

## 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 SHEET

BASIC UDI: 805697785FOAMSHEET010KP

FOA02MM5853	Ref.: OT0317
FOA03MM1807	Ref.: OT0300
FOA03MM10475	Ref.: OT0310
FOA04MM1305	Ref.: OT0214
FOA04MM1606	REF.: OT0324
FOA04MM2206	Ref.: OT0284
FOA04MM8461	Ref.: OT0220
FOA05MM0108	Ref.: OT0253
FOA05MM6749	Ref.: OT0219
FOA08MM1106	Ref.: OT0285
FOA08MM1305	Ref.: OT0213
FOA08MM1606	REF.: OT0323
FOA08MM4231	Ref.: OT0218
FOA10MM0104	Ref.: OT0254
FOA10MM0116	Ref.: OT0252
FOA10MM0804	Ref.: OT0215
FOA10MM0808	Ref.: OT0212
FOA10MM3425	Ref.: OT0217
FOA20MM1602	Ref.: OT0216
FOA20MM1712	Ref.: OT0221

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.



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The object above is in compliance with ISO 10993-1:2008 Biological evaluation of medical devices and ISO 14971:2019 Medical devices - application of risk management to medical devices.

Torino, 04/11/2024

Andrea Bottin CEO