ENGLISH EDITION

HF SURGICAL UNITS

alsa®

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MADE IN ITALY

alsa®

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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

PURE	Pure Cut, suitable also for use in under liquid surgery in case of minor hysteroscopy procedures
P PULSED	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
BLEND	Coagulating Cut
B PULSED 1	Coagulating Pulsed Cut. Similar to BLEND, but suitable to reduce the thermal effect and surgical smoke
B PULSED 2	Slow Coagulating Pulsed Cut. Similar to BLEND, but with slow pulses (i.e. for polypectomies)

MICRO	Delicate Coagulation, with low sparking effect
M PULSED	Delicate Micro-Coagulation, with single pulses, which are adjustable from 0.1 sec to 1 sec. It is indicated for all micro-coagulations
FULG	Macro-Coagulation “Fulguration” with strong sparks. It is indicated to coagulate all tissues, even in under liquid surgery, and to perform high-coagulating cuts
F PULSED	Macro-Coagulation “Fulguration”, with fast pulses. Similar to FULG, but more delicate. It is indicated to reduce surgical smoke

BIPOLAR CURRENTS

BIPOLAR	Bipolar Coagulation, to be used with forceps, scissors, double-needle electrodes and laparoscopic instruments

CURRENTS
ALSATOM SU 140/BD-MPC

PURE	Cut for use in Open Surgery or Laparoscopy
P PULSED	Pulsed Fast Cut, suitable to achieve detailed results, minimum thermal effect and reduction of surgical smoke
BLEND	Coagulating Cut, with greater thermal effect

MACRO	Coagulation, to be used with forceps, scissors, double-needle electrodes and laparoscopic instruments
M PULSED	Pulsed Coagulation. Similar to MACRO, but more delicate and useful to reduce surgical smoke
MICRO	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 **Error Codes** in the event of problems relating to: - general operation or activation errors (General Error Control) - output power (Output Error Control)
Power self-adjustment	By microprocessor with: **ADC System** - 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 SU 50-MPC**	**ALSATOM SU 100-MPC**	**ALSATOM SU 140-MPC**	**ALSATOM SU 140/D-MPC**
PURE	80 W - 500 Ω 980 Vpp - CF 1.5 M: no - D: 100%	100 W - 500 Ω 1000 Vpp - CF 1.5 M: no - D: 100%	140 W - 500 Ω 1000 Vpp - CF 1.5 M: no - D: 100%	160 W - 500 Ω 990 Vpp - CF 1.5 M: no - D: 100%
P PULSED	40 W - 500 Ω 1350 Vpp - CF 3 M: 50% - D: 100%	50 W - 500 Ω 1360 Vpp - CF 3 M: 50% - D: 100%	70 W - 500 Ω 1380 Vpp - CF 3 M: 50% - D: 100%	80 W - 500 Ω 1380 Vpp - CF 3 M: 50% - D: 100%
BLEND	80 W - 500 Ω 1400 Vpp - CF 2.3 M: no - D: 80%	100 W - 500 Ω 1400 Vpp - CF 2.3 M: no - D: 80%	120 W - 500 Ω 1400 Vpp - CF 2.3 M: no - D: 80%	140 W - 500 Ω 1410 Vpp - CF 2.3 M: no - D: 80%
B PULSED 1	40 W - 500 Ω 1550 Vpp - CF 3.5 M: 50% - D: 80%	50 W - 500 Ω 1550 Vpp - CF 3.5 M: 50% - D: 80%	60 W - 500 Ω 1550 Vpp - CF 3.5 M: 50% - D: 80%	70 W - 500 Ω 1600 Vpp - CF 3.5 M: 50% - D: 80%
B PULSED 2	35 W - 500 Ω 1580 Vpp - CF 3.6 M: 50% - D: 80%	38 W - 500 Ω 1580 Vpp - CF 3.6 M: 50% - D: 80%	38 W - 500 Ω 1580 Vpp - CF 3.6 M: 50% - D: 80%	38 W - 500 Ω 1630 Vpp - CF 3.6 M: 50% - D: 80%
MICRO	80 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%	80 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%	80 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%	100 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%
M PULSED	80 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%	80 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%	80 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%	100 W - 500 Ω 1530 Vpp - CF 3.4 M: no - D: 50%
FULG	80 W - 750 Ω 2250 Vpp - CF 3.5 M: no - D: 50%	100 W - 750 Ω 2300 Vpp - CF 3.5 M: no - D: 50%	120 W - 750 Ω 2300 Vpp - CF 3.5 M: no - D: 50%	120 W - 750 Ω 2280 Vpp - CF 3.5 M: no - D: 50%
F PULSED	40 W - 750 Ω 2300 Vpp - CF 5 M: 50% - D: 50%	48 W - 750 Ω 2300 Vpp - CF 5 M: 50% - D: 50%	60 W - 750 Ω 2300 Vpp - CF 5 M: 50% - D: 50%	60 W - 750 Ω 2270 Vpp - CF 5 M: 50% - D: 50%
Bipolar currents	**SU 50-MPC**	**SU 100-MPC**	**SU 140-MPC**	**SU 140/D-MPC**
BIPOLAR	80 W - 100 Ω 500 Vpp - CF 2.8 M: no - D: 100%	100 W - 100 Ω 500 Vpp - CF 2.8 M: no - D: 100%	100 W - 100 Ω 500 Vpp - CF 2.8 M: no - D: 100%	100 W - 100 Ω 500 Vpp - CF 2.8 M: no - D: 100%

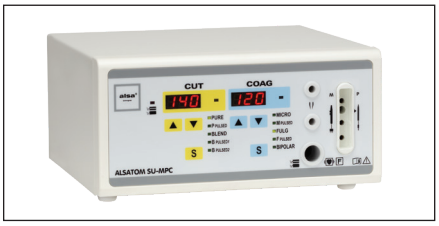
Bipolar currents	**ALSATOM SU 140/BD MPC**
PURE	120 W - 400 Ω 975 Vpp - CF 2.75 M: no - D: 100%
P PULSED	60 W - 400 Ω 990 Vpp - CF 3.98 M: 50% - D: 100%
BLEND	100 W - 400 Ω 975 Vpp - CF 2.8 M: no - D: 80%
MACRO	100 W - 100 Ω 640 Vpp - CF 3.6 M: no - D: 80%
M PULSED	50 W - 100 Ω 640 Vpp - CF 5 M: no -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

KEY

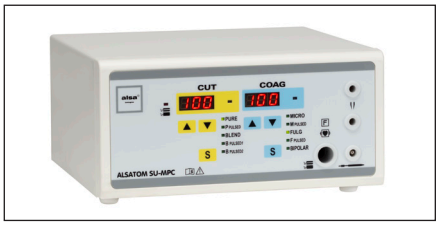
W: DELIVERED POWER
Ω: NOMINAL LOADS
Vpp: PEAK/NO-LOAD PEAK VOLTAGES
CF: CREST FACTORS
M: MODULATION
D: DUTY CYCLE

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



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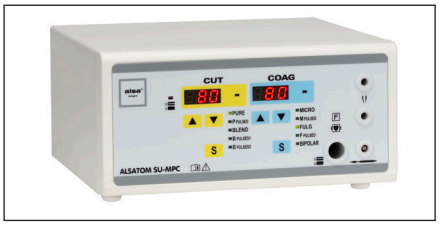

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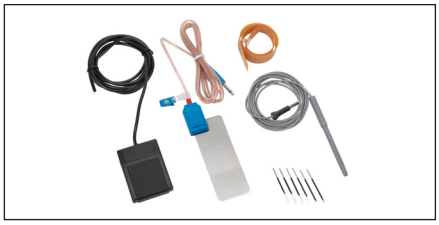
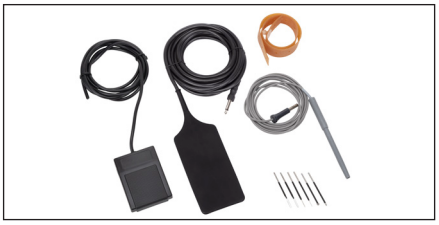
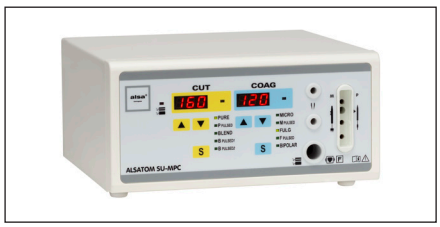
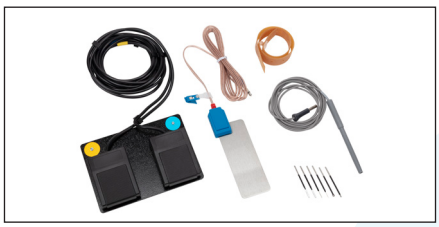

