

EC CERTIFICATE

Certificate No 672/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

FLAEM NUOVA SPA

25015 SAN MARTINO DELLA BATTAGLIA (BS) - VIA COLLI STORICI 221/223/225 (ITA) - Italy

manages in the factories of:

25015 SAN MARTINO DELLA BATTAGLIA (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

Respiratory physiotherapy rehabilitation unit

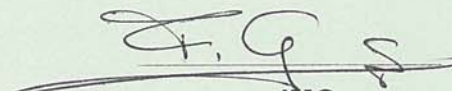
series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos: 10AD00174; 10AE00033; 10AF00152; 10AG00132; 10AG00178;
10AG00235; 10AH00175; 10AI00100; 10AJ00118; 10EK00045;
10EM00012; 10EM00067; DM13A0140051-01; 10EN00064; 10EO00043.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2003-11-11
Updated: 2014-07-29
Substitution Date: 2013-09-24



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 2018-09-02 (article 11, clause 11 of the Directive).

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

EC CERTIFICATE

Certificate No 672/MDD

Annex

Mini aspirators equipment and related accessories

Aerosoltherapy equipment and related accessories

Ultrasonic aerosoltherapy equipment and related accessories

Non invasive Sphygmomanometer

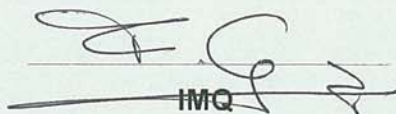
Hot steam jet inalators for thermal water

Rechargeable Nasal Wash

Respiratory physiotherapy rehabilitation unit

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

Date: 2003-11-11
Updated: 2014-07-29
Substitution Date: 2013-09-24



Handwritten signature and the IMQ logo.

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