MANUFACTURER'S DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC

MANUFACTURER:	ImpediMed Limited Unit 1, 50 Parker Court Pinkenba, Qld 4008 Australia
EUROPEAN REPRESENTATIVE:	Medimark Europe Sarl 11, Rue Emile Zola – BP 2332 38033, Grenoble Cedex 2 – France
PRODUCT:	SOZO® Body Impedance Analyzer/Monitor
PRODUCT CODE & UDI:	See attached
GMDN CODE:	Analyser, Fat/Lean [36022]
CLASSIFICATION:	Class IIa, Rule 10, according to Annex IX of the MDD
CONFORMITY ASSESSMENT ROUTE:	Annex II.3

We herewith declare that the above-mentioned products meet the transposition into national law under the provisions of Council Directive 93/42/EEC for medical devices, Directive 2011/65/EU 8 June 2011 on the Restriction of the Use of Certain Hazardous Substances in Electrical Equipment (RoHS) - as amended by Directive 2015/863/EU 31 March 2015 and Radio Equipment Directive (RD-D) 2014/53/EU. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:	See attached.
NOTIFIED BODY:	BSI Group Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
IDENTIFICATION NUMBER:	CE 2797
(EC) CERTIFICATE NUMBER:	CE 654813
PLACE:	Brisbane, Qld, Australia
DATE:	**26 FEBRUARY 2021**
SIGNATURE:	
NAME:	Ms. Lourna Barnett
POSITION:	Director, Quality Assurance

Product Name & UDI

Product name	UDI
SOZO system	++B2772726995SR
SOZO system (demonstration unit)	++B2772526995RX
SOZO system (refurbished)	++B2772426995RJ

Applied Standards:

Standard Number	Standards Organisation	Standard Title	Version
13485	EN/ISO	Medical Devices Quality Management Systems Requirements for Regulatory Purposes	2016
15223-1	EN/ISO	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	2016, Incorporating corrigendum January 2017
10993-1	EN/ISO	Biological Evaluation of Medical Devices - Evaluation and testing within a risk management process	2009/Technical Corrigendum 1 2010
10993-5	EN/ISO	Biological Evaluation of Medical Devices - Tests for in vitro cytotoxicity	2009
10993-10	EN/ISO	Biological Evaluation of Medical Devices - Tests for irritation and skin sensitization	2010
60601-1	IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	2015
60601-1-6	IEC	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2010 + A1:2015
60601-1-11	IEC	General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2015
62366	IEC	Application of usability engineering to medical devices	2008 + A1:2015
62304	IEC	Medical Device Software – Software Lifecycle Processes	2006 + A1:2015
14971	EN/ISO	Application of Risk Management to Medical Devices	2019