B700/A


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

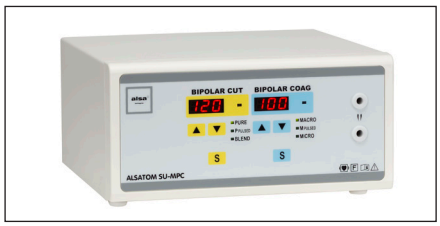


ALSATOM SU 140/D-MPC


B730/A


B730/B

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



ALSATOM SU 140/BD-MPC

EXCELL MCDSe

EXCELL 400/A 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

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

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

BIPOLAR CURRENTS

PURE	Pure cut with minimum coagulating effect
BLEND	Coagulating cut with strong coagulating effect

MICRO	Very delicate coagulation, Micro Precise type, with minimum sticking effect of tissue on the tips of the forceps
MICRO AUTO	Coagulation identical to Micro, but with Impedance Sensing automatic Auto Start/Auto Stop
MACRO	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: - **Main Self-check** when turned on - **Standard Self-check** during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific **Error Codes**, in the event of problems concerning: - general operation or activation errors (General Error Control) - output power (Output Error Control) - **HF Leakage Control**: 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 - Storage of the last 32 Error Codes
Power self-adjustment	By microprocessor with: - **ADC System** - Constant power: self-adjusts power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue
Operation memorisation	10 programs
Outputs	2 Monopolar and 1 Bipolar
Foot-operated controls	The EXCELL MCDSe can be equipped with: • A double pedal control selectable for monopolar or bipolar functions. • Two double pedal controls, one for monopolar and one for bipolar functions. 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 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 EXCELL 400 MCDSe, EXCELL 350 MCDSe, EXCELL 250 MCDSe, EXCELL 200 MCDSe: 38x35x16 cm – 15 Kg
Argon gas section (only in the EXCELL 400/A MCDSe model)	
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 3450 Vpp – CF: 1.6 M: no – D: no	350 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	280 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	200 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	400 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no
BLEND 1	300 W – 350 Ω 3600 Vpp – CF: 2.3 M: 29 kHz – D: 65%	300 W – 350 Ω 3600 Vpp – CF: 2.3 M: 29 kHz – D: 65%	280 W – 350 Ω 3540 Vpp – CF: 2.3 M: 29 kHz – D: 65%	200 W – 350 Ω 3500 Vpp – CF: 2.3 M: 29 kHz – D: 65%	300 W – 350 Ω 3600 Vpp – CF: 2.3 M: 29 kHz – D: 65%
BLEND 2	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%
ENDO	250 W – 350 Ω 1880 Vpp – CF: 2.2 50% Pure / 50% Coag	220 W – 350 Ω 1880 Vpp – CF: 2.2 50% Pure / 50% Coag	220 W – 350 Ω 1880 Vpp – CF: 2.2 50% Pure / 50% Coag	200 W – 350 Ω 1880 Vpp – CF: 2.2 50% Pure / 50% Coag	250 W – 350 Ω 1880 Vpp – CF: 2.2 50% Pure / 50% Coag
FULG FORCED	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%
PINPOINT CONTACT	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 56%	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 56%	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 56%	200 W – 250 Ω 3400 Vpp – CF: 2.6 M: 29 kHz – D: 56%	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 56%
SOFT	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	200 W – 250 Ω 3020 Vpp – CF: 2,5 M: 29 kHz – D: 56%	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%
SPRAY	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 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 790 Vpp – CF: 1.5 M: no – D: no	140 W – 300 Ω 790 Vpp – CF: 1.5 M: no – D: no	140 W – 300 Ω 790 Vpp – CF: 1.5 M: no – D: no	140 W – 300 Ω 790 Vpp – CF: 1.5 M: no – D: no	140 W – 300 Ω 790 Vpp – CF: 1.5 M: no – D: no
BLEND	120 W – 300 Ω 980 Vpp – CF: 1.8 M: 29 kHz – D: 75%	120 W – 300 Ω 980 Vpp – CF: 1.8 M: 29 kHz – D: 75%	120 W – 300 Ω 980 Vpp – CF: 1.8 M: 29 kHz – D: 75%	120 W – 300 Ω 980 Vpp – CF: 1.8 M: 29 kHz – D: 75%	120 W – 300 Ω 980 Vpp – CF: 1.8 M: 29 kHz – D: 75%
MICRO	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no
MICRO AUTO	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no
MACRO	120 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	120 W – 100 Ω 760 Vpp – CF: 1.7 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

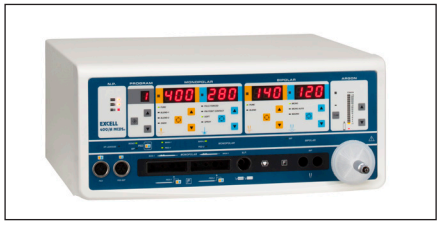
EXCELL 400 MCDSe, without accessories
EXCELL 350 MCDSe, without accessories
EXCELL 250 MCDSe, without accessories
EXCELL 200 MCDSe, without accessories
EXCELL 400/A MCDSe, without accessories
B610/A STANDARD ACCESSORIES SERIES including:
1 DS/E Double pedal control, electric, waterproof
1 NP/A Stainless 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

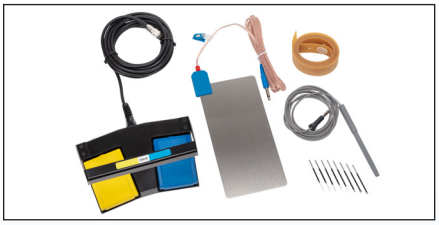

EXCELL 400 MCDSe

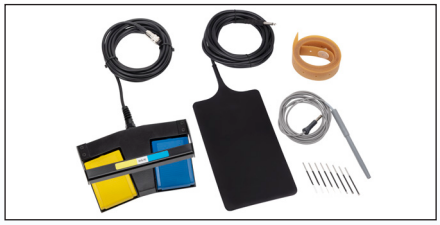

EXCELL 350 MCDSe


EXCELL 250 MCDSe


EXCELL 200 MCDSe


EXCELL 400/A MCDSe


B610/A


B610/B


alsa
bologna
PROGRAM
MONOPOLAR
BIPOLAR
400
150
140
120
EXCELL
400 MCDS
alsa

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

PURE	Non-modulated sinusoidal current for cutting without any coagulating effect
BLEND 1	Modulated and pulsed sinusoidal current for cutting with moderate coagulating effect
BLEND 2	Modulated and pulsed current for cutting with strong coagulating effect, Spray type, for surgery or laparoscopy
AUTO PURE	Non-modulated sinusoidal current for cutting without any coagulating effect
AUTO BLEND	Modulated and pulsed sinusoidal current for cutting with moderate coagulating effect
AUTO ENDO	Current with alternating cut and coagulation phases for flexible endoscopy
FULG FORCED	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
PINPOINT CONTACT	Modulated medium-voltage current, very similar to the previous one, but with a more delicate effect
SOFT	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
SPRAY	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

