

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 Sedex 2 - France

PRODUCT: Body Impedance Analyzer/Monitor
L-Dex U400

GMDNS CODE: Analyzer, 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: IEC 60601-1:1988 +A1:1991 + A2:1995, UL 60601-1,
IEC 60601-1-2: 2004, ISO 13485:2003

NOTIFIED BODY: SGS United Kingdom Ltd
202B Worle Parkway, Weston-Super-Mare
Somerset BS22 6WA UK

IDENTIFICATION NUMBER **CE** 0120

(EC) CERTIFICATE(S): AU05/64407

START OF CE-MARKING: 10 Oct 2005

PLACE: Brisbane, Qld, Australia

DATE OF ISSUE: 02 June 2011

SIGNATURE: 

NAME: Mr. Alden Kay

POSITION: ImpediMed Limited – VP Quality & Regulatory