

# HF SURGICAL UNITS

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**alsa<sup>®</sup>**

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Manufacturer of medical devices since 1932

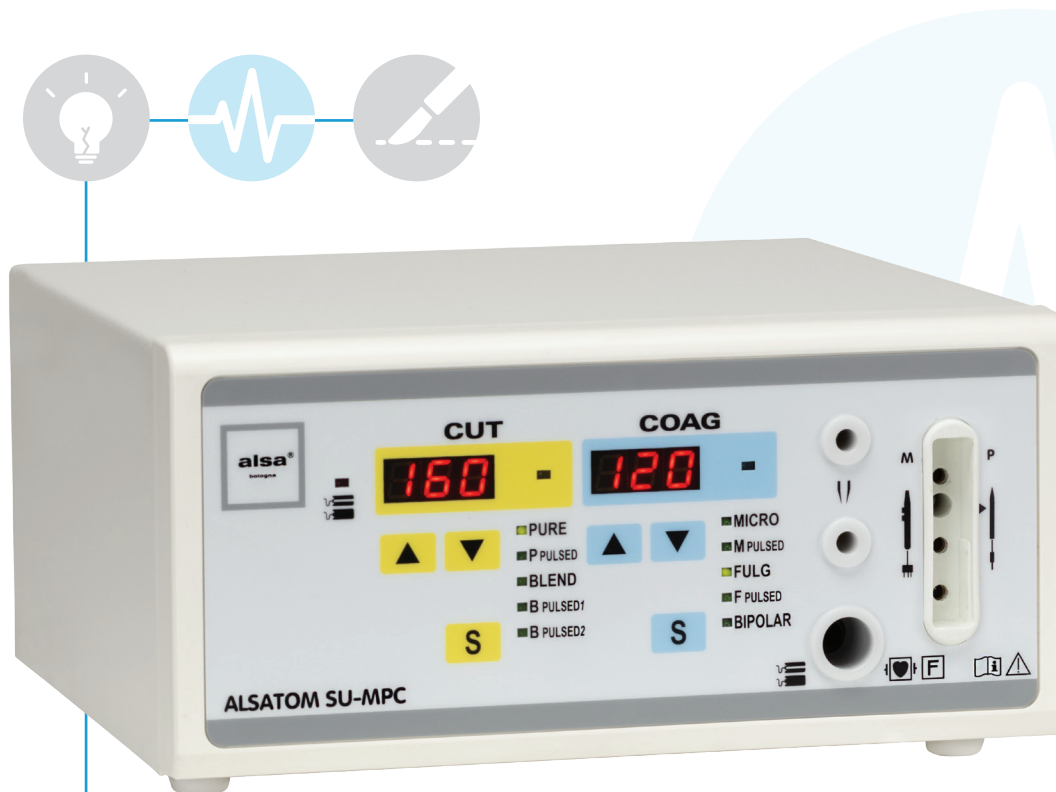


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# ALSATOM SU-MPC

ALSATOM SU 140/D-MPC



Electrosurgical unit for monopolar and bipolar surgery with direct, pulsed and timed currents

**ALSATOM SU-MPC** are intuitive high-performing electrosurgical units. They have both traditional currents and currents with pulsed delivery, which minimises thermal effects in tissues and reduces the harmful smokes generated by the use of electrosurgical units. By selecting them, operators can make fine cuts similar to those obtained with radiofrequency devices, and delicate coagulations that would otherwise be difficult to achieve. They are also equipped with a current for Micro-Coagulation that allows the delivery of single pulses varying from 0.1 sec to 1 sec.

**They are available in 5 models:**

- **ALSATOM SU 50-MPC, ALSATOM SU 100-MPC, ALSATOM SU 140-MPC, ALSATOM SU 140/D-MPC** for Monopolar, Bipolar, Monopolar use under liquid with miniresectors and 5Fr needles
- **ALSATOM SU 140/BD-MPC** for Bipolar use only in cutting and coagulation, as well as cutting, coagulation, saline vaporisation with miniresectors, 5Fr needles and arthroscopy instruments

## CURRENTS

### ALSATOM SU 50-MPC, SU 100-MPC, SU 140-MPC, SU 140/D-MPC

#### MONOPOLAR CURRENTS

|                   |                                                                                                                                                                     |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PURE</b>       | Pure Cut, suitable also for use in under liquid surgery in case of minor hysteroscopy procedures                                                                    |
| <b>P PULSED</b>   | Pure Pulsed Cut, suitable for very fine cuts, with minimum thermal effect (i.e. for conization of cervix or blepharoplasty) and to control surgical smoke           |
| <b>BLEND</b>      | Coagulating Cut                                                                                                                                                     |
| <b>B PULSED 1</b> | Coagulating Pulsed Cut. Similar to BLEND, but suitable to reduce the thermal effect and surgical smoke                                                              |
| <b>B PULSED 2</b> | Slow Coagulating Pulsed Cut. Similar to BLEND, but with slow pulses (i.e. for polypectomies)                                                                        |
| <b>MICRO</b>      | Delicate Coagulation, with low sparking effect                                                                                                                      |
| <b>M PULSED</b>   | Delicate Micro-Coagulation, with single pulses, which are adjustable from 0.1 sec to 1 sec. It is indicated for all micro-coagulations                              |
| <b>FULG</b>       | Macro-Coagulation "Fulguration" with strong sparks.<br>It is indicated to coagulate all tissues, even in under liquid surgery, and to perform high-coagulating cuts |
| <b>F PULSED</b>   | Macro-Coagulation "Fulguration", with fast pulses. Similar to FULG, but more delicate. It is indicated to reduce surgical smoke                                     |

#### BIPOLAR CURRENTS

|                |                                                                                                               |
|----------------|---------------------------------------------------------------------------------------------------------------|
| <b>BIPOLAR</b> | Bipolar Coagulation, to be used with forceps, scissors, double-needle electrodes and laparoscopic instruments |
|----------------|---------------------------------------------------------------------------------------------------------------|

## CURRENTS

### ALSATOM SU 140/BD-MPC

|                 |                                                                                                               |
|-----------------|---------------------------------------------------------------------------------------------------------------|
| <b>PURE</b>     | Cut for use in Open Surgery or Laparoscopy                                                                    |
| <b>P PULSED</b> | Pulsed Fast Cut, suitable to achieve detailed results, minimum thermal effect and reduction of surgical smoke |
| <b>BLEND</b>    | Coagulating Cut, with greater thermal effect                                                                  |
| <b>MACRO</b>    | Coagulation, to be used with forceps, scissors, double-needle electrodes and laparoscopic instruments         |
| <b>M PULSED</b> | Pulsed Coagulation. Similar to MACRO, but more delicate and useful to reduce surgical smoke                   |
| <b>MICRO</b>    | Micro-Coagulation, to be used with forceps, scissors, double-needle electrodes and laparoscopic instruments   |



## TECHNICAL FEATURES

|                                              |                                                                                                                                                                                                                                                                                 |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HF generator compliant with                  | IEC 60601-1 and IEC 60601-2-2                                                                                                                                                                                                                                                   |
| CE Classification                            | IIB                                                                                                                                                                                                                                                                             |
| IEC 60601-1 classification and type          | I CF                                                                                                                                                                                                                                                                            |
| IEC 60601-2-2 output circuit                 | Floating - protected for the use of a defibrillator (HF dispersion <150 mA)                                                                                                                                                                                                     |
| Monopolar and bipolar working frequency      | 450 kHz                                                                                                                                                                                                                                                                         |
| Operation check                              | Complete self-diagnosis using microprocessor, and possible operation lock with alarm by means of specific <b>Error Codes</b> in the event of problems relating to:<br>- general operation or activation errors (General Error Control)<br>- output power (Output Error Control) |
| Power self-adjustment                        | By microprocessor with:<br><b>ADC System</b> - Constant power: self-adjusts power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue                                                                           |
| Outputs                                      | 1 Monopolar and 1 Bipolar (for ALSATOM SU 140/BD-MPC 1 Bipolar only)                                                                                                                                                                                                            |
| Foot-operated controls                       | Single or double pneumatic control (for ALSATOM SU 140/D-MPC and ALSATOM SU 140/BD-MPC only)                                                                                                                                                                                    |
| Micro/macro power adjustment                 | 0-30 W = 1 W, over 30 W = 2 W                                                                                                                                                                                                                                                   |
| Panel                                        | Smooth, with digital displays and keys                                                                                                                                                                                                                                          |
| Neutral electrode safety circuit NPCC System | Control of the connection of the neutral electrode - and of the quality of the contact using double section/split electrodes - with alarm signal and possible lock of delivered power                                                                                           |
| Power supply                                 | 230 or 115 V - 50/60 Hz                                                                                                                                                                                                                                                         |
| Power consumption at 230 V                   | 370 VA                                                                                                                                                                                                                                                                          |
| Cooling                                      | Convection, without fan                                                                                                                                                                                                                                                         |
| Size (LxDxH) and weight                      | 25x24x12 cm – 4.5 Kg                                                                                                                                                                                                                                                            |

## OUTPUT POWERS

| Monopolar currents | ALSATOM<br>SU 50-MPC                                 | ALSATOM<br>SU 100-MPC                                 | ALSATOM<br>SU 140-MPC                                 | ALSATOM<br>SU 140/D-MPC                              |
|--------------------|------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| PURE               | 80 W - 500 Ω<br>980 Vpp - CF 1.5<br>M: no - D: 100%  | 100 W - 500 Ω<br>1000 Vpp - CF 1.5<br>M: no - D: 100% | 140 W - 500 Ω<br>1000 Vpp - CF 1.5<br>M: no - D: 100% | 160 W - 500 Ω<br>990 Vpp - CF 1.5<br>M: no - D: 100% |
| P PULSED           | 40 W - 500 Ω<br>1350 Vpp - CF 3<br>M: 50% - D: 100%  | 50 W - 500 Ω<br>1360 Vpp - CF 3<br>M: 50% - D: 100%   | 70 W - 500 Ω<br>1380 Vpp - CF 3<br>M: 50% - D: 100%   | 80 W - 500 Ω<br>1380 Vpp - CF 3<br>M: 50% - D: 100%  |
| BLEND              | 80 W - 500 Ω<br>1400 Vpp - CF 2.3<br>M: no - D: 80%  | 100 W - 500 Ω<br>1400 Vpp - CF 2.3<br>M: no - D: 80%  | 120 W - 500 Ω<br>1400 Vpp - CF 2.3<br>M: no - D: 80%  | 140 W - 500 Ω<br>1410 Vpp - CF 2.3<br>M: no - D: 80% |
| B PULSED 1         | 40 W - 500 Ω<br>1550 Vpp - CF 3.5<br>M: 50% - D: 80% | 50 W - 500 Ω<br>1550 Vpp - CF 3.5<br>M: 50% - D: 80%  | 60 W - 500 Ω<br>1550 Vpp - CF 3.5<br>M: 50% - D: 80%  | 70 W - 500 Ω<br>1600 Vpp - CF 3.5<br>M: 50% - D: 80% |
| B PULSED 2         | 35 W - 500 Ω<br>1580 Vpp - CF 3.6<br>M: 50% - D: 80% | 38 W - 500 Ω<br>1580 Vpp - CF 3.6<br>M: 50% - D: 80%  | 38 W - 500 Ω<br>1580 Vpp - CF 3.6<br>M: 50% - D: 80%  | 38 W - 500 Ω<br>1630 Vpp - CF 3.6<br>M: 50% - D: 80% |
| MICRO              | 80 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50%  | 80 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50%   | 80 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50%   | 100 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50% |
| M PULSED           | 80 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50%  | 80 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50%   | 80 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50%   | 100 W - 500 Ω<br>1530 Vpp - CF 3.4<br>M: no - D: 50% |
| FULG               | 80 W - 750 Ω<br>2250 Vpp - CF 3.5<br>M: no - D: 50%  | 100 W - 750 Ω<br>2300 Vpp - CF 3.5<br>M: no - D: 50%  | 120 W - 750 Ω<br>2300 Vpp - CF 3.5<br>M: no - D: 50%  | 120 W - 750 Ω<br>2280 Vpp - CF 3.5<br>M: no - D: 50% |
| F PULSED           | 40 W - 750 Ω<br>2300 Vpp - CF 5<br>M: 50% - D: 50%   | 48 W - 750 Ω<br>2300 Vpp - CF 5<br>M: 50% - D: 50%    | 60 W - 750 Ω<br>2300 Vpp - CF 5<br>M: 50% - D: 50%    | 60 W - 750 Ω<br>2270 Vpp - CF 5<br>M: 50% - D: 50%   |
| Bipolar currents   | SU 50-MPC                                            | SU 100-MPC                                            | SU 140-MPC                                            | SU 140/D-MPC                                         |
| BIPOLAR            | 80 W - 100 Ω<br>500 Vpp - CF 2.8<br>M: no - D: 100%  | 100 W - 100 Ω<br>500 Vpp - CF 2.8<br>M: no - D: 100%  | 100 W - 100 Ω<br>500 Vpp - CF 2.8<br>M: no - D: 100%  | 100 W - 100 Ω<br>500 Vpp - CF 2.8<br>M: no - D: 100% |

| Bipolar currents | ALSATOM<br>SU 140/BD MPC                              |
|------------------|-------------------------------------------------------|
| PURE             | 120 W - 400 Ω<br>975 Vpp - CF 2.75<br>M: no - D: 100% |
| P PULSED         | 60 W - 400 Ω<br>990 Vpp - CF 3.98<br>M: 50% - D: 100% |
| BLEND            | 100 W - 400 Ω<br>975 Vpp - CF 2.8<br>M: no - D: 80%   |
| MACRO            | 100 W - 100 Ω<br>640 Vpp - CF 3.6<br>M: no - D: 80%   |
| M PULSED         | 50 W - 100 Ω<br>640 Vpp - CF 5<br>M: no - D: 50%      |
| MICRO            | 100 W - 100 Ω<br>600 Vpp - CF 3.4<br>M: no - D: 50%   |

