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

MANUFACTURER:	ImpediMed Limited Unit 1, 50 Parker Court Pinkenba, Qld 4008 Australia
AUTHORIZED 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: ++B277292-STEYV Dual-tab electrodes DTE-292: ++B277292-DTEW Body Comp electrodes BCE-292: ++B277292-BCEUM
CLASSIFICATION:	Class I, Rule 1, according to Annex VIII of the MDR
CONFORMITY ASSESSMENT ROUTE:	ImpediMed Limited uses Annex VII of the Regulation MDR 2017/745 for the CE labelling of their product.

This declaration of conformity is issued under the sole responsibility of ImpediMed Limited. The device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745. 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:	**8 JUNE 2021**
SIGNATURE:	
NAME:	Ms. Lourna Barnett
POSITION:	Director, Quality Assurance

MANUFACTURER'S DECLARATION OF CONFORMITY: AMENDMENT

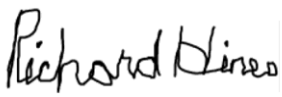
Electrode compliance to the following harmonized standards was confirmed after the MDD to MDR transition date of 26 May 2021.

Standard Number	Standards Organization	Standard Title	Version
10993-5	EN/ISO	Biological Evaluation of Medical Devices - Tests for in vitro cytotoxicity	2018
20471	EN/ISO	Medical Devices - Information to be Supplied by the Manufacturer	2021

EUROPEAN REPRESENTATIVE:

From	To
MediMark Europe Sarl 11, Rue Emile Zola – BP 2332 38033, Grenoble Cedex 2 – France	MDSS GmbH Schffgraben 41 30175 Hannover, Germany

DATE: **7JANUARY 2025**

SIGNATURE: 

NAME: **Richard Hines**
TITLE: **Senior Manager of Regulatory Affairs**

DATE: **7JANUARY 2025**

SIGNATURE: 

NAME: **Lourna Barnett**
TITLE: **Senior Director of Quality**