SEI EMG srl	**DECLARATION OF CONFORMITY**
DEVICE: SURFACE RECORDING ELECTRODES	**TF_A012-12-DC_en**

Declaration of conformity of the device referred as:

Surface Recording Electrodes ***series COPxxx, COPMxxx, CODxxx, CODMxxx, RICExxx, RIVExxx, EARxxx EARPLxxx*** *and variant*

In conformity of Annex IV of Regulation (EU) 2017/745.

THE MANUFACTURE: **SEI EMG srl**

REGISTERED OFFICE**: Via S.Chiara 12/1 – 35013 CITTADELLA (PD) ITALIA**

VAT NUMBER: **IT-01597140282**

SRN (Serial Registration Number): I**T-MF-000028347**

DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THIS MEDICAL DEVICE FAMILY CALLED

COPxxx, COPMxxx, CODxxx, CODMxxx, RICExxx, RIVExxx, EARxxx EARPLxxx and variant

BASIC UDI-DI: 805660059A0124S

RISK CLASS (rules of Annex VIII MDD (EU)2017/743): CLASS I

MEETS ALL APPLICABLE PROVISIONS IN THE MEDICAL DEVICE REGULATION (EU) 2017/745

MEETS THE FOLLOWING HARMONIZED STANDARDS:

- **UNI CEI EN ISO 13485:2016** "Quality management system for medical devices"
- **UNI CEI EN ISO 14971:2022** "Medical Devices: Risk Management"
- **UNI EN ISO 10993-1:2021** "Biological Evaluation of Medical Devices - Part 1"
- **UNI CEI EN ISO 20417:2021** "Medical Devices: Information supplied by the manufacturer"
- **UNI EN ISO 14155:2020** "Clinical investigation of medical device for human subjects – Good clinical practice"
- **ISO/TR20416:2020** "Medical Devices: Post-sales surveillance"
- **UNI CEI EN ISO 15223-1:2021** "Medical Devices: Symbols to be used as information"
- **IEC 62366-1:2015** "Medical Devices: Usability engineering"

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Date of first issue: 08/03/2022
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Current issue:08/03/2022

Authorized signature

Ing. Giorgio Didonè

This is a translation of the Italian text, which prevails in case of doubts