

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 and ISO 14971: 2019 "Medical devices - Application of risk management to medical devices".

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 NOVECENTO+

Basic UDI: 805697785DESKHDEMG001DS

Model:

960 channels

Ref.: OT0269

And its accessories

Basic UDI: 805697785ADACTPAS00539

Bio96-HD	Ref.: OT0255
Bio64-HD	Ref.: OT0256
Bio32-HD	Ref.: OT0257
Bio8-BP	Ref.: OT0258
Bio40-IM	Ref.: OT0259

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 tests of Electromagnetic Compatibility (EMC) EN 60601-1 Standard and Electrostatic Discharge (ESD) EN 60601-1-2 Standard of 20/02/2018, under Annex II of Regulation (EU) 2017/745 and is put on the market in compliance with Regulation (EU) 2017/745.

Turin, 04/11/2024

Andrea Bottin (CEO)

