



DECLARATION OF CONFORMITY

COGEL ECG - EEG

Directive 93/42/EEC ("Medical Devices Directive" with CE marking - art. 16 and art. 11)
And successive modifications according to Directive 2007/47/EEC

DECLARATION OF CONFORMITY CLASS I MEDICAL DEVICE

- procedure conformed to art. 11, attached VII -

Declaration of conformity of device named **COGEL ECG - EEG** produced by company
COMEDICAL S.a.s. di Gardumi Paola & C.
to essential requirements to the attached I of directive 93/42/EEC like prescribed in attached VII of
aforesaid directive 93/42/EEC.

COMEDICAL S.a.s. di Gardumi Paola & C. with legal situs in Via Degasperi, 34/3 - 38123 Trento - Italy - and operating center in Via della Cooperazione, 29 - 38123 Mattarello (TN) - Italy - Phone +39 0461 945876 Fax +39 0461 944570 - CF and P.IVA 01128170220 - manufacturer of device named "**COGEL ECG - EEG**" declares under the own responsibility that the device is object satisfies all the applicable dispositions in directive 93/42/EEC on the Medical Devices and successive modifications according to the directive 2007/47/EEC.

The such scope **COMEDICAL S.a.s. di Gardumi Paola & C.** guarantees and declares under the own responsibility how much follows:

- the device in object meets the essential requirements demanded in the attached one for directive 93/42/EEC;
- the device is considered to be parts of class I;
- the device is commercialized in NOT STERILE confection;
- the device is NOT A MEASURE INSTRUMENT;
- the manufacturer declares to keep and to put to disposition of the Authority, the specified technical documentation in attached the VII of directive 93/42/EEC for a period of five years from the last date of fabrication of the product.

Is declared therefore that the device comply with prescribed directive 93/42/EEC and successive modifications according to the directive 2007/47/EEC, and that will be put in commerce with CE marking, as decided in Article 17 of directive 93/42/EEC.

There have been moreover considered the following norms:

- Directive 93/42/EEC (Medical Devices with CE marking) and successive modifications according to Directive 2007/47/EEC;

Applicable qualities standard of assurance:

- UNI EN ISO 9001-2008

Harmonized norms about Medical Devices d.l. 46/97

- UNI EN ISO 10993 - applicable sections
- UNI EN 30993 applicable sections
- UNI CEI EN ISO 14971:2009



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CLASS I MEDICAL DEVICE**
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Product Code - Product Description

The following product descriptions and the relative codes regard the packaging of **COGEL ECG -EEG**

Lot: _____

Code	Description	Unit for Multiple Confection
20 00 0 00	COGEL ECG - EEG polyethylene bottle with distributing stopper, 260 mL contained	Carton box with 24 bottles
20 10 0 00	COGEL ECG - EEG polyethylene bottle with distributing stopper, 1.000 mL contained.	Carton box with 12 bottles
20 40 0 00	COGEL ECG - EEG polyethylene bag, 5.000 mL contained.	Carton box with 2 bags

Date: _____

Legal Representative Signature



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