### KEY

**W:** DELIVERED POWER

**Ω:** NOMINAL LOADS

**Vpp:** PEAK/NO-LOAD PEAK VOLTAGES

**CF:** CREST FACTORS

**M:** MODULATION

**D:** DUTY CYCLE

# DEVICES AND STANDARD ACCESSORIES

**ALSATOM SU 140-MPC**, without accessories

**ALSATOM SU 100-MPC**, without accessories

**ALSATOM SU 50-MPC**, without accessories

**B700/A** STANDARD ACCESSORIES SERIES including:

- 1 STOP/PN Single pedal control, pneumatic, waterproof, explosion-proof
- 1 EIP/9 Stainless steel neutral electrode, 2.5 m cable
- 1 FFE Fixing belt for electrodes
- 1 MPE/F Sterilisable electrode holder handle, 2.5 m cable
- 1 SEL/VI Series of 6 active electrodes (2 E1 - Straight blade electrode, 1 E5 - Thick needle electrode, 1 E7 - Fine needle electrode, 1 E12 - Straight ball electrode Ø 2.5 mm, 1 E14 - Straight ball electrode Ø 4 mm)

**B700/B** STANDARD ACCESSORIES SERIES identical to B700/A, but with NP/GP flexible conductive rubber neutral electrode

**B700/D** As above, but for dental use, without EIP/9 and SEL/VI replaced, respectively, by EIP/S

- Manual neutral electrode, 2.5 m cable and SEL/D - set of 8 dental electrode



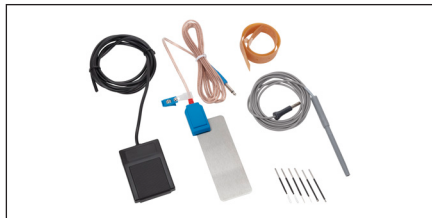
ALSATOM SU 140-MPC



ALSATOM SU 100-MPC



ALSATOM SU 50-MPC



B700/A



B700/B

**ALSATOM SU 140/D-MPC**, without accessories

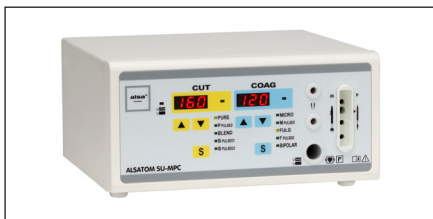
**B730/A** STANDARD ACCESSORIES SERIES including:

- 1 D-STOP/P Double pedal control, pneumatic, waterproof, explosion-proof
- 1 EIP/9 Stainless steel neutral electrode, 2.5 m cable
- 1 FFE Fixing belt for electrodes
- 1 MPE/F Sterilisable electrode holder handle, 2.5 m cable
- 1 SEL/VI Series of 6 active electrodes (2 E1 - Straight blade electrode, 1 E5 - Thick needle electrode, 1 E7 - Fine needle electrode, 1 E12 - Straight ball electrode Ø 2.5 mm, 1 E14 - Straight ball electrode Ø 4 mm)

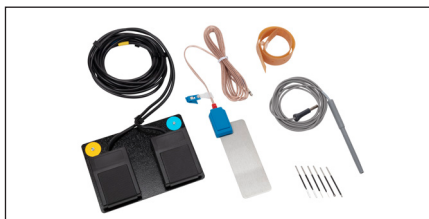
**B730/B** STANDARD ACCESSORIES SERIES identical to B730/A, but with NP/GP flexible conductive rubber neutral electrode

**B730/D** As above, but for dental use, without EIP/9 and SEL/VI replaced, respectively, by EIP/S

- Manual neutral electrode, 2.5 m cable and SEL/D - set of 8 dental electrodes



ALSATOM SU 140/D-MPC

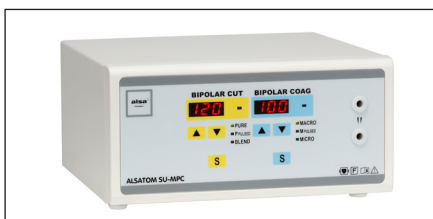


B730/A



B730/B

**ALSATOM SU 140/BD-MPC**, with D-STOP/P double pedal control



ALSATOM SU 140/BD-MPC

# EXCELL MCDSe



## Electrosurgical unit for monopolar and bipolar surgery

**EXCELL MCDSe** are electrosurgical units for advanced surgery, indicated for all monopolar, bipolar and monopolar techniques with Argon gas flow.

**They are available in 5 models:**

- **EXCELL 400 MCDSe, EXCELL 350 MCDSe, EXCELL 250 MCDSe, EXCELL 200 MCDSe** for electrosurgery
- **EXCELL 400/A MCDSe** both for electrosurgery and for electrosurgery with Argon gas, being equipped with an integrated Argon module

# CURRENTS

## MONOPOLAR CURRENTS

|                |                                                                                          |
|----------------|------------------------------------------------------------------------------------------|
| <b>PURE</b>    | Pure cut without any coagulating effect                                                  |
| <b>BLEND 1</b> | Coagulating cut with medium haemostatic effect                                           |
| <b>BLEND 2</b> | Coagulating cut with strong haemostatic effect, spray type                               |
| <b>ENDO</b>    | Coagulating cut with cut phases alternated to coagulation phases, for flexible endoscopy |

|                         |                                                                                |
|-------------------------|--------------------------------------------------------------------------------|
| <b>FULG FORCED</b>      | Coagulation with strong superficial and deep effect                            |
| <b>PINPOINT CONTACT</b> | Coagulation similar to the previous one, but softer                            |
| <b>SOFT</b>             | Very delicate coagulation, with soft superficial effect and strong deep action |
| <b>SPRAY</b>            | Coagulation without any contact and a very strong superficial effect           |

## BIPOLAR CURRENTS

|              |                                                |
|--------------|------------------------------------------------|
| <b>PURE</b>  | Pure cut with minimum coagulating effect       |
| <b>BLEND</b> | Coagulating cut with strong coagulating effect |

|                   |                                                                                                                             |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>MICRO</b>      | Very delicate coagulation, Micro Precise type, with minimum sticking effect of tissue on the tips of the forceps            |
| <b>MICRO AUTO</b> | Coagulation identical to Micro, but with Impedance Sensing automatic Auto Start/Auto Stop                                   |
| <b>MACRO</b>      | Coagulation Standard type, very rapid and efficacious, ideal for forceps with bigger section (for example, for laparoscopy) |



## TECHNICAL FEATURES

|                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HF generator compliant with                                     | IEC 60601-1 and IEC 60601-2-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| CE Classification                                               | IIb                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| IEC 60601-1 classification and type                             | I CF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| IEC 60601-2-2 output circuit                                    | Floating - protected for the use of a defibrillator (HF dispersion <150 mA)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Monopolar and bipolar working frequency                         | 440 kHz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Operation check                                                 | Complete self-diagnosis by means of a double microprocessor which performs: <ul style="list-style-type: none"> <li>- <b>Main Self-check</b> when turned on</li> <li>- <b>Standard Self-check</b> during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific <b>Error Codes</b>, in the event of problems concerning: <ul style="list-style-type: none"> <li>- general operation or activation errors (General Error Control)</li> <li>- output power (Output Error Control)</li> </ul> </li> <li>- <b>HF Leakage Control</b>: continuous verification, by means of a specific circuit, of any HF current dispersion to earth and possible automatic power reduction by means of an alarm signal</li> <li>- Storage of the last 32 Error Codes</li> </ul> |
| Power self-adjustment                                           | By microprocessor with: <ul style="list-style-type: none"> <li>- <b>ADC System</b> - Constant power: self-adjusts power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Operation memorisation                                          | 10 programs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Outputs                                                         | 2 Monopolar and 1 Bipolar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Foot-operated controls                                          | The EXCELL MCDSe can be equipped with: <ul style="list-style-type: none"> <li>• A double pedal control selectable for monopolar or bipolar functions.</li> <li>• Two double pedal controls, one for monopolar and one for bipolar functions.</li> </ul> The pedals are compliant with IEC 60601-2-2, waterproof (IP67), electric with 12 VDC low voltage power supply.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Micro/macro power adjustment                                    | Monopolar: 0-30 W = 1 W, 30-100 W = 2 W, 100-200 W = 5 W, over 200 W = 10 W<br>Bipolar: 0-10 W = 0.5 W, 10-30 W = 1 W, 30-100 W = 2 W, over 100 W = 5 W                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Panel                                                           | Smooth, with digital displays and keys                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Neutral electrode safety circuit NPCC System                    | Control of the connection of the neutral electrode - and of the quality of the contact using double section/split electrodes - with alarm signal and possible lock of delivered power.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Power supply                                                    | 230 or 115 V - 50/60 Hz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Power consumption at 230 V                                      | Max power 3.6 A = 828 VA, Stand-by 0.4 A = 92 VA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Cooling                                                         | Convection, without fan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Equipotential bonding                                           | Standard DIN 42801 plug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Size (LxDxH) and weight                                         | EXCELL 400/A MCDSe: 38x38x16 cm – 16 Kg<br>EXCELL 400 MCDSe, EXCELL 350 MCDSe, EXCELL 250 MCDSe, EXCELL 200 MCDSe: 38x35x16 cm – 15 Kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Argon gas section (only in the EXCELL 400/A MCDSe model)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Supply                                                          | One 5 litre cylinder or with centralised system                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Flow                                                            | Max 15 l/min                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Pressure                                                        | Inlet 2.5 atm / Outlet 1 atm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Flow check with Constant flow System                            | From 1 to 15 l/min by means of an electronic sensor with adjustment buttons and visual control on the LED bar. Automatic self-compensation based on the type of electrode used. Alarm if gas is absent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Pressure check in the Safety gas System circuit                 | Two-stage pressure reducer (on the cylinder and inside, with safety valve). Pressure sensor connected to the electronic control system, with Auto-Check when the gas section is switched on.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Protection of the supplied gas flow                             | Gas outlet equipped with antibacterial filter.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

# OUTPUT POWERS

| Monopolar currents | EXCELL 400 MCDSe                                           | EXCELL 350 MCDSe                                           | EXCELL 250 MCDSe                                           | EXCELL 200 MCDSe                                           | EXCELL 400/A MCDSe                                         |
|--------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| PURE               | 400 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 350 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 280 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 200 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 400 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       |
| BLEND 1            | 300 W – 350 Ω<br>3600 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 300 W – 350 Ω<br>3600 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 280 W – 350 Ω<br>3540 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 200 W – 350 Ω<br>3500 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 300 W – 350 Ω<br>3600 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  |
| BLEND 2            | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   |
| ENDO               | 250 W – 350 Ω<br>1880 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 220 W – 350 Ω<br>1880 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 220 W – 350 Ω<br>1880 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 200 W – 350 Ω<br>1880 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 250 W – 350 Ω<br>1880 Vpp – CF: 2.2<br>50% Pure / 50% Coag |
| FULG FORCED        | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  |
| PINPOINT CONTACT   | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 56%  | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 56%  | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 56%  | 200 W – 250 Ω<br>3400 Vpp – CF: 2.6<br>M: 29 kHz – D: 56%  | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 56%  |
| SOFT               | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | 200 W – 250 Ω<br>3020 Vpp – CF: 2,5<br>M: 29 kHz – D: 56%  | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  |
| SPRAY              | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   |
| Argon Coag         |                                                            |                                                            |                                                            |                                                            | SPRAY + ARGON GAS                                          |
|                    |                                                            |                                                            |                                                            |                                                            |                                                            |
| Bipolar currents   | EXCELL 400 MCDSe                                           | EXCELL 350 MCDSe                                           | EXCELL 250 MCDSe                                           | EXCELL 200 MCDSe                                           | EXCELL 400/A MCDSe                                         |
| PURE               | 140 W – 300 Ω<br>790 Vpp – CF: 1.5<br>M: no – D: no        | 140 W – 300 Ω<br>790 Vpp – CF: 1.5<br>M: no – D: no        | 140 W – 300 Ω<br>790 Vpp – CF: 1.5<br>M: no – D: no        | 140 W – 300 Ω<br>790 Vpp – CF: 1.5<br>M: no – D: no        | 140 W – 300 Ω<br>790 Vpp – CF: 1.5<br>M: no – D: no        |
| BLEND              | 120 W – 300 Ω<br>980 Vpp – CF: 1.8<br>M: 29 kHz – D: 75%   | 120 W – 300 Ω<br>980 Vpp – CF: 1.8<br>M: 29 kHz – D: 75%   | 120 W – 300 Ω<br>980 Vpp – CF: 1.8<br>M: 29 kHz – D: 75%   | 120 W – 300 Ω<br>980 Vpp – CF: 1.8<br>M: 29 kHz – D: 75%   | 120 W – 300 Ω<br>980 Vpp – CF: 1.8<br>M: 29 kHz – D: 75%   |
| MICRO              | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        |
| MICRO AUTO         | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no        |
| MACRO              | 120 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no        | 120 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no        |

## KEY

**W:** DELIVERED POWER  
**Ω:** NOMINAL LOADS  
**Vpp:** PEAK/NO-LOAD PEAK VOLTAGES  
**CF:** CREST FACTORS  
**M:** MODULATION  
**D:** DUTY CYCLE

# DEVICES AND STANDARD ACCESSORIES

**EXCELL 400 MCDSe**, without accessories

**EXCELL 350 MCDSe**, without accessories

**EXCELL 250 MCDSe**, without accessories

**EXCELL 200 MCDSe**, without accessories

**EXCELL 400/A MCDSe**, without accessories

**B610/A** STANDARD ACCESSORIES SERIES including:

1 DS/E Double pedal control, electric, waterproof

1 NP/A Stainless steel neutral electrode, 2.5 m cable

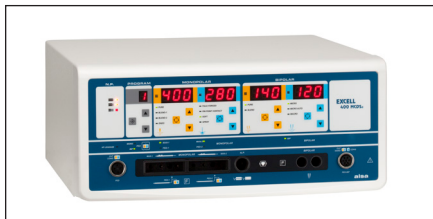
1 FGE Fixing belt for electrodes

2 MPE/E Sterilisable electrode holder, 3.5 m cable

1 SEL/E Series of 8 active electrodes (2 E1 - Straight blade electrode, 2 E5 – Thick needle electrode, 1 E7 - Fine needle electrode, 1 E12 - Straight ball electrode Ø 2.5 mm, 2 E14 - Straight ball electrode Ø 4 mm)

