIVE-IMPLANTABLE DEVICES, COCHLEAR
Basic UDI-DI:	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.
Device(s):	HiRes™ Ultra CI HiFocus™ MS Electrode CI-1600-04
Classification:	III
Device Group:	J0301 - AUDITORY ACTIVE-IMPLANTABLE DEVICES, COCHLEAR
Basic UDI-DI:	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.
Device(s):	HiRes™ Ultra CI HiFocus™ SlimJ Electrode CI-1600-05
Classification:	III
Device Group:	J0301 - AUDITORY ACTIVE-IMPLANTABLE DEVICES, COCHLEAR
Basic UDI-DI:	08400944CI160104Q2
Intended Purpose:	The HiRes™ Ultra 3D 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



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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 3D 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.

Device(s): HiRes™ Ultra 3D CI HiFocus™ MS Electrode CI-1601-04

Classification: III

Device Group: J0301 - AUDITORY ACTIVE-IMPLANTABLE DEVICES, COCHLEAR

Basic UDI-DI: 08400944CI160105Q4

Intended Purpose: The HiRes™ Ultra 3D 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 3D 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.

Device(s): HiRes™ Ultra 3D CI HiFocus™ SlimJ Electrode CI-1601-05

The validity of this certificate depends on conditions and/or is limited to the following: n./n.