

DECLARATION OF CONFORMITYMEDICAL

XSENSOR Technology Corporation declares that the products listed below in the version offered for sale meet all the basic requirements of the applicable sections of the relevant EU directives in design and type.

This declaration will be deemed invalid should any unauthorized modifications be made to the products. Follow the information as per the *User Guide* when setting-up and operating the system.

Product name:XSENSOR X3 Series Pressure Mapping SystemsType of equipment:Electrical Equipment for Laboratory UseManufacturer's name:XSENSOR Technology Corporation

European Representative:

John Adcock, Managing Director Advena Ltd. Milnwood, 13 North Parade Horsham, West Sussex RH12 2BT United Kingdom

Product list as covered by this Declaration

Component	
X3 DISPLAY Electronics Unit with 50 Watt 12 VDC Power Supply	X3 / X3 PRO Electronics Unit with 50 Watt 12 VDC Power Supply
X3 Sensor Pack / X3 Sensor Pack PRO	X3 NODE
X3 WIRELESS (10 Watt 9 VDC Power Supply for battery charging only)	Sensors (including, but not limited to PX100/200 Series, LX100/200 Series, IX500 Series)
X3 WIRELESS Bluetooth USB	XSENSOR Software

Products listed in this declaration meet the requirements of the following directives

• Medical Devices Directive (93/42/EEC) of 14 June 1993 concerning medical devices

Referenced Safety Standards	Referenced EMC Standards
IEC 60601-1: 1998, Amendment No 1 (1991) and	CISPR 11 Class A
Amendment No 2 (1995)	EN 60601-1-2: 2001

In accordance with Article 14 of the above council directive, notification to the United Kingdom Competent Authority, Medical Devices Agency is confirmed by registration no. CA 003710.

Furthermore, we ensure and declare that such distributed CE marked products, as mentioned and falling within Class 1 [non-measuring, non-sterile], meet the provision of the EC Directives which apply to them.

Robert Miller, Product Systems Engineer