

impedimed

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

NOTIFIED BODY: BSI Group,
Kitemark Court, Davy Avenue,
Knowlhill, Milton Keynes, MK5 8PP, United Kingdom

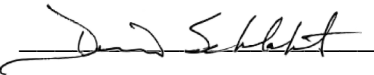
IDENTIFICATION NUMBER:  0086

(EC) CERTIFICATE NUMBER: 654813

START OF CE-MARKING: 10 Oct 2005

PLACE: Brisbane, Qld, Australia

DATE OF ISSUE: 14 September 2016

SIGNATURE: 

NAME: Mr. Dennis Schlaht

POSITION: ImpediMed Limited – SVP Quality