CERTIFICATO CE

Certificato n. 187/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

ALSA APPARECCHI MEDICALI SRL

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

mantiene nello stabilimento di:

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

un sistema qualità che assicura la conformità dei seguenti prodotti:

Aspiratori chirurgici

Accessori per elettrobisturi

Aspiratori di fumi elettrochirurgici

Elettrobisturi

Modd. come da documento 'Allegato al Certificato CE no. 187/MDD - Elenco dei Dispositivi' rev. 0 del 2021/03/05; tale allegato costituisce parte integrante e sostanziale del presente certificato.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

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; DM21-0060400-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Digitally signed by Grabazei Alexandru
Date: 2022.06.15 09:53:22 EEST
Reason: MoldSign Signature
Location: Moldova

Emesso il:	1999-05-10
Data aggiornamento:	2021-03-05
Sostituisce:	2019-11-25
Data scadenza:	2024-05-26

IMQ

DocuSign

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 electrosurgical units

Electrosurgical smoke evacuators

Electrosurgical unit

Type ref. as to document 'Annex of EC Certificate no. 187/MDD - Device List' rev. 0 dated 2021/03/05; this annex is integral and substantial part of this certificate.

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; DM21-0060400-01.

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:	2021-03-05
Substitution Date:	2019-11-25
Expiry Date:	2024-05-26

IMQ

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Aspiratori chirurgici** Surgical aspirators
Serie: Series:	**VACUMSOL**
Modello/i: Model(s):	**VACUMSOL AS-60;** **VACUMSOL AS-65;** **VACUMSOL AS-65/H**
Serie: Series:	**VORTEX-S**
Modello/i: Model(s):	**VORTEX-S AS-200/20LT;** **VORTEX-S AS-200/30LT;** **VORTEX-S AS-200/20LT VE;** **VORTEX-S AS-200/30LT VE**
Serie: Series:	**VORTECO**
Modello/i: Model(s):	**VORTECO AS-100/15LT;** **VORTECO AS-100/20LT;** **VORTECO AS-100/30LT;** **VORTECO AS-100/30LT VE**
Serie: Series:	**POLIVAC**
Modello/i: Model(s):	**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**

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rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Accessori per elettrobisturi** Accessories for electrosurgical units
Serie: Series:	**MPE e MLD**
Modello/i: Model(s):	**Manipoli porta elettrodi monopolari riusabili per utilizzo con comando a pedale** **Codici** / Codes: • **MPE/S; MPE/E; MPE/E5; MPE/F** • **MLD; MLD/F**
Serie: Series:	**MPE/CMS**
Modello/i: Model(s):	**Manipoli porta elettrodi monopolari riusabili per utilizzo con comando manuale a doppio pulsante** **Codici** / Codes: • **MPE/CMS; MPE/CMS5; MPE/CMS300; MPE/CMS300-4**
Serie: Series:	**E**
Modello/i: Model(s):	**Serie di elettrodi attivi monopolari riusabili per elettrochirurgia** **Codici** / Codes: • **SEL/VI; SEL/D; SEL/E**
Serie: Series:	**E**
Modello/i: Model(s):	**Elettrodi attivi monopolari riusabili per elettrochirurgia** **Codici** / Codes: • **E1; E1I; E3; E1L; E3L; E5; E6; E7; E7I; E8; E10; E12; E13; E14; E15; E16; E17; E18; E19; E21; E23; E23N; E25; E25N; E26: EXT/15** • **E27; E29; E30; E31; E32; E33; E34; E35; E37: E39;** • **E40I; E40; E41; E41I; E42; E43; E46; E47; E47/6;** • **E48; E49; E50; E51; E52; E53; E54; E55: E56; E57; E58** • **E101; E102; E103; E105; E106; E109; E110; E111: E112; E120; E121;** • **E/ND12; E/DR12; E/HK12; E/HY12;** • **E/ND18; E/DR18; E/HK18; E/HY18**
Serie: Series:	**SAD**
Modello/i: Model(s):	**Elettrodi attivi monopolari (aghi sottili) per elettrochirurgia** **Codici** / Codes: • **SAD; SAD/AN; SAD/1; SAD/1AN; SAD/2; SAD/2AN; SAD/3; SAD/3AN**
Serie: Series:	**AID**
Modello/i: Model(s):	**Elettrodi attivi monopolari (aghi sottili) per elettrochirurgia** **Codici** / Codes: • **AID**

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Categoria di dispositivo: Device category:	**Accessori per elettrobisturi** Accessories for electrosurgical units
Serie: Series:	**SAD e AID**
Modello/i: Model(s):	**Mandrino riduttore per aghi** **Codici /** Codes**:** • **MID**
Serie: Series:	**EL/MLH**
Modello/i: Model(s):	**Elettrodi attivi monopolari riusabili per laparoscopia** **Codici /** Codes**:** • **EL/MLH-J; EL/MLH-L**
Serie: Series:	**PMC e PBC**
Modello/i: Model(s):	**Pinze bipolari isolate standard** **Codici /** Codes**:** • **PMC/JR; PMC/JC; PMC/RS; PMC/CS; PMC/R; PMC/C; PMC/R25; PMC/C25; PMC/RSB; PMC/B; PMC/B25; PMC/BCD; PMC/BCU** • **PBC/R; PBC/C; PBC/R25; PBC/C25; PBC/B; PBC/B25; PBC/BCD; PBC/BCU**
Serie: Series:	**PMC/L e PBC/L**
Modello/i: Model(s):	**Pinze bipolari isolate con irrigazione** **Codici /** Codes**:** • **PMC/JRL; PMC/JCL; PMC/RSL; PMC/CSL; PMC/RL; PMC/CL; PMC/R25L; PMC/C25L; PMC/RSBL; PMC/BL; PMC/B25L; PMC/BCDL; PMC/BCUL** • **PBC/RL; PBC/CL; PBC/R25L: PBC/C25L; PBC/BL; PBC/B25L; PBC/BCDL; PBC/BCUL**
Serie: Series:	**PBC/ns, PMC/ns**
Modello/i: Model(s):	**Pinze bipolari isolate con punte no-stick** **Codici /** Codes**:** • **PMC/JRns; PMC/JCns; PMC/RSns; PMC/CSns; PMC/R15ns; PMC/C15ns; PMC/Rns; PMC/Cns; PMC/R25ns; PMC/C25ns; PMC/RSBns; PMC/B16ns; PMC/Bns; PMC/B25ns; PMC/BCDns; PMC/BCUns;** • **PBC/Rns; PBC/Cns; PBC/R25ns; PBC/C25ns; PBC/Bns; PBC/B25ns; PBC/BCDns; PBC/BCUns**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Accessori per elettrobisturi** Accessories for electrosurgical units
Serie: Series:	**EB**
Modello/i: Model(s):	**Elettrodi bipolari isolati rigidi** **Codici /** Codes: • **EBT; EBT20; EBT22; EBL; EBL16,5; EBA45; EBA90; EBD18; EBD20; EBD22**
Serie: Series:	**EL/BL**
Modello/i: Model(s):	**Elettrodi bipolari isolati rigidi per laparoscopia** **Codici /** Codes: • **EL/BL-J; EL/BL-J45; EL/BL-L; EL/BL-L45; EL/BL-DL; EL/BL-DV; EL/BL-DN**
Serie: Series:	**BITecD**
Modello/i: Model(s):	**Forbici bipolari isolate con lame delicate** **Codici /** Codes: • **BITecD-18; BITecD-21; BITecD-23; BITecD-28**
Serie: Series:	**BCS e BC**
Modello/i: Model(s):	**Pinze "clamps" bipolari isolate** **Codici /** Codes: • **BCS-15; BCS-19; BCS-S19; BCS-S23** • **BC-16; BC-20; BC-23; BC-26**
Serie: Series:	**POWER GRIP**
Modello/i: Model(s):	**Strumenti bipolari isolati per laparoscopia** **Codici /** Codes: • **POWER GRIP – LGF; 82400010; POWER GRIP – MFG; 82400014; POWER GRIP – FGC; 82400015; POWER GRIP – DCG; 82400011; POWER GRIP – MD; 82400019; POWER GRIP – CMS; 82400018**
Serie: Series:	**CPB e CPB/E**
Modello/i: Model(s):	**Cavi di collegamento per pinze, elettrodi, strumenti bipolari** **Codici /** Codes: • **CPB; CPB/5; CPB/U; CPB/U5; CPB/MU; CPB/MU5; CPB/RU; CPB/RU5;** • **CPB/E; CPB/E5; CPB/EM; CPB/EM5; CPB/ER; CPB/ER5; CPB/EU; CPB/EU5; CPB/EE; CPB/EE5; CPB/EE-4; CPB/EE5-4; CPB/EEM; CPB/EEM5; CPB/EES; CPB/EES5; CPB/EST; CPB/E-WMS; CPB/WMS**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Accessori per elettrobisturi** Accessories for electrosurgical units
Serie: Series:	**CPB/tec e CPB/E-tec**
Modello/i: Model(s):	**Cavi di collegamento per forbici bipolari isolate** **Codici /** Codes: • **CPB/E-tec; CPB/E-tec5;** • **CPB/tec; CPB/tec5; CPBS/tec; CPBS/tec5; CPBM/tec; CPBM/tec5; CPBV/tec; CPBV/tec5**
Serie: Series:	**PMI, PIC, PMI/P, FI e CFI**
Modello/i: Model(s):	**Pinze (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale)** **Codici /** Codes: • **PMI/1; PMI/1-20; PMI/1-25; PMI/1C25; PMI/2; PMI/2-25; PMI/B1-18; PMI/B2-18; PMI/B1; PMI/B; PMI/DB1-20; PMI/DB1-25; PMI/DB2-20; PMI/DB2-25**
Modello/i: Model(s):	**Pinze (senza collegamento all'elettrobisturi e utilizzo mediante contatto)** **Codici /** Codes: • **PIC/1; PIC/1-25; PIC/2; PIC/2-25; PIC/B1-18; PIC/B2-18; PIC/B1; PIC/B; PIC/DB1-20; PIC/DB1-25; PIC/DB2-20; PIC/DB2-25**
Modello/i: Model(s):	**Pinze (con collegamento all'elettrobisturi e utilizzo mediante comando manuale)** **Codici /** Codes: • **PMI/PB; PMI/PB14; PMI/PB19; PMI/PJ18; PMI/PJ21; PMI/PJ24**
Modello/i: Model(s):	**Forbici (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale)** **Codici /** Codes: • **FI/18; FI/18C; FI/24; FI/24C; FI/W18; FI/W18C; FI/W24; FI/W24C**
Modello/i: Model(s):	**Cannule di aspirazione (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale)** **Codici /** Codes: • **CFI/1; CFI/2; CFI/3**
Serie: Series:	**EL/ML**
Modello/i: Model(s):	**Strumenti attivi monopolari riusabili per laparoscopia** **Codici /** Codes: • **EL/ML-J; EL/ML-JS; EL/ML-L; EL/ML-LS**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Accessori per elettrobisturi** Accessories for electrosurgical units
Serie: Series:	**CPI, CPE, CEP3, CEP4M e CEP4**
Modello/i: Model(s):	**Cavi di collegamento per strumenti/elettrodi monopolari** **Codici /** Codes: • **CPI; CPI/5; CPI-M4; CPI/5-M4; CPI-M6; CPI-M8; CPI/SM; CPI/L** • **CPE/5; CPE-M4; CPE/5-M4; CPE-M6; CPE-M8;** • **CEP3; CEP3/5; CEP3-M4; CEP3/5-M4; CEP3-M6; CEP3-M8;** • **CEP4M; CEP4M/5; CEP4M-M4; CEP4M/5-M4; CEP4M-M6; CEP4M-M8;** • **CEP4; CEP4/5; CEP4-M4; CEP4/5-M4; CEP4-M6; CEP4-M8**
Serie: Series:	**NP/A e EIP**
Modello/i: Model(s):	**Elettrodi neutri con cavi di collegamento** **Codici /** Codes: • **EIP/9; EIP/9-5; EIP/S;** • **NP/A; NP/A5**
Serie: Series:	**CMS/E**
Modello/i: Model(s):	**Cavi di collegamento per elettrodi neutri** **Codici /** Codes: • **CMS/E; CMS/E5; CMS/EA; CMS/EA5; CMS/EEN; CMS/E5EN**
Serie: Series:	**NP/GA e NP/GP**
Modello/i: Model(s):	**Elettrodi neutri in gomma conduttiva** **Codici /** Codes: • **NP/GA** • **NP/GP**
Serie: Series:	**AC/E**
Modello/i: Model(s):	**Manico AC/HANDLE ed elettrodi attivi rigidi per chirurgia con gas argon** **Codici /** Codes: • **AC/HANDLE; AC/E25-C; AC/E100-C; AC/E320-C; AC/E320-H; AC/E40-A; AC/E100-A; AC/E40-L; AC/E100-L**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Accessori per elettrobisturi** Accessories for electrosurgical units
Serie: Series:	**AC/FP**
Modello/i: Model(s):	**Cavo di collegamento AC/CABLE ed elettrodi attivi flessibili per chirurgia con gas argon** **Codici /** Codes**:** • **AC/CABLE; AC/FP1; AC/FP1-5; AC/FP2; AC/FP3; AC/FP3s; AC/FP3-5; AC/FP4; AC/FP4-5**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Aspiratori di fumi elettrochirurgici** Electrosurgical smoke evacuators
Serie: Series:	**CS**
Modello/i: Model(s):	**CS200;** **CS200LC;** **CS900LC**

