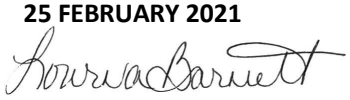
MANUFACTURER'S DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC

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]
UDI:	Single-tab electrodes STE-292: ++B277292STEEM Dual-tab electrodes DTE-292: ++B277292DTECA Body Comp electrodes BCE-292: ++B277292BCEAD
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 10993-1:2009
PLACE:	Brisbane, Qld, Australia
DATE:	**25 FEBRUARY 2021**
SIGNATURE:	
NAME:	Ms. Lourna Barnett
POSITION:	Director, Quality Assurance