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EC CONFORMITY DECLARATION

Tecnimed S.r.l., with office in 12, P.le Cocchi – 21040 VEDANO OLONA (VA) – Phone +39 0332-402350, Fax +39 0332-402347, declares to be the manufacturer of the medical device Ecosave, code 01000. It is an electrostimulator intended to reduce the pain and the swelling due to venomous bites/stings.

With this declaration, the manufacturer guarantees, under its own responsibility, that the medical device Ecosave 01000 meets all the applicable requirements set forth in Directive 93/42/EEC on the medical devices, as modified by 2007/47/EC Directive, and in CMDR (Canadian Medical Device Regulation).

To this end, Tecnimed S.r.l. guarantees and states that the medical device Ecosave:

- meets all essential requirements (Encl. I of the Directive) and the CMDR Safety and Effectiveness Requirements (points 10-20).
- belongs to class IIa, it is non invasive, active therapeutical, and intended to transmit energy, according to classification criteria of Annex IX and in particular definitions: 1,4 (active medical device) and 1,5 (active therapeutical device); classifications rules 1,1 rule 1 and 3,1 rule 9; and rule 9 (1) of annex 1 (Classification Rules for Medical Devices) of CMDR.
- has been submitted to the necessary risk assessment according to the UNI CEI EN ISO 14971:2012;
- is marketed in a non-sterilized packaging, does not incorporate, as an integral part, a substance or a human blood derivative referred to section 7.4 of Annex I of 2007/47/EC Directive and is not manufactured utilising tissues of animal;
- is not a measurement instrument;
- is not destined to clinical investigations;
- is manufactured following an appropriate production process and according to a Quality System ISO 9001:2008 and ISO 13485:2012 and according to GMP requirements and in compliance with the following technical Standards:

- EN 60601-1, 3rd edition
- EN 60601-1-2, 3rd edition
- EN 60601-1-6:2010
- EN 62366:2008

Accordingly to what declared above, the manufacturer applies the “CE conformity mark” to the Medical device:

Ecosave, code: 01000

using the graphic symbol “CE” provided for by the Directive (Encl. XII).

Moreover, Tecnimed S.r.l. commits itself to keeping the enclosed product dossier (Art. 17, paragraph 5 of Legislative Decree of 24.2.1997, no. 46) available for the supervision bodies verification for a 10 years period from the date in which the devices’ production is finished.

Vedano Olona, February 2nd, 2017

Signature