**B610/B** STANDARD ACCESSORIES SERIES identical to B610/A, but with NP/GA flexible conductive rubber neutral electrode for adults

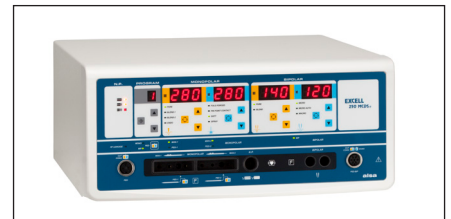
**B610/P** As above, with neutral paediatric electrode NP/GP



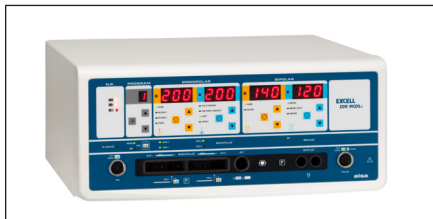
EXCELL 400 MCDSe



EXCELL 350 MCDSe



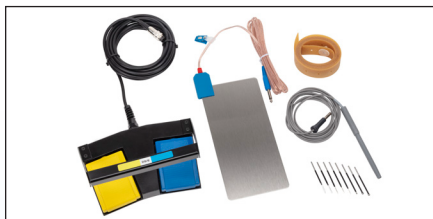
EXCELL 250 MCDSe



EXCELL 200 MCDSe



EXCELL 400/A MCDSe

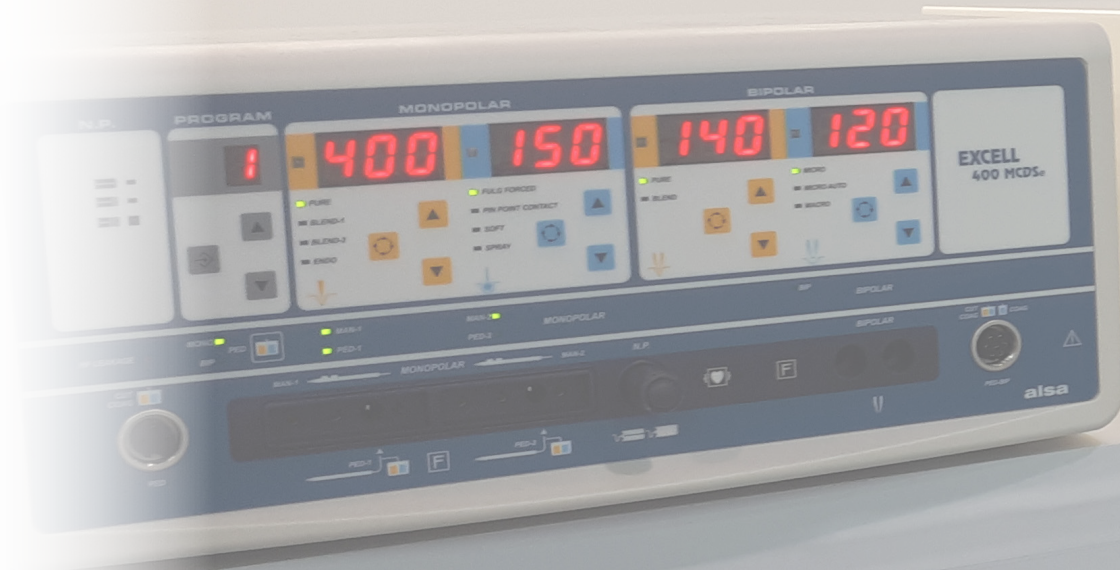


B610/A



B610/B

**alsa**  
bologna



# EXCELL NHP



EXCELL NHP 400/D

## Electrosurgical unit for monopolar and bipolar surgery

**EXCELL NHP** are electrosurgical units for advanced surgery, indicated for all monopolar, bipolar and monopolar techniques with Argon gas flow.

**They are available in 5 models:**

- **EXCELL NHP 400/D, EXCELL NHP 350/D and EXCELL NHP 250/D** for electrosurgery
- **EXCELL NHP 400/DA and EXCELL NHP 250/DA** both for electrosurgery and for electrosurgery with Argon gas, being equipped with an integrated Argon module

# CURRENTS

## MONOPOLAR CURRENTS

|                   |                                                                                                                 |
|-------------------|-----------------------------------------------------------------------------------------------------------------|
| <b>PURE</b>       | Non-modulated sinusoidal current for cutting without any coagulating effect                                     |
| <b>BLEND 1</b>    | Modulated and pulsed sinusoidal current for cutting with moderate coagulating effect                            |
| <b>BLEND 2</b>    | Modulated and pulsed current for cutting with strong coagulating effect, Spray type, for surgery or laparoscopy |
| <b>AUTO PURE</b>  | Non-modulated sinusoidal current for cutting without any coagulating effect                                     |
| <b>AUTO BLEND</b> | Modulated and pulsed sinusoidal current for cutting with moderate coagulating effect                            |
| <b>AUTO ENDO</b>  | Current with alternating cut and coagulation phases for flexible endoscopy                                      |

|                         |                                                                                                                                                                                                              |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>FULG FORCED</b>      | Modulated high-voltage current with optimum superficial and deep efficacy, suitable both for direct use with an active small section electrode and indirect use through insulated coagulation forceps        |
| <b>PINPOINT CONTACT</b> | Modulated medium-voltage current, very similar to the previous one, but with a more delicate effect                                                                                                          |
| <b>SOFT</b>             | Modulated low-voltage current with strong deep effect, and no superficial carbonisation. It is perfect for direct use with coagulation electrodes, or for indirect use through insulated coagulation forceps |
| <b>SPRAY</b>            | Modulated and pulsed very-high voltage current, with a very strong superficial effect and low penetration in the tissue. It is perfect for direct use without any contact, with small section electrodes     |

## BIPOLAR CURRENTS

|                   |                                                                                                                                                                                                                                                                                                     |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PURE</b>       | Non-modulated sinusoidal pulsed current for cut                                                                                                                                                                                                                                                     |
| <b>BLEND</b>      | Modulated and pulsed sinusoidal current for cut with coagulating effect                                                                                                                                                                                                                             |
| <b>MICRO CV</b>   | Non-modulated low voltage current for very delicate coagulations with Soft / Micro Precise effect, minimum superficial carbonisation, and no sticking on tissue                                                                                                                                     |
| <b>MICRO HC</b>   | Current with Standard Forced effect in order to rapidly coagulate vascularised sites and bleeding during procedures with saline solution, or to use instruments with large tips                                                                                                                     |
| <b>MICRO AUTO</b> | Identical to Micro CV, but with Impedance Sensing Auto Start / Auto Stop and Start Delay adjustable from 0 to 5 sec. It is perfect for the use with manual activation, and no need of special forceps with switch device                                                                            |
| <b>MACRO</b>      | Modulated and pulsed current with stronger effect than the Micro HC current                                                                                                                                                                                                                         |
| <b>SEAL HC</b>    | Pulsed current to coagulate and close big vessels with minimum superficial carbonization and no sticking of tissues. It can be activated through a pedal foot-switch, and thanks to the Auto Stop Impedance Sensing system it is very effective and easy to use, for laparoscopy procedures as well |

## TECHNICAL FEATURES

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HF generator compliant with                                                       | IEC 60601-1 and IEC 60601-2-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| CE Classification                                                                 | IIb                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| IEC 60601-1 classification and type                                               | I CF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| IEC 60601-2-2 output circuit                                                      | Floating - protected for the use of a defibrillator (HF dispersion <150 mA)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Monopolar and bipolar working frequency                                           | 440 kHz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Operation check                                                                   | Complete self-diagnosis by means of a double microprocessor which performs: <ul style="list-style-type: none"> <li>- <b>Main Self-check</b> when turned on</li> <li>- <b>Standard Self-check</b> during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific <b>Error Codes</b>, in the event of problems concerning: <ul style="list-style-type: none"> <li>- general operation or activation errors (General Error Control)</li> <li>- power supply (Output Error Control)</li> </ul> </li> <li>- <b>HF Leakage Control</b>: continuous verification, by means of a specific circuit, of any HF current dispersion to earth and possible automatic power reduction by means of an alarm signal</li> <li>- Storage of the last 32 Error Codes</li> </ul> |
| Power self-adjustment                                                             | By means of a microprocessor with two different systems: <ul style="list-style-type: none"> <li>- <b>ADC System</b> - Constant power: self-adjusts the power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue</li> <li>- <b>APC System</b> - Constant voltage: self-adjusts the power, keeping the voltage constant, based on a real-time feedback (7000 checks/sec) between device and patient's tissue</li> </ul>                                                                                                                                                                                                                                                                                                                                    |
| Operation memorisation                                                            | 100 programs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Outputs                                                                           | 2 Monopolar and 2 Bipolar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Foot-operated controls                                                            | EXCELL NHP units can be fitted with: <ul style="list-style-type: none"> <li>• A double pedal control selectable for monopolar or bipolar functions.</li> <li>• Two double pedal controls, one for monopolar and one for bipolar functions.</li> </ul> The pedals are compliant with IEC 60601-2-2, waterproof (IP67), electric with 12 VDC low voltage power supply.                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Micro/macro power adjustment                                                      | Monopolar: 0-30 W = 1 W, 30-100 W = 2 W, 100-200 W = 5 W, over 200 W = 10 W<br>Bipolar: 0-10 W = 0.5 W, 10-30 W = 1 W, 30-100 W = 2 W, over 100 W = 5 W                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Panel                                                                             | Smooth, with digital displays and keys                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Neutral electrode safety circuit NPCC System                                      | Control of the connection of the neutral electrode - and of the quality of the contact using double section/split electrodes - with alarm signal and possible lock of delivered power.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Power supply                                                                      | 230 or 115 V - 50/60 Hz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Power consumption at 230 V                                                        | Max power 3.6 A = 828 VA, Stand-by 0.4 A = 92 VA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Cooling                                                                           | Convection, without fan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Equipotential bonding                                                             | Standard DIN 42801 plug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Size (LxDxH) and weight                                                           | EXCELL NHP 400/DA and EXCELL NHP 250/DA: 38x38x16 cm – 16 Kg<br>EXCELL NHP 400/D, EXCELL NHP 350/D and EXCELL NHP 250/D: 38x35x16 cm – 15 Kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Argon gas section (only in EXCELL NHP 400/DA and EXCELL NHP 250/DA models)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Supply                                                                            | One 5 litre cylinder or with centralised system                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Flow                                                                              | Max 15 l/min                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Pressure                                                                          | Inlet 2.5 atm / Outlet 1 atm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Flow check with Constant flow System                                              | From 1 to 15 l/min by means of an electronic sensor with adjustment buttons and visual control on the LED bar. Automatic self-compensation based on the type of electrode used. Alarm if gas is absent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Pressure check in the Safety gas System circuit                                   | Two-stage pressure reducer (on the cylinder and inside, with safety valve). Pressure sensor connected to the electronic control system, with Auto-Check when the gas section is switched on.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Protection of the supplied gas flow                                               | Gas outlet equipped with antibacterial filter.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

# OUTPUT POWERS

Current self-adjustment

| Monopolar currents | EXCELL NHP 400/D                                           | EXCELL NHP 350/D                                           | EXCELL NHP 250/D                                           | EXCELL NHP 400/DA                                          | EXCELL NHP 250/DA                                          | ADC | APC |
|--------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|-----|-----|
| PURE               | 400 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 350 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 280 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 400 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 280 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | X   |     |
| BLEND 1            | 300 W – 350 Ω<br>3600 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 300 W – 350 Ω<br>3600 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 280 W – 350 Ω<br>3540 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 300 W – 350 Ω<br>3600 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 280 W – 350 Ω<br>3540 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | X   |     |
| BLEND 2            | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | X   |     |
| AUTO PURE          | 400 W – 350 Ω<br>1470 Vpp – CF: 1.6<br>M: no – D: no       | 350 W – 350 Ω<br>1350 Vpp – CF: 1.6<br>M: no – D: no       | 280 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       | 400 W – 350 Ω<br>1470 Vpp – CF: 1.6<br>M: no – D: no       | 280 W – 350 Ω<br>3450 Vpp – CF: 1.6<br>M: no – D: no       |     | X   |
| AUTO BLEND         | 300 W – 350 Ω<br>1930 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 300 W – 350 Ω<br>1930 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 280 W – 350 Ω<br>3540 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 300 W – 350 Ω<br>1930 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  | 280 W – 350 Ω<br>3540 Vpp – CF: 2.3<br>M: 29 kHz – D: 65%  |     | X   |
| AUTO ENDO          | 250 W – 350 Ω<br>1890 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 220 W – 350 Ω<br>1710 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 220 W – 350 Ω<br>1880 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 250 W – 350 Ω<br>1890 Vpp – CF: 2.2<br>50% Pure / 50% Coag | 220 W – 350 Ω<br>1880 Vpp – CF: 2.2<br>50% Pure / 50% Coag |     | X   |
| FULG FORCED        | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | 150 W – 350 Ω<br>4700 Vpp – CF: 4.5<br>M: 78 kHz – D: 35%  | X   |     |
| PINPOINT CONTACT   | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 50%  | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 50%  | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 50%  | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 50%  | 250 W – 250 Ω<br>3460 Vpp – CF: 2.6<br>M: 29 kHz – D: 50%  | X   |     |
| SOFT               | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | 280 W – 250 Ω<br>3440 Vpp – CF: 2.5<br>M: 29 kHz – D: 56%  | X   |     |
| SPRAY              | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | 140 W – 600 Ω<br>7600 Vpp – CF: 8.1<br>M: 19 kHz – D: 9%   | X   |     |
| Argon Coag         |                                                            |                                                            |                                                            | SPRAY + ARGON GAS                                          | SPRAY + ARGON GAS                                          | X   |     |