PURE	Non-modulated sinusoidal pulsed current for cut
BLEND	Modulated and pulsed sinusoidal current for cut with coagulating effect
MICRO CV	Non-modulated low voltage current for very delicate coagulations with Soft / Micro Precise effect, minimum superficial carbonisation, and no sticking on tissue
MICRO HC	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
MICRO AUTO	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
MACRO	Modulated and pulsed current with stronger effect than the Micro HC current
SEAL HC	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: - **Main Self-check** when turned on - **Standard Self-check** during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific **Error Codes**, in the event of problems concerning: - general operation or activation errors (General Error Control) - power supply (Output Error Control) - **HF Leakage Control**: 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 - Storage of the last 32 Error Codes
Power self-adjustment	By means of a microprocessor with two different systems: - **ADC System** - Constant power: self-adjusts the power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue - **APC System** - 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
Operation memorisation	100 programs
Outputs	2 Monopolar and 2 Bipolar
Foot-operated controls	EXCELL NHP units can be fitted with: • A double pedal control selectable for monopolar or bipolar functions. • Two double pedal controls, one for monopolar and one for bipolar functions. 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 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 EXCELL NHP 400/D, EXCELL NHP 350/D and EXCELL NHP 250/D: 38x35x16 cm – 15 Kg
Argon gas section (only in EXCELL NHP 400/DA and EXCELL NHP 250/DA models)	
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 3450 Vpp – CF: 1.6 M: no – D: no	350 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	280 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	400 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	280 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	X	
BLEND 1	300 W – 350 Ω 3600 Vpp – CF: 2.3 M: 29 kHz – D: 65%	300 W – 350 Ω 3600 Vpp – CF: 2.3 M: 29 kHz – D: 65%	280 W – 350 Ω 3540 Vpp – CF: 2.3 M: 29 kHz – D: 65%	300 W – 350 Ω 3600 Vpp – CF: 2.3 M: 29 kHz – D: 65%	280 W – 350 Ω 3540 Vpp – CF: 2.3 M: 29 kHz – D: 65%	X	
BLEND 2	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	X	
AUTO PURE	400 W – 350 Ω 1470 Vpp – CF: 1.6 M: no – D: no	350 W – 350 Ω 1350 Vpp – CF: 1.6 M: no – D: no	280 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no	400 W – 350 Ω 1470 Vpp – CF: 1.6 M: no – D: no	280 W – 350 Ω 3450 Vpp – CF: 1.6 M: no – D: no		X
AUTO BLEND	300 W – 350 Ω 1930 Vpp – CF: 2.3 M: 29 kHz – D: 65%	300 W – 350 Ω 1930 Vpp – CF: 2.3 M: 29 kHz – D: 65%	280 W – 350 Ω 3540 Vpp – CF: 2.3 M: 29 kHz – D: 65%	300 W – 350 Ω 1930 Vpp – CF: 2.3 M: 29 kHz – D: 65%	280 W – 350 Ω 3540 Vpp – CF: 2.3 M: 29 kHz – D: 65%		X
AUTO ENDO	250 W – 350 Ω 1890 Vpp – CF: 2.2 50% Pure / 50% Coag	220 W – 350 Ω 1710 Vpp – CF: 2.2 50% Pure / 50% Coag	220 W – 350 Ω 1880 Vpp – CF: 2.2 50% Pure / 50% Coag	250 W – 350 Ω 1890 Vpp – CF: 2.2 50% Pure / 50% Coag	220 W – 350 Ω 1880 Vpp – CF: 2.2 50% Pure / 50% Coag		X
FULG FORCED	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	150 W – 350 Ω 4700 Vpp – CF: 4.5 M: 78 kHz – D: 35%	X	
PINPOINT CONTACT	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 50%	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 50%	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 50%	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 50%	250 W – 250 Ω 3460 Vpp – CF: 2.6 M: 29 kHz – D: 50%	X	
SOFT	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	280 W – 250 Ω 3440 Vpp – CF: 2.5 M: 29 kHz – D: 56%	X	
SPRAY	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 M: 19 kHz – D: 9%	140 W – 600 Ω 7600 Vpp – CF: 8.1 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 850 Vpp – CF: 1.5 M: no – D: no	160 W – 300 Ω 850 Vpp – CF: 1.5 M: no – D: no	160 W – 300 Ω 850 Vpp – CF: 1.5 M: no – D: no	160 W – 300 Ω 850 Vpp – CF: 1.5 M: no – D: no	160 W – 300 Ω 850 Vpp – CF: 1.5 M: no – D: no	X	
BLEND	130 W – 300 Ω 1000 Vpp – CF: 1.8 M: 29 kHz – D: 75%	130 W – 300 Ω 1000 Vpp – CF: 1.8 M: 29 kHz – D: 75%	130 W – 300 Ω 1000 Vpp – CF: 1.8 M: 29 kHz – D: 75%	130 W – 300 Ω 1000 Vpp – CF: 1.8 M: 29 kHz – D: 75%	130 W – 300 Ω 1000 Vpp – CF: 1.8 M: 29 kHz – D: 75%	X	
MICRO CV	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no		X
MICRO HC	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	X	
MICRO AUTO	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 450 Vpp – CF: 1.7 M: no – D: no		X
MACRO	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 760 Vpp – CF: 1.7 M: no – D: no	X	
SEAL HC	130 W – 100 Ω 710 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 710 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 710 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 710 Vpp – CF: 1.7 M: no – D: no	130 W – 100 Ω 710 Vpp – CF: 1.7 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

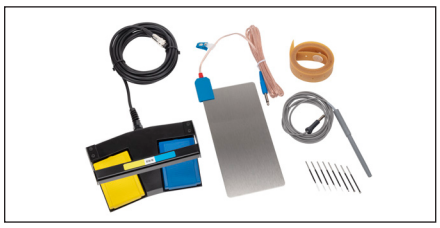
DEVICES AND STANDARD ACCESSORIES

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


02
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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

PURE	Non-modulated sinusoidal current for pure cut without coagulating effect
BLEND 1	Sinusoidal modulated current for coagulating cut
BLEND 2	Modulated current for cut with strong coagulating effect, Spray type, for surgery and laparoscopy
AUTO PURE	Non-modulated sinusoidal current for cut without coagulating effect
AUTO BLEND	Sinusoidal modulated current for coagulating cut
AUTO ENDO	Current with alternating cut and coagulation phases for flexible endoscopy

FULG FORCED	Modulated high voltage current with strong coagulating superficial and deep effect
PINPOINT	Modulated medium voltage current with medium coagulating superficial and deep effect
SOFT	Modulated low voltage current with delicate coagulating effect without superficial carbonisation
SPRAY	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

STANDARD	Pulsed current for cut
SALINE	Pulsed current for endoscopic cut in saline solution

MICRO	Pulsed current for coagulation Soft / Micro Precise type and for coagulation in saline solution
MACRO	Pulsed current for coagulation Standard / Forced type in laparoscopy
SEAL	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: - **Main Self-check** when turned on - **Standard Self-check** during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific **Error Codes**, in the event of problems concerning: - general operation or activation errors (General Error Control) - output power (Output Error Control) - **HF Leakage Control**: 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 - Storage of the last 32 Error Codes
Power self-adjustment	By means of a microprocessor with two different systems: - **ADC System** - Constant power: self-adjusts the power, controlling voltage and current, based on real-time feedback (7000 checks/sec) between device and patient's tissue - **APC System** - 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
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. 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 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	Current self-adjustment ADC	APC
PURE	350 W - 350 Ω 3450 Vpp - CF: 1.6 M: no - D: no	X	
BLEND 1	300 W - 350 Ω 3600 Vpp - CF: 2.3 M: 29 kHz - D: 65%	X	
BLEND 2	140 W - 600 Ω 7600 Vpp - CF: 8.1 M: 19 kHz - D: 9%	X	
AUTO PURE	350 W - 350 Ω 1350 Vpp - CF: 1.6 M: no - D: no		X
AUTO BLEND	300 W - 350 Ω 1930 Vpp - CF: 2.3 M: 29 kHz - D: 65%		X
AUTO ENDO	220 W - 350 Ω 1710 Vpp - CF: 2.2 50% Pure 50% Blend I		X
FULG FORCED	150 W - 350 Ω 4700 Vpp - CF: 4.5 M: 78 kHz - D: 3,5%	X	
PINPOINT	250 W - 250 Ω 3460 Vpp - CF: 2.6 M: 29 kHz - D: 50%	X	
SOFT	280 W - 250 Ω 3440 Vpp - CF: 2.5 M: 29 kHz - D: 56%	X	
SPRAY	140 W - 600 Ω 7600 Vpp - CF: 8.1 M: 19 kHz - D: 9%	X	

Bipolar currents	EXCELL NHP ENDOMED	Current self-adjustment ADC	APC
STANDARD	180 W - 350 Ω 1200 Vpp - CF: 1.5 M: no - D: no	X	
SALINE	320 W - 50 Ω 1200 Vpp - CF: 1.5 M: no - D: no	X	
MICRO	130 W - 100 Ω 420 Vpp - CF: 1.7 M: no - D: no		X
MACRO	130 W - 200 Ω 1050 Vpp - CF: 1.7 M: no - D: no	X	
SEAL	130 W (200 W) - 100 Ω 420 Vpp - CF: 1.7 M: no - D: no		X

