| SEI EMG srl | DECLARATION OF CONFORMITY |
|---|---|
| DEVICE: *CAPS FOR EEG IN ELASTIC TUBE* | DC_008en |

**Declaration of conformity of the device referred as "CAPS for EEG in elastic tube" manufactured by the company SEI EMG srl** (already STRUMENTAZIONE ELETTRONICA INDUSTRIALE di Didonè Ing. Giorgio & C. snc), to the **essential requirements of Annex I and Annex VII of Directive 93/42/EEC as amended by Directive 2007/47/EC.**

The writing firm **SEI EMG s.r.l.** established in Cittadella, Via S. Chiara 10,
VAT Number: IT-01597140282
manufacturer of the device family called **CUEPxxx** and **CUMMxxx**
declare under our sole responsibility that this medical device satisfies all applicable provisions in the Medical Device Directive 93/42/EEC amended by Directive 2007/47/EC.

For this purpose, the undersigned represent and warrant under his own responsibility:

- The device in question meets the essential requirements of Annex I to Directive 93/42/EEC updated by Directive 2007/47/EC;
- the device is considered in Class I;
- the device is sold in packs NOT STERILE;
- the device is not an instrument of measure;
- the device is not intended for clinical investigations;
- the manufacturer must undertake to establish a procedure to review experience gained, as required by Annex VII, paragraph 4;
- The manufacturer shall undertake to preserve and make available the technical documentation of the Notified Body, as specified in Annex VII of Directive 93/42/EEC for a period of five years after the last date of manufacture of the product..

He therefore declares that the medical device is in accordance with the requirements of Directive 93/42/EEC and which will be marketed with the CE marking, as required by Article 17 of Directive 93/42/EEC.

*First issue: 16/06/1998*

*Replace the certificate issued on : 08/01/2009*

*Current issue: 22/01/2010*

*Authorized signature*

**SEI EMG s.r.l.**
*Ing. Giorgio Didonè*

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

Digitally signed by Grabazei Alexandru
Date: 2019.06.10 23:57:12 EEST
Reason: MoldSign Signature
Location: Moldova