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UE DECLARATION OF CONFORMITY

This is a declaration made in compliance with the general safety and performance requirements set out in Annex I of MDR 2017/745

This declaration of conformity is issued under the sole responsibility of the manufacturer:

OT Bioelettronica S.R.L

Object of the declaration, cl. I rule 1 Annex VIII:

MULTICHANNEL BIOELECTRICAL SIGNAL AMPLIFIER MUOVIPRO

Basic UDI: 805697785PORTABLEEMG002SF

Models:

32 channels	Ref.: OT0130A
64 channels	Ref.: OT0130B
96 channels	Ref.: OT0130C
128 channels	Ref.: OT0130D
MuoviLite	Ref.: OT0190

As follow:

Basic UDI: 805697785ADACTPAS00539

Muovi probe with 32 channels	Ref.: OT0138
SyncStation base for charge and synchronization	Ref.: OT0139
SyncStation+ base for charge and synchronization	Ref.: OT0160
MuoviSC	Ref.: OT0162
EEG-Cap20MV	Ref.: OT0245

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Basic UDI: 805697785MECHPART007J6

MuoviStrap	Ref.: OT0177

The object of the declaration above fulfills the general safety and performance requirements of Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The object above is following Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011, on the restriction of certain hazardous substances in electrical and electronic equipment, and Directive 2015/863 of 31 March 2015 laying down modification of Annex II of Directive 2011/65/EC.

As certified by passing the Electromagnetic Compatibility (EMC) tests EN 60601-1 Standard, Electrostatic Discharge (ESD) EN 60601-1-2 Standard and Electromagnetic and Radio Compatibility ETSI EN 301489-1 v.2.2.0 Standard: Part 1 of 25/03/2021, under Annex II of Regulation (EU) 2017/745 and is put on the market in compliance with Regulation (EU) 2017/745.

Turin, 26/03/2021

Andrea Bottin (CEO)