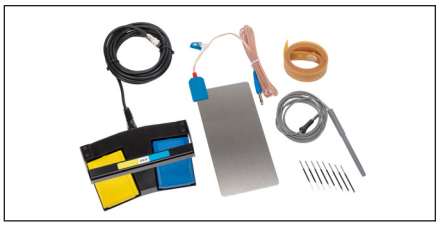
KEY

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

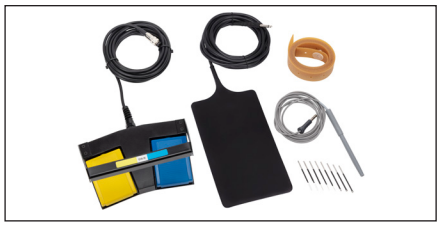
DEVICE AND STANDARD ACCESSORIES

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

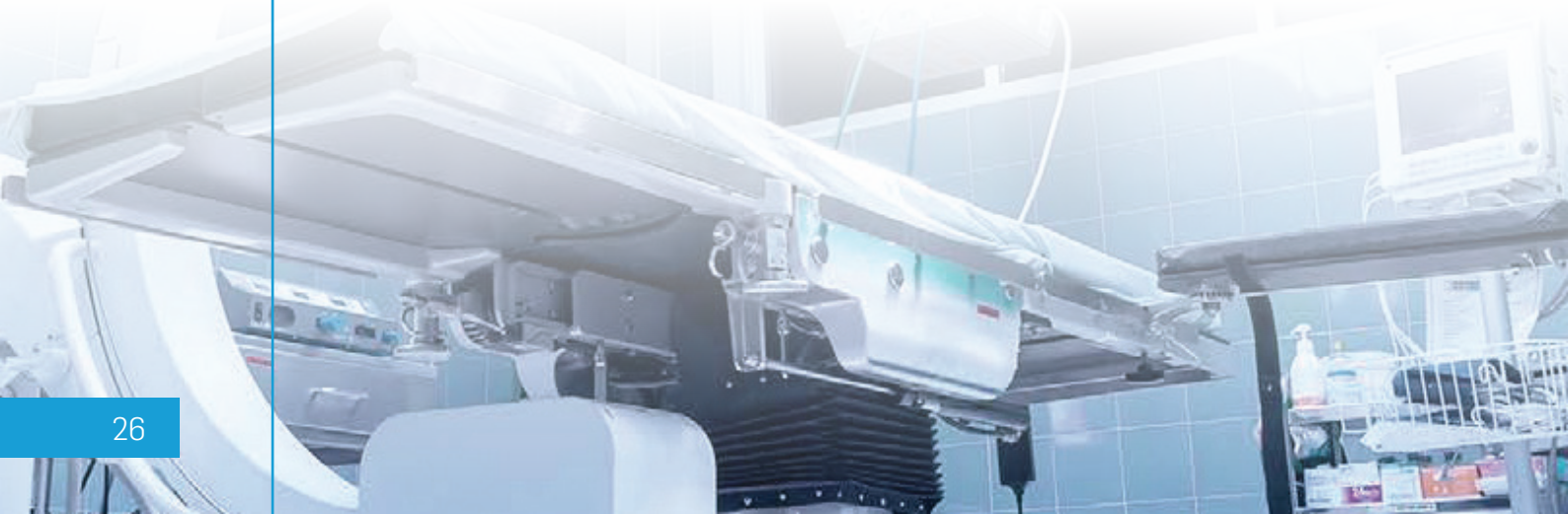
EXCELL NHP/TA-400

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

PURE CUT	Pure cut without coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)
BLEND CUT 1	Blended cut with medium coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)
BLEND CUT 2	Blended cut with very high coagulating effect. For open or laparoscopic surgery
PURE CUT PULSED	Pure pulsed cut without coagulating effect. For open or laparoscopic surgery (suitable to reduce surgical smoke)
BLEND CUT PULSED	Blended pulsed cut with medium coagulating effect. For open or laparoscopic surgery (suitable to reduce surgical smoke)
AUTO PURE CUT MICRO	"Constant voltage", delicate, pure cut without coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)
AUTO BLEND CUT MICRO	"Constant voltage", delicate cut blended with a medium coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP and TURV procedures)
AUTO PAPILLO PURE CUT	"Constant voltage" pure cut, without coagulating effect, for flexible endoscopy. With four modes of delivery: continuous and pulsed (slow, medium, fast)
AUTO POLIPO BLEND CUT	"Constant voltage" cut, blended with a medium coagulating effect, for flexible endoscopy. With four modes of delivery: continuous and pulsed (slow, medium, fast)
AUTO ENDOCUT	"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

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

BIPOLAR CURRENTS

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

SOFT MICRO BICOAG	Very precise and delicate coagulation. For open or laparoscopic surgery, under liquid endoscopy (TURPis and TURVis procedures) and flexible endoscopy
FORCED MACRO BICOAG	Fast coagulation. For open or laparoscopic surgery
AUTO SOFT MICRO BICOAG	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
SEALING	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
AUTO SEALING	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: - **Main Self-check** when turned on - **Standard Self-check** during operation and, if any, operation lock (within 100 milliseconds), with alarm signalling to operators through specific **Error Codes**, in the event of problems concerning: - general operation or activation errors (General Error Control) - output power (Output Error Control) - **HF Leakage Control**: 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 - Storage of the last 32 Error Codes
Power self-adjustment	By means of a microprocessor with two different systems: - **ADC System** - 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). - **APC System** - 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).
Operation memorisation	100 programs
Outputs	2 Monopolar and 2 Bipolar
Foot-operated controls	EXCELL NHP/T can be fitted with: • A double pedal control with push button selector for monopolar or bipolar functions. • Two double pedal controls, one for monopolar and one for bipolar functions. 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 EXCELL NHP/TA-400 and EXCELL NHP/TA-200: 38x38x20 cm – 10.5 Kg
Argon gas section (only in EXCELL NHP/TA-400 and EXCELL NHP/TA-200 models)	
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	Current self-adjustment ADC	APC
PURE CUT	400 W - 400 Ω 2550 Vpp - CF: 1.46 M: no - D: 100%	200 W - 400 Ω 2550 Vpp - CF: 1.46 M: no - D: 100%	400 W - 400 Ω 2550 Vpp - CF: 1.46 M: no - D: 100%	200 W - 400 Ω 2550 Vpp - CF: 1.46 M: no - D: 100%	X	
BLEND CUT 1	300 W - 400 Ω 3390 Vpp - CF: 1.94 M: 17 kHz - D: 95%	200 W - 400 Ω 3390 Vpp - CF: 1.94 M: 17 kHz - D: 95%	300 W - 400 Ω 3390 Vpp - CF: 1.94 M: 17 kHz - D: 95%	200 W - 400 Ω 3390 Vpp - CF: 1.94 M: 17 kHz - D: 95%	X	
BLEND CUT 2	250 W - 400 Ω 3330 Vpp - CF: 2.29 M: 17 kHz - D: 65%	200 W - 400 Ω 3330 Vpp - CF: 2.29 M: 17 kHz - D: 65%	250 W - 400 Ω 3330 Vpp - CF: 2.29 M: 17 kHz - D: 65%	200 W - 400 Ω 3330 Vpp - CF: 2.29 M: 17 kHz - D: 65%	X	
PURE CUT PULSED	200 W - 400 Ω 2640 Vpp - CF: 2 M: 3 Hz - D: 50%	100 W - 400 Ω 2640 Vpp - CF: 2 M: 3 Hz - D: 50%	200 W - 400 Ω 2640 Vpp - CF: 2 M: 3 Hz - D: 50%	100 W - 400 Ω 2640 Vpp - CF: 2 M: 3 Hz - D: 50%	X	
BLEND CUT PULSED	150 W - 400 Ω 3330 Vpp - CF: 3.2 M: 50 Hz - D: 50%	100 W - 400 Ω 3330 Vpp - CF: 3.2 M: 50 kHz - D: 50%	150 W - 400 Ω 3330 Vpp - CF: 3.2 M: 50 Hz - D: 50%	100 W - 400 Ω 3330 Vpp - CF: 3.2 M: 50 kHz - D: 50%	X	
AUTO PURE CUT MICRO	300 W - 300 Ω 1137 Vpp - CF: 1.5 M: no - D: 100%	200 W - 300 Ω 1137 Vpp - CF: 1.5 M: no - D: 100%	300 W - 300 Ω 1137 Vpp - CF: 1.5 M: no - D: 100%	200 W - 300 Ω 1137 Vpp - CF: 1.5 M: no - D: 100%		X
AUTO BLEND CUT MICRO	300 W - 300 Ω 1500 Vpp - CF: 1.98 M: 17 kHz - D: 90%	200 W - 300 Ω 1500 Vpp - CF: 1.98 M: 17 kHz - D: 90%	300 W - 300 Ω 1500 Vpp - CF: 1.98 M: 17 kHz - D: 90%	200 W - 300 Ω 1500 Vpp - CF: 1.98 M: 17 kHz - D: 90%		X
AUTO PAPILLO PURE CUT	300 W - 300 Ω 1140 Vpp - CF: 1.5 M: no - D: 100%	200 W - 300 Ω 1140 Vpp - CF: 1.5 M: no - D: 100%	300 W - 300 Ω 1140 Vpp - CF: 1.5 M: no - D: 100%	200 W - 300 Ω 1140 Vpp - CF: 1.5 M: no - D: 100%		X
AUTO POLIPO BLEND CUT	300 W - 300 Ω 1490 Vpp - CF: 1.98 M: 17 kHz - D: 95%	200 W - 300 Ω 1490 Vpp - CF: 1.98 M: 17 kHz - D: 95%	300 W - 300 Ω 1490 Vpp - CF: 1.98 M: 17 kHz - D: 95%	200 W - 300 Ω 1490 Vpp - CF: 1.98 M: 17 kHz - D: 95%		X
AUTO ENDOCUT	300 W - 300 Ω 1670 Vpp - CF: 2.20	200 W - 300 Ω 1670 Vpp - CF: 2.20	300 W - 300 Ω 1670 Vpp - CF: 2.20	200 W - 300 Ω 1670 Vpp - CF: 2.20		X
FULG FORCED COAG	150 W - 300 Ω 4500 Vpp - CF: 6.45 M: 60 kHz - D: 18%	150 W - 300 Ω 4500 Vpp - CF: 6.45 M: 60 kHz - D: 18%	150 W - 300 Ω 4500 Vpp - CF: 6.45 M: 60 kHz - D: 18%	150 W - 300 Ω 4500 Vpp - CF: 6.45 M: 60 kHz - D: 18%	X	
SPRAY COAG	200 W - 700 Ω 7750 Vpp - CF: 7.75 M: 30 kHz - D: 7%	200 W - 700 Ω 7750 Vpp - CF: 7.75 M: 30 kHz - D: 7%	200 W - 700 Ω 7750 Vpp - CF: 7.75 M: 30 kHz - D: 7%	200 W - 700 Ω 7750 Vpp - CF: 7.75 M: 30 kHz - D: 7%	X	
PULSED SPRAY COAG	100 W - 700 Ω 7850 Vpp - CF: 11.54 M: 3 Hz - D: 50%	100 W - 700 Ω 7850 Vpp - CF: 11.54 M: 3 Hz - D: 50%	100 W - 700 Ω 7850 Vpp - CF: 11.54 M: 3 Hz - D: 50%	100 W - 700 Ω 7850 Vpp - CF: 11.54 M: 3 Hz - D: 50%	X	
PINPOINT CONTACT COAG	300 W - 400 Ω 3700 Vpp - CF: 2.2 M: 17 kHz - D: 85%	200 W - 400 Ω 3700 Vpp - CF: 2.2 M: 17 kHz - D: 85%	300 W - 400 Ω 3700 Vpp - CF: 2.2 M: 17 kHz - D: 85%	200 W - 400 Ω 3700 Vpp - CF: 2.2 M: 17 kHz - D: 85%	X	
SOFT MICRO COAG	280 W - 300 Ω 3300 Vpp - CF: 2.16 M: 17 kHz - D: 75%	200 W - 300 Ω 2875 Vpp - CF: 2.1 M: 17 kHz - D: 75%	280 W - 300 Ω 3300 Vpp - CF: 2.16 M: 17 kHz - D: 75%	200 W - 300 Ω 2875 Vpp - CF: 2.1 M: 17 kHz - D: 75%	X	
SPRAY COAG + GAS ARGON	-	-	200 W - 700 Ω 7750 Vpp - CF: 7.75 M: 30 kHz - D: 7%	200 W - 700 Ω 7750 Vpp - CF: 7.75 M: 30 kHz - D: 7%	X	
PULSED SPRAY COAG + GAS ARGON	-	-	100 W - 700 Ω 7850 Vpp - CF: 11.54 M: 3 Hz - D: 50%	100 W - 700 Ω 7850 Vpp - CF: 11.54 M: 3 Hz - D: 50%	X	

