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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: **Mega Electronics Ltd (Mega Elektroniikka Oy)**

Address: Pioneerinkatu 6, FI-70800 Kuopio, Finland

Products:

FemiScan Product Family:
FemiScan HomeTrainer
FemiScan MultiTrainer
FemiScan Clinic Set
FemiScan Clinic System
FemiScan Cover (electrode)
FemiScan PC-software

ME6000 Product Family:
Muscle Tester ME6000-series, 4ch, 8ch and 16ch
Biomonitor ME6000-series, 4ch, 8ch and 16ch
MegaWin PC-software
Analog Isolator ME3750-ISO
Analog Isolator ME3750-EMG
DBC EMG Monitor EM6000

Wireless Bio Amplifier Product Family:
WBA System, 4ch, 8ch and 16ch with software and accessories
eMotion LAB system (HRV) with software and accessories
eMotion EMG system with software and accessories
MT-WBA Bio Amplifier sensors with accessories
XRCISE Wireless ECG Bluetooth system
XRCISE Wireless 8 channel ECG receiver

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

NeurOne Product Family:
NeurOne System with accessories
NeurOne PC software

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

MDD Classification: **Class IIa**

CE 0537

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

15th April 2015

Mega Electronics Ltd
Arto Remes
President