MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

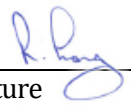
This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

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

18 June 2019

Date

Richard Long

Name

Senior Quality Associate – ImpediMed Limited

Position

Attachment 1 – Medical devices:

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

Attachment 2 – Standards Applied

Standard Number	Standards Organisation	Standard Title	Version
13485	EN/ISO	Medical Devices Quality Management Systems Requirements for Regulatory Purposes	2016
60601-1	EN/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	EN/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	EN/IEC	Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability	2010 + A1:2015
62366	EN/IEC	Medical devices – Application of usability engineering to medical devices	2008+A1:2015
62304	EN/IEC	Medical Device Software – Software life-cycle processes	2006+A1:2015
14971	EN/ISO	Medical Devices – Application of Risk Management to Medical Devices	2012
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
10933-1	EN/ISO	Biological Evaluation of Medical Devices - Evaluation and testing within a risk management process	2009
10933-5	EN/ISO	Biological Evaluation of Medical Devices - Tests for in vitro cytotoxicity	2009
10933-10	EN/ISO	Biological Evaluation of Medical Devices - Tests for irritation and skin sensitization	2010
10933-12	EN/ISO	Biological Evaluation of Medical Devices - Sample preparation and reference materials	2012
1041	BS/EN	Information Supplied by the Manufacturer of Medical Devices	2008+A1:2013