Declaration of Conformity
VibroSense Meter II

Revision A

We, VibroSense Dynamics AB, Medeon Science Park, SE-205 12 Malmö, Sweden,

Declare under our sole responsibility that the product:

***Product name:* VibroSense Meter II**
Part number: 95-0010

to which this declaration relates is in conformity with the g*eneral safety and performance requirements* and *other relevant requirements* of the European Medical Devices Regulation 2017/745 and the RoHS Directive 2011/65/EU (RoHS 2) and Directive 2012/19/EU of 4 July 2012 on waste electrical and electronic equipment (WEEE).

The product is in conformity with the following standards and/or other normative documents:

Medical Devices Regulation

Manufacturer	VibroSense Dynamics AB
EUDAMED registration number (SRN)	SE-MF-000003787
Basic UDI-DI	-
Conformity assessment procedure	Self-certification of the European Medical Devices Regulation 2017/745
Product name	VibroSense Meter II (VSM II)
Product number (REF)	95-0010
Intended use	The VSM II is a non-invasive medical device intended for transient use with the purpose of measuring vibration perception thresholds (VPT) of the intact skin on the hand or foot in humans by Quantitative Sensory Testing* (QST) . The measurement result can be compared to reference values of subjects above 20 years with normal vibration perception and can be used when diagnosing loss of vibration perception due to sensory neuropathy.
Risk classification and rule	Class 1 according to rule 13

SAFETY	Medical electrical equipment, class 1	IEC60601-1 IEC/EN 60601-1-2 ed. 4
RoHS	Restriction of Hazardous Substances	EN 50581, EN 62321:2009
WEEE	Waste Electrical & Electronic Equipment	EN 50625

Waste Electrical & Electronic Equipment Regulations (WEEE) requires that any of our products showing this marking must not be disposed of with other household or commercial waste

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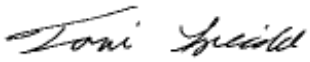
Supplementary information

Medical Device file held by: VibroSense Dynamics AB, Medeon Science Park, SE-205 12 Malmö, Sweden

This Declaration of Conformity applies to above-listed products placed on the EU market after **May 26, 2021.**

May 26, 2021

Signature: 

Name of Authorised Signatory: Toni Speidel

Position of the Signatory: CTO & PRRC*

* Person Responsible Regulatory Compliance

This statement is based on the knowledge as of the date of issue, makes no warranties, expressed or implied and assumes no liability in connection with the use of this information outside of **VibroSense Dynamics AB** control.

Summary of results

Immunity EMC:

Test	Passed the test	Note
EN 61000-4-2: Electrostatic discharge	Yes	
EN 61000-4-3: Radiated electromagnetic fields	Yes	
EN 61000-4-4: Electrical fast transients	Yes	
EN 61000-4-5: Surge immunity test	Yes	
EN 61000-4-6: Conducted disturbances	Yes	
EN 61000-4-8: Power frequency magnetic field	Yes	
EN 61000-4-11: Voltage dips and interruptions	Yes	
Mains terminal continuous disturbance voltage	Yes	
Tele terminal continuous disturbance voltage	N/A	Not Applicable
Radiated electromagnetic field	Yes	
Mains terminal discontinuous disturbance voltage	N/A	Not Applicable
Harmonic Current	N/A	External power supply
Voltage fluctuations & flicker	N/A	External power supply

Immunity ESD:

Test point #	Test level [kV]	Air/ Contact	Polarity (+/-)	Pass/ Fail	Comment/ mode of operation
1	8	Contact	+/-	Pass	
2	8	Contact	+/-	Pass	
3	8	Contact	+/-	Pass	
4	15	Air	+/-	Pass	
5	15	Air	+/-	Pass	
6	15	Air	+/-	Pass	

Emission EMC:

Test #.	Freq. [MHz]	Ant. dist.	Level [V/m]	Pol. V/H	Operating mode/ Exposed side	Pass/ Fail	Comment/ mode of operation
1	80-1000	3m	3	V	0°,Front	Pass	EMC worst case testmode
2	80-1000	3m	3	V	90°	Pass	EMC worst case testmode
3	80-1000	3m	3	V	180°	Pass	EMC worst case testmode
4	80-1000	3m	3	V	270°	Pass	EMC worst case testmode
5	80-1000	3m	3	H	0°,Front	Pass	EMC worst case testmode
6	80-1000	3m	3	H	90°	Pass	EMC worst case testmode
7	80-1000	3m	3	H	180°	Pass	EMC worst case testmode
8	80-1000	3m	3	H	270°	Pass	EMC worst case testmode
9	1000-2700	1m	3	V	0°,Front	Pass	EMC worst case testmode
10	1000-2700	1m	3	V	90°	Pass	EMC worst case testmode
11	1000-2700	1m	3	V	180°	Pass	EMC worst case testmode
12	1000-2700	1m	3	V	270°	Pass	EMC worst case testmode
13	1000-2700	1m	3	H	0°,Front	Pass	EMC worst case testmode
14	1000-2700	1m	3	H	90°	Pass	EMC worst case testmode
15	1000-2700	1m	3	H	180°	Pass	EMC worst case testmode
16	1000-2700	1m	3	H	270°	Pass	EMC worst case testmode

Biocompatibility ISO10993-1:

Test	Passed the test	Note
Cytotoxicity, ISO10993-5	Yes	
Chemical Characterization , ISO 10993-12	Yes	