

EC CERTIFICATE

Certificate No 187/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:

ALSA APPARECCHI MEDICALI SRL

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

manages in the factories of:

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

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

Surgical aspirators

Accessories for medical suction units and vacuum-extractors

Accessories for electrosurgical units

Electrosurgical smoke evacuators

Electrosurgical unit

Non electrical trolleys for electrosurgical equipments, electrosurgical smoke evacuators and medical suction units

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:

10A9800405; 10A9900240; 10AA00040; 10AA00016; 10AA00060; 10AA00156;
10AA00262; 10AB00169; 10AB000170; 10AC00210; 10AE00050; 10AF00011;
10AF00032; 10AF00192; 10AG00183; 10AH00132; 10AH00244; 10AI00034;
10AI00127; 10AI00122; 10AJ00093; 10EL00005; COMEDCONMHDM110021912-
01; 10SN00082; DM16-0007485-01; 10AN00148; 10EO00012; DM16-0007485-01.

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: 1999-05-10
Updated: 2017-03-14
Substitution Date: 2014-04-15
Expiring Date: 2022-03-13



IMQ



IMQ S.p.A. - I-20138 Milano
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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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MOD. 1475A / 2

Annex

Surgical aspirators

Series: VACUMSOL Type ref. VACUMSOL AS-60; VACUMSOL AS-65; VACUMSOL AS-65/H.

Series: VORTEX-S Type ref. VORTEX-S AS-200/30LT; VORTEX-S AS-200/20LT VE; VORTEX-S AS-200/30LT VE; VORTEX-S AS-200/20LT.

Series: VORTECO Type ref. VORTECO AS-100/15LT; VORTECO AS-100/20LT; VORTECO AS-100/30LT; VORTECO AS-100/20LT VE; VORTECO AS-100/30LT VE.

Series: POLIVAC Type ref. POLIVAC B4/SLT 30 1; POLIVAC B4/SLT 30 2; POLIVAC B4/SLT 30 P; POLIVAC B4/SLT 50 2; POLIVAC B4/SLT 30 1-EXP; POLIVAC B4/SLT 30 2-EXP; POLIVAC B4/SLT 30 P-EXP; POLIVAC B4/SLT 50 E; POLIVAC B4/SLT 30 1VE-EXP; POLIVAC B4/SLT 30 PVE-EXP; POLIVAC B4/SLT 30 2-EXP "TROLLEY".

Series: SUPERSUCTION Type ref. SUPERSUCTION 4T; SUPERSUCTION 4T Extra; SUPERSUCTION 4T EXP; SUPERSUCTION 4T Extra EXP.

Series: SUPERVAC/SLT Type ref. SUPERVAC/SLT 30 1; SUPERVAC/SLT 30 2; SUPERVAC/SLT 30 P; SUPERVAC/SLT 50 2.

Accessories for medical suction units and vacuum-extractors

Type ref. Cannulae for medical and surgical aspiration series C, C/F, C/J, C/S; Cannulae for endouterine aspiration series SET; Cups for vacuum-extraction series VE;

See "Elenco-AccAspir#A" of 29.03.2005 attached; valid only if provided with IMQ stamp.

Accessories for electrosurgical units

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Type ref. Electrode-Handles for use by foot-switch series MPE and MLD; Electrode-Handles for use by hand-switch series MPE/CMS; Monopolar active electrodes for electrosurgery series E, SAD, EL/MLH, AID; Insulated forceps for bipolar coagulation series PBC, PMC, PBC/L, PMC/L, PBC/ns, PMC/ns; Rigid and insulated bipolar electrodes series EB, EL/BL; Connecting cables for bipolar forceps and electrodes series CPB and CPB/E; Insulated forceps, scissors and cannulae for monopolar coagulation series PMI, PIC, FI, CFI, PMI/P; Connecting cables for monopolar instruments and electrodes series CPI, CPE, CEP3, CEP4M, CEP4; Stainless steel neutral electrodes with connecting cables series NP/A and EIP; Connecting cables for neutral electrodes series CMS/E; Flexible neutral electrodes, made of conductive rubber, with connecting cables series NP/GA and NP/GP; Insulated bipolar scissors series BITec, BITecD; Insulated bipolar "clamps" forceps series BC, BCS; Insulated bipolar instruments for laparoscopy series TK707, POWER GRIP; Connecting cables for insulated bipolar scissors series CPB/tec, CPB/E-tec; Reusable active monopolar instruments for laparoscopy serie EL/ML; Securing sashes for neutral electrodes series FFE, FGE; Handle model AC/HANDLE and rigid active electrodes for argon gas surgery serie AC/E; Connecting cable model AC/CABLE and flexible active electrodes for argon gas surgery serie AC/FP; Foot-switches series STOP/PN, D-STOP/P, DS/E, DS/B; Stainless steel boxes for accessories series BOX/TE, BOX/RA, Connecting adaptors for monopolar cable, bipolar cables and neutral electrodes cables series RD/5, RD/70, RD/BF, RD/F, RD/EN
See "AccElettr-Elenco#D" of 30.03.2008 attached; valid only if provided with IMQ stamp.

Electrosurgical smoke evacuators

Series: CS Type ref. CS200; CS200LC; CS900LC

Electrosurgical unit

Series: ALSATOM Type ref. ALSATOM SU 50-MPC; ALSATOM SU 100-MPC; ALSATOM SU 140-MPC; ALSATOM SU 140/D-MPC; ALSATOM SU 140/BD-MPC; ALSATOM SU 140/D-MPC (100V-60Hz).

Series: MCDSe Type ref. EXCELL 200 MCDSe; EXCELL 250 MCDSe; EXCELL 350 MCDSe; EXCELL 400 MCDSe; EXCELL 250/A MCDSe; EXCELL 400/A MCDSe.

Series: NHP Type ref. EXCELL NHP 250/D; EXCELL NHP 350/D; EXCELL NHP 400/D; EXCELL NHP 250/DA; EXCELL NHP 400/DA; EXCELL NHP ENDOMED.

Type ref. SURGICUT CPC
Trade mark GHS

Type ref. MB 140-PRO
Trade mark ALCYON

Type ref. BIPOLAR HF 100; BIPOLAR HF 140.
Trade mark BUTTERFLY ITALIA

Series: NHP/T Type ref. EXCELL NHP/T-400; EXCELL NHP/T-200; EXCELL NHP/TA-400; EXCELL NHP/TA-200.

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**Non electrical trolleys for electrosurgical equipments, electrosurgical smoke
evacuators and medical suction units**

Type ref. H10; H10/AB; H23/SE; H25; H26

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