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:	Body Impedance Analyzer/Monitor SOZO
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:	ISO 13485:2016; IEC 6061-1: 2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007; IEC 60601-1-2:2015; IEC 6061-1-6:2010 + A1:2015; IEC 62366:2008 + A1:2015; IEC 62304:2006 + A1:2015; EN/ISO 14971:2012; EN/ISO 15223-1:2016; EN/ISO 10993-1:2018; EN/ISO 10993-5:2009; EN/ISO 10993-10:2010; EN/ISO 10993-12:2012; EN 1041:2008 + A1:2013
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:	18 June 2019
SIGNATURE:	_____
NAME:	Mr. Richard Long
POSITION:	Senior Quality Associate – ImpediMed Limited