



EU Declaration of Conformity

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