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C.F./P.IVA: 09550700018

R.E.A.: 1061971

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 SESSANTAQUATTRO+

Basic UDI: 805697785PORTABLEEMG002SF

Ref.: OT0225

And its accessories

Basic UDI: 805697785ADACTPAS00539

CUSB01SP	Ref.: OT0227
AD8x1SP	Ref.: OT0229
ADx2SP	Ref.: OT0230
AD1x16SP	Ref.: OT0231
AD4x8SP	Ref.: OT0249
ADx8SP	Ref.: OT0248
AD2x32SP	Ref.: OT0228
AD1x64SP	Ref.: OT0226
EEG-Cap20SP	Ref.: OT0242
EEG-Cap64SP	Ref.: OT0239
Forza-J+	Ref.: OT0247
ISO-AUXSP	Ref.: OT0246
SyncMini	Ref.: OT0274

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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 in compliance with 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 09/07/2019, under Annex II of Regulation (EU) 2017/745 and is put on the market in compliance with Regulation (EU) 2017/745.

Turin, 11/07/2022

Andrea Bottin (CEO)