

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:

EMG ADHESIVE GRID

Basic UDI: 805697785ELECARRAY009C6

GR02MM2610	Ref.: OT0273
GR03MM1807	Ref.: OT0293
GR04MM1305	Ref.: OT0117
GR04MM2206	Ref.: OT0283
GR04MM2605	Ref.: OT0296
GR04MM2610	Ref.: OT0272
GR04MM3208	Ref.: OT0297
GR05MM3805	Ref.: OT0204
GR08MM1305	Ref.: OT0112
GR08MM1305N15	Ref.: OT0298
GR08MM1305N25	Ref.: OT0271
GR10MM0804	Ref.: OT0116
GR10MM0808	Ref.: OT0113
GR10MM1604	Ref.: OT0286
GR20MM1305	Ref.: OT0195
GR20MM1604	Ref.: OT0210
GR20MM1604B	Ref.: OT0211
GR30MM1305	Ref.: OT0193
HD02MM0808	Ref.: OT0309
HD02MM1305	Ref.: OT0304
HD04MM0808	Ref.: OT0305
HD04MM1305	Ref.: OT0171
HD04MM1606	Ref.: OT0307
HD05MM0804	Ref.: OT0289
HD05MM3201	Ref.: OT0270
HD08MM1106	Ref.: OT0282
HD08MM1305	Ref.: OT0170
HD08MM1606	Ref.: OT0281
HD10MM0804	Ref.: OT0168
HD10MM0808	Ref.: OT0169
HD10MM1103	Ref.: OT0276

HD20MM1602

EL10MM1007

EL10MM1305

Ref.: OT0172

Ref.: OT0208

Ref.: OT0290

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, ISO 10993-1:2008 Biological evaluation of medical devices and ISO 14971:2019 Medical devices - application of risk management to medical devices.

Turin, 04/11/2024

Andrea Bottin (CEO)