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rev. 0 del/of **2021/03/05**

Categoria di dispositivo: Device category:	**Elettrobisturi** Electrosurgical unit
Serie: Series:	**ALSATOM**
Modello/i: Model(s):	**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).**
Serie: Series:	**MCDSe**
Modello/i: Model(s):	**EXCELL 200 MCDSe;** **EXCELL 250 MCDSe;** **EXCELL 350 MCDSe;** **EXCELL 400 MCDSe;** **EXCELL 400/A MCDSe**
Serie: Series:	**NHP**
Modello/i: Model(s):	**EXCELL NHP 250/D;** **EXCELL NHP 350/D;** **EXCELL NHP 400/D;** **EXCELL NHP 250/DA;** **EXCELL NHP 400/DA;** **EXCELL NHP ENDOMED**
Serie: Series:	**NHP/T**
Modello/i: Model(s):	**EXCELL NHP/T-400;** **EXCELL NHP/T-200;** **EXCELL NHP/TA-400;** **EXCELL NHP/TA-200**
Serie: Series:	**TopTom**
Modello/i: Model(s):	**TopTom SU 50;** **TopTom SU 100;** **TopTom SU 140;** **TopTom SU 140/D**

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Marca Trade mark:	**BUTTERFLY ITALIA**

Categoria di dispositivo: Device category:	**Elettrobisturi** Electrosurgical unit
Modello/i: Model(s):	**BIPOLAR HF 100;** **BIPOLAR HF 140.**

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rev. 0 del/of **2021/03/05**

Marca Trade mark:	**TONTARRA**

Categoria di dispositivo: Device category:	**Elettrobisturi** Electrosurgical unit
Modello/i: Model(s):	**PWT-400**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

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rev. 0 del/of **2021/03/05**

Marca Trade mark:	**AMNOTEC**

Categoria di dispositivo: Device category:	**Elettrobisturi** Electrosurgical unit
Serie: Series:	**AMNOTOM**
Modello/i: Model(s):	**AMNOTOM 160 BASE;** **AMNOTOM 400 COMPACT;** **AMNOTOM 400 PREMIUM;** **AMNOTOM 400 PREMIUM A**

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rev. 0 del/of **2021/03/05**

Marca Trade mark:	**ZACCANTI S.p.A.**

Categoria di dispositivo: Device category:	**Elettrobisturi** Electrosurgical unit
Modello/i: Model(s):	**BIPOGYN**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

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rev. 0 del/of **2021/03/05**

Marca Trade mark:	**EFER ENDOSCOPY**

Categoria di dispositivo: Device category:	**Elettrobisturi** Electrosurgical unit
Modello/i: Model(s):	**SIRIUS 900**

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of **2021/03/05**

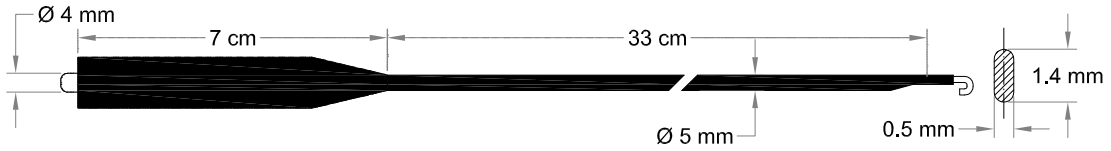
Marca Trade mark:	**MEDICAL SWAN**

Categoria di dispositivo: Device category:	**Elettrobisturi** Electrosurgical unit
Modello/i: Model(s):	**PULSAR MB350**

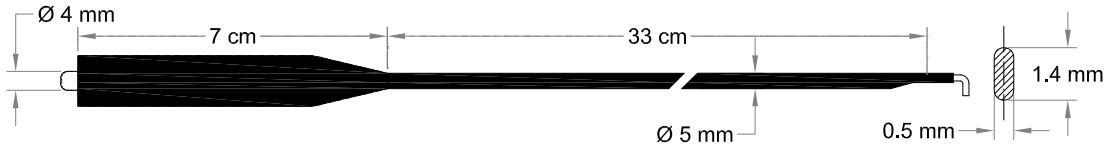
ACCESSORI MONOPOLARI PER LAPAROSCOPIA
MONOPOLAR ACCESSORIES FOR LAPAROSCOPIC SURGERY
ACCESSOIRES MONOPOLAIRES DE LAPAROSCOPIE
ACCESORIOS MONOPOLARES DE LAPAROSCOPIA

134° C
Autoclave

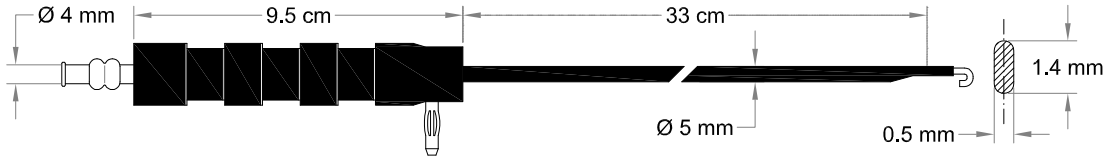
alsa® bologna
apparecchi medicali s.r.l.



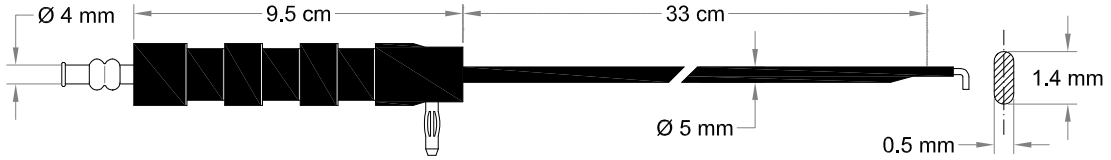
J/HOOK-Pedal Control — Senza aspirazione / Without suction / Sans aspiration / Sin aspiración — EL/ML-J



L/HOOK-Pedal Control — Senza aspirazione / Without suction / Sans aspiration / Sin aspiración — EL/ML-L

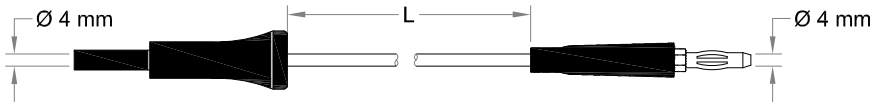


J/HOOK-Pedal Control — Con aspirazione / With suction / Avec aspiration / Con aspiración — EL/ML-JS

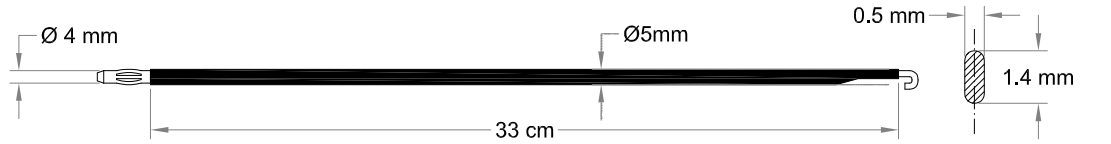


L/HOOK-Pedal Control — Con aspirazione / With suction / Avec aspiration / Con aspiración — EL/ML-LS

