XSENSOR® Technology Corporation
Innovators in Pressure Imaging

EU DECLARATION OF CONFORMITY – MEDICAL

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 has been issued under the sole responsibility of the manufacturer. The object of the declaration is in conformity with the relevant Union Harmonisation Legislation and the CE mark may be affixed. 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.

General product name:	**ForeSite Pressure Mapping System**
Product names:	**ForeSite SS Pressure Mapping System** **ForeSite OR Pressure Mapping System** **ForeSite PT Pressure Mapping System**
GMDN code:	43829, Pressure measurement/mapping system, anatomical
Intended use:	Display the pressure distribution between two objects that come into contact.
MDD classification:	Class 1 Medical Device (non-measuring, non-sterile)
Notified body:	N/A
MDD assessment route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on market.
Manufacturer's name:	**XSENSOR Technology Corporation** 133 12 Avenue SE, Calgary AB, T2G 0Z9 Canada
EU authorized rep:	**Advena Limited** Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Product list as covered by this Declaration

Component	
X4 Wireless Sensor Pack / X4 Wired Sensor Pack	5V Power Supply
Sensors (including, but not limited to, PX100 Series, PX200 Series, IX500 Series, LX100 Series, LX205 Series, LX210 Series, IX510 Series, and HX210 Series)	XSENSOR ForeSite SS Software XSENSOR ForeSite OR Software XSENSOR ForeSite PT software
ForeSitePT Sensor with Sensor Pack Electronics Unit	ForeSitePT Display Terminal with 12 VDC Power Supply

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

- **Medical Device Directive (93/42/EEC)** amended by 2007/47/EC concerning medical devices

Referenced Safety Standards	Referenced EMC Standards
IEC 60601-1: Edition 3.1: 2005+AMD1:2012 CSV/COR1:2012	IEC 60601-1-2: Edition 4.0:2014

Ian Main, President