

# 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 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. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.


Reference to IMQ files Nos:

10AD00174; 10AE00033; 10AF00152; 10AG00132; 10AG00178; 10AG00235;  
10AH00175; 10AI00100; 10AJ00118; 10EK00045; 10EM00012; 10EM00067;  
DM13A0140051-01; 10EN00064; 10EO00043; DM15E0389991-01; 10AO00262;  
DM15E0501867-01; DM16E0595570-01; DM16E0595603-01; DM16E0595636-01;  
DM17-0015790; DM18-0021924-01.

**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: 2018-04-12  
Substitution Date: 2017-12-12  
Expiry Date: 2023-04-11

  
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 **IMQ** ESQ  
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano  
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tel. + 39 0250731  
www.imq.it

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".

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

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## Annex

**Mini aspirators equipment and related accessories**

**Aerosoltherapy equipment and related accessories**

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**Non invasive Sphygmomanometer**


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**Rechargeable Nasal Wash**

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Type ref. As to document "Annex of IMQ CE Certificate No. 672/MDD" Rev. at dated 2017/11/29; valid only if provided with IMQ stamp.

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