



## EUROPEAN DECLARATION OF CONFORMITY

We, **IntelaMetrix™**, located at 6246 Preston Avenue, Livermore, CA 94551, telephone number (925) 606-7044, and fax number (925) 371-3903, declare under our sole responsibility that the product

### **BodyMetrix, Ultrasonic Fat Thickness Measurement System**

**described as an ultrasound device for measuring the thickness of tissue layers that can accurately measure the thickness of fat tissue and muscle tissue on the human body. These measurements can then be used to estimate the Body Fat Percentage (%BF)**

to which this declaration relates is in conformity with the following directive or standard(s) or other normative document(s)

EMC Directive 89/336/EEC as amended by Directive 93/68/EEC, IEC 60601-1:2005 Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance. IEC 60601-1-2:2007 including: CISPR11:2009 Class A, EN6100-4-2:2008, EN 61000-4-3:2008 & EN61000-4-8:2010

### **Test Summary**

<b>Test Type</b>	<b>Test Level</b>	<b>Compliance Level</b>
Radiated Emissions CISPR 11:2009	Class A, 30 MHz to 1GHz	Class A, 30MHz to 1GHz
Electrostatic Immunity IEC 60601-1-2:2007	± 4kV contact discharge; ± 8kV air discharge	± 2, 4kV contact discharge; ± 4, 8kV air discharge
Radiated Immunity IEC 60601-1-2:2007	80MHz-1GHz 3V/m 80%@1kHz	80MHz-1GHz 3V/m 80%@1kHz

**Applicable Documents:** **CISPR 11:2009** (Industrial, Scientific and Medical [ISM] Radio-Frequency Equipment – Radio disturbance characteristics – Limits and methods of measurements); **IEC 60601-1:2005** (General Requirements for Basic Safety); **EN 61000-4-2:2008** (Electrostatic Discharge Immunity Test); **EN 61000-4-3: 2008** (Radiated Radio-Frequency Electromagnetic Immunity Test)

The BodyMetrix covered by this Declaration of Conformity must not be put into service until the computer into which it is to be connected has been declared in conformity with the provisions of the applicable Directive(s).

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Luiz B. Da Silva, CTO