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)	Intended Purpose
Vibrosonic alpha Refill Pack Ear Canal Modules (Variants Ø8mm, Ø10mm, Ø12mm)	FICV001-08, FICV001-10, FICV001-12	426070005FICV001VB	I	5	1)
Vibrosonic alpha Refill Pack Depth Measuring Tools	FGTV002	426070005FGTV0022H	I	5	2)
Vibrosonic alpha Refill Pack Ear Canal Modules (Variants XS, S, M, L, XL)	FICV002-XS, FICV002-S, FICV002-M, FICV002-L, FICV002-XL	426070005FICV002VD	I	5	3)
Vibrosonic alpha Refill Pack Depth Indicators	FGTV003	426070005FGTV0032K	I	5	4)

1) The product is a refill pack to refill the stock of single use ear canal modules in Vibrosonic alpha Fitting Kit, which are used for size selection of the ear canal module of Vibrosonic alpha.
2) The product is a refill pack to refill the stock of singe use depth measuring tools in Vibrosonic alpha Fitting Kit, which are used for selection of the magnetic cable and determination of the correct insertion depth of the ear canal module of Vibrosonic alpha.
3) The product is a refill pack to refill the stock of single use ear canal modules in Vibrosonic alpha Fitting Kit and Vibrosonic alpha Sizing Kit, which are used for size selection of the ear canal module of Vibrosonic alpha.
4) The product is a refill pack to refill the stock of singe use depth measuring tools in Vibrosonic alpha Fitting Kit and Vibrosonic alpha Sizing Kit, which are used for selection of the magnetic cable and determination of the correct insertion depth of the ear canal module of Vibrosonic alpha.

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

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

Mannheim, 2025-02-28

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

Dok-ID: P03Z02 / rev. 003