

<b>SEI EMG srl</b>	<b>DECLARATION OF CONFORMITY</b>	
<b>DEVICE: EEG HEADCAP IN ELSATIC FABRIC WITH PREASSEMBED ELECTRODES</b>	<b>DC_013en</b>	

**Declaration of conformity of the device referred as “EEG headcap in elastic fabric with preassembled electrodes and similar” 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 **CUEFxx , CUEExx, CUERxx , CUETxx , CUPExx and similar,**

**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: 25/01/2010*

*Authorized signature*

**SEI EMG s.r.l.**

*Ing. Giorgio Didonè*

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