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:	L-Dex U400 Body Impedance Analyzer/Monitor
PRODUCT CODE & UDI:	See attached
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 - as amended by Directive 98/79/EC on in vitro diagnostic medical devices and Directive 2007/47 EC. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:	See attached.
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:	**25 FEBURARY 2021**
SIGNATURE:	
NAME:	Ms. Lourna Barnett
POSITION:	Director, Quality Assurance

Product Name & UDI

Product name	UDI
L-Dex U400 system	B277222LDEXU4000
L-Dex U400 system (demo unit)	B277252LDEXU4000
L-Dex U400 system (refurbished)	B277242LDEXU4000

Applied Standards:

Standard Number	Standards Organisation	Standard Title	Version
13485	EN/ISO	Medical Devices Quality Management Systems Requirements for Regulatory Purposes	2016
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
	EN/ISO	Biological Evaluation of Medical Devices - Tests for irritation and skin sensitization	2010
60601-1	IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	2015
14971	EN/ISO	Application of Risk Management to Medical Devices	2019

MANUFACTURER'S DECLARATION OF CONFORMITY: AMENDMENT

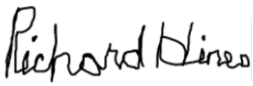
L-Dex U400's compliance to the following harmonized standards was confirmed after the MDD to MDR transition date of 26 May 2021.

Standard Number	Standards Organization	Standard Title	Version
10993-5	EN/ISO	Biological Evaluation of Medical Devices - Tests for in vitro cytotoxicity	2018
20471	EN/ISO	Medical Devices - Information to be Supplied by the Manufacturer	2021

EUROPEAN REPRESENTATIVE:

From	To
MediMark Europe Sarl 11, Rue Emile Zola – BP 2332 38033, Grenoble Cedex 2 – France	MDSS GmbH Schffgraben 41 30175 Hannover, Germany

DATE: **7 January 2025**

SIGNATURE: 

NAME: **Richard Hines**
TITLE: **Senior Manager of Regulatory Affairs**

DATE: **7 JANUARY 2025**

SIGNATURE: 

NAME: **Lourna Barnett**
TITLE: **Senior Director of Quality**