



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 factory 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. 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:

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; DM17-0017739-01; DM18-0029069-01; DM18-0029585-01; DM18-0031303; DM19-0046045-01.

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: 2019-11-25
 Substitution Date: 2018-11-07
 Expiry Date: 2022-03-13

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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-100/30LT VE.

Series: POLIVAC Type ref. POLIVAC B4/SLT 30 1; POLIVAC B4/SLT 30 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.

Accessories for medical suction units and vacuum-extractors

Type ref. As to annexed document "Elenco-AccAspir#A" dated 29.03.2005 attached; valid only if provided with IMQ stamp.

Accessories for electro-surgical units

Type ref. as to annexed document "AccElett-Elenco#D" dated 30.03.2008; 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. 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.

Type ref. PWT-400
Trade mark TONTARRA

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Electrosurgical unit

Series: TopTom Type ref. TopTom SU 50; TopTom SU 100; TopTom SU 140; TopTom SU 140/D.

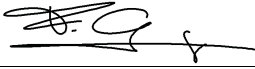
Series: AMNOTOM Type ref. AMNOTOM 160 BASE; AMNOTOM 400 COMPACT; AMNOTOM 400 PREMIUM; AMNOTOM 400 PREMIUM A.

Trade mark AMNOTEC

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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