Declaration of Conformity

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Name of Devices:

NeuroTrac® TENS	[Model: ECS300A]
NeuroTrac® MultiTENS	[Model: C6V350]
NeuroTrac® Continence	[Model: ECS400A]
NeuroTrac® Sports	[Model: ECS401A]
NeuroTrac® Sports XL	[Model: ETS201]
NeuroTrac® Simplex	[Model: ESS102]
NeuroTrac® Pelvitone	[Model: ETS200]
NeuroTrac® Obstetric TENS	[Model: ECS310A]
NeuroTrac® Rehab	[Model: ECS305A]
NeuroTrac® MyoPlus Pro	[Model: MYO120P]
NeuroTrac® MyoPlus2	[Model: MYO220A]
NeuroTrac Myoplus 2 Pro	[Model: MYO220P]
NeuroTrac® MyoPlus4	[Model: MYO420A]
NeuroTrac® MyoPlus4 PRO	[Model: MYO420P
NeuroTrac® IFC Rehab	[Model: IFC184]
NeuroTrac® Alpha 2E	[Model: ALP152]

I, the undersigned, hereby declare that the above Class IIa medical devices bearing the CE mark, conform with the application provisions of the EC Directive 93/42/EEC from the European Council dated June 14th, 1993 concerning medical devices as amended by all subsequent Directives including 2007/47/EC; as well as:

1. EN60601-1 (all Devices)
2. EN60601-1-2 (all Devices)
3. EN60601-1-6 (all Devices)
4. EN60601-1-11 (all Devices)
5. EN60601-2-10 (STIM, TENS ETS devices)
6. EN60601-2-40 (EMG, ETS devices)
7. EN62304 (all Devices)

Is subject to the procedures set out in Annex II (Excluding Section 4) of the Directive 93/42 under the supervision of Notified Body No 0088, Lloyd's Register Quality Assurance Limited (LRQA), 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, UK.

Signed: _____ Dated: 17/5/19
Nigel C.Verity, Managing Director