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 MANAGEMENT SYSTEM

This is a declaration made in accordance with the requirements of Clause 5.7 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated devices.

Reference:	No schedule attached
Manufacturer's Name:	**ImpediMed Limited**
Business Address:	Unit 1, 50 Parker Court, Pinkenba, Qld. 4008 Australia
Classification:	Class IIa from Schedule 2 (Regulation 3.2), Part 4, Rule 4.3, 2(a)
GMDNS Code and term:	Analyzer, Fat/Lean [36022]
Scope of Application:	All Bioimpedance Analysers
System or Procedure Pack:	L-Dex® U400 BIS Extra Cellular Fluid Analyser (ARTG81853) L-Dex® U400 Lymphoedema Analysis PC Software (ARTG81853) Imp DF50 Body Composition Analyser (ARTG81853) Body Composition Analyser PC Software (ARTG81853) Imp XCA Extra Cellular Fluid Analyser (ARTG81853) XCA Lymphoedema Analysis PC Software (ARTG81853) Imp SFB7 Multi-frequency Body Composition Analyser (ARTG81853) BioImp Body Composition Analyser (ARTG81853) ImpediMed®BIA Electrodes (ARTG1071087) Briemarpak Skin Cleansing Swabs (ARTG22149)
Other Registration of Listing:	None

Each kind of medical device included in the above system pack, have been subject to the relevant conformity assessment procedures by the manufacturer of the medical device and each medical device included in the system pack has been shown by its manufacturer to comply with the applicable provisions of the essential principles.

Each medical device in the system pack is intended to be used for its original intended purpose and each medicine or other therapeutic good in the package is intended to be used within the approved indications for use, specified by the manufacturer of those items.

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The mutual compatibility of each medical device, medicine or other therapeutic goods, and any other goods, in the package has been verified in accordance with any instructions for use provided by the manufacturer of each item or the approved indications for use of each item.

Where applicable, the system or procedure pack has been manufactured in accordance with the original manufacturer's instruction (if any) or indications.

The information supplied with the system or procedure pack for the use of the system or procedure pack includes instructions for use provided by the manufacturer of each item in the package.

The process of manufacturing the system or procedure pack, and the verification and packaging of the system or procedure pack has been subjected to a documented method of internal control and inspection that ensures safety, quality, performance and effectiveness of each item in the package.

Production Quality Management System Certificate:

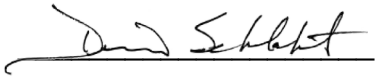
Quality Certificate:	ISO13485:2003
Assessment Body:	BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom
Certificate Number:	**MD 654817**
TGA File Number:	2009/003817
Assessment Body:	Australian Government Therapeutic Goods Administration PO Box 100, Woden, ACT 2606, Australia
Certificate Number:	AU Q00077/02

Conformity Assessment Standards Applied:

IEC60601-1 3rd Ed. Amendment 1,
IEC60601-1-2:2004, ISO13485:2003

Therapeutic Goods Act 1989

Authorised Signatory:

SIGNATURE:	
NAME:	Mr. Dennis Schlaht
POSITION:	ImpediMed Limited – SVP Quality
Date:	14 September 2016