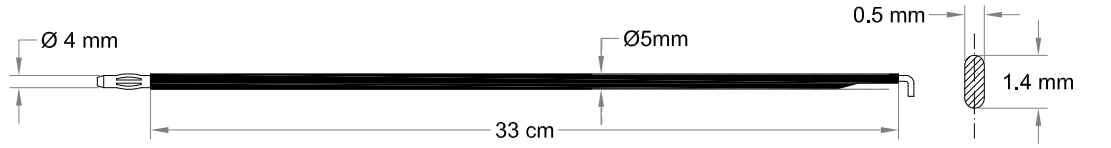
Cavo di collegamento per elettrodi EL/ML / Connecting cable for EL/ML electrodes
Câble de connection pour electrodes EL/ML / Cable de conexión para electrodos EL/ML



CPE (L = 3.5 m)
CPE/5 (L = 5 m)

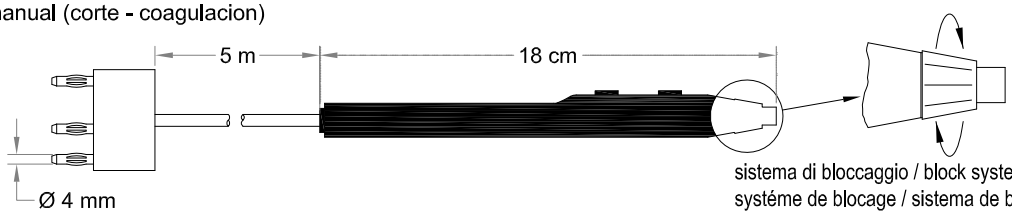


J/HOOK-Hand Control — Senza aspirazione / With no suction / Sans aspiration / Sin aspiración — EL/MLH-J



L/HOOK-Hand Control — Senza aspirazione / With no suction / Sans aspiration / Sin aspiración — EL/MLH-L

Manipolo con controllo manuale (taglio - coagulazione) / Pencil with hand control (cut - coag)
Poigneé porte-electrodes avec commande manuelle (coupe - coagulation) / Mango porta electrodos para mando manual (corte - coagulacion)



MPE/CMS-300/4

Elettrodo a lama per manico MPE/CMS 300-4 / Knife electrode for MPE/CMS 300-4 handle
Electrode à lame droite pour poigneé MPE/CMS 300-4 / Electrodo de cuchillo para mango MPE/CMS 300-4

EL/1-4

www.imq.it

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. **9120.ALSA**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ALSA APPARECCHI MEDICALI SRL

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

UNITA' OPERATIVE / *OPERATIVE UNITS*

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

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, immissione in commercio, assistenza tecnica e produzione conto terzi di elettrobisturi con o senza gas ARGON e relativi accessori, aspiratori chirurgici e relativi accessori, aspiratori di fumi elettrochirurgici e relativi accessori
Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-05-05	2022-03-18	2025-12-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

ALSA APPARECCHI MEDICALI SRL

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

has implemented and maintains a

Quality Management System

for the following scope:

Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: **2022 - 03 - 18**
Expires on: ***2025 - 12 - 19***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 1231

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. **9124.ALS2**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ALSA APPARECCHI MEDICALI SRL

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

UNITA' OPERATIVE / *OPERATIVE UNITS*

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

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione, immissione in commercio, assistenza tecnica e produzione conto terzi di elettrobisturi con o senza gas ARGON e relativi accessori, aspiratori chirurgici e relativi accessori, aspiratori di fumi elettrochirurgici e relativi accessori
Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1998-11-30	2022-03-18	2025-12-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 005 A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

IMQ
Organismo di Certificazione Federato CISQ
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FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 243267-2017-CE-KOR-NA-PS Rev. 2.0 Project No.: PRJC-533956-2015-MSL-KOR Valid Until: 27 May 2024

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

For design, production and final product inspection/testing of:

Ultrasound Doppler System with Foetal Doppler System Probes, Electric breast pump, Infant warmer, and Infant incubator

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 17 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Eugenie Winger Husebye
Technical Reviewer

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1012401, Rev 3.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	01 September 2017
1.0	EU Rep change	13 April 2018
2.0	**Recertification (Certificate no. 215934-2017-CE-KOR-NA-PS has been merged after the recertification audit completed)**	**17 March 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Ultrasound Doppler system with Probes	▪ BT-200L - AY-DOP-200L (2M) ▪ BT-200C - AY-DOP-200C (2M) ▪ BT-200S - AY-DOP-200S (2M) ▪ BT-200T - AY-DOP-200T (3M) ▪ BT-200V - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M) ▪ F-10 - AY-2MHZDOP-010 ▪ BT-220L - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-220C - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-250 - AY-DOP-250 (2M)	IIa
Electric Breast Pump	▪ BT-100 ▪ Milk Genie ▪ BT-150, BT-150L, BT-150B, BT-150S	IIa

Infant warmer	▪ BT-550	IIb
Infant incubator	▪ BT-500	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachiro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EU Representative

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

Management System Certificate

Certificate No.: 243275-2017-AQ-KOR-NA-PS Rev 4.0 Initial Certification Date: 12 August 2004 Valid Until: 09 September 2024

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

has been found to conform to the Quality Management System standard:

ISO 13485:2016/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

Design and Development, Manufacturing, Sales, Distribution, and Servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.

Place and date:
Høvik, 23 June 2021

For the issuing office:
DNV Product Assurance AS

Tone Kolpus

Tone Elise Kolpus
Lead Auditor

Check Validity

NORWEGIAN ACCREDITATION

MSYS 018

Site Name	Address	Site Specific Scope
Head Office	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea	Design and Development, Sales, Distribution, and Servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.
Factory	116~122ho, Jungang Induspia 3, 27, Sagimakgol-ro 105beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea	Manufacturing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.

Declaration of Conformity

Application of Council Directive(s):	Medical Device Directive 93/42/EEC
Standard(s) to which Conformity is Declared:	Safety: EN 60601-1 : 1990 EN 60601-1-1:2001 EN 60601-2-12:1998 EMC: EN 60601-1-2:2001
Manufacturer's Name: **Manufacturer's Address:**	CareFusion 22745 Savi Ranch Parkway Yorba Linda, CA 92887 USA
EU Notified Body: **European Authorized Representative:**	B.S.I. Product Services (Reg. No. 0086) CareFusion Germany 234 GmbH Leibnizstrasse 7 97204 Hoechberg - Germany
Conformity Assessment:	Medical Device Directive 93/42/EEC Annex I, II
Quality System:	ISO 13485:2003
Risk Assessment:	ISO/EN 14971:2000/A1:2003
Type of Equipment:	Medical Equipment, Adult/Pediatric Lung Ventilator
Tradename:	AVEA Series Ventilators
Device Classification:	**Class IIb**

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Place: Yorba Linda, CA 92262

Date: January 07, 2010

(Signature)

Thomas Gutierrez
(Full Name)

Director Regulatory Affairs
(Position/Title)

CareFusion

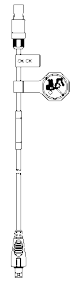
22745 Savi Ranch Pkwy., Yorba Linda, CA 92887 * Telephone: 714-283-2228 * 800-328-4139 * FAX: 714-283-8420
www.CareFusion.com


partsformed.com
Датчик потока 16465 для ИВЛ Avea Carefusion / Viasys / Vyaire

Reusable Heater Wire Adaptors

900MR858

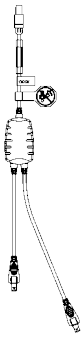
Inspiratory Heater Wire Adaptor for reusable circuits Lemo™ style



For use with the MR850 humidifier when paired with an inspiratory heated, reusable circuit

900MR556

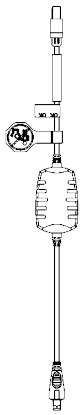
Dual Heater Wire Adaptor for reusable circuits Lemo™ style



For use with the MR730 humidifier when paired with a dual heated, reusable circuit

900MR558

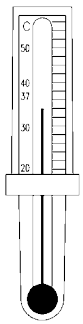
Inspiratory Heater Wire Adaptor for reusable circuits Lemo™ style



For use with the MR730 humidifier when paired with an inspiratory heated, reusable circuit

900MR033

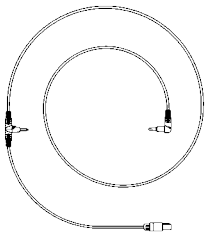
Airway Thermometer



- For measuring gas temperature when used in conjunction with the MR410 humidifier
- Available in packs of 3

900MR860-869 Temperature/Flow Probes for MR850 Humidifier

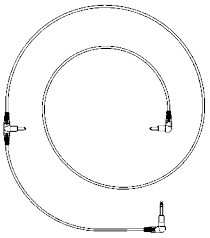
Right Angle Airway Probe



900MR863	for use with circuits 0.7m (28”) in length
900MR868	for use with circuits 1.1m (44”) in length
900MR860	for use with circuits 1.3m (52”) in length
900MR869	for use with circuits 1.5m (60”) in length
900MR861	for use with circuits 1.8m (72”) in length

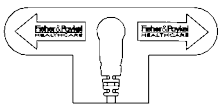
900MR560-571 Temperature Probes for MR700 & HC500 Series Humidifiers

Right Angle Airway Probe



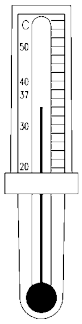
900MR563	for use with circuits 0.7m (28”) in length
900MR568	for use with circuits 1.1m (44”) in length
900MR560	for use with circuits 1.3m (52”) in length
900MR569	for use with circuits 1.5m (60”) in length
900MR561	for use with circuits 1.8m (72”) in length
900MR571	for use with circuits 2.5m (92”) in length

900MR208 Reflective Shield for Temperature Probe



- Protects airway temperature probe from radiant heat to improve humidifier performance with infant radiant warmers
- Available in packs of 20

900MR033 Airway Thermometer



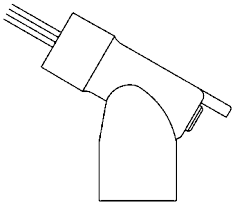
- For measuring gas temperature when used in conjunction with the MR410 humidifier
- Available in packs of 3

Reusable Inspiratory Heater Wires

Infant

900MR754 

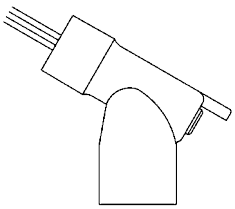
Heater Wire



- Flows ≥ 4L/min
- Use with reusable inspiratory tubing approximately 1.1m (43”) in length
- Compatible with MR850 & MR700 humidifiers
- Available as single item

900MR755 

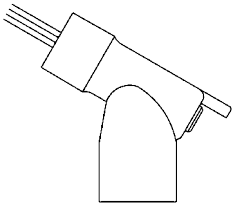
Heater Wire



- Flows < 4L/min
- Use with reusable inspiratory tubing approximately 1.1m (43”) in length
- Compatible with MR850 & MR700 humidifiers
- Available as single item

