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
GMDN 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 under the provisions of Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:	EN/ISO 13485:2016, EN/ISO 15223-1:2016; EN/ISO 10993-1:2018; EN/ISO 10993-5:2009; EN/ISO 10993-10:2010; EN/ISO 10993-12:2012
PLACE:	Brisbane, Qld, Australia
DATE:	18 June 2019
SIGNATURE:	_____
NAME:	Mr. Richard Long
POSITION:	Senior Quality Associate – ImpediMed Limited