Current self-adjustment

| Bipolar currents | EXCELL NHP 400/D                                          | EXCELL NHP 350/D                                          | EXCELL NHP 250/D                                          | EXCELL NHP 400/DA                                         | EXCELL NHP 250/DA                                         | ADC | APC |
|------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----|-----|
| PURE             | 160 W – 300 Ω<br>850 Vpp – CF: 1.5<br>M: no – D: no       | 160 W – 300 Ω<br>850 Vpp – CF: 1.5<br>M: no – D: no       | 160 W – 300 Ω<br>850 Vpp – CF: 1.5<br>M: no – D: no       | 160 W – 300 Ω<br>850 Vpp – CF: 1.5<br>M: no – D: no       | 160 W – 300 Ω<br>850 Vpp – CF: 1.5<br>M: no – D: no       | X   |     |
| BLEND            | 130 W – 300 Ω<br>1000 Vpp – CF: 1.8<br>M: 29 kHz – D: 75% | 130 W – 300 Ω<br>1000 Vpp – CF: 1.8<br>M: 29 kHz – D: 75% | 130 W – 300 Ω<br>1000 Vpp – CF: 1.8<br>M: 29 kHz – D: 75% | 130 W – 300 Ω<br>1000 Vpp – CF: 1.8<br>M: 29 kHz – D: 75% | 130 W – 300 Ω<br>1000 Vpp – CF: 1.8<br>M: 29 kHz – D: 75% | X   |     |
| MICRO CV         | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       |     | X   |
| MICRO HC         | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | X   |     |
| MICRO AUTO       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>450 Vpp – CF: 1.7<br>M: no – D: no       |     | X   |
| MACRO            | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>760 Vpp – CF: 1.7<br>M: no – D: no       | X   |     |
| SEAL HC          | 130 W – 100 Ω<br>710 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>710 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>710 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>710 Vpp – CF: 1.7<br>M: no – D: no       | 130 W – 100 Ω<br>710 Vpp – CF: 1.7<br>M: no – D: no       | X   |     |

## KEY

**W:** DELIVERED POWER

**Ω:** NOMINAL LOADS

**Vpp:** PEAK/NO-LOAD PEAK VOLTAGES

**CF:** CREST FACTORS

**M:** MODULATION

**D:** DUTY CYCLE

**ADC:** CONSTANT POWER

**ADC:** CONSTANT VOLTAGE

## DEVICES AND STANDARD ACCESSORIES

**EXCELL NHP 400/D**, without accessories

**EXCELL NHP 350/D**, without accessories

**EXCELL NHP 250/D**, without accessories

**EXCELL NHP 400/DA**, without accessories

**EXCELL NHP 250/DA**, without accessories

**B610/A** STANDARD ACCESSORIES SERIES including:

1 DS/E Double pedal control, electric, waterproof

1 NP/A Stainless steel neutral electrode, 2.5 m cable

1 FGE Fixing belt for electrodes

2 MPE/E Sterilisable electrode holder, 3.5 m cable

1 SEL/E Series of 8 active electrodes (2 E1 - Straight blade electrode, 2 E5 - Thick needle electrode, 1 E7 - Fine needle electrode, 1 E12 - Straight ball electrode Ø 2.5 mm, 2 E14 - Straight ball electrode Ø 4 mm)

**B610/B** STANDARD ACCESSORIES SERIES identical to B610/A, but with NP/GA flexible conductive rubber neutral electrode for adults

**B610/P** As above, with neutral paediatric electrode NP/GP



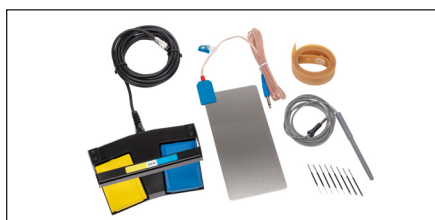
EXCELL NHP 400/D



EXCELL NHP 350/D



EXCELL NHP 250/D



B610/A



B610/B



# EXCELL NHP ENDOMED



EXCELL NHP ENDOMED

## Electrosurgical unit for monopolar and bipolar surgery

**EXCELL NHP ENDOMED** is a complete technologically advanced electrosurgical unit suitable for any type of monopolar and bipolar technique. It is also equipped with a special

bipolar cutting current in liquid, particularly suitable for the new bipolar endoscopic procedures in urology and gynaecology in saline solution.

# CURRENTS

## MONOPOLAR CURRENTS

|                    |                                                                                                                                                             |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PURE</b>        | Non-modulated sinusoidal current for pure cut without coagulating effect                                                                                    |
| <b>BLEND 1</b>     | Sinusoidal modulated current for coagulating cut                                                                                                            |
| <b>BLEND 2</b>     | Modulated current for cut with strong coagulating effect, Spray type, for surgery and laparoscopy                                                           |
| <b>AUTO PURE</b>   | Non-modulated sinusoidal current for cut without coagulating effect                                                                                         |
| <b>AUTO BLEND</b>  | Sinusoidal modulated current for coagulating cut                                                                                                            |
| <b>AUTO ENDO</b>   | Current with alternating cut and coagulation phases for flexible endoscopy                                                                                  |
| <b>FULG FORCED</b> | Modulated high voltage current with strong coagulating superficial and deep effect                                                                          |
| <b>PINPOINT</b>    | Modulated medium voltage current with medium coagulating superficial and deep effect                                                                        |
| <b>SOFT</b>        | Modulated low voltage current with delicate coagulating effect without superficial carbonisation                                                            |
| <b>SPRAY</b>       | Modulated very high voltage current for very strong superficial coagulation with a low tissue penetration, even without any contact of the active electrode |

## BIPOLAR CURRENTS

|                 |                                                                                                 |
|-----------------|-------------------------------------------------------------------------------------------------|
| <b>STANDARD</b> | Pulsed current for cut                                                                          |
| <b>SALINE</b>   | Pulsed current for endoscopic cut in saline solution                                            |
| <b>MICRO</b>    | Pulsed current for coagulation Soft / Micro Precise type and for coagulation in saline solution |
| <b>MACRO</b>    | Pulsed current for coagulation Standard / Forced type in laparoscopy                            |
| <b>SEAL</b>     | Pulsed current with automatic stop for sealing of big vessels up to 7 mm diameter               |



## TECHNICAL FEATURES

|                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HF generator compliant with                  | IEC 60601-1 and IEC 60601-2-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| CE Classification                            | IIb                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| IEC 60601-1 classification and type          | I CF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| IEC 60601-2-2 output circuit                 | Floating - protected for the use of a defibrillator (HF dispersion <150 mA)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Monopolar and bipolar working frequency      | 440 kHz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Operation check                              | Complete self-diagnosis by means of a double microprocessor which performs: <ul style="list-style-type: none"> <li>- <b>Main Self-check</b> when turned on</li> <li>- <b>Standard Self-check</b> during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific <b>Error Codes</b>, in the event of problems concerning: <ul style="list-style-type: none"> <li>- general operation or activation errors (General Error Control)</li> <li>- output power (Output Error Control)</li> </ul> </li> <li>- <b>HF Leakage Control</b>: continuous verification, by means of a specific circuit, of any HF current dispersion to earth and possible automatic power reduction by means of an alarm signal</li> <li>- Storage of the last 32 Error Codes</li> </ul> |
| Power self-adjustment                        | By means of a microprocessor with two different systems: <ul style="list-style-type: none"> <li>- <b>ADC System</b> - Constant power: self-adjusts the power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue</li> <li>- <b>APC System</b> - Constant voltage: self-adjusts the power, keeping the voltage constant, based on a real-time feedback (7000 checks/sec) between device and patient's tissue</li> </ul>                                                                                                                                                                                                                                                                                                                                    |
| Operation memorisation                       | 100 programs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Outputs                                      | 2 Monopolar and 1 Bipolar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Foot-operated control                        | EXCELL NHP ENDOMED can be equipped with a double pedal control that can be selected for monopolar or bipolar functions.<br>The pedal is compliant with IEC 60601-2-2, waterproof (IP67), electric with 12 VDC low voltage power supply.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Micro/macro power adjustment                 | Monopolar: 0-30 W = 1 W, 30-100 W = 2 W, 100-200 W = 5 W, over 200 W = 10 W<br>Bipolar: 0-10 W = 0.5 W, 10-30 W = 1 W, 30-100 W = 2 W, over 100 W = 5 W                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Panel                                        | Smooth, with digital displays and keys                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Neutral electrode safety circuit NPCC System | Control of the connection of the neutral electrode - and of the quality of the contact using double section/split electrodes - with alarm signal and possible lock of delivered power.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Power supply                                 | 230 or 115 V - 50/60 Hz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Power consumption at 230 V                   | Max power 3.6 A = 828 VA, Stand-by 0.4 A = 92 VA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Cooling                                      | Convection, without fan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Equipotential bonding                        | Standard DIN 42801 plug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Size (LxDxH) and weight                      | 38x35x16 cm – 15 Kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

## OUTPUT POWERS

| Monopolar currents | EXCELL NHP ENDOMED                                                 |
|--------------------|--------------------------------------------------------------------|
| PURE               | 350 W - 350 $\Omega$<br>3450 Vpp - CF: 1.6<br>M: no - D: no        |
| BLEND 1            | 300 W - 350 $\Omega$<br>3600 Vpp - CF: 2.3<br>M: 29 kHz - D: 65%   |
| BLEND 2            | 140 W - 600 $\Omega$<br>7600 Vpp - CF: 8.1<br>M: 19 kHz - D: 9%    |
| AUTO PURE          | 350 W - 350 $\Omega$<br>1350 Vpp - CF: 1.6<br>M: no - D: no        |
| AUTO BLEND         | 300 W - 350 $\Omega$<br>1930 Vpp - CF: 2.3<br>M: 29 kHz - D: 65%   |
| AUTO ENDO          | 220 W - 350 $\Omega$<br>1710 Vpp - CF: 2.2<br>50% Pure 50% Blend I |
| FULG FORCED        | 150 W - 350 $\Omega$<br>4700 Vpp - CF: 4.5<br>M: 78 kHz - D: 3,5%  |
| PINPOINT           | 250 W - 250 $\Omega$<br>3460 Vpp - CF: 2.6<br>M: 29 kHz - D: 50%   |
| SOFT               | 280 W - 250 $\Omega$<br>3440 Vpp - CF: 2.5<br>M: 29 kHz - D: 56%   |
| SPRAY              | 140 W - 600 $\Omega$<br>7600 Vpp - CF: 8.1<br>M: 19 kHz - D: 9%    |

Current self-adjustment

| ADC | APC |
|-----|-----|
| X   |     |
| X   |     |
| X   |     |
|     | X   |
|     | X   |
|     | X   |
| X   |     |
| X   |     |
| X   |     |
| X   |     |



| Bipolar currents | EXCELL NHP ENDOMED                                                 |
|------------------|--------------------------------------------------------------------|
| STANDARD         | 180 W - 350 $\Omega$<br>1200 Vpp - CF: 1.5<br>M: no - D: no        |
| SALINE           | 320 W - 50 $\Omega$<br>1200 Vpp - CF: 1.5<br>M: no - D: no         |
| MICRO            | 130 W - 100 $\Omega$<br>420 Vpp - CF: 1.7<br>M: no - D: no         |
| MACRO            | 130 W - 200 $\Omega$<br>1050 Vpp - CF: 1.7<br>M: no - D: no        |
| SEAL             | 130 W (200 W) - 100 $\Omega$<br>420 Vpp - CF: 1.7<br>M: no - D: no |

Current self-adjustment

| ADC | APC |
|-----|-----|
| X   |     |
| X   |     |
|     | X   |
| X   |     |
|     | X   |

### KEY

**W:** DELIVERED POWER  
**(W):** STARTING IMPULSE  
 **$\Omega$ :** NOMINAL LOADS  
**Vpp:** PEAK/NO-LOAD PEAK VOLTAGES  
**CF:** CREST FACTORS  
**M:** MODULATION  
**D:** DUTY CYCLE  
**ADC:** CONSTANT POWER  
**ADC:** CONSTANT VOLTAGE



# DEVICE AND STANDARD ACCESSORIES

**EXCELL NHP ENDOMED**, without accessories

**B610/A** STANDARD ACCESSORIES SERIES including:

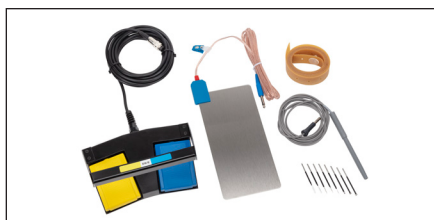
- 1 DS/E Double pedal control, electric, waterproof
- 1 NP/A Stainless steel neutral electrode, 2.5 m cable
- 1 FGE Fixing belt for electrodes
- 2 MPE/E Sterilisable electrode holder, 3.5 m cable
- 1 SEL/E Series of 8 active electrodes (2 E1 - Straight blade electrode, 2 E5 - Thick needle electrode, 1 E7 - Fine needle electrode, 1 E12 - Straight ball electrode Ø 2.5 mm, 2 E14 - Straight ball electrode Ø 4 mm)

**B610/B** STANDARD ACCESSORIES SERIES identical to B610/A, but with NP/GA flexible neutral conductive rubber electrode for adults

**B610/P** As above, with neutral paediatric electrode NP/GP



EXCELL NHP ENDOMED



B610/A



B610/B



# EXCELL NHP/T

EXCELL NHP/TA-400



Electrosurgical unit for monopolar and bipolar surgery with 7" touch screen display

**EXCELL NHP/T** are electrosurgical units for advanced surgery, indicated for all monopolar, bipolar and monopolar techniques with Argon gas flow.

