OHHMED	Document Title: **OhhMed's Vertica Declaration of Conformity**		
	Document No. **001-Regel-005**	Revision: **01**	Page 1 of 1

MEDICAL DEVICE REGULATION EU 2017/745

Manufacturer:

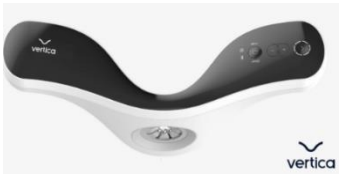
OhhMed Medical
1st Tsivonit St.,
Tiberias,
1410002,
Israel

CE 2797

Under sole responsibility of OhhMed Medical manufacturer of medical RF devices, as detailed hereunder, that are placed in the European market, declare that our product, Vertica, conforms and meets the GSPR set out in Annex I, and the applicable conformity procedure conforms with Annex IX, according to the regulation requirements of the European Medical Device Regulation (MDR) EU 2017/745.

We have pointed BSI, ID 2797, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam - Netherlands, to act as our notified body.

Vertica	**IIa**	**Annex VIII Rule 9**	**7290018772VerticaYC**	**TBD**
Product	*Classification*	*Followed*	*Basic UDI-DI*	*SRN*



Intended use:
The Vertica® is a battery powered hand-held medical device that makes use of RF energy to improve erectile function. The device is intended for home use.

Within these requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures, have appointed **G&D&Y** (Tolstraat 112 ,1077 EL Amsterdam, The Netherlands) to act as our Authorized Representative in the European Community, and have appointed **Qsite** (Tania Zilberfaine) to act as our PRRC.

OhhMed's manufacturing is CE certified, Certificate No' MDR 736618.

OhhMed's manufacturing is in compliance with ISO 13485:2016, Certificate No' MD 731749.

Tania Zilberfaine	**QA/RA Manager and PRRC**	*Tania Zilberfaine*	**19-December-2022**	OhhMed
Name	*Position*	*Signature*	*Date*	*Pace of issue*