



**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: 

(EC) CERTIFICATE NUMBER: CE 654813

PLACE: Brisbane, Qld, Australia

DATE: **25 FEBURARY 2021**

SIGNATURE: 

NAME: Ms. Louna 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
10933-10	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