

# Declaration of Conformity VibroSense Meter II

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: 12-0001

Type: 95-0010 Measuring unit

to which this declaration relates is in conformity with the *essential requirements* and *other relevant requirements* of the Directive MDD93/42/EEC 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:

SAFETY Class 1 Medical Device IEC60601-1

IEC/EN 60601-1-2 ed. 4

**RoHS** Restriction of Hazardous Substances EN 50581, EN 62321:2009

WEEE Waste Electrical & Electronic EN 50625

Equipment



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

#### Supplementary information

Technical 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 **July 1**, **2018**.

February 4, 2019 Signature:

Name of Authorised Signatory: Toni Speidel

Position of the Signatory: CEO

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.



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## **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:

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

### **Emission EMC:**

| Test<br>#. | Freq.<br>[MHz] | Ant.<br>dist. | Level<br>[V/m] | Pol.<br>V/H | Operating mode/<br>Exposed side | Pass/<br>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              | Н           | 0°,Front                        | Pass          | EMC worst case testmode    |
| 6          | 80-1000        | 3m            | 3              | Н           | 90°                             | Pass          | EMC worst case testmode    |
| 7          | 80-1000        | 3m            | 3              | Н           | 180°                            | Pass          | EMC worst case testmode    |
| 8          | 80-1000        | 3m            | 3              | Н           | 270°                            | Pass          | EMC worst case testmode    |
| 9          | 1000-2700      | 1m            | 3              | V           | 0°,Front                        | Pass          | EMC worst case testmode    |
| 10         | 1000-2700      | lm            | 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              | Н           | 0°,Front                        | Pass          | EMC worst case testmode    |
| 14         | 1000-2700      | 1m            | 3              | Н           | 90°                             | Pass          | EMC worst case testmode    |
| 15         | 1000-2700      | 1m            | 3              | Н           | 180°                            | Pass          | EMC worst case testmode    |
| 16         | 1000-2700      | lm            | 3              | Н           | 270°                            | Pass          | EMC worst case testmode    |