



## ELECTROMEDICAL EQUIPMENTS

Via Ugo La Malfa nr.31  
43010 Pilastro (PR) ITALY  
Tel.+39 0521 637133 - 631138 Fax. +39 0521 639041  
P.IVA 00977090349

[www.ca-mi.it](http://www.ca-mi.it)



**ISO 9001:2000 / ISO 13485:2003  
CERTIFIED**

## DECLARATION OF CONFORMITY

**Manufacturer:** CA-MI snc

**Address:** Via Ugo La Malfa n°31

**Equipment:** Thermal Inhalator

**Trade name, model:** NEW VAPINAL

**Intended purpose:** NEW VAPINAL is a thermal waters inhalator endowed with stainless steel boiler, inside of that works an electric resistance with 230V ~ / 50Hz feeding. The device develops through a sprinkler, using venturi system, damp warm vapor. The device is able to mix the vapor, developed by the boiler with the principles of thermal waters placed in the bottle outside of the device.

**Ratings:** 230V ~ / 50Hz 600W

The above mentioned equipment is complying with the European Directives : Medical Devices Directive 93/42/EEC and following updating

The above mentioned equipment is complying with the European Standards:

**Safety Std:** EN 60601-1 + Annex

**EMC Std:** EN 60601-1-2 :2001

### Addition Informations:

Mentioned equipment has been classified as Medical Device with risk class IIa according to the roles of Annex IX of 93/42/EEC Directive.

EC marking procedure has been carried out according to the provisions of Annex VII (Declaration of Conformity) and Annex V (EC Declaration of conformity – Production Quality Assurance) [Nemko AS Certificate no. EU 0411407]

**Notified Body:** NEMKO AS  
Gautstadallèen 30  
N-0371 Oslo – Norway

**CE 0470**

**Date of issue:** mercoledì 25 gennaio 2006

President of the Company

**Mario Attolini**