

TRUE COPY

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

Type ref. As to document "FLAEM NUOVA" attached; valid only if provided by 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.

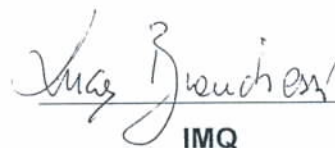
Reference to IMQ files Nos: 10AD00174; 10AE00033; 10AF00152; 10AG00132; 10AG00178;
10AG00235; 10AH00175; 10AI00100.

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.



16 APR. 2009

Date: 2003-11-11
Updated: 2008-09-12
Substitution Date: 2008-02-18


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

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VIA COLLI STORICI 221/223/225
25010 SAN MARTINO DELLA BATTAGLIA BS

Your ref: ---
Our ref: EM-1340/09-fv10
Date: 2009-04-16

Dear Sirs


Certificate No 672/MDD.

With reference to your request, we are pleased to confirm you, that:

- EC Certificate No. 672/MDD, issued by IMQ to FLAEM NUOVA on 2003-11-11 and further modifications, is valid until 2013-09-11.

Best regards,

IMQ S.p.A.
Domestic and Professional Products Department
Department Manager


(Vincenzo La Fraga)



INSIEME PER LA QUALITA' E LA SICUREZZA