EC Declaration of Conformity

We herewith declare under our sole responsibility that the product listed below is in conformity with the provisions of the Council Directive 93/42/EEC (and related Finnish national laws) as amended by the directive 2007/47/EC concerning medical devices.

Manufacturer: **Bittium Biosignals Ltd (Bittium Biosignals Oy)**

Address: Pioneerinkatu 6, FI-70800 Kuopio, Finland

Products:

FemiScan Product Family:
FemiScan HomeTrainer
FemiScan Clinic Set
FemiScan Cover (electrode)

ME6000 Product Family:
Muscle Tester ME6000-series, 4ch, 8ch and 16ch
Analog Isolator ME3750-ISO

Wireless Bio Amplifier Product Family:
WBA System, 4ch, 8ch and 16ch with software and accessories
eMotion EMG system with software and accessories

Faros Product Family:
Faros 90, 180 and 360 sensors with accessories
Faros ECG Mobile
Cardiac Navigator

NeurOne Product Family:
NeurOne System with accessories

BrainStatus Product Family
BrainStatus Device

Sleep Product Family
SAPlot software

KOTO™ mobile healthcare management system
With KOTO™ eHealth Monitor, KOTO™ Mobile and KOTO™ WebMonitor applications

MDD Classification: **Class IIa**

Assessment route: Annex II, Section 3 (full quality assurance system)

CE
0537

Kuopio, February 28, 2020

Bittium Biosignals Ltd (Bittium Biosignals Oy)
Arto Pietilä
Senior Vice President