

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 DUE+

Basic UDI: 805697785PORTABLEEMG002SF

Models:

| | |
|-------------|--------------|
| DUE+LITE | Ref.: OT0157 |
| 2 channels | Ref.: OT0262 |
| 4 channels | Ref.: OT0263 |
| 6 channels | Ref.: OT0264 |
| 8 channels | Ref.: OT0265 |
| 16 channels | Ref.: OT0260 |

As follow:

Basic UDI: 805697785ADACTPAS00539

| | |
|---|--------------|
| Due+ probe with 2 channels | Ref.: OT0159 |
| SyncStationBipolar base for charge and synchronization | Ref.: OT0266 |
| SyncStationBipolar+ base for charge and synchronization | Ref.: OT0261 |
| BipolarSC | Ref.: OT0163 |

Basic UDI: 805697785MECHPART007J6

Due+Strap

Ref.: OT0287

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, 06/2023

Andrea Bottin (CEO)