**They are available in 4 models:**

- **EXCELL NHP/T-400** and **EXCELL NHP/T-200** for electrosurgery
- **EXCELL NHP/TA-400** and **EXCELL NHP/TA-200** both for electrosurgery and for electrosurgery with Argon gas, being equipped with the integrated Argon module

# CURRENTS

## MONOPOLAR CURRENTS

|                              |                                                                                                                                                                                                                  |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PURE CUT</b>              | Pure cut without coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)                                                                                  |
| <b>BLEND CUT 1</b>           | Blended cut with medium coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)                                                                           |
| <b>BLEND CUT 2</b>           | Blended cut with very high coagulating effect. For open or laparoscopic surgery                                                                                                                                  |
| <b>PURE CUT PULSED</b>       | Pure pulsed cut without coagulating effect. For open or laparoscopic surgery (suitable to reduce surgical smoke)                                                                                                 |
| <b>BLEND CUT PULSED</b>      | Blended pulsed cut with medium coagulating effect. For open or laparoscopic surgery (suitable to reduce surgical smoke)                                                                                          |
| <b>AUTO PURE CUT MICRO</b>   | "Constant voltage", delicate, pure cut without coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)                                                    |
| <b>AUTO BLEND CUT MICRO</b>  | "Constant voltage", delicate cut blended with a medium coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)                                            |
| <b>AUTO PAPILO PURE CUT</b>  | "Constant voltage" pure cut, without coagulating effect, for flexible endoscopy. With four modes of delivery: continuous and pulsed (slow, medium, fast)                                                         |
| <b>AUTO POLIPO BLEND CUT</b> | "Constant voltage" cut, blended with a medium coagulating effect, for flexible endoscopy. With four modes of delivery: continuous and pulsed (slow, medium, fast)                                                |
| <b>AUTO ENDOCUT</b>          | "Constant voltage" cut with alternating phases of BLEND and CUT, for flexible endoscopy. With four modes of delivery: 90% BLEND and 10% CUT, 80% BLEND and 20% CUT, 60% BLEND and 40% CUT, 50% BLEND and 50% CUT |

|                              |                                                                                                                                                              |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>FULG FORCED COAG</b>      | High-voltage, contact free coagulation. For open or laparoscopic surgery, under liquid endoscopy (TURP and TURV procedures), and for flexible endoscopy      |
| <b>SPRAY COAG</b>            | Very high voltage, contact-free coagulation. For open or laparoscopic surgery, under liquid endoscopy (TURP and TURV procedures), and for flexible endoscopy |
| <b>PULSED SPRAY COAG</b>     | Identical to the SPRAY COAG current, but pulsed and more delicate                                                                                            |
| <b>PINPOINT CONTACT COAG</b> | Medium voltage, contact coagulation. For open or laparoscopic surgery, under liquid endoscopy (TURP and TURV procedures), and for flexible endoscopy         |
| <b>SOFT MICRO COAG</b>       | Delicate, low voltage coagulation. For open or laparoscopic surgery                                                                                          |

## BIPOLAR CURRENTS

|                           |                                                                                                                                                                                  |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>STANDARD BICUT</b>     | Cut for open or laparoscopic surgery                                                                                                                                             |
| <b>BLEND BICUT</b>        | Blended cut with very high coagulating effect (Coagulation 95%) for open or laparoscopic surgery                                                                                 |
| <b>SALINE URO-GYN CUT</b> | Cut in saline with two modes of delivery: continuous and pulsed. For under liquid endoscopy (TURPis and TURVis procedures). The continuous delivery is suitable for vaporization |
| <b>SALINE ARTHRO CUT</b>  | Cut in saline with two modes of delivery: continuous and pulsed. For arthroscopy. The continuous delivery is suitable for vaporization                                           |

|                               |                                                                                                                                                                                                                                                       |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SOFT MICRO BICOAG</b>      | Very precise and delicate coagulation. For open or laparoscopic surgery, under liquid endoscopy (TURPis and TURVis procedures) and flexible endoscopy                                                                                                 |
| <b>FORCED MACRO BICOAG</b>    | Fast coagulation. For open or laparoscopic surgery                                                                                                                                                                                                    |
| <b>AUTO SOFT MICRO BICOAG</b> | Identical to SOFT MICRO BICOAG, but with Impedance Sensing automatic activation/deactivation. It is not suitable for endoscopy in saline. Activation with delay adjustable from 0 to 5 seconds and deactivation with two-tone, grave, acoustic signal |
| <b>SEALING</b>                | Current to coagulate/seal vessels up to 7 mm in open and laparoscopic surgery. Activation with pedal and automatic Impedance Sensing deactivation with two-tone, acute, acoustic signal                                                               |
| <b>AUTO SEALING</b>           | Identical to SEALING, but with Impedance Sensing automatic activation/deactivation. It is not suitable for endoscopy in saline. Activation with delay adjustable from 0 to 5 seconds and deactivation with two-tone, grave, acoustic signal           |

## TECHNICAL FEATURES

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| HF generator compliant with                                                       | IEC 60601-1 and IEC 60601-2-2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| CE Classification                                                                 | IIB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| IEC 60601-1 classification and type                                               | I CF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| IEC 60601-2-2 output circuit                                                      | Floating - protected for the use of a defibrillator (HF dispersion <150 mA)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Monopolar and bipolar working frequency                                           | 440 kHz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Operation check                                                                   | Complete self-diagnosis by means of a double microprocessor which performs: <ul style="list-style-type: none"> <li>- <b>Main Self-check</b> when turned on</li> <li>- <b>Standard Self-check</b> during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific <b>Error Codes</b>, in the event of problems concerning: <ul style="list-style-type: none"> <li>- general operation or activation errors (General Error Control)</li> <li>- output power (Output Error Control)</li> </ul> </li> <li>- <b>HF Leakage Control</b>: continuous verification, by means of a specific circuit, of any HF current dispersion to earth and possible automatic power reduction by means of an alarm signal</li> <li>- Storage of the last 32 Error Codes</li> </ul> |
| Power self-adjustment                                                             | By means of a microprocessor with two different systems: <ul style="list-style-type: none"> <li>- <b>ADC System</b> - Constant power: self-adjusts the power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue. The powers are equipped with Micro and Macro progressive regulation with steps from 0.1 W to 10 W. Monopolar (from 1 W to 10 W), Bipolar (from 0.1 W to 5 W).</li> <li>- <b>APC System</b> - Constant voltage: self-adjusts the power, keeping the voltage constant, based on a real-time feedback (7000 checks/sec) between device and patient's tissue. The powers are equipped with regulation with 10 effects (for each one the maximum power delivered in W is indicated).</li> </ul>                                              |
| Operation memorisation                                                            | 100 programs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Outputs                                                                           | 2 Monopolar and 2 Bipolar                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Foot-operated controls                                                            | EXCELL NHP/T can be fitted with: <ul style="list-style-type: none"> <li>• A double pedal control with push button selector for monopolar or bipolar functions.</li> <li>• Two double pedal controls, one for monopolar and one for bipolar functions.</li> </ul> The pedals are compliant with IEC 60601-2-2, waterproof (IP67), electric with 12 VDC low voltage power supply.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Panel                                                                             | 7" touch screen LCD display                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Neutral electrode safety circuit NPCC System                                      | Control of the connection of the neutral electrode - and of the quality of the contact using double section/split electrodes - with alarm signal and possible lock of delivered power. It can be used in two different ways: Large electrodes for adults, Small electrodes for paediatric patients/newborns. It allows using cables with both European "Ø 6.35 mm" and US "2 pins" connectors.                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Power supply                                                                      | 100-230 V - 50/60 Hz – Automatic switching supply.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Power consumption at 230V                                                         | Max power 3.6 A = 828 VA, Stand-by 0.4 A = 92 VA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Cooling                                                                           | Convection, without fan                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Equipotential bonding                                                             | Standard DIN 42801 plug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Software upgrade, calibration                                                     | Upgrade via serial port connected to a PC, on-site calibration.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Size (LxDxH) and weight                                                           | EXCELL NHP/T-400 and EXCELL NHP/T-200: 38x38x20 cm – 10 Kg<br>EXCELL NHP/TA-400 and EXCELL NHP/TA-200: 38x38x20 cm – 10.5 Kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Argon gas section (only in EXCELL NHP/TA-400 and EXCELL NHP/TA-200 models)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Supply                                                                            | One 5 litre cylinder or with centralised system                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Flow                                                                              | Max 15 l/min                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Pressure                                                                          | Inlet 2.5 atm / Outlet 1 atm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Flow check with Constant flow System                                              | From 1 to 15 l/min by electronic sensor with adjustment buttons and numerical control on the display. Automatic self-compensation based on the type of electrode used. Alarm if gas is absent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Pressure check in the Safety gas System circuit                                   | Two-stage pressure reducer (on the cylinder and inside, with safety valve). Pressure sensor connected to the electronic control system, with Auto-Check when the gas section is switched on.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Protection of the supplied gas flow                                               | Gas outlet equipped with antibacterial filter.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

# OUTPUT POWERS

| Monopolar currents            | EXCELL NHP/T-400                                           | EXCELL NHP/T-200                                           | EXCELL NHP/TA-400                                          | EXCELL NHP/TA-200                                          |
|-------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| PURE CUT                      | 400 W - 400 Ω<br>2550 Vpp - CF: 1.46<br>M: no - D: 100%    | 200 W - 400 Ω<br>2550 Vpp - CF: 1.46<br>M: no - D: 100%    | 400 W - 400 Ω<br>2550 Vpp - CF: 1.46<br>M: no - D: 100%    | 200 W - 400 Ω<br>2550 Vpp - CF: 1.46<br>M: no - D: 100%    |
| BLEND CUT 1                   | 300 W - 400 Ω<br>3390 Vpp - CF: 1.94<br>M: 17 kHz - D: 95% | 200 W - 400 Ω<br>3390 Vpp - CF: 1.94<br>M: 17 kHz - D: 95% | 300 W - 400 Ω<br>3390 Vpp - CF: 1.94<br>M: 17 kHz - D: 95% | 200 W - 400 Ω<br>3390 Vpp - CF: 1.94<br>M: 17 kHz - D: 95% |
| BLEND CUT 2                   | 250 W - 400 Ω<br>3330 Vpp - CF: 2.29<br>M: 17 kHz - D: 65% | 200 W - 400 Ω<br>3330 Vpp - CF: 2.29<br>M: 17 kHz - D: 65% | 250 W - 400 Ω<br>3330 Vpp - CF: 2.29<br>M: 17 kHz - D: 65% | 200 W - 400 Ω<br>3330 Vpp - CF: 2.29<br>M: 17 kHz - D: 65% |
| PURE CUT PULSED               | 200 W - 400 Ω<br>2640 Vpp - CF: 2<br>M: 3 Hz - D: 50%      | 100 W - 400 Ω<br>2640 Vpp - CF: 2<br>M: 3 Hz - D: 50%      | 200 W - 400 Ω<br>2640 Vpp - CF: 2<br>M: 3 Hz - D: 50%      | 100 W - 400 Ω<br>2640 Vpp - CF: 2<br>M: 3 Hz - D: 50%      |
| BLEND CUT PULSED              | 150 W - 400 Ω<br>3330 Vpp - CF: 3.2<br>M: 50 Hz - D: 50%   | 100 W - 400 Ω<br>3330 Vpp - CF: 3.2<br>M: 50 Hz - D: 50%   | 150 W - 400 Ω<br>3330 Vpp - CF: 3.2<br>M: 50 Hz - D: 50%   | 100 W - 400 Ω<br>3330 Vpp - CF: 3.2<br>M: 50 Hz - D: 50%   |
| AUTO PURE CUT MICRO           | 300 W - 300 Ω<br>1137 Vpp - CF: 1.5<br>M: no - D: 100%     | 200 W - 300 Ω<br>1137 Vpp - CF: 1.5<br>M: no - D: 100%     | 300 W - 300 Ω<br>1137 Vpp - CF: 1.5<br>M: no - D: 100%     | 200 W - 300 Ω<br>1137 Vpp - CF: 1.5<br>M: no - D: 100%     |
| AUTO BLEND CUT MICRO          | 300 W - 300 Ω<br>1500 Vpp - CF: 1.98<br>M: 17 kHz - D: 90% | 200 W - 300 Ω<br>1500 Vpp - CF: 1.98<br>M: 17 kHz - D: 90% | 300 W - 300 Ω<br>1500 Vpp - CF: 1.98<br>M: 17 kHz - D: 90% | 200 W - 300 Ω<br>1500 Vpp - CF: 1.98<br>M: 17 kHz - D: 90% |
| AUTO PAPILO PURE CUT          | 300 W - 300 Ω<br>1140 Vpp - CF: 1.5<br>M: no - D: 100%     | 200 W - 300 Ω<br>1140 Vpp - CF: 1.5<br>M: no - D: 100%     | 300 W - 300 Ω<br>1140 Vpp - CF: 1.5<br>M: no - D: 100%     | 200 W - 300 Ω<br>1140 Vpp - CF: 1.5<br>M: no - D: 100%     |
| AUTO POLIPO BLEND CUT         | 300 W - 300 Ω<br>1490 Vpp - CF: 1.98<br>M: 17 kHz - D: 95% | 200 W - 300 Ω<br>1490 Vpp - CF: 1.98<br>M: 17 kHz - D: 95% | 300 W - 300 Ω<br>1490 Vpp - CF: 1.98<br>M: 17 kHz - D: 95% | 200 W - 300 Ω<br>1490 Vpp - CF: 1.98<br>M: 17 kHz - D: 95% |
| AUTO ENDOCUT                  | 300 W - 300 Ω<br>1670 Vpp - CF: 2.20                       | 200 W - 300 Ω<br>1670 Vpp - CF: 2.20                       | 300 W - 300 Ω<br>1670 Vpp - CF: 2.20                       | 200 W - 300 Ω<br>1670 Vpp - CF: 2.20                       |
| FULG FORCED COAG              | 150 W - 300 Ω<br>4500 Vpp - CF: 6.45<br>M: 60 kHz - D: 18% | 150 W - 300 Ω<br>4500 Vpp - CF: 6.45<br>M: 60 kHz - D: 18% | 150 W - 300 Ω<br>4500 Vpp - CF: 6.45<br>M: 60 kHz - D: 18% | 150 W - 300 Ω<br>4500 Vpp - CF: 6.45<br>M: 60 kHz - D: 18% |
| SPRAY COAG                    | 200 W - 700 Ω<br>7750 Vpp - CF: 7.75<br>M: 30 kHz - D: 7%  | 200 W - 700 Ω<br>7750 Vpp - CF: 7.75<br>M: 30 kHz - D: 7%  | 200 W - 700 Ω<br>7750 Vpp - CF: 7.75<br>M: 30 kHz - D: 7%  | 200 W - 700 Ω<br>7750 Vpp - CF: 7.75<br>M: 30 kHz - D: 7%  |
| PULSED SPRAY COAG             | 100 W - 700 Ω<br>7850 Vpp - CF: 11.54<br>M: 3 Hz - D: 50%  | 100 W - 700 Ω<br>7850 Vpp - CF: 11.54<br>M: 3 Hz - D: 50%  | 100 W - 700 Ω<br>7850 Vpp - CF: 11.54<br>M: 3 Hz - D: 50%  | 100 W - 700 Ω<br>7850 Vpp - CF: 11.54<br>M: 3 Hz - D: 50%  |
| PINPOINT CONTACT COAG         | 300 W - 400 Ω<br>3700 Vpp - CF: 2.2<br>M: 17 kHz - D: 85%  | 200 W - 400 Ω<br>3700 Vpp - CF: 2.2<br>M: 17 kHz - D: 85%  | 300 W - 400 Ω<br>3700 Vpp - CF: 2.2<br>M: 17 kHz - D: 85%  | 200 W - 400 Ω<br>3700 Vpp - CF: 2.2<br>M: 17 kHz - D: 85%  |
| SOFT MICRO COAG               | 280 W - 300 Ω<br>3300 Vpp - CF: 2.16<br>M: 17 kHz - D: 75% | 200 W - 300 Ω<br>2875 Vpp - CF: 2.1<br>M: 17 kHz - D: 75%  | 280 W - 300 Ω<br>3300 Vpp - CF: 2.16<br>M: 17 kHz - D: 75% | 200 W - 300 Ω<br>2875 Vpp - CF: 2.1<br>M: 17 kHz - D: 75%  |
| SPRAY COAG + GAS ARGON        | -                                                          | -                                                          | 200 W - 700 Ω<br>7750 Vpp - CF: 7.75<br>M: 30 kHz - D: 7%  | 200 W - 700 Ω<br>7750 Vpp - CF: 7.75<br>M: 30 kHz - D: 7%  |
| PULSED SPRAY COAG + GAS ARGON | -                                                          | -                                                          | 100 W - 700 Ω<br>7850 Vpp - CF: 11.54<br>M: 3 Hz - D: 50%  | 100 W - 700 Ω<br>7850 Vpp - CF: 11.54<br>M: 3 Hz - D: 50%  |

