otbioelettronica.it

e.mail: mail@otbioelettronica.it - mail@pec.otbioelettronica.it
Sede legale: Via San Marino 21, 10134 Torino, Italy
Tel: +39 011 19720518 **Fax:** +39 011 19720519
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 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 QUATTROCENTO

Basic UDI: 805697785DESKHDEMG001DS

Models:

96 canali	Ref.: OT0001A
192 canali	Ref.: OT0001B
288 canali	Ref.: OT0001C
384 canali	Ref.: OT0001D

And its accessories

Basic UDI: 805697785ADACTPAS00539

AD16	Ref.: OT0098
AD2x8	Ref.: OT0013
AD4x4	Ref.: OT0014
AD64	Ref.: OT0140
AD64S	Ref.: OT0141
Sp-Box-QR	Ref.: OT0095
AD8x2JD	Ref.: OT0016
ADx5	Ref.: OT0101
ADx5G	Ref.: OT0102
ADx5JN	Ref.: OT0020
AD64F	Ref.: OT0165

otbioelettronica.it

e.mail: mail@otbioelettronica.it - mail@pec.otbioelettronica.it
Sede legale: Via San Marino 21, 10134 Torino, Italy
Tel: +39 011 19720518 **Fax:** +39 011 19720519
C.F./P.IVA: 09550700018
R.E.A.: 1061971

Forza	Ref.: OT0082
Forza-B	Ref.: OT0180

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, 10/12/2021

Andrea Bottin (CEO)