Amendments

The below administrative changes are needed to support compliance/registrations in 3rd countries relying on the CE marking as part of the marketing authorization process in these territories

Date	Section affectd	Change
7 May 2021	**New**	Addition of Single Registration Number (SRN) of the EU Authorized Representative: **DE-AR-000005642**
2 December 2021	**New**	Added Swiss Single Registration Number (CHRN): **CHRN-AR-20000462**
25 April 2022	**7**	Updated of ISO 13485 Certificate Rev. number from 00 to 01 and updated expiration date, with the issuing of new certificate on 25 April 2022: **Certificate QMS Q5 *Q5 077725 0004 Rev. 01 Valid Until: 2025-04-24***
18 May 2022	**13**	Removed the following products under section 13 items, which expired in 18 April 2022 and are no longer sold. **13. Products covered by the EC DE Certificate: I7 077725 0008 Rev. 00** *Valid Until: 2022-04-18* **Product: Cochlear Implants** **Accessories for Cochlear Implant Systems** **Model No:** — **Model Name:** CI-1500-01 — HiRes 90K™ Advantage CI HiFocus™ 1j Electrode CI-1500-02H — HiRes 90K™ Advantage CI HiFocus Helix™ Electrode CI-1500-04 — HiRes 90K™ Advantage CI HiFocus™ MS Electrode CI-4254 — HiFocus™ Mid-Scala Claw Tool CI-4347 — HiFocus™ Mid-Scala Cochleostomy Gauge CI-4507 — HiFocus™ MS Electrode Insertion Tool Kit CI-4207 — HiFocus™ MS Electrode Insertion Tool

		, which were registered under MDR:
18 May 2022	**8**	Updated DoCs wording for section 8 to implement requirements of the Swiss Medical Devices Ordinance : (MedDO 812.213) : **The legal manufacturer declares under their sole responsibility that the object of the declaration is in conformity with the Medical Devices Ordinance (MedDo 812.213), the Medical Device Regulation (EU) 2017/745 transitional provisions, AIMDD 90/385/EEC, and certified according to its Annex 2 for the Complete Quality Assurance System:** *Certificate FQA, Annex 2.3* I1 077725 0005 Rev. 00 *Valid Until: 2024-05-26* *Certificate DE, Annex 2.4*
27 March 2023	**15**	Provide updated information regarding certificate I7 077725 0009 Rev. 00 extended under amendments to EU regulation 2017/745: **Products covered by the EC DE Certificate: I7 077725 0009 Rev. 00** *Valid Until: 2023-03-11* *On March 20 2023, regulation 2023/607 describing the amendment 2017/745 extended the validity of the certificate that meets requirements of Article 120. With this amendment, the validity of already expired directive certs is set to 31 December 2027*

DECLARATION OF CONFORMITY

According to EU Directive 90/385/EEC

DoC-2021-05
Amendment
2023-04

Advanced bionics hereby confirm that the content of the original Declaration of conformity attached (signed before date of application May 26, 2021) is still valid but amended by the following administrative changes

Author

DocuSigned by:
Jenny Goldring
Signer Name: Jenny Goldring
Signing Reason: I am the author of this document
Signing Time: 4/19/2023 | 11:23:38 AM PDT
B6FEF0CC495B463C8AB798B9988D011C

4/19/2023

Jenny Goldring
Regulatory Affairs Manager
Advanced Bionics

Date

Reviewer

DocuSigned by:
Carolin Frohne-Buechner
Signer Name: Carolin Frohne-Buechner
Signing Reason: I approve this document
Signing Time: 4/20/2023 | 4:04:20 AM PDT
CZ60524E5A74A82A06E509FEE589AD6

4/20/2023

Carolin Frohne-Buechner Date
Regulatory Affairs Manager & EU PRRC-AR

Date