

EC CERTIFICATE

Certificate No 718/MDD

Full Quality Assurance System Approval Certificate

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

SIEM - NOVA SRL

20089 ROZZANO (MI) - VIA VARALLI 1 (ITA) - Italy

manages in the factories of:

20089 ROZZANO (MI) - VIA VARALLI 1 (ITA) - Italy

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

Surgical aspirators

Aerosoltherapy equipment

Ultrasonic aerosoltherapy equipment

Surgical aspirator for centralized vacuum

Mastosuctors

Surgical smoke filtrations

Suction Filter

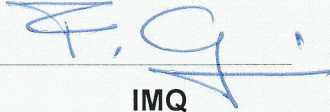
series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing).

Reference to IMQ files Nos: 10AE00026; 10AF00108; 10AG00067; 10EK00040.

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: 2004-02-23
Updated: 2010-07-13
Substitution Date: 2009-02-18


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 2014-02-17 (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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Annex

Surgical aspirators

Type ref. 6110-A1 CURET-MAX; 6110-A1 LIPO-MAX; 6110-A1 MAX; 6110-A2 CURET-SPEEDY; 6110-A2 LIPO-SPEEDY; 6110-A2 SPEEDY; 6110-A3 SIEM; 6110-A4 LIPO-YUNIOR; 6110-A4 YUNIOR; 6110-A5 GASTRO-EVER; 6110-A6 ASTRO-YUNIOR; 6110-A7 GASTRO-PLEURICO-TORACICO; 6110-A8 PLEURICO-TORACICO; 6110-A9 VENTOSA-MAX; 6110-A10 VENTOSA-SIEM

Aerosoltherapy equipment

Type ref. 1001 AS UNO; 1001 AS UNO R

Ultrasonic aerosoltherapy equipment

Type ref. 1001 NEB

Surgical aspirator for centralized vacuum

Type ref. 6110 A1 CENTRAL MAX; 6110 A3 CENTRAL SIEM; 6110 A4 CENTRAL JUNIOR; 6110 A5 CENTRAL GASTRO; 6110 A6 CENTRAL GASTRO UNIOR; 6110 A7 CENTRAL GASTRO PLEURICO TORACICO; 6110 A8 CENTRAL PLEURICO TORACICO

Mastosuctors

Type ref. MS SIEM ; MS DUPLEX

Surgical smoke filtrations

Type ref. FILTRUM; SMOKE BUSTER.

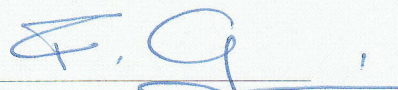
Suction Filter

Series: 6000 Type ref. SUCTION FILTER

Series: 7000 Type ref. VENT FILTER

Series: 8000 Type ref. SMOKE FILTER

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