900MR524

Heater Wire

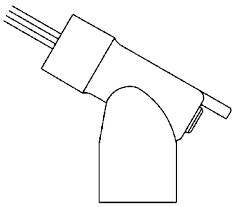


- For high frequency ventilation
- Use with reusable inspiratory tubing approximately 0.8m (30”) in length
- Compatible with MR700 humidifiers
- Available as single item

Adult

900MR751 

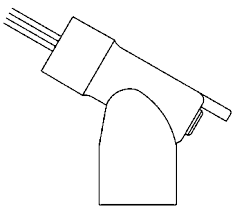
Heater Wire



- Heater wire assembly
- Use with reusable inspiratory tubing approximately 1.5m (60”) in length
- Compatible with MR850 and MR730 humidifiers
- Lemo™ connection
- Available as single item

900MR510 

Heater Wire



- Heater wire assembly
- Use with reusable inspiratory tubing approximately 1.3m (52”) in length
- Lemo™ connection
- Compatible with MR850 & MR730 humidifiers
- Available as single item

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010815 0038 Rev. 01

Manufacturer:

Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place
East Tamaki, Auckland 2013
NEW ZEALAND

Product Category(ies):

Respiratory Gas Delivery Systems, Heated Humidifiers, Continuous Positive Airway Pressure Units, Gas Powered Pulmonary Resuscitators, Nasal and/or Oral Interfaces for Delivery of Respiratory Gases, Patient Monitoring Software for Use with Fisher & Paykel Healthcare Medical Devices, Insufflation Gas Conditioning Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JAQ235040717**

Valid from: **2019-12-12**
Valid until: **2024-05-26**

Date, **2019-12-12**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010815 0038 Rev. 01

Facility(ies):

Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place, East Tamaki,
Auckland 2013, NEW ZEALAND

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010815 0037 Rev. 01

Holder of Certificate:
Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place
East Tamaki, Auckland 2013
NEW ZEALAND

Facility(ies):
Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place, East Tamaki,
Auckland 2013, NEW ZEALAND

See scope of certificate

Certification Mark:

Scope of Certificate:
Design and Development, Production and Distribution of Respiratory Gas Delivery Systems,
Heated Humidifiers, Infant Radiant Warmers,
Continuous Positive Airway Pressure Units,
CPAP Data Transmission Equipment,
Gas Powered Pulmonary Resuscitators,
Nasal and/or Oral Interfaces for Delivery of Respiratory Gases, Patient Monitoring Software for
Use with Fisher & Paykel Healthcare Medical Devices, Insufflation Gas Conditioning Systems

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 010815 0037 Rev. 01

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010815 0037 Rev. 01

Report No.:	**JA1669262**
Valid from:	**2021-11-14**
Valid until:	**2024-11-13**

Date, **2021-11-11**

Christoph Dicks
Head of Certification/Notified Body

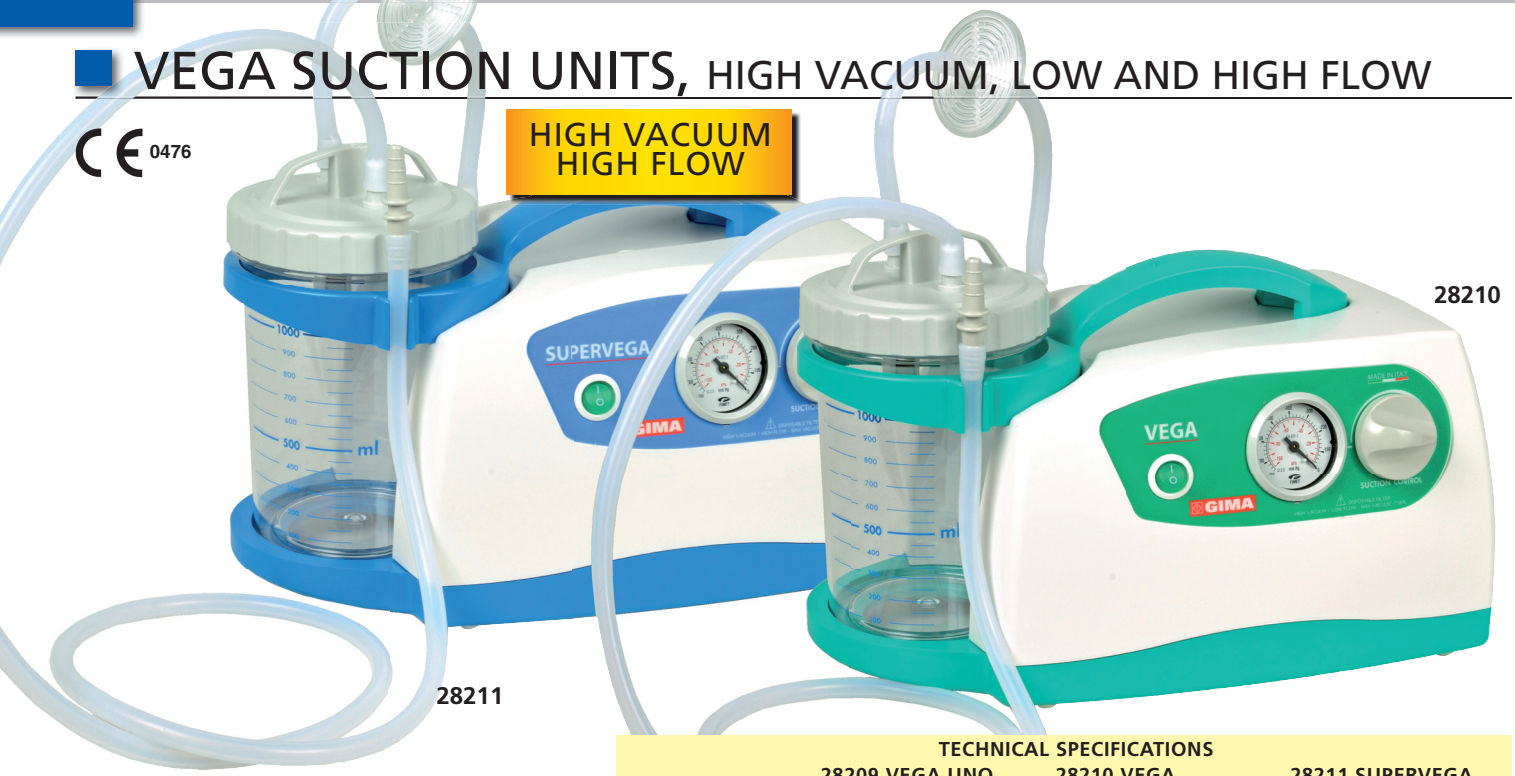
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

VEGA SUCTION UNITS, HIGH VACUUM, LOW AND HIGH FLOW

CE 0476

HIGH VACUUM
HIGH FLOW



28210

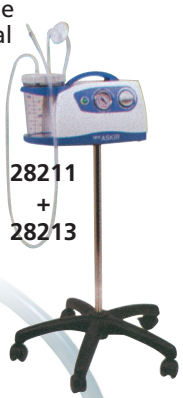
28211

VEGA SUCTION UNITS
A line of stylish, compact and reliable aspirators for small surgery. Silent, high flow and maintenance - free pumps allow long product life and durability.
Recommended for nasal aspiration, oral aspiration, tracheal aspiration of body liquids (mucus, catarrh or blood) in adults or children.
Equipped with vacuum regulator continuously adjustable, vacuum indicator, unbreakable 1,000 ml or 2,000 ml bottle, autoclavable at 121°C, with safety float control valve to prevent overflow. Optional bottle autoclavable at 134°C. Manufactured in electric and thermal insulated plastic body.
Autoclavable and disposable collection system: In addition to standard autoclavable jar is available a disposable collection system composed by a rigid reusable container and a polyethylene disposable liner with cover, hermetically sealed, and hydrophobic, antireflux, bacterial filter operating as an overflow valve.
Made in Italy.

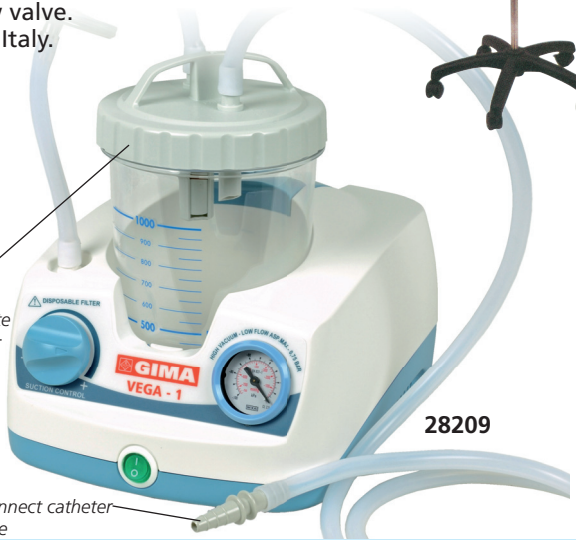
TECHNICAL SPECIFICATIONS

	28209 VEGA UNO	28210 VEGA	28211 SUPERVEGA
Operating Voltage:	220-230 V - 50/60 Hz 110 V - 60 Hz (on request)	220-230 V - 50/60 Hz 110 V - 60 Hz (on request)	220-230 V - 50/60 Hz or 110 V - 60 Hz
Power consumption:	184 W	184 W	106 W
Bottle capacity:	1,000 ml	1,000 ml	1,000 ml or 2,000 ml
Flow (air litres/min):	15 l/min	16 l/min	40 l/min
Max suction:	-0.75 bar (563 mm/Hg)	-0.75 bar (563mm/Hg)	-0.80 bar (600mm/Hg)
Operating cycle:	continuous	continuous	continuous
Size:	25x19x16.5 cm	35x21x18 cm	35x21x18 cm
Weight:	2.2 kg	2.5 kg	3.6 kg
Norms:	93/42/ECC	93/42/ECC	93/42/ECC

GIMA code	VEGA SUCTION ASPIRATOR	Operating power	Flow
28209	Vega Uno	220-230 V - 50/60 Hz	15 l/m
28210	Vega	220-230 V - 50/60 Hz	16 l/m
28211	Super Vega 1l	220-230 V - 50/60 Hz	40 l/m
28212	Super Vega 2l	220-230 V - 50/60 Hz	40 l/m
28189	Super Vega 1l	110 V - 60 Hz	40 l/m