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

K E Y

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)

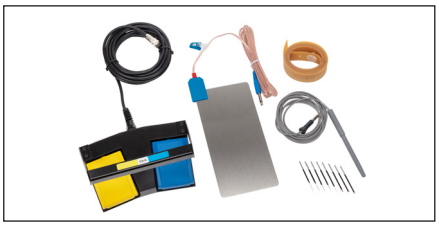
B610/Bsw STANDARD ACCESSORIES SERIES identical to B610/Asw, but with flexible conductive rubber neutral electrode NP/GA for adults
B610/Psw As above, with neutral paediatric electrode NP/GP

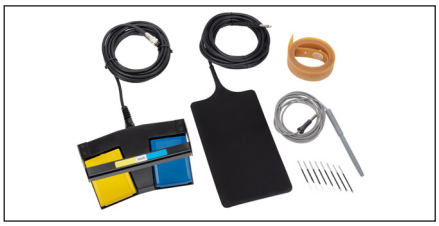
EXCELL NHP/T-400

EXCELL NHP/T-200

EXCELL NHP/TA-400

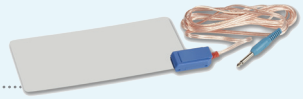
EXCELL NHP/TA-200


B610/Asw


B610/Bsw


alsa
bologna
50
50
40
e3
CS900LC
alsa

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 Ø 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, Ø 2.5 mm
E13 As above, angled
E14 Ball electrode, straight, Ø 4 mm
E15 As above, angled
E16 Ball electrode, straight, Ø 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 Ø 5 mm)
E23 As above, Ø 10 mm
E25 As above, Ø 15 mm
E23/N Loop electrode (ribbon, round Ø 10 mm)
E25/N As above, Ø 15 mm
E26 Plate electrode
EXT/15 Extension l. 15 cm for all electrodes with stem Ø 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 Ø 5 mm)
E44 As above, Ø 10 mm
E45 As above, Ø 15 mm
E46 Ball electrode, straight, Ø 2.5 mm
E47 As above, Ø 4 mm
E47/6 As above, Ø 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

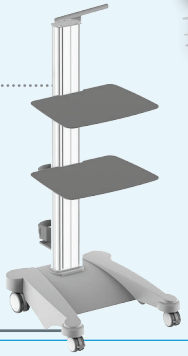
ACCESSORIES FOR SURGERY WITH ARGON GAS

(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

alsa®

bologna

PRODUCTS DESIGNED AND MANUFACTURED BY:
ALSA APPARECCHI MEDICALI SRL
via C. Bonazzi, 16
40013 Castel Maggiore (BO) - ITALIA
Tel: +39 051 700101 Email: alsa@alsamed.com
www.alsamed.com

ISO 9001
9120.ALSA

IT - 1231

ISO 13485
9124.ALS2

CE 0051

ELB-EN_Rev.0_06/22

CERTIFICATO UE DI SISTEMA DI GESTIONE DELLA QUALITA'

Certificato n. 083/MDR

Visto l'esito delle verifiche condotte in conformità all'Allegato IX capi I e III del Regolamento (UE) 2017/745, si dichiara che il sistema completo di gestione della qualità istituito, documentato e implementato:

dal Fabbricante: **ALSA APPARECCHI MEDICALI SRL**

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

SRN: IT-MF-000019170

per i seguenti dispositivi:

Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori

è conforme e assicura la conformità di tali dispositivi ai requisiti applicabili del Regolamento UE suddetto ed è sottoposto alla sorveglianza prevista alla sezione 3 del medesimo Allegato.

Ulteriori informazioni sono presenti nell'Allegato tecnico che costituisce parte integrante e sostanziale del presente certificato.

Questo Certificato UE è rilasciato da IMQ S.p.A. quale Organismo Notificato n. 0051 per il Regolamento (UE) 2017/745 relativo ai dispositivi medici.

Gli esami ed i test effettuati (inclusi i riferimenti alle Specifiche comuni e/o alle norme applicate) sono documentati nel pertinente Rapporto di valutazione della conformità redatto da IMQ, tracciabile attraverso la Pratica IMQ (indicata nella sezione "Storico delle revisioni" che segue) e disponibile su richiesta.

