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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 DRY GRID

Basic UDI: 805697785ELECARRAY009C6

GR100ML1305	Ref.: OT0148
HD20MM1602B	Ref.: OT0288
HD20MM1602BG	Ref.: OT0328
HD15MM1604B	Ref.: OT0301
HD15MM1804BG	Ref.: OT0335
HD15MM1604BL	Ref.: OT0340
BIPOLARBRACELET	Ref.: OT0339

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, 26/06/2025

Andrea Bottin (CEO)