28211
+
28213



1 l policarbonate autoclavable jar with overflow safety valve

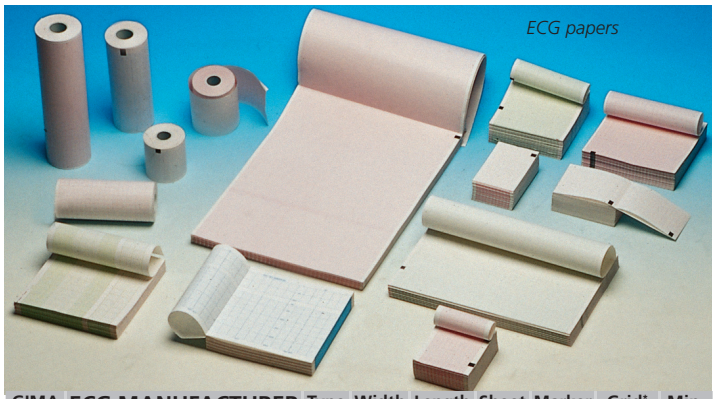
28209

28252
Adaptor to connect catheter to silicone tube

GIMA code	SPARE ACCESSORIES FOR VEGA AND TOBI LINE
28229	Hydrophobic, 99% antibacterial filter
28226	121°C autoclavable jar 1 l with cover and overflow system
28236	121°C autoclavable jar 2 l with cover and overflow system
28227	Cover and overflow valve system for 28226 and 28236
28185	134°C autoclavable jar 1 l with cover and overflow system
28186	134°C autoclavable jar 2 l with cover and overflow system
28184	Cover and overflow valve system for 28185 and 28186
28271	Disposable liner 1 l (cover + bag)
28270	Container for disposable liner 1 l
28268	Disposable liner 1 l (cover + bag) - box of 50
28273	Disposable liner 2 l (cover + bag)
28269	Disposable liner 2 l (cover + bag) - box of 50
28272	Container for disposable liner 2 l Ø 13 cm top, 9.5 cm bottom
25468	Silicone tube 6x10 mm - roll of 30 m
28252	Adaptor to connect catheter to silicone tube
	Suction catheter - see at page 43
28213	Trolley for Vega and Super Vega (not for Vega Uno)
28276	Vacuum indicator for Vega and Super Vega (not for Vega Uno)

STANDARD ACCESSORIES
Autoclavable jar (1 or 2 l) with overflow valve system
Antibacterial and hydrophobic filter
Set of silicone tubes 6x10 mm
Conical connector for probes
6 languages user manual (GB, FR, IT, DE, ES, PT) **28229**

GIMA ECG THERMAL PAPERS FOR DIFFERENT ECG BRANDS


ECG papers

GIMA code	ECG MANUFACTURER AND MODEL	Type	Width mm	Length m	Sheet	Marker	Grid*	Min. order
	ASPEL							
32951	Ascard A4, B56, Mr. Blue, Mr. Silver 3 Topaz, grey, v.07.204, orange, red, v.07.303	roll	112	25	-	no	or/red	10
32996	Ascard B5 eco, Mr. Green, mint	roll	58	25	-	no	or/red	20
32952	Ascard, Mr. Gold, Gold/3	roll	210	25	-	no	or/red	5
	BIOCARE							
32968	101G	roll	50	20	-	no	or/red	20
32989	300G, 3010	roll	63	30	-	no	or/red	20
32969	iE3	roll	80	20	-	no	or/red	10
33002	3030, 6010	roll	112	27	-	no	or/red	10
32992	1200	roll	210	30	-	no	or/red	5
32962	1210, 1215	pack	210	140	215	yes	or/red	10
33004	iE12, iE15	pack	210	150	200	yes	or/red	10
	BIOLIGHT							
32969	BLT, 1203A, E 30	roll	80	20	-	no	or/red	10
32966	E70, E80	pack	210	295	150	yes	or/red	1
	BIONET							
32950	Cardiocare/Cardiotouch	roll	215	25	-	no	or/red	5
	BIOSET-HORMAN							
32969	3800	roll	80	20	-	no	or/red	10
33050	Bioset 3600/3601/3700	pack	110	100	200	yes	or/red	10
33051	Bioset 8000 - 8100 - 9000 - 9100	pack	210	150	400	yes	or/red	5
	BTL							
32996	BTL 08/MT, 08/MD, 08/MD3	roll	58	25	-	no	or/red	20
32953	08 MT, MD	roll	112	23	-	no	or/red	10
32952	BTL 08/LC, 08/LT	roll	210	25	-	no	or/red	5
	BURDICK							
32954	Atria 3100/6100, quest	pack	210	300	200	yes	or/red	1
	CARDIOLINE							
32955	Elan 100	pack	112	100	300	yes	or/red	25
32956	Delta 1 plus	pack	60	100	300	yes	or/red	25
32957	Delta 1 plus	roll	60	30	-	no	or/red	20
32958	Delta 3 plus	pack	112	100	300	yes	or/red	25
32959	Delta 30	roll	183	30	-	no	or/red	5
32960	Delta 60 plus	roll	210	30	-	no	or/red	5
32961	Elan 2100, Delta 612	pack	210	280	200	yes	or/red	1
33053	ECG 100+	pack	100	150	200	yes	or/red	10
33054	AR/2100 (VIEW/ADV) - 66010042	pack	210	140	200	yes	or/red	8
33055	ECG 200+	pack	210	295	180	yes	or/red	1
	CAREWELL							
32963	ECG-1101B, 1101C, 1101G	roll	50	25	-	no	or/red	20
33025	ECG-1103B, 1103G, 1103L	roll	63	30	-	no	or/red	20
33058	ECG-1103GW, 1103LW	roll	80	30	-	no	or/red	10
33059	ECG-1106G, 1106L	roll	112	25	-	no	or/red	10
32950	ECG-1112L, 112M, T/12	roll	215	25	-	no	or/red	5
	COMEN							
32969	CM300	roll	80	20	-	no	or/red	10
32965	CM600	roll	110	20	-	no	or/red	20
32992	CM 1200 A/B	roll	210	30	-	no	or/red	5
32966	CM 1200 A/B	pack	210	295	150	yes	or/red	1
	CONTEC							
32968	90A, 100G	roll	50	20	-	no	or/red	20
32969	300G, 300GT	roll	80	20	-	no	or/red	10
32970	600G	roll	110	20	-	no	or/red	10
32967	1200, 1201	roll	210	30	-	no	or/red	5
	DIMED							
32963	LTD400	roll	50	25	-	no	or/red	20
32996	LTD410, Heartscreen 60G	roll	58	25	-	no	or/red	20
32964	LTD405S, LTD405W, LTD415 Heartscr. 80G	roll	80	25	-	no	or/red	10
32951	LTD418, Heartscreen 112	roll	112	25	-	no	or/red	10
32965	LTD440, LTD445/S	pack	110	140	143	yes	or/red	20
32960	LTD450, LTD455/S, LTD455/W	roll	210	30	-	no	or/red	5
32966	LTD450, LTD455/S, LTD455/W	pack	210	295	150	yes	or/red	1
	EDAN							
32963	SE-1	roll	50	25	-	no	or/red	20
32964	SE-3	roll	80	25	-	no	or/red	10
32965	SE-601	pack	110	140	143	yes	or/red	20
32966	SE-6, 12, 1200 EXP	pack	210	295	150	yes	or/red	1
32960	SE-6, 12, 1200 EXP	roll	210	30	-	no	or/red	5
32962	SE/1201	pack	210	140	215	yes	or/red	10
	ELETTRONICA TRENTINA/CARDIETTE/CARDIOLINE							
32971	Autoruler 12/1, comp. 1x12	roll	50	30	-	yes	blue	20
32972	Start 100	roll	130	27	-	yes	blue	10
32973	AR 600	roll	60	15	-	yes	blue	25
32977	AR 600 Adv	pack	60	75	250	yes	blue	25
32974	AR 1200	roll	120	18	-	yes	blue	10
32978	AR 1200 (View/Adv)	pack	120	100	300	yes	blue	10
32975	Daedalus, AR2100	roll	210	20	-	yes	blue	5
32976	Daedalus, Start 200, AR2100	pack	210	150	200	yes	blue	8
	ESAOTE BIOMEDICA							
32980	P 80 base	roll	90	28	-	no	or/red	10
32981	P 80 base	pack	90	70	400	yes	or/red	25
32982	P 80 Power, P 80 SIX	pack	210	280	215	yes	or/red	1
32983	P8000 base	pack	80	70	300	yes	or/red	20
32984	P8000 Power	pack	210	280	200	yes	or/red	1
32985	Archimed 4240, Archiwin	pack	210	300	200	yes	or/red	1
32986	Personal 120	pack	126	150	170	yes	white	20
32987	My Cardiopad base	pack	114	90	200	yes	or/red	20
33040	Esaote my Cardiopad 2157036	pack	210	140	180	yes	or/red	5
	FUKUDA ME - FUKUDA DENSHI							
32988	501A, FX121, FCP-500, OP18TE	roll	50	30	-	no	or/red	20
32989	FCP15, FCP11, OP110TE, OP119TE FCP2101, 2155, FX 2111, CASE10, FCP 7101, FX 7102	roll	63	30	-	no	or/red	20
32994	OP/358TE, FCP/131, FX3010, FX3101, FX-8822	roll	145	30	-	no	or/red	10
32990	OP 111 TE, OP 115 TE, FX102	pack	50	75	400	yes	or/red	20
32991	OP 112 TE, FX 2111, FX 7101, FX 7102, FCP 2201 G	pack	63	75	400	yes	or/red	25
32992	FCP231, OP69TE, FX7402, FX7542, FX 8322	roll	210	30	-	no	or/red	5
32993	OP/382TE, FX-3010, FX-8222	pack	145	75	400	yes	or/red	10
32965	OP222TE, FX7202	pack	110	140	143	yes	or/red	20
	GIMA							
32996	Cardiogima 1M, 3M	roll	58	25	-	no	or/red	20
32953	Cardiogima 6M, colour	roll	112	23	-	no	or/red	10
32950	Cardiogima 12, 12M	roll	215	25	-	no	or/red	5
	HEWLETT PACKARD							
32999	Page Writer 100/200, M1709A, M2483A	pack	210	300	200	hole	or/red	1
32988	40453 A, 43120	roll	50	30	-	no	or/red	20
	INNOMED							
32996	HearthMirror IKO 3, HeartScreen 60 IKO, 60 G	roll	58	25	-	no	or/red	20
32964	HeartScreen IKO 80G-L, 80C-L	roll	80	25	-	no	or/red	10
32953	HeartScreen 112 C-D	roll	112	23	-	no	or/red	10
	KENZ - SUZUKEN							
33002	Cardico 302/601	roll	112	27	-	no	or/red	10
33003	Cardico 302/601	pack	112	90	200	yes	or/red	20
32960	Kenz-Cardico 1210, 1211	roll	210	30	-	no	or/red	5
32988	103, R50-30R, TEC 8300	roll	50	30	-	no	or/red	20
	MARQUETTE - HELLIGE - GE							
33010	MAC PC	roll	108	23	-	no	or/red	10
33011	Case 10-12-15, MAC 3000-5000	pack	215	280	300	hole	or/red	1
32966	Cardiosmart, MAC 1200/1600	pack	210	295	150	yes	or/red	1
33012	MAC 400, MAC 600	pack	80	90	280	yes	or/red	25
33013	MAC 800	pack	110	140	200	yes	or/red	25
	MINDRAY							
33014	Beneheart R3	roll	80	20	-	no	or/red	10
33016	Beneheart R3	pack	80	70	200	yes	or/red	25
32966	BeneHeart R12	pack	210	295	150	yes	or/red	1
	MORTARA							
33017	Eli 50	pack	50	70	200	yes	or/red	25
33010	Eli 100	roll	108	23	-	no	or/red	10
33019	Eli 210, 250, 280, 350, 380	pack	210	300	250	yes	or/red	1
33020	Eli 150	pack	108	140	200	yes	or/red	25
33021	Eli 230	roll	210	20	-	no	or/red	5
	NIHON KOHDEN							
33025	CARDIOFAX 8110, 9620, 1150K	roll	63	30	-	no	or/red	20
33026	Cardio-fax GEM/1250/1950, ECG-9010/9020/9022	pack	210	140	215	yes	white	10
32962	Cardio-fax GEM/1250/1950, ECG-9010/9020/9022	pack	210	140	215	yes	or/red	10
33027	GEM 9010, 9020, 9022, 1250, 1950	pack	110	140	143	yes	white	20
33028	1500, 1550, 9110, 9130, 9132, 9320, 2250	pack	210	295	170	yes	white	1
	PHILIPS							
32998	Page Writer TC/10	roll	110	25	-	no	or/red	10
32999	Page Writer TC/50 - TC/70	pack	210	300	200	hole	or/red	1
32997	Touch, TRIM I / II / III, Page Writer TC/20, TC/30	pack	210	300	100	hole	or/red	1
	PROGETTI							
32953	EPG 612	roll	112	23	-	no	or/red	10
32996	EPG Basik-pocket	roll	58	25	-	no	or/red	20
	SCHILLER							
33037	AT 1, AT 4	pack	90	90	390	yes	green	25
32982	AT 2, CS 200	pack	210	280	215	yes	or/red	1
33038	AT 10	pack	210	140	250	yes	green	10
32983	AT 101	pack	80	70	300	yes	or/red	20
32984	AT 102	pack	210	280	200	yes	or/red	1
33039	AT110, AT 10 Plus,AT 2 Plus	pack	210	140	150	yes	green	5
32987	Cardiopad, MS 2010	pack	114	90	200	yes	green	20
33040	Esaote my Cardiopad 2157036	pack	210	140	180	yes	or/red	5
	SIEMENS							
32990	Cardiostat 1	pack	50	75	400	yes	or/red	20
32991	Cardiostat 11	pack	63	75	400	yes	or/red	25
	TRISMED							
32989	Cardipia 201N	roll	63	30	-	no	or/red	20
33046	Cardipia 400, 406RS	roll	110	30	-	no	or/red	25
33047	Cardipia 800, 812RS	roll	215	30	-	no	or/red	5