Data di prima emissione: 2023-03-17

Data di scadenza: 2028-03-16

DocuSign

IMQ

IMQ S.p.A. | I-20138 Milano | Via Quintiliano 43 | www.imq.it

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 083/MDR

On the basis of the assessment carried out according to the Annex IX chapters I and III of the Regulation (EU) 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer: **ALSA APPARECCHI MEDICALI SRL**

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

SRN: IT-MF-000019170

for the following devices:

High frequency electrosurgery equipment and related accessories

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation and it is subject to surveillance as required by the same Annex, section 3.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date: 2023-03-17

Expiry Date: 2028-03-16

IMQ

DocuSign

Allegato Tecnico al Certificato UE n. 083/MDR

Technical Attachment of EU Certificate no. 083/MDR

Scheda tecnica n. 1

Technical sheet no. 1

Categoria di dispositivo:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori**
Device category:	*High frequency electrosurgery equipment and related accessories*
Destinazione d'uso:	**Le unità elettrochirurgiche e relativi accessori hanno lo scopo di tagliare e/o asportare tessuto, coagulare e controllare il sanguinamento mediante l'utilizzo di corrente elettrica ad alta frequenza, con tecnica monopolare e/o bipolare, durante le procedure chirurgiche.**
Intended purpose:	*Electrosurgical units and related accessories are intended to cut and/or remove tissue, coagulate and control bleeding through the use of high-frequency electrical current, with monopolar and/or bipolar technique, during the surgical procedures.*
Classe di rischio:	**IIb**
Risk class:	IIb
Sito/i del Fabbricante / *Manufacturer's site(s):*	**- 40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy**
Riferimenti ad altri certificati necessari per l'immissione sul mercato dei dispositivi in questione:	**Non applicabile**
Reference to other certificates required for the placing on the market of the covered devices:	*Not applicable*
Condizioni o limitazioni di validità:	**Nessuna**
Conditions for or limitations to the validity:	*None*
Altre informazioni rilevanti:	**Nessuna**
Other relevant data:	*None*
Dati dei dispositivi:	**I dati dei dispositivi sono elencati nel documento 'Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR' rev. 1 del 2023/03/17 allegato al presente certificato. Tale documento costituisce parte integrante e sostanziale del presente certificato.**
Device data:	*Data of the devices are listed in the document 'List of the devices covered by the EU Certificate no. 083/MDR' rev. 1 dated 2023/03/17 attached to this certificate. This document is integral and substantial part of this certificate.*

Allegato Tecnico al Certificato UE n.083/MDR

Technical Attachment of EU Certificate no. 083/MDR

Storico delle revisioni

Revision history

N. *No.*	**Data** *Date*	**Riferimento Pratica IMQ** *Reference to IMQ Project*	**Descrizione** *Description*
1	2023-03-17	DM22-0080460-01	**Prima emissione** *First Issue*

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
ALSATOM SU 50-MPC	ALSATOM SU 50-MPC	ALSA
ALSATOM SU 100-MPC	ALSATOM SU 100-MPC	ALSA
ALSATOM SU 140-MPC	ALSATOM SU 140-MPC	ALSA
ALSATOM SU 140/D-MPC	ALSATOM SU 140/D-MPC	ALSA
ALSATOM SU 140/BD-MPC	ALSATOM SU 140/BD-MPC	ALSA
EXCELL 200 MCDSe	EXCELL 200 MCDSe	ALSA
EXCELL 250 MCDSe	EXCELL 250 MCDSe	ALSA
EXCELL 350 MCDSe	EXCELL 350 MCDSe	ALSA
EXCELL 400 MCDSe	EXCELL 400 MCDSe	ALSA
EXCELL 400/A MCDSe	EXCELL 400/A MCDSe	ALSA
EXCELL NHP 250/D	EXCELL NHP 250/D	ALSA
EXCELL NHP 350/D	EXCELL NHP 350/D	ALSA
EXCELL NHP 400/D	EXCELL NHP 400/D	ALSA
EXCELL NHP 250/DA	EXCELL NHP 250/DA	ALSA
EXCELL NHP 400/DA	EXCELL NHP 400/DA	ALSA
EXCELL NHP ENDOMED	EXCELL NHP ENDOMED	ALSA
EXCELL NHP/T-400	EXCELL NHP/T-400	ALSA
EXCELL NHP/T-200	EXCELL NHP/T-200	ALSA
EXCELL NHP/TA-400	EXCELL NHP/TA-400	ALSA
EXCELL NHP/TA-200	EXCELL NHP/TA-200	ALSA
TOPTOM SU 100	TOPTOM SU 100	ALSA
TOPTOM SU 140	TOPTOM SU 140	ALSA
BIPOLAR HF 140	BIPOLAR HF 140	--
PWT-400	PWT-400	--
AMNOTOM 160 BASE	AMNOTOM 160 BASE	--

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
AMNOTOM 400 COMPACT	AMNOTOM 400 COMPACT	--
AMNOTOM 400 PREMIUM	AMNOTOM 400 PREMIUM	--
AMNOTOM 400 PREMIUM A	AMNOTOM 400 PREMIUM A	--
BIPOGYN	BIPOGYN	--
PULSAR MB350	PULSAR MB350	--
ESU-X 200 NT	ESU-X 200 NT	--
ESU-X 300 NT	ESU-X 300 NT	--
ESU-X 400 HT	ESU-X 400 HT	--
ESU-A 400 HT	ESU-A 400 HT	--
ESU-X 500 TT	ESU-X 500 TT	--
ESU-A 500 TT	ESU-A 500 TT	--
VITRUVIO 200	VITRUVIO 200	--
TEKNO TOM 211	TEKNO TOM 211	--
TEKNO TOM 411	TEKNO TOM 411	--
TEKNO TOM 212	TEKNO TOM 212	--
TEKNO TOM 412	TEKNO TOM 412	--
TEKNO TOM 212A	TEKNO TOM 212A	--
TEKNO TOM 412A	TEKNO TOM 412A	--
TEKNO TOM 411 PRO	TEKNO TOM 411 PRO	--
TEKNO TOM 500, 200W	TEKNO TOM 500, 200W	--
TEKNO TOM 500, 400W	TEKNO TOM 500, 400W	--
TEKNO TOM 500, 200W, ARGON	TEKNO TOM 500, 200W, ARGON	--
TEKNO TOM 500, 400W, ARGON	TEKNO TOM 500, 400W, ARGON	--
TEKNO TOM 80	TEKNO TOM 80	--
TEKNO TOM 141DPS	TEKNO TOM 141DPS	--

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
TEKNO TOM 100	TEKNO TOM 100	--
EXCELL 400 MCDSe	EXCELL 400 MCDSe	--
EXCELL NHP/T-400	EXCELL NHP/T-400	--
EXCELL NHP/TA-400	EXCELL NHP/TA-400	--
EIP/8	EIP/8	ALSA
EIP/9	EIP/9	ALSA
EIP/S	EIP/S	ALSA
NP/A	NP/A	ALSA
NP/A5	NP/A5	ALSA
NP/GA	NP/GA	ALSA
NP/GP	NP/GP	ALSA
CMS/E	CMS/E	ALSA
CMS/E5	CMS/E5	ALSA
MPE/S	MPE/S	ALSA
MPE/F	MPE/F	ALSA
MPE/E	MPE/E	ALSA
MPE/E5	MPE/E5	ALSA
MLD	MLD	ALSA
MLD/F	MLD/F	ALSA
MPE/CMS	MPE/CMS	ALSA
MPE/CMS5	MPE/CMS5	ALSA
SEL/VI	SEL/VI	ALSA
SEL/VI-M.S.	SEL/VI-M.S.	ALSA
SEL/E	SEL/E	ALSA
SEL/D	SEL/D	ALSA

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
SEL/DB	SEL/DB	ALSA
E1	E1	ALSA
E1/I	E1/I	ALSA
E1/L	E1/L	ALSA
E3	E3	ALSA
E3/L	E3/L	ALSA
E5	E5	ALSA
E6	E6	ALSA
E7	E7	ALSA
E7/I	E7/I	ALSA
E8	E8	ALSA
E10	E10	ALSA
E11	E11	ALSA
E12	E12	ALSA
E13	E13	ALSA
E14	E14	ALSA
E15	E15	ALSA
E16	E16	ALSA
E17	E17	ALSA
E18	E18	ALSA
E19	E19	ALSA
E21	E21	ALSA
E23	E23	ALSA
E23/N	E23/N	ALSA
E25	E25	ALSA

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
E25/N	E25/N	ALSA
E26	E26	ALSA
EXT/15	EXT/15	ALSA
E27	E27	ALSA
E29	E29	ALSA
E30	E30	ALSA
E31	E31	ALSA
E32/I	E32/I	ALSA
E33	E33	ALSA
E34	E34	ALSA
E35	E35	ALSA
E37	E37	ALSA
E39	E39	ALSA
E40	E40	ALSA
E40/I	E40/I	ALSA
E41	E41	ALSA
E42	E42	ALSA
E42/I	E42/I	ALSA
E43	E43	ALSA
E44	E44	ALSA
E45	E45	ALSA
E46	E46	ALSA
E47	E47	ALSA
E48	E48	ALSA
E49	E49	ALSA

