| COMEDICAL® s.a.s. | **DECLARATION OF CONFORMITY** | **COGEL ULTRASOUND** |
|---|---|---|

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 ULTRASOUND** produced by company **COMEDICAL S.a.s. di Gardumi Paola & C.** to essential requirements to the attached I of directive 93/42/EE like prescribed in attached VII of aforesaid directive 93/42/EE.

**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 ULTRASOUND"** 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 responsability how much follows:

- the device in object meets the essential requirements demanded in the attached one for directive 93/42/EE;
- 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

| COMEDICAL® s.a.s. | DECLARATION OF CONFORMITY | COGEL ULTRASOUND |
|---|---|---|

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

CE

**DECLARATION OF CONFORMITY**
**CLASS I MEDICAL DEVICE**
- procedure conformed to art. 11, attached VII -

**Product Code - Product Description**

The following product descriptions and the relative codes regard the packaging of COGEL ULTRASOUND

**Lot:**_____

| Code | Description | Unit for Multiple Confection |
|---|---|---|
| 10 00 0 00 | COGEL ULTRASOUND polyethilene bottle with distributing stopper, 260 mL contained | Carton box with 24 bottles |
| 10 10 0 00 | COGEL ULTRASOUND polyethilene bottle with distributing stopper, 1.000 mL contained. | Carton box with 12 bottles |
| 10 20 5 00 | COGEL ULTRASOUND polyethilene jar with 132 mm Ø hole, 5.000 mL contained. | Carton box with 2 jars |
| 10 40 0 00 | COGEL ULTRASOUND PVC bag, 1.000 mL contained. | Carton box with 12 bags |
| 10 50 5 00 | COGEL ULTRASOUND polyethilene bag, 5.000 mL contained. | Carton box with 2 bags |

**Date:**

Legal Representative Signature

Stamp
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