



EU Declaration of Conformity

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| Manufacturer: | AUDIA AKUSTIK GMBH, Franz-Mehring-Str. 13, 99610 Sömmerda, Germany |
| Single Registration Number: | SRN DE-MF-000015972 |
| Products covered: | See Annex 1 |
| Products intended purpose: | Bone conducting hearing aid is a medical device intended to be used for human beings for the medical purpose of compensation for disability. |
| Products risk class: | Class IIa |
| Applicable standards: | ISO 14971 DIN EN 352-2 ISO 10993-1 ISO 10993-5 ISO 10993-10 EN ISO 15223-1 EN ISO 20417 EN ISO 60318-4 EN ISO 60318-5 EN 60318-6 IEC 60118-9 EN 60118-0 EN 60118-7 EN 62366 EN 60601 |
| Applicable common specification: | None |
| MDR Certificate/Notified Body: | G10 081447 008 rev. 00, issued by TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany (NB No.: 0123) |
| Conformity Assessment Route: | Annex IX |
| ISO Certificate/Certifying Body: | N° Q5 08147 007 Rev. 01 (ISO 13485:2016), issued by TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany (NB No.: 0123) |
| Directive 2011/65/EU | Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) |
| Directive 2012//19/EU | Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) |

We, AUDIA AKUSTIK GMBH under sole responsibility, hereby declare that the products listed in the Annex 1 are in conformity with the legislation detailed above, and Regulation (EU) 2017/745 of the European Parliament and of The Council on medical devices.

Sömmerda, 01.02.2024
Location, day/month/year

Lars Kraft
Managing Director



Annex 1
to EU Declaration of Conformity

| Product Reference | Basic UDI-DI | UDI-DI | GMDN | Product Name | Classification Rule (Annex VIII) |
|-------------------|---------------------------|----------------|---------|--|----------------------------------|
| 48312 | 426017609labellebcLT | 04260176092940 | Y214509 | la belle BC D70 links oben | 9 |
| 48313 | | 04260176092957 | Y214509 | la belle BC D70 links unten | 9 |
| 48314 | | 04260176092964 | Y214509 | la belle BC D70 rechts oben | 9 |
| 48315 | | 04260176092971 | Y214509 | la belle BC D70 rechts unten | 9 |
| 48304 | | 04260176092827 | Y214509 | la belle BC D50 links oben | 9 |
| 48305 | | 04260176092834 | Y214509 | la belle BC D50 links unten | 9 |
| 48306 | | 04260176092841 | Y214509 | la belle BC D50 rechts oben | 9 |
| 48307 | | 04260176092858 | Y214509 | la belle BC D50 rechts unten | 9 |
| 48478 | 426017609labelleheadsetQA | 04260176092766 | Y214509 | la belle headset BC D50, links stereo | 9 |
| 48389 | | 04260176092773 | Y214509 | la belle headset BC D50, rechts stereo | 9 |
| 48300 | | 04260176092742 | Y214509 | la belle headset BC D50 links | 9 |
| 48301 | | 04260176092759 | Y214509 | la belle headset BC D50 rechts | 9 |
| 48302 | 426017609labellejuniorS7 | 04260176092780 | Y214509 | la belle junior BC D50, links | 9 |
| 48303 | | 04260176092797 | Y214509 | la belle junior BC D50, rechts | 9 |