Current self-adjustment

| ADC | APC |
|-----|-----|
| X   |     |
| X   |     |
| X   |     |
| X   |     |
| X   |     |
|     | X   |
|     | X   |
|     | X   |
|     | X   |
|     | X   |
| X   |     |
| X   |     |
| X   |     |
| X   |     |
| X   |     |
| X   |     |
| X   |     |

| Bipolar currents       | EXCELL NHP/T-400                                          | EXCELL NHP/T-200                                          | EXCELL NHP/TA-400                                         | EXCELL NHP/TA-200                                         |
|------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|
| STANDARD BICUT         | 200 W - 300 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 200 W - 300 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 200 W - 300 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 200 W - 300 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    |
| BLEND BICUT            | 160 W - 200 Ω<br>740 Vpp - CF: 1.57<br>M: 17 kHz - D: 95% | 160 W - 200 Ω<br>740 Vpp - CF: 1.57<br>M: 17 kHz - D: 95% | 160 W - 200 Ω<br>740 Vpp - CF: 1.57<br>M: 17 kHz - D: 95% | 160 W - 200 Ω<br>740 Vpp - CF: 1.57<br>M: 17 kHz - D: 95% |
| SALINE URO-GYN CUT     | 300 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 300 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 300 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 300 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    |
| SALINE ARTHRO CUT      | 230 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 230 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 230 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    | 230 W - 350 Ω<br>1070 Vpp - CF: 1.5<br>M: no - D: 100%    |
| SOFT MICRO BICOAG      | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    |
| FORCED MACRO BICOAG    | 200 W - 100 Ω<br>550 Vpp - CF: 1.6<br>M: no - D: 100%     | 200 W - 100 Ω<br>550 Vpp - CF: 1.6<br>M: no - D: 100%     | 200 W - 100 Ω<br>550 Vpp - CF: 1.6<br>M: no - D: 100%     | 200 W - 100 Ω<br>550 Vpp - CF: 1.6<br>M: no - D: 100%     |
| AUTO SOFT MICRO BICOAG | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    | 140 W - 100 Ω<br>460 Vpp - CF: 1.56<br>M: no - D: 100%    |
| SEALING                | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     |
| AUTO SEALING           | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     | 320 W - 50 Ω<br>780 Vpp - CF: 2.47<br>M: no - D: 100%     |

Current self-adjustment

| ADC | APC |
|-----|-----|
| X   |     |
| X   |     |
| X   |     |
| X   |     |
|     | X   |
| X   |     |
|     | X   |
|     | X   |
|     | X   |

## KEY

**W:** DELIVERED POWER

**Ω:** NOMINAL LOADS

**Vpp:** PEAK/NO-LOAD PEAK VOLTAGES

**CF:** CREST FACTORS

**M:** MODULATION

**D:** DUTY CYCLE

**ADC:** CONSTANT POWER

**ADC:** CONSTANT VOLTAGE

# DEVICES AND STANDARD ACCESSORIES

**EXCELL NHP/T-400**, without accessories

**EXCELL NHP/T-200**, without accessories

**EXCELL NHP/TA-400**, without accessories

**EXCELL NHP/TA-200**, without accessories

**B610/Asw** STANDARD ACCESSORIES SERIES including:

1 DS/Esw Double pedal control, electric, waterproof

1 NP/A Stainless steel neutral electrode, 2.5 m cable

1 FGE Fixing belt for electrodes

2 MPE/E Sterilisable electrode holder, 3.5 m cable

1 SEL/E Series of 8 active electrodes (2 E1 - Straight blade electrode, 2 E5 - Thick needle electrode, 1 E7 - Fine needle electrode, 1 E12 - Straight ball electrode Ø 2.5 mm, 2 E14 - Straight ball electrode Ø 4 mm)

**B610/Bsw** STANDARD ACCESSORIES SERIES identical to B610/Asw, but with flexible conductive rubber neutral electrode NP/GA for adults

**B610/Psw** As above, with neutral paediatric electrode NP/GP



EXCELL NHP/T-400



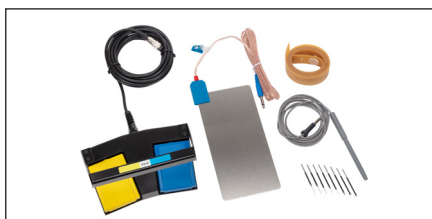
EXCELL NHP/T-200



EXCELL NHP/TA-400



EXCELL NHP/TA-200



B610/Asw



B610/Bsw

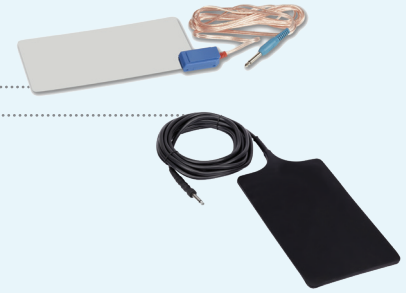
**alsa**  
bologna



# GENERAL LIST OF ACCESSORIES

## REUSABLE NEUTRAL ELECTRODES

- EIP/9** Stainless steel electrode (16x6 cm), 3 m cable
- NP/A** Stainless steel electrode (25x12 cm), 3 m cable
- NP/GA** Conductive flexible rubber electrode (25x15 cm), 4.5 m cable
- NP/GP** Conductive flexible rubber electrode (15x8 cm), 4.5 m cable
- EIP/S** Manual neutral electrode, 2 m cable
- FFE** Elastic belt for fixing electrodes, with double button, L. 50 cm (\*)
- FGE** Elastic belt for fixing electrodes, with double button, L. 150 cm (\*)



## DISPOSABLE ADHESIVE NEUTRAL ELECTRODES

- CMS/E** Reusable connection cable, 3 m
- CMS/E5** As above, 5 m
- EIP/DA** Single section non Split adhesive electrode for adults (25-pc pack) (\*)
- EIP/SA** As above, Split type with double section (25-pc pack) (\*)
- EIP/DP** Single section non Split paediatric adhesive electrode (25-pc pack) (\*)
- EIP/SP** As above, Split type with double section (25-pc pack) (\*)

## HANDLES FOR USE WITH FOOT CONTROLS

- MPE/F** Autoclavable handle, 2.5 m cable
- MPE/E** Sterilisable electrode holder handle, 3.5 m cable
- MPE/E5** As above, 5 m cable
- MLD/F** Needle holder microsurgery handpiece, autoclavable, 2 m cable

## HANDLES WITH DOUBLE BUTTON MANUAL CONTROLS

- MPE/CMS** Electrode holder handle with blade electrode, 3 m cable (100 times sterilisable)
- MPE/CMS5** As above, 5 m cable

## ACTIVE ELECTRODES stainless steel, insulated stem $\varnothing$ 2.3 ÷ 2.4 mm, sterilisable

- SHORT TYPE, L. 70 mm**
- E1** Blade electrode, straight
- E1/I** Blade electrode, straight, all insulated except the last 5 mm
- E3** Blade electrode, angled
- E1/L** Lancet electrode, straight
- E3/L** As above, angled
- E5** Thick needle electrode, straight
- E6** As above, angled
- E7** Thin needle electrode, straight
- E7/I** Thin needle electrode, straight, all insulated except the last 5 mm
- E8** Thin needle electrode, angled
- E10** Ultra-thin needle electrode, 0.40 mm diam.
- E12** Ball electrode, straight,  $\varnothing$  2.5 mm
- E13** As above, angled
- E14** Ball electrode, straight,  $\varnothing$  4 mm
- E15** As above, angled
- E16** Ball electrode, straight,  $\varnothing$  6 mm
- E17** As above, angled
- E18** Loop electrode (diamond-shaped 5x10 mm)
- E19** As above, diamond-shaped 10x10 mm
- E21** Loop electrode (wire, round  $\varnothing$  5 mm)
- E23** As above,  $\varnothing$  10 mm
- E25** As above,  $\varnothing$  15 mm
- E23/N** Loop electrode (ribbon, round  $\varnothing$  10 mm)
- E25/N** As above,  $\varnothing$  15 mm
- E26** Plate electrode
- EXT/15** Extension l. 15 cm for all electrodes with stem  $\varnothing$  2.3 ÷ 2.4 mm
- LONG TYPE, L. 130 mm**
- E40** Blade electrode, straight
- E40/I** Blade electrode, straight, all insulated except the last 5 mm
- E41** Thick needle electrode, straight
- E42** Thin needle electrode, straight
- E42/I** Thin needle electrode, straight, all insulated except the last 5 mm
- E43** Loop electrode, straight (wire, round  $\varnothing$  5 mm)
- E44** As above,  $\varnothing$  10 mm
- E45** As above,  $\varnothing$  15 mm
- E46** Ball electrode, straight,  $\varnothing$  2.5 mm
- E47** As above,  $\varnothing$  4 mm
- E47/6** As above,  $\varnothing$  6 mm



## ■ ELECTRODES FOR GYNECOLOGY L. 130 mm

- E48 Round loop electrode, 20x15 mm
- E49 As above, 10x7 mm
- E50 As above, 10x10 mm
- E51 As above, 15x12 mm
- E52 As above, 15x10 mm
- E53 As above, 20x8 mm
- E54 As above, 20x10 mm
- E55 As above, 20x20 mm
- E56 Square loop electrode, 10x5 mm
- E57 As above, 10x8 mm
- E58 As above, 10x10 mm
- E59 As above, 5x5 mm

## ■ ELECTRODES FOR MICROSURGERY, STERILISABLE

- MID Needle reducer (for all electrode handles)
- SAD Series of 10 needles, Ø 0.10 mm
- SAD/1 As above, Ø 0.15 mm
- SAD/2 As above, Ø 0.20 mm
- SAD/3 As above, Ø 0.40 mm

## ■ INSULATED MONOPOLAR FORCEPS FOR COAGULATION, WITHOUT CONNECTION CABLES TO THE EQUIPMENT, STERILISABLE

- PIC/1 Straight forceps (Cushing/Potts-Smith) ("grasping" tips 1 mm - L. 18 cm)
- PIC/1-25 As above, L. 25 cm
- PIC/2 Straight forceps (Cushing/Potts-Smith) ("grasping" tips 2 mm - L. 25 cm)

## ■ INSULATED MONOPOLAR FORCEPS FOR COAGULATION, WITH CONNECTION CABLES TO THE EQUIPMENT, STERILISABLE

- CPI Connection cable for PMI, L. 3.5 m
- CPI/5 As above, L. 5 m
- PMI/1 Straight forceps (Cushing/Potts-Smith) ("grasping" tips 1 mm - L. 18 cm)
- PMI/1-20 As above, L. 20 cm
- PMI/1-25 As above, L. 25 cm
- PMI/2 Straight forceps (Cushing/Potts-Smith) ("grasping" tips 2 mm - L. 25 cm)
- PMI/B Bayonet forceps (Jansen/Yasargil) ("grasping" tips 2 mm - L. cm. 20 cm)

