MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

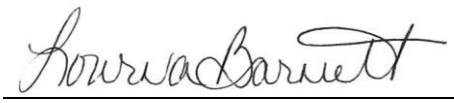
This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	ImpediMed® Limited
Business address:	Unit 1, 50 Parker Court Pinkenba, Qld, 4008
Medical device(s):	See attached schedule
Classification:	Class IIa
GMDN code and term:	Analyzer, Fat/Lean [36022]
Scope of application:	All bioimpedance spectroscopy devices

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	European conformity assessment certificate under Annex II.3 of the Directive 93/42/EEC on Medical Device
Design examination certificate (if applicable):	
Standards applied:	See Attached Schedule for multiple standards

Authorised signatory:



Signature

26 February 2021
Date

Lourna Barnett
Name

Director Quality Assurance
Position

Attachment 1 – Medical devices:

SOZO Body Fluid Analyser	(ARTG134672)
L-Dex® U400 BIS Extracellular Fluid Analyser	(ARTG134672)
Lymphoedema Analysis PC Software	
Imp SFB7 Multi-frequency Body Composition Analyser	(ARTG134672)
BioImp Body Composition Analysis Software	

Attachment 2a – Standards Applied

Standard Number	Standards Organisation	Standard Title	Version
13485	EN/ISO	Medical Devices Quality Management Systems Requirements for Regulatory Purposes	2016
60601-1	IEC	Medical Electrical Equipment – Part 1 General requirements for basic safety and essential performance	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007
60601-1-2	IEC	Medical Electrical Equipment – Part 1-2 General requirements for safety Collateral standard: Electromagnetic compatibility	2004
60601-1-6	IEC	Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability	2010 (Third Edition) + A1:2013 for use in conjunction with IEC 62366:2007 (First Edition) + A1:2014
62366	EN/IEC	Medical devices – Application of usability engineering to medical devices	2007
62304	EN/IEC	Medical Device Software – Software life-cycle processes	2006
14971	EN/ISO	Medical Devices – Application of Risk Management to Medical Devices	2019
15223-1	EN/ISO	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	2012
10933-1	EN/ISO	Biological Evaluation of Medical Devices - Evaluation and testing within a risk management process	2009
1041	BS/EN	Information Supplied by the Manufacturer of Medical Devices	2008+A1:2013

Attachment 2a – Standards Applied (SOZO only)

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