vibro|sonic

CE DECLARATION OF CONFORMITY

Name of Manufacturer:	Vibrosonic GmbH
Address of Manufacturer:	Franz-Volhard-Straße 3 68167 Mannheim Germany
Single registration number (SRN):	DE-MF-000022006

Product	Reference	Basic UDI-DI	Class	Classification Rule(s)
Vibrosonic alpha			IIa	
- Vibrosonic alpha Patient Kit	FPTK002	426070005FPTK0023R	IIa	5, 9
- Vibrosonic alpha Fitting Kit	FFTK002	426070005FFTK002XL	IIa	5

Intended purpose: The hearing aid Vibrosonic alpha is used to compensate a hearing loss. It senses sound, processes it and applies a mechanical vibration to the tympanic membrane.

The undersigned declares that the medical devices (according to article 2 (1)) specified above meet the provisions of the Medical Device Regulation (EU) 2017/745, Annex I. This declaration of conformity is issued under the sole responsibility of the manufacturer.

The conformity assessment procedure used is "CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION" according to the Medical Device Regulation (EU) 2017/745, Annex IX.

The product is classified in class IIa according to MDR Annex VIII and subject to the quality management system of Vibrosonic GmbH.

Certificate Registration No.	D1445600006
Date:	2023-07-24
Issued by:	mdc medical device certification GmbH Kriegerstraße 6, 70191 Stuttgart, GERMANY
NotifiedBodyNo.:	0483

The conformity is declared according to the Regulation (EU) 2017/745, Annex IV and is valid from date of signature.

The undersigned also declares under the sole responsibility of the manufacturer that above products, including all related accessories, are in compliance with Council Directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Mannheim, 2025-04-24

Dr. Jonathan Schächtele
Person responsible for regulatory compliance (PRRC)