## ■ MONOPOLAR ACCESSORIES FOR LAPAROSCOPY, request specific details.

## ■ CONNECTION CABLES FOR MONOPOLAR INSTRUMENTS FOR LAPAROSCOPY

- CPE Connection cable for instruments with male or female connector Ø 4 mm, L. 3.5 m
- CPE/5 As above, L. 5 m

## ■ CABLES FOR FLEXIBLE ENDOSCOPY, request specific details.

## ■ CONNECTION CABLES FOR BIPOLAR FORCEPS OR ELECTRODES AND FOR HOOKS, FORCEPS AND BIPOLAR SCISSORS FOR LAPAROSCOPY, STERILISABLE

- CPB/E Connection cable, 3 m
- CPB/E5 As above, L. 5 m

## ■ RIGID BIPOLAR INSULATED CLAMPS AND ELECTRODES, STERILISABLE

### Standard forceps for bipolar coagulation

- PMC/JR Straight forceps (Jeweler) (straight tips 0.5 mm - L. 11.5/12 cm)
- PMC/JC As above, angled tips
- PMC/RS Straight forceps (Cushing/Potts-Smith) (straight tips 0.7 mm - L. 15.5 / 16 cm)
- PMC/CS As above, angled tips
- PMC/R Straight forceps (Cushing/Potts-Smith) (straight tips 1 mm - L. 20 cm)
- PMC/C As above, angled tips
- PBC/R Straight forceps (Cushing/Potts-Smith) (straight tips 2 mm - L. 20 cm)
- PBC/C As above, angled tips
- PMC/R25 Straight forceps (Cushing/Potts-Smith) (straight tips 1 mm - L. 25 cm)
- PMC/C25 As above, angled tips
- PBC/R25 Straight forceps (Cushing/Potts-Smith) (straight tips 2 mm - L. 25 cm)
- PBC/C25 As above, angled tips
- PMC/RSB Bayonet forceps (Jensen/Yasargil) (straight tips 0.7 mm - L. 16.5 / 17 cm)
- PMC/B Bayonet forceps (Jensen/Yasargil) (straight tips 1 mm - L. 20 cm)
- PMC/BCD As above, angled tips pointing down
- PMC/BCU As above, angled tips pointing up
- PBC/B Bayonet forceps (Jensen/Yasargil) (straight tips 2 mm - L. 20 cm)
- PBC/BCD As above, angled tips pointing down
- PBC/BCU As above, angled tips pointing up



**PMC/B25** Bayonet forceps (Jensen/Yasargil) (straight tips 1 mm - L. 25 cm)  
**PBC/B25** Bayonet forceps (Jensen/Yasargil) (straight tips 2 mm - L. 25 cm)

- **FORCEPS WITH IRRIGATION FOR BIPOLAR COAGULATION**, request specific details.
- **FORCEPS WITH NON-STICK TIPS FOR BIPOLAR COAGULATION**, request specific details.
- **RIGID ELECTRODES FOR BIPOLAR COAGULATION OF TURBINATES OR LARYNX**, request specific details.
- **HOOKS, FORCEPS AND BIPOLAR SCISSORS FOR LAPAROSCOPY**, request specific details.
- **BIPOLAR FORCEPS FOR COAGULATION/SEALING OF LARGE VESSELS FOR SURGERY AND LAPAROSCOPY WITH RELATIVE CABLES**, request specific details.

#### ■ **ADAPTERS FOR USE OF NON-STANDARD ALSA CABLES**

**RD/5** For monopolar cables with plugs with Ø from 2 to 8 mm, or Martin standard. ....  
**RD/BF** For bipolar cables with double plug Ø 4 mm (International standard) or with Valleylab/Conmed standard plug.  
**RD/BF1** For bipolar cables with coaxial plug Ø 12.5 mm (Erbe/Storz standard)  
**RD/BF2** For bipolar cables with coaxial plug Ø 8 mm (Martin/Bertchold standard)

#### ■ **TROLLEYS**

**H23/SE** Trolley with 3 shelves. Size: 50x50x80 cm, antistatic wheels, 2 with brakes .....  
**H26** Trolley with 2 shelves and seat for Argon cylinder. Size: 52x55x90 cm, antistatic wheels, 2 with brakes

#### ■ **FOOT CONTROLS**

**STOP/PN** Foot control, pneumatic, waterproof, explosion-proof (single) (ALSATOM SU 50-MPC, ALSATOM SU 100-MPC, ALSATOM SU 140-MPC)  
**D-STOP/P** Foot control, pneumatic, waterproof, explosion-proof (double) (ALSATOM SU 140/D-MPC, ALSATOM SU 140/BD-MPC)  
**DS/E** Double pedal electric control, waterproof (IP67) (EXCELL MCDSe, EXCELL NHP)  
**DS/Esw** Double pedal electric control, waterproof (IP67) (EXCELL NHP/T) .....  
**DS/B** Double pedal electric control, waterproof (IP67), for bipolar operation only (EXCELL MCDSe, EXCELL NHP, EXCELL NHP/T)

#### ■ **ACCESSORIES HOLDER BOXES**

**BOX/TE** Stainless steel round box for electrodes  
**BOX/RA-2** Stainless steel rectangular box for accessories, 30x20x6 cm

#### **ACCESSORIES FOR SURGERY WITH ARGON GAS**

(with EXCELL 400/A MCDSe, EXCELL NHP 250/DA, EXCELL NHP 400/DA, EXCELL NHP/TA-200, EXCELL NHP/TA-400)

#### ■ **HANDLE WITH MANUAL CONTROLS AND ELECTRODES FOR SURGERY/LAPAROSCOPY**

**AC/HANDLE** Double button handle, sterilisable, 3.5 m cable .....  
**AC/E25-C** Rigid electrode for coagulation, l. 25 mm, sterilisable .....  
**AC/E100-C** As above, l. 100 mm  
**AC/E320-C** As above, l. 320 mm (for laparoscopy only)  
**AC/E320-H** Rigid hook L-shaped electrode, l. 320 mm, sterilisable (for laparoscopy only)  
**AC/E40-A** Rigid needle electrode, l. 40 mm, sterilisable  
**AC/E100-A** As above, l. 100 mm  
**AC/E40-L** Rigid blade electrode, l. 40 mm, sterilisable  
**AC/E100-L** As above, l. 100 mm .....

#### ■ **CABLE AND ELECTRODES/PROBES FOR FLEXIBLE ENDOSCOPY**

**AC/CABLE+** Connection cable for electrodes/probes, sterilisable, l. 3.5 m .....  
**AC/FP1+** Flexible electrode for endoscopy d. 1.5 mm, l. 1.5 m  
**AC/FP2+** As above, d. 2.3 mm, l. 1.0 m .....  
**AC/FP3+** As above, d. 2.3 mm, l. 2.2 m  
**AC/FP4+** As above, d. 3.2 mm, l. 2.2 m  
**AC/FP3+s** As above, d. 2.3 mm, l. 2.2 m, with side opening

#### ■ **TROLLEY, CYLINDERS, PRESSURE REDUCER, ANTIBACTERIAL FILTER**

**H26** Trolley with 2 shelves and seat for Argon cylinder.  
 Size: 52x55x90 cm, antistatic wheels, 2 with brakes .....  
**B5** 5 l argon gas cylinder  
**RD/P** Pressure reducer for B5 cylinder  
**ESU/TG** Gas supply pipe with quick connector (for B5)  
**ESU/F** Antibacterial filter for argon gas outlet  
**ESU/FC** Metal connector for filter

(\*) items not CE0051 certified



## Notes

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# **alsa<sup>®</sup>**

## **bologna**

PRODUCTS DESIGNED AND MANUFACTURED BY:  
**ALSA APPARECCHI MEDICALI SRL**  
via C. Bonazzi, 16  
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## 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.

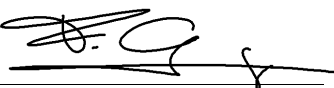
ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di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

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** DocuSign

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

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

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|                                                      |                                                                                                                                                                                                                                                                             |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Categoria di dispositivo:</b><br>Device category: | <b>Aspiratori chirurgici</b><br>Surgical aspirators                                                                                                                                                                                                                         |
| <b>Serie:</b><br>Series:                             | <b>VACUMSOL</b>                                                                                                                                                                                                                                                             |
| <b>Modello/i:</b><br>Model(s):                       | <b>VACUMSOL AS-60;</b><br><b>VACUMSOL AS-65;</b><br><b>VACUMSOL AS-65/H</b>                                                                                                                                                                                                 |
| <b>Serie:</b><br>Series:                             | <b>VORTEX-S</b>                                                                                                                                                                                                                                                             |
| <b>Modello/i:</b><br>Model(s):                       | <b>VORTEX-S AS-200/20LT;</b><br><b>VORTEX-S AS-200/30LT;</b><br><b>VORTEX-S AS-200/20LT VE;</b><br><b>VORTEX-S AS-200/30LT VE</b>                                                                                                                                           |
| <b>Serie:</b><br>Series:                             | <b>VORTECO</b>                                                                                                                                                                                                                                                              |
| <b>Modello/i:</b><br>Model(s):                       | <b>VORTECO AS-100/15LT;</b><br><b>VORTECO AS-100/20LT;</b><br><b>VORTECO AS-100/30LT;</b><br><b>VORTECO AS-100/30LT VE</b>                                                                                                                                                  |
| <b>Serie:</b><br>Series:                             | <b>POLIVAC</b>                                                                                                                                                                                                                                                              |
| <b>Modello/i:</b><br>Model(s):                       | <b>POLIVAC B4/SLT 30 1;</b><br><b>POLIVAC B4/SLT 30 2;</b><br><b>POLIVAC B4/SLT 30 1-EXP;</b><br><b>POLIVAC B4/SLT 30 2-EXP;</b><br><b>POLIVAC B4/SLT 30 P-EXP;</b><br><b>POLIVAC B4/SLT 50 E;</b><br><b>POLIVAC B4/SLT 30 1VE-EXP;</b><br><b>POLIVAC B4/SLT 30 PVE-EXP</b> |

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|------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Categoria di dispositivo:</b><br>Device category: | <b>Accessori per elettrobisturi</b><br>Accessories for electrosurgical units                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Serie:</b><br>Series:                             | <b>MPE e MLD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Modello/i:</b><br>Model(s):                       | <b>Manipoli porta elettrodi monopolari riusabili per utilizzo con comando a pedale</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                                                      | <b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• MPE/S; MPE/E; MPE/E5; MPE/F</li> <li>• MLD; MLD/F</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Serie:</b><br>Series:                             | <b>MPE/CMS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Modello/i:</b><br>Model(s):                       | <b>Manipoli porta elettrodi monopolari riusabili per utilizzo con comando manuale a doppio pulsante</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                      | <b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• MPE/CMS; MPE/CMS5; MPE/CMS300; MPE/CMS300-4</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Serie:</b><br>Series:                             | <b>E</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Modello/i:</b><br>Model(s):                       | <b>Serie di elettrodi attivi monopolari riusabili per elettrochirurgia</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|                                                      | <b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• SEL/VI; SEL/D; SEL/E</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Serie:</b><br>Series:                             | <b>E</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi attivi monopolari riusabili per elettrochirurgia</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                                      | <b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• E1; E11; E3; E1L; E3L; E5; E6; E7; E7L; E8; E10; E12; E13; E14; E15; E16; E17; E18; E19; E21; E23; E23N; E25; E25N; E26: EXT/15</li> <li>• E27; E29; E30; E31; E32; E33; E34; E35; E37; E39;</li> <li>• E40I; E40; E41; E41I; E42; E43; E46; E47; E47/6;</li> <li>• E48; E49; E50; E51; E52; E53; E54; E55; E56; E57; E58</li> <li>• E101; E102; E103; E105; E106; E109; E110; E111; E112; E120; E121;</li> <li>• E/ND12; E/DR12; E/HK12; E/HY12;</li> <li>• E/ND18; E/DR18; E/HK18; E/HY18</li> </ul> |
| <b>Serie:</b><br>Series:                             | <b>SAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi attivi monopolari (aghi sottili) per elettrochirurgia</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                                                      | <b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• SAD; SAD/AN; SAD/1; SAD/1AN; SAD/2; SAD/2AN; SAD/3; SAD/3AN</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Serie:</b><br>Series:                             | <b>AID</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi attivi monopolari (aghi sottili) per elettrochirurgia</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                                                      | <b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• AID</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

