



EC DECLARATION OF CONFORMITY AND ORIGIN
 For CE-marking according to Annex II of MDD 93/42/EEC
 Following to the declaration of conformity issued by **IMQ** Notified Body

Product: **MEDICAL EQUIPMENTS WITH ACCESSORIES**

Surgical aspirators Type:
 DOMI DC (with battery code 66131.); DOMI AC (code 66132.)
Aerosoltherapy equipment Type:
 Modd.(*): 1001ASUNO (code 14500.); 1001ASUNOR (code 14550.)
Ultrasonic aerosoltherapy equipment Type:
 1001 NEB (code 14010.)
Surgical smoke filtrations Type:
 FILTRUM (code 81000.); SMOKE BUSTER (code 80000.)

Surgical aspirators Type:
 6110-A1 MAX (code 66191.); 6110-A2 SPEEDY (code 66194.); 6110-A3 SIEM (code 66130.);
 6110-A4 JUNIOR (code 66134.);
Surgical aspirators for histero suction Type:
 6110-A1 CURET-MAX (code 66192.); 6110-A2 CURET-SPEEDY (code 66196.);
Surgical aspirators for lipo suction Type:
 6110-A1 LIPO-MAX (code 66193.); 6110-A2 LIPO-SPEEDY (code 66198.); 6110-A4 LIPO-
 JUNIOR (code 66136.);
 Modd(**): **Surgical aspirators for drainage Type:**
 6110-A5 GASTRO-EVER (code 66140.); 6110-A6 GASTRO JUNIOR (code 66145.); 6110-A7
 GASTRO-PLEURICO-TORACICO (code 66150.); 6110-A8 PLEURICO TORACICO (code 66155.);
Fetal vacuum extractor Type:
 6110-A9 VENTOSA-MAX (code 66199.); 6110-A10 VENTOSA-SIEM (code 66200.);
Surgical aspirator for centralized vacuum Type:
 6110 A1 CENTRAL MAX (code 66202.); 6110 A3 CENTRAL SIEM (code 66203.); 6110 A4
 CENTRAL JUNIOR (code 66209.); 6110 A5 CENTRAL GASTRO (code 76110.); 6110 A6
 CENTRAL GASTRO JUNIOR (code 66206.); 6110 A7 CENTRAL GASTRO PLEURICO TORACICO
 (code 66207.); 6110 A8 CENTRAL PLEURICO TORACICO (code 66208.)

Classification: **IIa (*) - IIb (**)**

Manufacturer: **SIEM-NOVA S.r.l.**
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Applied Directive: **DDM 93/42 CEE** (D. Lgs. 46/97) e s.m.i. (2007/47/CE)

Applied Quality Standard: **ISO 9001:2015** Quality management system – Requirements
ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

Applied Safety Standard: EN ISO 14971:2012: Medical devices – Application of risk management to medical devices
 EN 60601-1: 2006 + AM1 (2013): Medical electrical equipment - General requirements for basic safety and essential performance
 IEC 60601-1-12:2014:General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
 IEC 60601-1-11:2015:General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
 EN 1789:2008+A2:2014: Medical vehicles and their equipment - Road ambulances
 EN ISO 10079-1:2015: Medical suction equipment – Electrically powered suction equipment

Certificate CE date 2004-02-23; n. **718/MDD**
 Updated: 2019-02-07
 Substitution Date: 2017-01-19
Expiry Date: 2024-02-06

Siem-Nova S.r.l.
L'Amministratore Gabriele Veronesi

CE0051

Rozzano: 2019-02-07

