Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates)

Manufacturer name	MED-EL Elektromedizinische Geräte GmbH
Manufacturer address and contact details	Fürstenweg 77a 6020 Innsbruck, Austria
Single Registration Number (SRN) (if available)	AT-MF-000020243

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[1]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☑ Expired/expires *after* 20 March 2023:

- I7017853 0100 Rev.01
- 17 017853 0110 Rev.01
- G1 017853 0131 Rev. 02
- I7 017853 0132 Rev.01
- I7 017853 0133 Rev. 01
- I7 017853 0134 Rev.00
- I7 017853 0137 Rev.02
- I7 017853 0140 Rev.02
- I7 017853 0141 Rev.02
- I7 017853 0142 Rev. 00
- I7 017853 0143 Rev.00
- G1S 017853 0146 Rev. 00
- I7 017853 0153 Rev. 00
- I7 017853 0154 Rev.00
- I7 017853 0155 Rev.00
- 17 017853 0156 Rev.00

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☑ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024. - I7 017853 0132 Rev.01

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement: Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Signed for and on behalf of MED-EL Elektromedizinische Geräte GmbH:

Innsbruck, 2024-02-12

Dr. Ingeborg Hochmair
Chief Executive Officer

Elizabeth Gföller
Corporate Director, Regulatory Affairs

Dr. Martin Herzog
Corporate Director, Quality Assurance

MED EL

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Fixation Clip	I7 017853 0134 Rev. 00, NB0123	19 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
BCI Sizer Kit	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
BCI 601 Implant Kit	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
BCI Lifts (1,2,3 and 4 mm)	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
BCI 602 Implant Kit	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
BCI 602 Lifts (1 mm)	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
BCI 602 Sizer Kit	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Medical Screwdriver SD 2	G1 017853 0131 Rev. 02, NB0123	26 May 2024	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
VORP 502 Implant (Vibrating Ossicular Prosthesis VORP	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable

[2] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
502A, Vibrating Ossicular Prosthesis VORP 502B)						
Vibroplasty Couplers	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
VORP 503 Set (VORP 503 Implant Kit & VORP 503 Sizer Kit)	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
VORP 503 Sizer Kit	I7 017853 0140 Rev. 03, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Medical Screwdriver SD503	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	YES
Implant Template, single-use, for the SONATA TI100	I7 017853 0100 Rev.01, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
Mi1210 Implant Template	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
Mi1000 Implant Template	I7 017853 0153 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Mi1000 Implant Template PIN	I7 017853 0153 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Mi1200 Implant Template	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Mi1200 Implant Template PIN	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Mi1250 Implant Template	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
SONATATI[100] implant [CI]	I7 017853 0100 Rev.01, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
Mi1000 CONCERTO (PIN) [CI]	I7 017853 0153 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
Mi1000 CONCERTO (PIN) [ABI]	I7 017853 0153 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
Mi1210 SYNCHRONY ST [CI]	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
Mi1200 SYNCHRONY (PIN) [ABI]	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Mi1200 SYNCHRONY (PIN) [CI]	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Mi1250 SYNCHRONY 2 (PIN) [CI]	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Mi1260 SONATA 2 [CI]	I7 017853 0141 Rev. 02, NB0123	25 Apr. 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
Mi1050 CONCERTO 2 [CI]	I7 017853 0153 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
AudioLink	I7 017853 0132 Rev.01, NB0123	14 February 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	26 May 2024	N/A
OPUS 2 Audio Processor	I7 017853 0142 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
RONDO Audio Processor	I7 017853 0143 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
RONDO 2 Audio Processor	I7 017853 0143 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
SONNET / SONNET EAS Audio Processor	I7 017853 0133 Rev. 01, NB0123	20 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
RONDO 3 Audio Processor	I7 017853 0155 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
SAMBA BB Audio Processor	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
SAMBA Audio Processor (incl. Remote Control)	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
SAMBA 2 BB Audio Processor	I7 017853 0137 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
SAMBA 2 Audio Processor	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
SYMFIT 7.0 software	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
SYMFIT BAO software	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable
SYMFIT 8.0 [Application Software]	I7 017853 0140 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
MAESTRO 9.x	I7 017853 0154 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
RemoteCheck app	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	YES
PMEI Stapesplasty	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
PMEI Tympanoplasty	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
PMEI Sizer	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
Micro Forceps (straight)	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
Micro Forceps Angled Set	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
Micro Forceps left angled	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
Micro Forceps right angled	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Surgical Claw Angled	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
Surgical Claw Straight	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
NemuStim Stimulation Cables	G1S 017853 0146 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123?	31 Dec.2028	N/A
NemuStim	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
PromStim Electrodes Long/Short	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
PromStim Electrode Cable	G1S 017853 0146 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123?	31 Dec.2028	N/A
PromStim System Stimulator Box	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	YES
Auditory Nerve Test System (ANTS)	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
ANTS Connector Cable	G1S 017853 0146 Rev. 00, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	YES
ANTS Stimulator Box	G1 017853 0131 Rev. 02, NB0123	24 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	YES

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
ECE 50	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
N/AN/AINCAT Inner Ear Catheter	G1 017853 0131 Rev. 02, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2028	N/A
ABI Placing Electrode	I7 017853 0110 Rev. 01, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	N/A
ABI Placing System Connector Cable	I7 017853 0110 Rev. 01, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	YES
ABI Placing System Stimulation Box	I7 017853 0110 Rev. 01, NB0123	26 May 2024	TÜV SÜD Product Service GmbH, NB0123	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	YES
ADHEAR Configuration Software 1.0	N/A - Device did not require a Notified Body certificate under Directives	N/A	N/A	TÜV SÜD Product Service GmbH, NB0123	31 Dec.2027	Applicable