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

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|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Categoria di dispositivo:</b><br>Device category: | <b>Accessori per elettrobisturi</b><br>Accessories for electrosurgical units                                                                                                                                                                                                                                                                                                                                  |
| <b>Serie:</b><br>Series:                             | <b>SAD e AID</b>                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Modello/i:</b><br>Model(s):                       | <b>Mandrino riduttore per aghi</b><br><b>Codici / Codes:</b><br><ul style="list-style-type: none"> <li><b>MID</b></li> </ul>                                                                                                                                                                                                                                                                                  |
| <b>Serie:</b><br>Series:                             | <b>EL/MLH</b>                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi attivi monopolari riusabili per laparoscopia</b><br><b>Codici / Codes:</b><br><ul style="list-style-type: none"> <li><b>EL/MLH-J; EL/MLH-L</b></li> </ul>                                                                                                                                                                                                                                        |
| <b>Serie:</b><br>Series:                             | <b>PMC e PBC</b>                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Modello/i:</b><br>Model(s):                       | <b>Pinze bipolari isolate standard</b><br><b>Codici / Codes:</b><br><ul style="list-style-type: none"> <li><b>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</b></li> <li><b>PBC/R; PBC/C; PBC/R25; PBC/C25; PBC/B; PBC/B25; PBC/BCD; PBC/BCU</b></li> </ul>                                                                                       |
| <b>Serie:</b><br>Series:                             | <b>PMC/L e PBC/L</b>                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Modello/i:</b><br>Model(s):                       | <b>Pinze bipolari isolate con irrigazione</b><br><b>Codici / Codes:</b><br><ul style="list-style-type: none"> <li><b>PMC/JRL; PMC/JCL; PMC/RSI; PMC/CSI; PMC/RI; PMC/CL; PMC/R25L; PMC/C25L; PMC/RSBL; PMC/BL; PMC/B25L; PMC/BCDL; PMC/BCUL</b></li> <li><b>PBC/RI; PBC/CL; PBC/R25L; PBC/C25L; PBC/BL; PBC/B25L; PBC/BCDL; PBC/BCUL</b></li> </ul>                                                           |
| <b>Serie:</b><br>Series:                             | <b>PBC/ns, PMC/ns</b>                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Modello/i:</b><br>Model(s):                       | <b>Pinze bipolari isolate con punte no-stick</b><br><b>Codici / Codes:</b><br><ul style="list-style-type: none"> <li><b>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;</b></li> <li><b>PBC/Rns; PBC/Cns; PBC/R25ns; PBC/C25ns; PBC/Bns; PBC/B25ns; PBC/BCDns; PBC/BCUns</b></li> </ul> |

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|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Categoria di dispositivo:</b><br>Device category: | <b>Accessori per elettrobisturi</b><br>Accessories for electrosurgical units                                                                                                                                                                                                                                                                                                                                       |
| <b>Serie:</b><br>Series:                             | <b>EB</b>                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi bipolari isolati rigidi</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>EBT; EBT20; EBT22; EBL; EBL16,5; EBA45; EBA90; EBD18; EBD20; EBD22</li> </ul>                                                                                                                                                                                                                            |
| <b>Serie:</b><br>Series:                             | <b>EL/BL</b>                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi bipolari isolati rigidi per laparoscopia</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>EL/BL-J; EL/BL-J45; EL/BL-L; EL/BL-L45; EL/BL-DL; EL/BL-DV; EL/BL-DN</li> </ul>                                                                                                                                                                                                         |
| <b>Serie:</b><br>Series:                             | <b>BITecD</b>                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Modello/i:</b><br>Model(s):                       | <b>Forbici bipolari isolate con lame delicate</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>BITecD-18; BITecD-21; BITecD-23; BITecD-28</li> </ul>                                                                                                                                                                                                                                           |
| <b>Serie:</b><br>Series:                             | <b>BCS e BC</b>                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Modello/i:</b><br>Model(s):                       | <b>Pinze "clamps" bipolari isolate</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>BCS-15; BCS-19; BCS-S19; BCS-S23</li> <li>BC-16; BC-20; BC-23; BC-26</li> </ul>                                                                                                                                                                                                                            |
| <b>Serie:</b><br>Series:                             | <b>POWER GRIP</b>                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Modello/i:</b><br>Model(s):                       | <b>Strumenti bipolari isolati per laparoscopia</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>POWER GRIP – LGF; 82400010; POWER GRIP – MFG; 82400014; POWER GRIP – FGC; 82400015; POWER GRIP – DCG; 82400011; POWER GRIP – MD; 82400019; POWER GRIP – CMS; 82400018</li> </ul>                                                                                                               |
| <b>Serie:</b><br>Series:                             | <b>CPB e CPB/E</b>                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Modello/i:</b><br>Model(s):                       | <b>Cavi di collegamento per pinze, elettrodi, strumenti bipolari</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>CPB; CPB/5; CPB/U; CPB/U5; CPB/MU; CPB/MU5; CPB/RU; CPB/RU5;</li> <li>CPB/E; CPB/E5; CPB/EM; CPB/EM5; CPB/ER; CPB/ER5; CPB/EU; CPB/EU5;</li> <li>CPB/EE; CPB/EE5; CPB/EE-4; CPB/EE5-4; CPB/EEM; CPB/EEM5; CPB/EES;</li> <li>CPB/EES5; CPB/EST; CPB/E-WMS; CPB/WMS</li> </ul> |

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

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|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Categoria di dispositivo:</b><br>Device category: | <b>Accessori per elettrobisturi</b><br>Accessories for electrosurgical units                                                                                                                                                                                                                                  |
| <b>Serie:</b><br>Series:                             | <b>CPB/tec e CPB/E-tec</b>                                                                                                                                                                                                                                                                                    |
| <b>Modello/i:</b><br>Model(s):                       | <b>Cavi di collegamento per forbici bipolari isolate</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>CPB/E-tec; CPB/E-tec5;</li> <li>CPB/tec; CPB/tec5; CPBS/tec; CPBS/tec5; CPBM/tec; CPBM/tec5; CPBV/tec; CPBV/tec5</li> </ul>                                                         |
| <b>Serie:</b><br>Series:                             | <b>PMI, PIC, PMI/P, FI e CFI</b>                                                                                                                                                                                                                                                                              |
| <b>Modello/i:</b><br>Model(s):                       | <b>Pinze (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale)</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>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</li> </ul> |
| <b>Modello/i:</b><br>Model(s):                       | <b>Pinze (senza collegamento all'elettrobisturi e utilizzo mediante contatto)</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>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</li> </ul>                           |
| <b>Modello/i:</b><br>Model(s):                       | <b>Pinze (con collegamento all'elettrobisturi e utilizzo mediante comando manuale)</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>PMI/PB; PMI/PB14; PMI/PB19; PMI/PJ18; PMI/PJ21; PMI/PJ24</li> </ul>                                                                                   |
| <b>Modello/i:</b><br>Model(s):                       | <b>Forbici (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale)</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>FI/18; FI/18C; FI/24; FI/24C; FI/W18; FI/W18C; FI/W24; FI/W24C</li> </ul>                                                                          |
| <b>Modello/i:</b><br>Model(s):                       | <b>Cannule di aspirazione (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale)</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>CFI/1; CFI/2; CFI/3</li> </ul>                                                                                                      |
| <b>Serie:</b><br>Series:                             | <b>EL/ML</b>                                                                                                                                                                                                                                                                                                  |
| <b>Modello/i:</b><br>Model(s):                       | <b>Strumenti attivi monopolari riutilizzabili per laparoscopia</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>EL/ML-J; EL/ML-JS; EL/ML-L; EL/ML-LS</li> </ul>                                                                                                                           |

# 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

|                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Accessori per elettrobisturi</b><br>Accessories for electrosurgical units                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Serie:</b><br>Series:                             | <b>CPI, CPE, CEP3, CEP4M e CEP4</b>                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Modello/i:</b><br>Model(s):                       | <b>Cavi di collegamento per strumenti/elettrodi monopolari</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• CPI; CPI/5; CPI-M4; CPI/5-M4; CPI-M6; CPI-M8; CPI/SM; CPI/L</li> <li>• CPE/5; CPE-M4; CPE/5-M4; CPE-M6; CPE-M8;</li> <li>• CEP3; CEP3/5; CEP3-M4; CEP3/5-M4; CEP3-M6; CEP3-M8;</li> <li>• CEP4M; CEP4M/5; CEP4M-M4; CEP4M/5-M4; CEP4M-M6; CEP4M-M8;</li> <li>• CEP4; CEP4/5; CEP4-M4; CEP4/5-M4; CEP4-M6; CEP4-M8</li> </ul> |
| <b>Serie:</b><br>Series:                             | <b>NP/A e EIP</b>                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi neutri con cavi di collegamento</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• EIP/9; EIP/9-5; EIP/S;</li> <li>• NP/A; NP/A5</li> </ul>                                                                                                                                                                                                                                                                                   |
| <b>Serie:</b><br>Series:                             | <b>CMS/E</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Modello/i:</b><br>Model(s):                       | <b>Cavi di collegamento per elettrodi neutri</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• CMS/E; CMS/E5; CMS/EA; CMS/EA5; CMS/EEN; CMS/E5EN</li> </ul>                                                                                                                                                                                                                                                                               |
| <b>Serie:</b><br>Series:                             | <b>NP/GA e NP/GP</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Modello/i:</b><br>Model(s):                       | <b>Elettrodi neutri in gomma conduttiva</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• NP/GA</li> <li>• NP/GP</li> </ul>                                                                                                                                                                                                                                                                                                               |
| <b>Serie:</b><br>Series:                             | <b>AC/E</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Modello/i:</b><br>Model(s):                       | <b>Manico AC/HANDLE ed elettrodi attivi rigidi per chirurgia con gas argon</b><br><b>Codici / Codes:</b> <ul style="list-style-type: none"> <li>• 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</li> </ul>                                                                                                                                                                                                    |

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

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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Accessori per elettrobisturi</b><br>Accessories for electrosurgical units                                                                                  |
| <b>Serie:</b><br>Series:                             | <b>AC/FP</b>                                                                                                                                                  |
| <b>Modello/i:</b><br>Model(s):                       | <b>Cavo di collegamento AC/CABLE ed elettrodi attivi flessibili per chirurgia con gas argon</b>                                                               |
|                                                      | <b>Codici / Codes:</b> <ul style="list-style-type: none"><li><b>AC/CABLE; AC/FP1; AC/FP1-5; AC/FP2; AC/FP3; AC/FP3s; AC/FP3-5; AC/FP4; AC/FP4-5</b></li></ul> |

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

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

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

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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Elettrobisturi</b><br>Electrosurgical unit                                                                                                                        |
| <b>Serie:</b><br>Series:                             | <b>ALSATOM</b>                                                                                                                                                       |
| <b>Modello/i:</b><br>Model(s):                       | <b>ALSATOM SU 50-MPC;<br/>ALSATOM SU 100-MPC;<br/>ALSATOM SU 140-MPC;<br/>ALSATOM SU 140/D-MPC;<br/>ALSATOM SU 140/BD-MPC;<br/>ALSATOM SU 140/D-MPC (100V-60Hz).</b> |
| <b>Serie:</b><br>Series:                             | <b>MCDSe</b>                                                                                                                                                         |
| <b>Modello/i:</b><br>Model(s):                       | <b>EXCELL 200 MCDSe;<br/>EXCELL 250 MCDSe;<br/>EXCELL 350 MCDSe;<br/>EXCELL 400 MCDSe;<br/>EXCELL 400/A MCDSe</b>                                                    |
| <b>Serie:</b><br>Series:                             | <b>NHP</b>                                                                                                                                                           |
| <b>Modello/i:</b><br>Model(s):                       | <b>EXCELL NHP 250/D;<br/>EXCELL NHP 350/D;<br/>EXCELL NHP 400/D;<br/>EXCELL NHP 250/DA;<br/>EXCELL NHP 400/DA;<br/>EXCELL NHP ENDOMED</b>                            |
| <b>Serie:</b><br>Series:                             | <b>NHP/T</b>                                                                                                                                                         |
| <b>Modello/i:</b><br>Model(s):                       | <b>EXCELL NHP/T-400;<br/>EXCELL NHP/T-200;<br/>EXCELL NHP/TA-400;<br/>EXCELL NHP/TA-200</b>                                                                          |
| <b>Serie:</b><br>Series:                             | <b>TopTom</b>                                                                                                                                                        |
| <b>Modello/i:</b><br>Model(s):                       | <b>TopTom SU 50;<br/>TopTom SU 100;<br/>TopTom SU 140;<br/>TopTom SU 140/D</b>                                                                                       |



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| <b>Marca</b><br>Trade mark: | <b>BUTTERFLY ITALIA</b> |
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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Elettrobisturi</b><br>Electrosurgical unit |
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| <b>Modello/i:</b><br>Model(s): | <b>BIPOLAR HF 100;</b><br><b>BIPOLAR HF 140.</b> |
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| <b>Marca</b><br>Trade mark: | <b>TONTARRA</b> |
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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Elettrobisturi</b><br>Electrosurgical unit |
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| <b>Modello/i:</b><br>Model(s): | <b>PWT-400</b> |
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| <b>Marca</b><br>Trade mark: | <b>AMNOTEK</b> |
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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Elettrobisturi</b><br>Electrosurgical unit |
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| <b>Serie:</b><br>Series: | <b>AMNOTOM</b> |
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| <b>Modello/i:</b><br>Model(s): | <b>AMNOTOM 160 BASE;</b><br><b>AMNOTOM 400 COMPACT;</b><br><b>AMNOTOM 400 PREMIUM;</b><br><b>AMNOTOM 400 PREMIUM A</b> |
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## Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

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| <b>Marca</b><br>Trade mark: | <b>ZACCANTI S.p.A.</b> |
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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Elettrobisturi</b><br>Electrosurgical unit |
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| <b>Modello/i:</b><br>Model(s): | <b>BIPOGYN</b> |
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| <b>Marca</b><br>Trade mark: | <b>EFER ENDOSCOPY</b> |
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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Elettrobisturi</b><br>Electrosurgical unit |
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| <b>Modello/i:</b><br>Model(s): | <b>SIRIUS 900</b> |
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| <b>Marca</b><br>Trade mark: | <b>MEDICAL SWAN</b> |
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| <b>Categoria di dispositivo:</b><br>Device category: | <b>Elettrobisturi</b><br>Electrosurgical unit |
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| <b>Modello/i:</b><br>Model(s): | <b>PULSAR MB350</b> |
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**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*

|              |                                             |                                     |                    |
|--------------|---------------------------------------------|-------------------------------------|--------------------|
| <b>DATE:</b> | PRIMA CERTIFICAZIONE<br>FIRST CERTIFICATION | EMISSIONE CORRENTE<br>CURRENT ISSUE | SCADENZA<br>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



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



Organismo di Certificazione Federato CISQ  
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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*

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

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WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

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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  
1998-11-30

EMISSIONE CORRENTE  
CURRENT ISSUE  
2022-03-18

SCADENZA  
EXPIRY  
2025-12-19

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Management Systems Division - Flavio Ornago



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