impedimed®
Unit 1, 50 Parker Court
Pinkenba, QLD 4008 Australia
www.impedimed.com

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCT 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 from Schedule 2 (Regulation 3.2), Part 4, Rule 4.3, 2(a)
GMDN code and term:	Analyzer, Fat/Lean [36022]
Scope of application:	All bioimpedance spectroscopy devices

For each kind of medical device to which the product quality assurance procedures have been applied, the type examination procedures have also been applied. The kind of device conforms to the approved type.

Product quality assurance procedures certificate:	**Quality Certificate:**	Directive 93/42/EEC Annex II excluding Section 4
	Assessment Body:	BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom
	Certificate Number:	CE 654813
Standards applied:	See attached	

Authorised signatory:

Signature	20 Sep 2017 Date
Mr. Richard Long Name	ImpediMed Limited – Senior Quality Associate Position

Attachment 1- Medical devices:

System or Procedure Pack:

SOZO Body Fluid Analyser	(ARTG134672)
L-Dex® U400 BIS Extra Cellular Fluid Analyser Lymphoedema Analysis PC Software	(ARTG134672)
Imp SFB7 Multi-frequency Body Composition Analyser BioImp Body Composition Analysis PC Software	(ARTG134672)
ImpediMed Bioimpedance Electrodes	(ARTG107108)

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Attachment 2 – Standards Applied:

Standard Number	Standards Organisation	Standard Title	Version
13485	EN/ISO	Medical Devices Quality Management Systems Requirements for Regulatory Purposes	2012
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 + A1:2012
60601-1-2	EN/IEC	Medical Electrical Equipment – Part 1-2 General requirements for safety Collateral standard: Electromagnetic compatibility	2014
60601-1-6	EN/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
60601-1-11	EN/IEC	MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: 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 (Second Edition)
62366	EN/IEC	Medical devices – Application of usability engineering to medical devices	2007 (First Edition) + A1: 2014
62304	EN/IEC	Medical Device Software – Software life-cycle processes	2006
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/Technical Corrigendum 1 2010
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