

# EC CERTIFICATE

Certificate No 672/MDD

## Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, section 3 of Legislative Decree of 1997-02-24, No 46, national transposition of the Directive 93/42/EEC, we hereby certify that:

### FLAEM NUOVA SPA

manages in the factories of:

S.MARTINO DELLA BAT. (BS) - VIA COLLI STORICI 221/223/225 (ITA) - Italy

a full quality assurance system ensuring the conformity of the following products:

**Mini aspirators equipment and related accessories**

**Aerosoltherapy equipment and related accessories**

**Ultrasonic aerosoltherapy equipment and related accessories**

**Non invasive Sphygmomanometer**

**Hot steam jet inalators for thermal water**

**Rechargeable Nasal Wash**

Type ref. As to document "FLAEM NUOVA" attached; valid only if provided with IMQ stamp.


with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos: 10AD00174; 10AE00033; 10AF00152; 10AG00132; 10AG00178; 10AG00235; 10AH00175; 10AI00100; 10AJ00118.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC.

Notified Body notified to European Commission under number: 0051.

Date: 2003-11-11  
Updated: 2009-07-23  
Substitution Date: 2008-09-12

  
IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".  
In any case, it does not remain valid after 2013-09-11 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

