

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: Bioimpedance Electrodes

GMDNS CODE: Disposable Monitoring Electrodes, single use [35035]

CLASSIFICATION: Class I, Rule 1, according to Annex IX of the MDD

CONFORMITY ASSESSMENT ROUTE: Annex VII

We herewith declare that the above mentioned products meet the transposition into national law the provisions of Council Directive 93/42/EEC for medical devices - as amended by Directive 98/79/EC on in vitro diagnostic medical devices.

All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED: ISO 10993-1, ISO 13485:2003

NOTIFIED BODY: SGS United Kingdom Ltd
Worle Park, Weston-Super-Mare
Somerset BS22 OWA UK

START OF CE-MARKING: 10 Oct 2005

PLACE: Brisbane, Qld, Australia

DATE OF ISSUE: 30 June 2014

SIGNATURE:

NAME

POSITION

A handwritten signature in black ink, appearing to read "Dennis Schlaht", written over a horizontal line.

Mr Dennis Schlaht

ImpediMed Limited – VP Quality