

CERTIFICATE OF CONFORMITY  
WITH EUROPEAN DIRECTIVE



Certificate No.: EU0411407  
Order No.: 33418

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 27 January 1995 relating to medical devices pursuant to act no. 6 of 12<sup>th</sup> January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the **Annex V** of the aforementioned directive.

Name and address of the manufacturer: CA.MI Snc.di Attolini Mario & C.  
Via Ugo La Malfa n. 31  
43010 PILASTRO (PR)  
ITALY

Device categories: Thermal Water Inhaler

Models: NEW VAPINAL - REF. RE 320000  
INALATORE FARMAMEDICA - REF. RE 320000/001  
KLIMAR - REF. RE 320000/02  
TERMALFLY - REF. RE 320000/04  
TABIOJET - REF. RE 320000/05

Risk class: Ila

Provisions: The audit of the quality system was based on the provisions in Annex V of the EU-Directive 93/42/EEC

Date of initial audit: 2004-02-18/19

Date of the end of the validity: 2009-12-01

Conditions in Annex V: See sub clause 3.4 and 5.1


Other relevant conditions: Article 17.2 of the EU-Directive 93/42/EEC

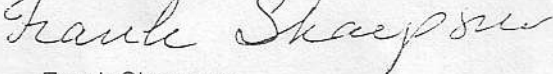
Nemko EC notification No.: 0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled for the manufacturer and the relevant subcontractors.

Date of issue: 2004-11-24

Date of verification: 2004-11-24

  
Signature: Arild Hansgård  
Principal Engineer

  
Signature: Frank Skarpsno  
Lead auditor / Principal Engineer

**CE 0470**