*or/red: grid could be orange or red colour

GIMA ULTRASOUND GEL

GIMA code	ULTRASOUND GEL	Minimum order
33269	Sterile ultrasound gel - sachet - 20ml - transp	box of 48
33271	Ultrasound gel - sachet - 20ml - transparent	box of 200
33270	Ultrasound gel - tube 60 ml - transparent	box of 12
33272	Ultrasound gel - tube 250 ml - blue	box of 40
33273	Ultrasound gel - tube 250 ml - transparent	box of 40
33274	Ultrasound gel - bottle 1 l - blue	box of 12
33275	Ultrasound gel - bottle 1 l - transparent	box of 12
33276	Ultrasound gel - tank 5 l - blue	box of 2*
33277	Ultrasound gel - tank 5 l - transparent	box of 2*
33278	Ultrasound gel - bag 5 l - blue	box of 4**
33279	Ultrasound gel - bag 5 l - transparent	box of 4**
33283	Pump for tank 5 l and bag 5 l	

**includes 2 empty bottles 250 ml ** includes 4 empty bottles 250 ml and 1 nozzle*

GIMA ULTRASOUND GEL
Hypoallergenic, water soluble gel suitable for ultrasonography, doppler and defibrillator applications. It ensures the ultrasound waves come to the equipment display in a clear and uninterrupted way. Salt, formaldehyde, fragrance free.

GEL CLEANER

• 33281 GEL PROBE CLEANER 250 ml
It removes the gel left over the probe, makes the image clearer and extends the probe life.
Thanks to the active agents contained, it prevents the bacteria to pass from patient to patient, and it ensures hygiene.
Alcohol-free.

TECARTHERAPY CREAM

• 33251 TECARTHERAPY CREAM 1 l
It allows to reduce the contact impedance between the probe and the skin.
The high conductivity ensures the best results both in the capacitive phase and in the resistive phase of the treatment.
Preservatives and dyes used are non-toxic.
Latex free.

EEG PASTE

• 33262 EEG PASTE - 400 g
Used with EEG electrodes in EEG application for brain mapping. Thanks to the active substances in its content, it allows the electrode to cling to the strand of hair easily and provides conductivity.
It is hypoallergenic, does not irritate skin, soluble in water and can be cleaned easily.
Does not contain oil and oily substances.
It has no toxic effects and odour.

COSMETIC GEL

KONIX COSMETIC LASER & CAVITATION GEL
Laser & Cavitation gel reduces the pain that patients experience during depilation and makes the device last longer by cooling the device head and window.
Thanks to the vacuum technology, its active substances and its high viscosity it preserves probe from damages.
It is not affected by the body salt during the use, ensures an easy application.
Technical properties: it is hypoallergenic, does not irritate skin, is water soluble and easily cleanable.
Oily substances, formaldehyde and salt free.
No toxic effects and odourless.

GIMA code	COSMETIC LASER & CAVITATION GEL	Minimum order
33253	Cosmetic gel - tube 250 ml	box of 40
33254	Cosmetic gel - bottle 1 l	box of 12
33255	Cosmetic gel - bag 5 l	box of 4**
33283	Pump for bag 5 l	

*** includes 4 empty bottles 250 ml and 1 nozzle for easy refill*

CERTIFICATE

Reg. Number	10164 - M	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid until	2024-10-14		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and production, packaging and service of:
General non-active, non-implantable medical devices (except: injection, infusion, transfusion and dialysis; disinfecting, cleaning, rinsing; IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except: extra-corporal circulation, infusion and haemopheresis; stimulation or inhibition, rehabilitation devices and active prostheses; IVF, ART; software; medical gas supply systems and parts thereof), Monitoring devices, Devices for imaging and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices (IVD).
Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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www.kiwa.it

GIMA S.p.A.
Registered Headquarters
- Via Grossi, 2 20121 Milano Italia

Certified Sites
- Via Marconi, 1 20060 Gessate (MI) - Italia

SGQ N° 007A

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

Sede Operativa / *Operational Headquarter:*
Via Marconi, 1
20060 Gessate, MI - Italia
Sede Legale / *Registered Headquarter*
Via Tommaso Grossi, 2
20121 Milano, MI - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*
Dispositivi per aerosolterapia / *Aerosol therapy devices*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxigen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

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Rif. rapporto di audit/ *Ref. audit report:* del/dated 1-2/3/2021

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:11:29

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1104

Marca / *Brandname:*
VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / Model:

Aspiratori chirurgici / Surgical aspirators

Codici / Codes:

28220 ; 28216 ; 28209 ; 28214 ; 28210 ; 28232 ; 28211 ; 28202 ; 28212 ; 28233 ; 28243 ; 28234 ; 28222 ; 28194 ; 28224; 28196 ; 28208 ; 28198 ; 28190 ; 28200 ; 28191 ; 28192 ; 28201 ; 28231 28203 ; 28215 ; 28204 ; 28193 ; 28183 ; 28182

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

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Chief Operating Officer
Giampiero Belcredi

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CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Modello / Model:

Spatula cervicale monouso sterile in plastica o legno / Disposable sterile plastic or wooden cervical spatula

Codici / Codes:

29745 ; 29748-29749

Modello / Model:

Speculum vaginale monouso sterile perno centrale - mix / Disposable sterile vaginal speculum central pin - mix

Codici / Codes:

29991

Modello / Model:

Speculum vaginale monouso sterile perno centrale - piccolo, medio, grande / Disposable sterile vaginal speculum central pin - small, medium, large

Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

Speculum vaginale monouso sterile tache - mix / Disposable sterile vaginal speculum tache - mix

Codici / Codes:

29987

Modello / Model:

Speculum vaginale monouso sterile vite centrale - mix / Disposable sterile vaginal speculum middle screw - mix

Codici / Codes:

29995

Modello / Model:

Speculum vaginale monouso sterile vite laterale - mix / Disposable sterile vaginal speculum side screw - mix

Codici / Codes:

29986

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Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Modello / Model:

Speculum vaginale monouso sterile vite laterale (piccolo, medio, grande) / Disposable sterile vaginal speculum side screw - small, medium, large

Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di trasport in plastica sterile / Sterile plastic transport swab

Codici / Codes:

29753

Marca / *Brandname:*
Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Codici / Codes:

29735 ;29736 ; 29737

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Proctoscopio adulti / Adult proctoscope

Codici / Codes:

25957

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Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per aerosolterapia / *Aerosol therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Modello / Model:

Aerosol a pistone adulti e bambini / Adult and Kids compressor nebulizers

Codici / Codes:

28091 ; 28092

Marca / *Brandname:*
EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / *Brandname:*
MISTRAL

Modello / Model:

Aerosol professionale a pistone per uso domiciliare / Professional compressor nebulizers for home healthcare environment

Codici / Codes:

28102

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Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 0104

Marca / *Brandname:*
BOSTON / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TECNICO PROFEXIONAL / DAYTON

Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:
32731 ; 32747; 32749 ; 32719 ; 32725; 32726 ; 32709; 32727; 32728; 32738; 32734 ; 32693/10965 ; 32735 ; 32745

Marca / *Brandname:*
SIRIO

Modello / Model:
Manometro Aneroide / Aneroid manometer

Codici / Codes:
32904

Marca / *Brandname:*
YTON

Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:
32720; 32703; 32693; 32701

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MDS 7010

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Chief Operating Officer
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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital SphygmomanometersWRIST / ARM

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / *Brandname:*
DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxigen saturation measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Codici / Codes:

34266; 34282; 34285, 34285-10997, 34340; 34342; 34265; 35091; 35092; 35093; 35095; 35090 ; 35100

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Chief Operating Officer
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Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:13:36

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

Marca / *Brandname:*
DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

Marca / *Brandname:*
FARMAMED / LINEA F / CARREFOUR / GS /PBpharma / 36.2 T&B / SUCCHIOTTO °C / BASALE / GIMA

Modello / Model:

Termometri clinici digitali classici e flessibili / Digital clinical thermometers classic and flexible

Codici / Codes:

25560; 305026-10945; 25561; 25560-10907; 305027-10946 ; 25608

Marca / *Brandname:*
FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / *Brandname:*
PBpharma /GIMA

Modello / Model:

Termometri clinici digitali auricolari e frontali multifunzione / Digital clinical ear and ahaed multifunction thermometers

Codici / Codes:

25580 ; 25585

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

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CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 1301, MD 0104

Modello / Model:

Altimetro - Plicometro - Metro per neonati / Height meter - Skinfold caliper - Baby measuring meter

Codici / Codes:

27335 ; 27344; 27331

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0101, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Codici / Codes:

34431, 34432, 34433, 34434, 34435, 34436, 34437, 34438; 34383; 34439

Modello / Model:

Maschere in silicone autoclavabili / Maschere autoclavabili in silicone GIMA PLUS / Silicone autoclavable face masks / Silicone autoclavable face masks GIMA PLUS

Codici / Codes:

34220, 34221, 34222, 34223, 34224, 34225 ; 34252, 34253, 34254, 34255; 34250

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Codici / Codes:

34424; 34425, 34426, 34427, 34428, 34429

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Chief Operating Officer
Giampiero Belcredi

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Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit
Codici / Codes:

34245, 34246, 34247; 34248, 34277, 34249 ; 34244

Modello / Model:

Reservoir monouso (sacche ossigeno) e valvola / Oxygen reservoir and valve
Codici / Codes:

34257; 34258; 34275; 34279

Modello / Model:

Valvola PEEP e adattatore / Valvola antireflusso e posteriore / Peep valve and adapter / Non-rebreathing valve and intake valve
Codici / Codes:

34227 ; 34228 ; 34259 ; 34256

Tipologia / *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack
Codici / Codes:

34110 ; 34111

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:15:10

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

Kit per rimozione sutura / kit procedurale sutura / Suture removal pack / Suture procedure pack

Codici / Codes:

38950 ; 38951

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

Forbici per bende di Lister / Forbici chirurgiche standard / Lister bandage scissors / Standard surgical scissors

Codici / Codes:

388xx

Modello / Model:

Pinza di Magill / Pinza di Hartmann per orecchio / Magill forceps / Hartmann ear forceps

Codici / Codes:

388xx

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
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Firmato digitalmente da:BELCREDI GIAMPIERO
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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Modello / Model:

Forbici di Mayo / Forbici di Metzenbaum / Forbici Iris / Forbice ombelicale / Forbice per chirurgia orecchio di Bellucci / Pinze per medicazione standard / Pinze di Hunter-Splinter / Pinze emostatiche di Adson / Pinze emostatiche Halstead-Mosquito / Pinza per dissezione McIndoe / Pinze di Pean / Pinza di Spencer-Wells / Pinza portatamponi di Foerster / Portaghi di Hegar- Mayo / Portaghi di Crile-Wood / Mayo scissors / Metzenbaum scissors / Iris scissors / Umbilical scissors / Bellucci ear scissors / Standard dressing forceps / Hunter-Splinter forceps/ Adson haemostatic forceps/ Halstead-Mosquito dissection forceps / McIndoe dissection forceps/ Pean forceps / Spencer-Wells forceps/ Foerster polypus forceps/ Hegar-Mayo needle holder / Crile-Wood needle holder

Codici / Codes:

388xx ; 389xx

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
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Data:25/05/2021 10:16:08

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

TUBULAR ELASTIC EEG HEAD CAP
FOR BRIDGE ELECTRODES
SILICONE RUBBER
REUSABLE

Packaging: box containing 1 piece.

CODE	*BANDS*	*BAND DIAMETER*	*TYPE OF ELASTIC*
CUEP05R	*5 x 2*	*4 mm*	*Silicone rubber*

Packaging: box containing 1 piece.

CODE	*BANDS*	*BAND DIAMETER*	*TYPE OF ELASTIC*
CUEP15R	*6 x 2*	*4 mm*	*Silicone rubber*

Packaging: box containing 1 piece.

CODE	*BANDS*	*BAND DIAMETER*	*TYPE OF ELASTIC*
CUEP25R	*5 x 4*	*4 mm*	*Silicone rubber*

EAR ELECTRODE
REUSABLE

This electrode with elastic clamp must be placed on the ear lobe.
The electrode is made up of a plastic body and an Ag/AgCl recording area.

Packaging: box containing 1 piece.

CODE	*DIAMETER*	*CABLE LENGTH*	*INSTRUMENT END*
EARPLD1-10	10 mm	1.0 m	Ø 1.5 mm touchproof DIN42802

CONNECTION CABLE WITH Ø 2.5 mm PLUG FOR EEG BRIDGE ELECTRODES

REUSABLE

This cable is suitable for quick connection to the bridge electrodes with a Ø 2.5 mm hole.

Packaging: box containing 1 piece.

CODE	*CABLE LENGTH*	*INSTRUMENT END*
CUPL25P1-09	0.9 m	Ø 2.5 mm plug
CUPL25P1-12	1.2 m	Ø 2.5 mm plug

COLOUR: Yellow	*More available colours*

connection cable: extra-flexible antistatic TINSEL

CONNECTION
electrode end: Ø 2.5 mm inox male plug
EEG box end: Ø 1.5 mm touchproof DIN42802

CERTIFICATO CE

Certificato n. 121/MDD

Dichiarazione di approvazione del sistema qualità

(Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

SEI EMG SRL

35013 CITTADELLA (PD) - VIA SANTA CHIARA 12/1 (ITA) - Italy

mantiene nello stabilimento di:

35013 CITTADELLA (PD) - VIA SANTA CHIARA 10 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Agoelettrodi concentrici monouso per emg

Agoelettrodi monopolari monouso per emg e eeg

Agoelettrodi monopolari riusabili per emg, eeg e e.p

Agoelettrodi monouso per iniezione tossina botulinica

Elettrodi monouso a filo per emg

Modd. come da documento "ALLEGATO LISTA CODICI DISPOSITIVI CLASSE IIA rev. 00 del 06/04/2020"; valido solo se provvisto di timbro IMQ.

ai requisiti essenziali ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'All. V. Per i dispositivi di Classe IIb, questo certificato è valido solamente con il relativo certificato di Allegato III.

Riferimento pratiche IMQ:
10A9800252; 10A9800253; 10AA00181; 10AA00182; 10AA00183; 10AA00184; 10AB0007; 10AD00152; 10EK00019; COMEDCONMHDM120074952-01; DM13A0133601-01; DM15E0387553-01; DM16-0000436; DM19-0042884-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	1998-11-02
Data aggiornamento:	2020-04-23
Sostituisce:	2016-10-11
Data scadenza:	2024-05-26

DocuSign

IMQ

EC CERTIFICATE

Certificate No 121/MDD

Production Quality Assurance System Approval Certificate

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

SEI EMG SRL

35013 CITTADELLA (PD) - VIA SANTA CHIARA 12/1 (ITA) - Italy

manages in the factory of:

35013 CITTADELLA (PD) - VIA SANTA CHIARA 10 (ITA) - Italy

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

Single-use concentric electrode-needles for emg

Single-use monopolar for emg and eeg

Reusable monopolar electrode needle for emg, eeg and e.p

Single-use electrode needle for injection of botulinic toxine

Single-use filament electrodes for emg

Type ref. as to document "ALLEGATO LISTA CODICI DISPOSITIVI CLASSE IIA rev. 00 dated 06/04/2020"; valid only if provided with IMQ stamp.

with relevant essential requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V. For class IIb devices, this certificate is valid only with the relevant certificate of Annex III.

Reference to IMQ files Nos:
10A9800252; 10A9800253; 10AA00181; 10AA00182; 10AA00183; 10AA00184; 10AB0007; 10AD00152; 10EK00019; COMEDCONMHDM120074952-01; DM13A0133601-01; DM15E0387553-01; DM16-0000436; DM19-0042884-01.

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:	1998-11-02
Updated:	2020-04-23
Substitution Date:	2016-10-11
Expiry Date:	2024-05-26

DocuSign

IMQ

SEMG srl	PROGRAMMA DI ASSICURAZIONE QUALITÀ ALLEGATO
ALLEGATO – LISTA CODICI DISPOSITIVI CLASSE IIA	TF_000LC
Revisione: 00 Data: 06/04/2020	

La seguente tabella raccoglie la lista dei codici relativi ai dispositivi medici in classe IIa sottoposti a sorveglianza da parte dell'Ente Notificato CE0051 IMQ spa.