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
E50	E50	ALSA
E51	E51	ALSA
E52	E52	ALSA
E53	E53	ALSA
E54	E54	ALSA
E55	E55	ALSA
E56	E56	ALSA
E57	E57	ALSA
E58	E58	ALSA
E59	E59	ALSA
E101	E101	ALSA
E101B	E101B	ALSA
E102	E102	ALSA
E102B	E102B	ALSA
E103	E103	ALSA
E105	E105	ALSA
E106	E106	ALSA
E109	E109	ALSA
E110	E110	ALSA
E111	E111	ALSA
E112	E112	ALSA
E120	E120	ALSA
E121	E121	ALSA
AID	AID	ALSA
SAD	SAD	ALSA

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
SAD1	SAD1	ALSA
SAD2	SAD2	ALSA
SAD3	SAD3	ALSA
CPI	CPI	ALSA
CPI/5	CPI/5	ALSA
CPI/SM	CPI/SM	ALSA
CPE	CPE	ALSA
CPE/5	CPE/5	ALSA
CPI/L	CPI/L	ALSA
CEP3	CEP3	ALSA
PMI/1	PMI/1	ALSA
PMI/1C25	PMI/1C25	ALSA
PMI/2	PMI/2	ALSA
PMI/B	PMI/B	ALSA
PIC/1	PIC/1	ALSA
PIC/1-25	PIC/1-25	ALSA
CPB/E	CPB/E	ALSA
CPB/E5	CPB/E5	ALSA
CPB/EU	CPB/EU	ALSA
CPB/E AESCULAP	CPB/E AESCULAP	ALSA
CPB/EUV	CPB/EUV	ALSA
CPB	CPB	ALSA
CPB/5	CPB/5	ALSA
CPB/E-WMS	CPB/E-WMS	ALSA
CPB/WMS	CPB/WMS	ALSA

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
CPB/EE	CPB/EE	ALSA
CPB/E-Tech	CPB/E-Tech	ALSA
CPB/Tech	CPB/Tech	ALSA
PMC/JR	PMC/JR	ALSA
PMC/JC	PMC/JC	ALSA
PMC/RS	PMC/RS	ALSA
PMC/CS	PMC/CS	ALSA
PMC/R18	PMC/R18	ALSA
PMC/C18	PMC/C18	ALSA
PMC/R	PMC/R	ALSA
PMC/C	PMC/C	ALSA
PMC/R25	PMC/R25	ALSA
PMC/C25	PMC/C25	ALSA
PBC/R18	PBC/R18	ALSA
PBC/C18	PBC/C18	ALSA
PBC/R	PBC/R	ALSA
PBC/C	PBC/C	ALSA
PBC/R25	PBC/R25	ALSA
PBC/C25	PBC/C25	ALSA
PMC/RSB	PMC/RSB	ALSA
PMC/B	PMC/B	ALSA
PMC/B25	PMC/B25	ALSA
PMC/BCU	PMC/BCU	ALSA
PMC/BCD	PMC/BCD	ALSA
PBC/B	PBC/B	ALSA

Elenco dei dispositivi oggetto del Certificato UE n. 083/MDR

List of the devices covered by the EU Certificate no. 083/MDR

rev. 1 del of **2023/03/17**

Categoria di dispositivo: Device category:	**Apparecchi per elettrochirurgia ad alta frequenza e relativi accessori** High frequency electrosurgery equipment and related accessories

Modello/i: Model(s):	**Nome/i commerciale/i:** Trade name(s):	**Marca/Marche:** Trade mark(s):
PBC/B25	PBC/B25	ALSA
PBC/BCU	PBC/BCU	ALSA
PBC/BCD	PBC/BCD	ALSA
PMC/JRns	PMC/JRns	ALSA
PMC/JCns	PMC/JCns	ALSA
PMC/RSns	PMC/RSns	ALSA
PMC/CSns	PMC/CSns	ALSA
PMC/Rns	PMC/Rns	ALSA
PMC/Cns	PMC/Cns	ALSA
PBC/Rns	PBC/Rns	ALSA
PBC/Cns	PBC/Cns	ALSA
PMC/RSBns	PMC/RSBns	ALSA
PMC/Bns	PMC/Bns	ALSA
PBC/Bns	PBC/Bns	ALSA
PMC/B25ns	PMC/B25ns	ALSA
PBC/B25ns	PBC/B25ns	ALSA
BCS-15	BCS-15	ALSA
BCS-19	BCS-19	ALSA
BC-16	BC-16	ALSA
BC-20	BC-20	ALSA
BC-23	BC-23	ALSA
BC-26	BC-26	ALSA

REA MI 1595884
C.F./P.I. 12898410159
Cap. Soc. € 4.000.000

N. di protocollo / *Protocol No.*: **FP-2606/24-nc10**

Data / *Date*: **2024/05/02**

Lettera di conferma dell'Organismo Notificato / *Notified Body Confirmation Letter*
Riferimento / *Reference*: 1001C03017968C_CL

A chi di competenza / *To whom it may concern,*

Conferma dello stato di una domanda formale, di un accordo scritto e di un'appropriata sorveglianza nell'ambito del Regolamento (UE) 2023/607 che modifica i Regolamenti (UE) 2017/745 e 2017/746 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici e dispositivi medico-diagnostici in vitro.

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

La presente lettera conferma che IMQ S.p.A., un Organismo Notificato (nel seguito, "ON") designato ai sensi del Regolamento (UE) 2017/745 (MDR) e identificato con il numero 0051 su NANDO, ha ricevuto una domanda formale in conformità alla sezione 4.3, primo comma dell'Allegato VII del MDR e firmato un accordo scritto in conformità alla sezione 4.3, secondo comma dell'Allegato VII del MDR con il seguente **fabbricante**:

*This letter confirms that IMQ S.p.A., a Notified Body (hereinafter, "NB") designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0051 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following **manufacturer***:

ALSA APPARECCHI MEDICALI SRL

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

SRN: IT-MF-000019170

I dispositivi oggetto della domanda formale e dell'accordo scritto di cui sopra sono identificati nelle Tabelle che seguono; in particolare:

- la Tabella 1 identifica i dispositivi per i quali IMQ S.p.A. ha ricevuto una domanda formale MDR, ha concluso un accordo scritto ed è anche responsabile dell'appropriata sorveglianza dei corrispondenti dispositivi ai sensi della Direttiva 90/385/CEE o della Direttiva 93/42/CEE (nel seguito, "(AI)MDD"),
- la Tabella 2 identifica i dispositivi per i quali IMQ S.p.A. ha ricevuto una domanda formale MDR, ha concluso un accordo scritto ma non ha assunto la responsabilità dell'appropriata sorveglianza dei corrispondenti dispositivi ai sensi della (AI)MDD.

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below; in particular:

- *Table 1 identifies the devices for which IMQ S.p.A. has received a MDR formal application, has concluded a written agreement and is also responsible for appropriate surveillance of the corresponding devices under the* Directive 90/385/EEC or Directive 93/42/EEC (hereinafter, "(AI)MDD"),
- *Table 2 identifies the devices for which IMQ S.p.A. has received a MDR formal application, has concluded a written agreement but has not taken the responsibility for appropriate surveillance of the corresponding devices under the (AI)MDD*.

Nel caso di dispositivi oggetto di certificati rilasciati ai sensi della (AI)MDD (nel seguito, "certificato (AI)MDD") che sono scaduti dopo il 26 maggio 2021 e prima del 20 marzo 2023, senza essere stati ritirati, questa lettera conferma anche che il fabbricante ha firmato l'accordo scritto ai sensi del MDR entro la data di scadenza del pertinente certificato (AI)MDD *oppure* ha fornito l'evidenza che un'Autorità Competente di uno Stato membro ha concesso una deroga o un'esenzione dalla procedura di valutazione della conformità applicabile ai sensi, rispettivamente, dell'articolo 59(1)del MDR o dell'articolo 97(1) del MDR, entro il 20 Marzo 2023 per i dispositivi in questione.

