



**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

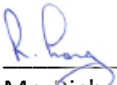
**CONFORMITY ASSESSMENT ROUTE:** Annex VII

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:**   
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**NAME:** Mr. Richard Long  
**POSITION:** Senior Quality Associate – ImpediMed Limited