Categoria di Prodotto:	**Agoelettrodi concentrici monouso per EMG serie GA... GU...**
Codici :	**GAxxxyzz** **GA** = sigla fissa identificativa (agoelettrodo concentico uscita assiale) **xxx** = Lunghezza della cannula da 20 a 150millimetri **y** = Codifica del diametro della cannula (**A**=0,45; **B**=0,50; **C**=0,35; **D**=0,70; **E**=0,40 **F**=0,30) **zz** =nucleo esplorante (77=nucleo in Nickel Cromo, 31=nucleo platinato, **1L**= uscita laterale SFEMG) **GUxxxyzz-ll** **GU** = sigla fissa identificativa (agoelettrodo concentico uscita laterale) **xxx** = Lunghezza della cannula da 20 a 150millimetri **y** = Codifica del diametro della cannula (**A**=0,45; **B**=0,50; **C**=0,35; **D**=0,70; **E**=0,40 **F**=0,30) **zz** = nucleo esplorante (77=nucleo in Acciaio, 31=nucleo platinato) **-ll**= lunghezza del cavo di connessione in decimetri per ago non sganciabile (massimo 3 metri)

Categoria di Prodotto:	**Agoelettrodi monopolari monouso per EMG EEG e EP serie MU... e 42...**
Codici :	**MUxxxttyzz-ll** **MU** = Elettrodo monopolare monouso (sigla fissa) **xxx** = Lunghezza dello stelo espressa in millimetri (diametro spirale per tipologia R) da 10mm a 150mm **tt** = Carattere/i identificativo della tipologia (**S**=stelo dritto **T**= stelo dritto teflonato **U**=stelo ad uncino **R**=stelo ritorto a spirale **F**=stelo dritto con filo corto **G**=stelo uncino con filo corto **W**=stelo dritto con cavo/i e connettore **WC**== Codifica riservata a cavi piatti multivie **X**=stelo ad uncino con cavo e connettore) **Hn**=con n steli dritto con n cavi ritorti e connettori **A**=2 steli dritti accoppiati con cavi doppi ritorti e connettori) **ll**= lunghezza del cavo di connessione in decimetri per ago non sganciabile (massimo 3 metri) *per tipologia S T U F G:* **yz** = Diametro dello stelo espresso in centesimi di millimetro (da 0,15mm a 2,00mm) *per tipologia W X H A:* **y** = Codifica diametro stelo (**C**=0,35mm **F**=0,25mm **D**=0,60)

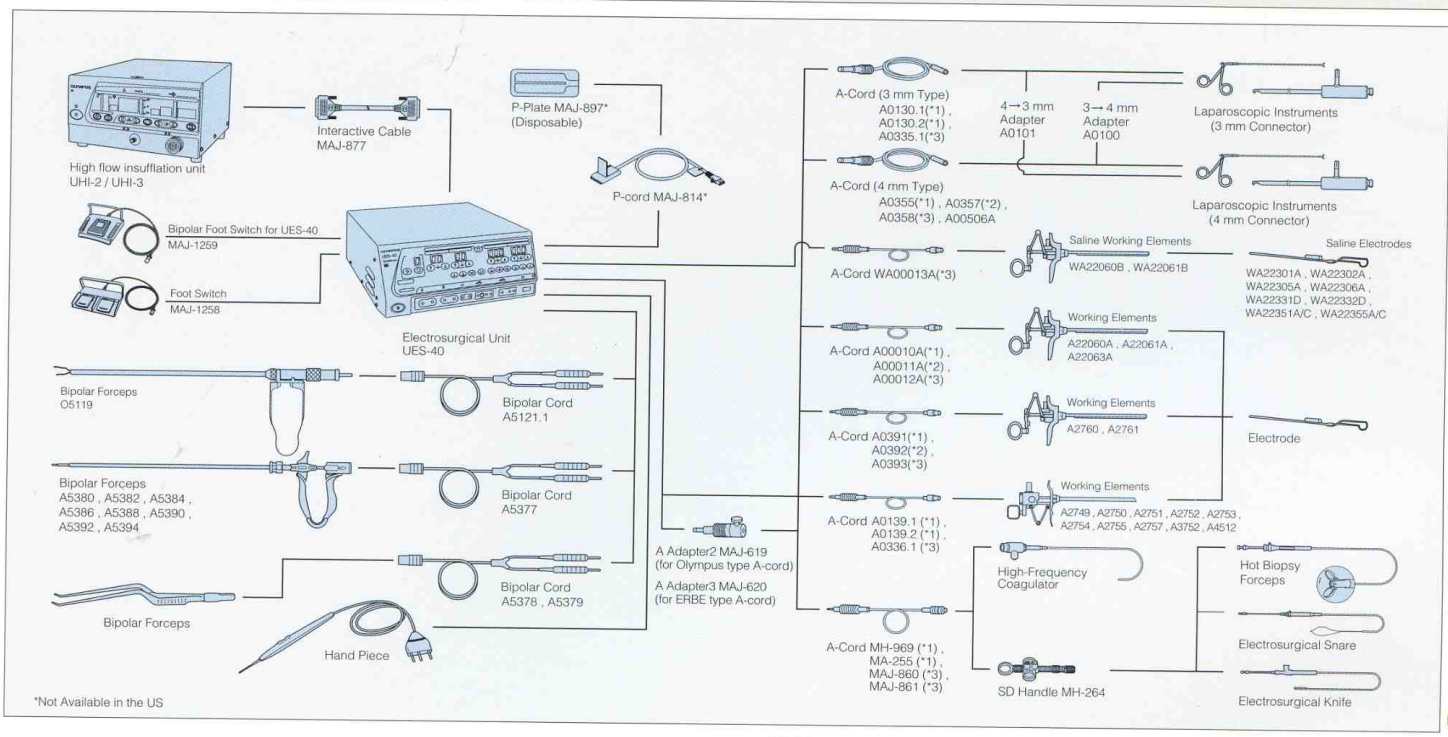
	z = Codifica plug terminale (**1**=sicurezza **2**=plug) il cavo schermato viene indicato con **SC** **42-xxxx** **42** = Elettrodo monopolare monouso per Dr.Langer (sigla fissa) **xxxx=** identificativo numerico da 0047 a 0065

Categoria di Prodotto:	**Agoelettrodi monopolari riusabili per EMG EEG e EP serie M...**
Codici :	**Mxxxtyybz-ll** **M** = Elettrodo monopolare riusabile (sigla fissa) **xxx** = Lunghezza dello stelo espressa in millimetri da 10mm a 150mm **t** = Carattere identificativo della tipologia (**S**=stelo dritto **U**=stelo ad uncino) **yy** = Diametro dello stelo espresso in centesimi di millimetro (da 0,15mm a 2,00mm) **b** = codifica cavo o attacco (**P**=PVC **S**=Silicone **J**=pin 0,5mm **K**=pin 1mm) **z** =Cifra indicante il tipo di plug terminale (**1**=femmina di sicurezza da 1,5mm 2=plug) **ll**= lunghezza del cavo di connessione se presente (massimo 3 metri)

Categoria di Prodotto:	**Agoelettrodi monouso per iniezione tossina botulinica serie ATF...**
Codici :	**ATFxxxy-ll** **ATF** = Elettrodo monouso per iniezione tossina botulinica (sigla fissa) **xxx** = Lunghezza della cannula espressa in millimetri da 25mm a 200mm **y** = Codifica diametro cannula (**A**=0,45mm; **B**=0,50; **C**=0,35; **D**=0,70; **E**=0,40; **F**=0,30; **G**=1.00) **ll**= lunghezza del cavo di connessione se presente (massimo 3 metri)

Categoria di Prodotto:	**Agoelettrodi monouso a filo per EMG serie FU...**
Codici :	**FUxxyzz** **FU** = Elettrodo monouso a filo (sigla fissa) **xx** = Lunghezza della cannula espressa in millimetri da 25mm a 99mm **y** = Codifica numero fili interni (M=2 fili S=1 filo) **zz**=Codifica tipo filo(**20**=Nickel-Cromo **77**=acciaio inox **21**=Nickel e puntalino 1mm)

System Chart



(*1) A Adapter2 MAJ-619 is required (*2) A Adapter3 MAJ-620 is required (*3) Directly connectable to UES-40

Standard Set

Electrosurgical Unit UES-40
Foot Switch for UES-40 MAJ-1258
Power Cord

Optional Accessories

Bipolar Electrode
O5119 / A5380 / A5382 / A5384 /
A5386 / A5388 / A5390 / A5392 / A5394

Bipolar Cord
A5121.1 / A5377 / A5378 / A5379

A Adapter2 MAJ-619
(for Olympus type A-cord)

A Adapter3 MAJ-620
(for ERBE type A-cord)

A-Cord
A0130.1 / A0130.2 / A0139.1 /
A0139.2 / A0335.1 / A0336.1 /
A0355 / A0357 / A0358 /
A0391 / A0392 / A0393 /
MA-255 / MH-969(A8406) /
MAJ-860(A02915A) / MAJ-861*(A02916A)
*Not Available in the US

Specifications

Item		Specification			
Applicability	Applicable field	General and endoscopic electrosurgery (restricted to endoscopes suitable for electrosurgery)			
High-frequency output	Output method	Monopolar , Bipolar, and saline modes			
	Output types	Monopolar Cutting modes: 3 modes (PURE, BLEND, URO) Coagulation modes: 3 modes (COAG.1, COAG.2, SPRAY)	Bipolar Cutting modes: 1 mode (PURE) Coagulation modes: 3 modes (SOFT1, SOFT2, HARD)		Saline Cutting modes: 2 modes (PURE, BLEND) Coagulation modes: 2 modes (COAG.1, COAG.2)
	Maximum output	Monopolar PURE : 300 W BLEND : 250 W URO : 300 W COAG.1 : 120 W COAG.2 : 120 W SPRAY : 120 W	Bipolar PURE : 90 W SOFT1 : 90 W SOFT2 : 90 W	HARD L1 : 80 W L2 : 120 W L3 : 160 W	Saline PURE : 320 W BLEND : 320 W COAG.1 : 200 W COAG.2 : 80 W
	Adjustment increments	5 W increments	0 to 20 W : 1 W increments 20 to 30 W : 2 W increments 30 to 90 W : 5 W increments	1LEVEL increments	5 W increments
	Rated load resistance	Monopolar 300 Ω	Bipolar 100 Ω (HARD 50 Ω)		
	Fundamental frequency	350 kHz / 1 MHz (for SPRAY)			
	Output control	Control by Foot Switch, Hand Switch or Handpiece. The following terminals can be controlled with the switches:			
		Foot switch for the UES-40 (MAJ-1258) ・Bipolar connector 1 ・Handpiece connector 1 ・Active connector ・Saline connector	Bipolar foot switch for the UES-40 (MAJ-1259) ・Bipolar connector 2		Handpiece for monopolar ・Handpiece connector 1 ・Handpiece connector 2
	Output time	10 seconds ON, 30 seconds OFF (in case of continuous output, keep the output time below 10 seconds)			
Power supply	Voltage	120 V / 220 - 240 V AC			
	Frequency	50 / 60 Hz			
	Input current	12 A (120 V) 6 A (220 - 240 V)			
	Electric power consumption	MAX 1,440 W (120 V) 1,380 W (220 - 240 V)			
Size	Dimensions	350 mm (W) x 150 mm (H) x 400 mm (D)			
	Weight	12.0 kg			

Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.

OLYMPUS®

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