In the case of devices covered by certificates issued under (AI)MDD (hereinafter, "(AI)MDD certificate") that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of expiry of the relevant (AI)MDD certificate or provided evidence that a Competent Authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

Di seguito sono riportati i periodi di transizione che si applicano ai dispositivi oggetto della presente lettera, a condizione che il fabbricante continui a rispettare le altre condizioni specificate nell'articolo 120 (3 quater) del MDR (come modificato dal Regolamento (UE) 2023/607):

a) 31 dicembre 2027, per tutti i dispositivi della classe III, e per i dispositivi impiantabili della classe IIb ad eccezione delle tecnologie ben consolidate (WET - materiali per sutura, graffette, materiali per otturazioni dentarie, apparecchi ortodontici, corone dentali, viti, cunei, placche e protesi, fili, chiodi, clip e connettori),

b) 31 dicembre 2028, per i dispositivi della classe IIb diversi da quelli di cui al punto a) che precede, per i dispositivi della classe IIa e per i dispositivi della classe I immessi sul mercato in condizione sterile (Is) o con funzione di misura (Im),

c) 31 dicembre 2028 per i dispositivi per i quali la procedura di valutazione della conformità a norma della MDD non richiedeva l'intervento di un ON ma per i quali la procedura di valutazione della conformità a norma del MDR richiede l'intervento di un ON, ad esempio, dispositivi della classe I che si qualificano come Strumenti chirurgici riutilizzabili (Ir).

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR (as amended by Regulation (EU) 2023/607), are shown below:

a) 31 December 2027, for all class III devices, and for class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors),

b) 31 December 2028, for class IIb devices other than those covered by point (a) above, for class IIa devices, and for class I devices placed on the market in sterile condition (Is) or having a measuring function (Im),

c) 31 December 2028 for devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a NB but for which the conformity assessment procedure pursuant to MDR requires the involvement of a NB, e.g., class I devices that qualify as re-usable surgical instruments (Ir).

Distinti saluti / Best regards

IMQ S.p.A.
Responsabile Divisione Dispositivi Medici
Medical device Division Manager

(B. Venturelli)

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
MPE/S; MPE/E; MPE/E5; MPE/F	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
MLD; MLD/F	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
MPE/CMS; MPE/CMS5	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
SEL/VI; SEL/D; SEL/E	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

[1] Classificazione del dispositivo oggetto della Domanda MDR proposta dal fabbricante ai sensi dell'All. VIII del MDR e verificata in via preliminare dall'ON ai sensi della sezione 4.2 (d) dell'Allegato VII del MDR / *Classification of the device under MDR application, as proposed by the manufacturer according to Annex VIII of the MDR and preliminary verified by the NB according to Section 4.2 (d) of Annex VII of the MDR*

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** ***(1)***	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
E1; E1/I; E3; E1/L; E3/L; E5; E6; E7; E7/I; E8; E10; E12; E13; E14; E15; E16; E17; E18; E19; E21;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD *Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD*			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
E23; E23/N; E25; E25/N; E26; EXT/15; E27; E29; E30; E31; E33; E34; E35; E37; E39; E40/I; E40; E41; E42; E43;			

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
E46; E47; E48; E49; E50; E51; E52; E53; E54; E55; E56; E57; E58			
E101; E102; E103; E105; E106; E109; E110;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
E111; E112; E120; E121			
SAD; SAD1; SAD2; SAD3;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
AID	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PMC/JR; PMC/JC; PMC/RS; PMC/CS; PMC/R; PMC/C; PMC/R25; PMC/C25;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** (1)	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
PMC/RSB; PMC/B; PMC/B25; PMC/BCD; PMC/BCU			
PBC/R; PBC/C; PBC/R25; PBC/C25; PBC/B; PBC/B25; PBC/BCD; PBC/BCU	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PMC/JRns; PMC/JCns; PMC/RSns; PMC/CSns; PMC/Rns; PMC/Cns; PMC/RSBns;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
PMC/Bns; PMC/B25ns			
PMC/Rns	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	PMC/R25ns	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PMC/Cns	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	PMC/C25ns	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PBC/Rns; PBC/Cns; PBC/R25ns; PBC/Bns; PBC/B25ns	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PBC/Rns	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	PBC/R25ns	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD

Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD

Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
PBC/Cns	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	PBC/C25ns	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
BCS-15; BCS-19	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
BC-16; BC-20; BC-23; BC-26	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
CPB; CPB/5; CPB/E; CPB/E5; CPB/EU; CPB/EE; CPB/E-WMS; CPB/WMS;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** (1)	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
CPB/E-Tech; CPB/Tech			
CPB/E	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	CPB/EST	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
CPB/EE	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	CPB/EE-4	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PMI/1; PMI/1C25; PMI/2; PMI/B	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PMI/1	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	PMI/1-20; PMI/1-25	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
PIC/1; PIC/1-25	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PIC/1	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	PIC/2	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
CPI; CPI/5; CPI/SM; CPI/L	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
CPE/5	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
CEP3	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
EIP/9; EIP/S	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
NP/A; NP/A5	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
CMS/E; CMS/E5	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
NP/GA; NP/GP	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
ALSATOM SU 50-MPC; ALSATOM SU 100-MPC; ALSATOM SU 140-MPC;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
ALSATOM SU 140/D-MPC; ALSATOM SU 140/BD-MPC			
ALSATOM SU 140/D-MPC	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	ALSATOM SU 140/D-MPC (100V-60Hz)	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
EXCELL 200 MCDSe; EXCELL 250 MCDSe; EXCELL 350 MCDSe; EXCELL 400 MCDSe; EXCELL 400/A MCDSe	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
EXCELL NHP 250/D; EXCELL NHP 350/D; EXCELL NHP 400/D; EXCELL NHP 250/DA; EXCELL NHP 400/DA;	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** *(1)*	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
EXCELL NHP ENDOMED			
EXCELL NHP/T-400; EXCELL NHP/T-200; EXCELL NHP/TA-400; EXCELL NHP/TA-200	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
TOPTOM SU 100; TOPTOM SU 140	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
BIPOLAR HF 140	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PWT-400	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
AMNOTOM 160 BASE;	IIb diverso da impiantabile non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** ***(1)***	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
AMNOTOM 400 COMPACT; AMNOTOM 400 PREMIUM; AMNOTOM 400 PREMIUM A	/ IIb other than implantable non-WET		
BIPOGYN	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
PULSAR MB350	IIb diverso da impiantabile non-WET / IIb other than implantable non-WET	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
VACUMSOL AS-65; VACUMSOL AS-65/H	IIa	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051
VORTEX-S AS-200/20LT; VORTEX-S AS-200/30LT	IIa	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 1: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. è anche responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD ***Table 1: Devices covered by this letter and for which IMQ S.p.A. is also responsible for appropriate surveillance of the corresponding devices under the (AI)MDD***			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** ***(1)***	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
POLIVAC B4/SLT 30 2; POLIVAC B4/SLT 30 2-EXP; POLIVAC B4/SLT 30 P-EXP; POLIVAC B4/SLT 50 E	IIa	n/a	Certificato / *Certificate*: 187/MDD ON / *NB*: 0051

Tabella 2: Dispositivi oggetto della presente lettera e per i quali IMQ S.p.A. non è responsabile dell'appropriata sorveglianza dei dispositivi corrispondenti ai sensi della (AI)MDD *Table 2: Devices covered by this letter and for which IMQ S.p.A. is not responsible for appropriate surveillance of the corresponding devices under the (AI)MDD*			
Dispositivo (Nome o UDI-DI di base) oggetto della Domanda MDR ***Device (Name or Basic UDI-DI) under MDR application***	**Classificazione del Dispositivo oggetto della Domanda MDR** ***Classification of the device under MDR application*** (1)	**Se il dispositivo oggetto della Domanda MDR è un dispositivo sostitutivo, identificazione del corrispondente dispositivo (AI)MDD** ***If the device under MDR application is a substitute device, identification of the corresponding (AI)MDD device***	**Riferimento del/i pertinente/i certificato/i (AI)MDD e identificazione dell'ON** ***Reference to relevant (AI)MDD certificate(s) and the NB identification***
n/a	n/a	n/a	n/a

Tabella 3: Storico delle revisioni della presente lettera di conferma ***Table 3: Revision history of this confirmation letter***		
Data / ***Date***	**N. di protocollo** / Protocol No.	**Azione** / Action
2024/03/18	FP-1752/24-nc10	Prima emissione / *First issue*
2024/05/02	FP-2606/24-nc10	Aggiunta dei seguenti dispositivi alla Tabella 1 / *Addition of following devices to the Table 1:* VACUMSOL AS-65; VACUMSOL AS-65/H; VORTEX-S AS-200/20LT; VORTEX-S AS-200/30LT; POLIVAC B4/SLT 30 2; POLIVAC B4/SLT 30 2-EXP; POLIVAC B4/SLT 30 P-EXP; POLIVAC B4/SLT 50 E