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 hereby 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

Expiring date of the CE Declaration of Conformity: 2028-07-23

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

Mannheim, 2023-08-31

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