

DIATERMO MB 122 AND MB 160 MONO-BIPOLAR - 120 W - 160 W



- 30540 DIATERMO MB 122 - mono-bipolar - 120 W
 - 30541 DIATERMO MB 160 - mono-bipolar - 160 W
- MB 122 and 160 are HF electrocautery units suitable to perform middle monopolar or bipolar electrocautery. By selection of the modes of operation they provide pure cut, coagulated cut, forced coagulation, soft coagulation and, with forceps, bipolar coagulation. The use of either split or normal neutral plate is allowed. MB 160 is recommended in case of damp operational fields, for instance mucous, with consequent need to have reserve of usable power. For these reasons, MB 160 is suggested for Gynecological and orthopedic surgery.
- Leading-Edge Technology.** This advanced concept device enables highly professional surgery intervention thanks to ergonomic and safety features derived from high power theatre apparatus.
- Complete safety.** Open Circuit (OC) Alarm warns the user that connection into the neutral plate has not been made or that the cable is disconnected or the neutral plate is not in contact with the patient. The alarm is signaled by an intermittent beep together with a flashing red light on the front panel. In this case HF emission for cut and coagulation operation is switched off.
- OVT Alarm.** The unit includes an internal circuit protection warning when the current delivery is exceeding.

STANDARD ACCESSORIES

- MB single-use two button handle
- MB waterproof foot-switch 30577 (usable as alternative to handle)
- MB flat neutral plate with cable 30564
- Power cable 2 m
- Kit of 6 (MB 122) or 10 (MB 160) short autoclavable electrodes, Ø 2.4 mm
- User manual: available in GB, ES, IT, FR, PL

TECHNICAL SPECIFICATIONS

	MB122	MB160	Crest Factor
Minimum preselectable power	0	0	
Level step	1	1	
Maximum output power CUT (W)	120 250Ω	160 250Ω	1.5
Maximum output power BLEND (W)	90 200Ω	120 200Ω	2.1
Maximum output power COAG FORCED (W)	80 150Ω	100 150Ω	2.0
Maximum output power COAG SOFT (W)	60 100Ω	80 100Ω	1.7
Maximum output power BIPOLAR (W)	40 100Ω	60 100Ω	1.5
Working frequency	600 kHz	600 kHz	
Weight kg	7	7	
Size LxHxD mm	260x110x265	260x110x265	
Operating voltage (switchable)	115 -230	115 -230	
Mains frequency (Hz)	50-60	50-60	
Fuses 230Vac (5x20) TIMED	2x 3.15A	2x 3.15A	
Fuses 115Vac (5x20) TIMED	2x 6.3A	2x 6.3A	
Electrical input power (VA)	300	350	
Electrical input current (230 Vac) (A)	1.3	1.5	
Electrical input current (115 Vac) (A)	2.6	3	
Five steps adjustable sound level (from 55 to 75dBA)	•	•	
Self-check	•	•	
Power accuracy output warning	•	•	
Split or not split patient plate allowed	•	•	
Last working condition storing	•	•	
Electrical Class (EN60601 - 1)	I CF	I CF	
MDD 93/42/EEC Class	II b	II b	
Patient circuit	F	F	

MONOPOLAR ELECTROSURGERY UNIT - 50 W



- 30516 DIATERMO 106 - 50W - monopolar

This HF electrocautery unit is particularly suitable for small operations and is recommended for dentistry, first aid and dermatology work. It offers precision of cut and immediate coagulation and give excellent results in a wide range of applications: from uterine coagulation to microcoagulation in dermatology. The modes of operation, CUT, COAG or BLEND,



TECHNICAL SPECIFICATIONS

Output power: CUT	50 W/400 ohm
COAG	40 W/400 ohm
BLEND	45 W/400 ohm
Working frequency:	600 kHz ±10%
Size:	180x180x100 mm
Weight:	2.8 kg
Operating Voltage:	115/230 V - 50/60 Hz switchable
Electric input power:	90 VA
Fuse:	2x1 AT
Alarm for overheating	
Footswitch operating	
Norms: EN60601-1 Class I CF, EN60601-2-2 93/42/EEC (Class IIb)	

STANDARD ACCESSORIES

- KIRKY single-use handle without buttons
- MB waterproof foot-switch (30577)
- Flat neutral plate with cable (30564)
- Kit of 6 short autoclavable electrodes, Ø 2.4 mm, length 5 cm
- Power cable 2 m - Schuko plug
- User manual: available in GB, IT, ES, FR

can be easily selected by a switch on the front panel. The complete isolation between patient and the unit and strict respect of international norms guarantee total safety.

MADE IN ITALY

MONO-BIPOLAR ELECTROSURGICAL UNITS 80W, 120W, 160W



CASUALTY SURGERY
 PEDIATRIC SURGERY*
 PLASTIC SURGERY*
 VASCULAR SURGERY
 DERMATOLOGY
 FIRST AID
 OTORHINOLARYNGOLOGY
 UROLOGY*
 GYNAECOLOGY
 VETERINARY
 DENTISTRY**
 *Diatermo MB160 only
 **Diatermo MB120 only



- 30627 DIATERMO MB 80D - mono-bipolar - 80 W
- 30628 DIATERMO MB 120D - mono-bipolar - 120 W
- 30629 DIATERMO MB 160D - mono-bipolar - 160 W

30629



Diatermo MB are high frequency electro-surgical units suitable for minor and medium surgery.

MB allows pure CUT, cut-coagulation BLEND, superficial coagulation FORCED COAG, deep coagulation in absence of necrosis SOFT COAG and, with forceps, BIPOLAR coagulation. The digital reading of delivered power and the monitoring of operative function by microcontroller guarantee absolute reliability of working conditions.

MB allows a highly professional surgery through ergonomic features. Neutral electrode connection and patient/plate contact are constantly monitored.

The possibility of output functions and output power delivery control, by handle, allows surgical procedures without divert attention from operation field.

Features:

- minimum invasive surgery
- possibility to use bipolar forceps
- possibility to use split neutral electrodes
- memorization of the last used settings
- power activation by pedal and/or handle
- digital adjustment and indication of the output power
- adjustment of the acoustic indicator intensity.

TECHNICAL SPECIFICATIONS

	MB 80D	MB 120D	MB 160D
Max output power CUT	80 W-250 Ω	120 W-250 Ω	160 W-250 Ω
Max output power BLEND	60 W-250 Ω	90 W-200 Ω	120 W-200 Ω
Max output power FORCED COAG	50 W-150 Ω	80 W-150 Ω	100 W-150 Ω
Max output power SOFT COAG	40 W-100 Ω	60 W-100 Ω	80 W-100 Ω
Max output power BIPOLAR	30 W-100 Ω	40 W-100 Ω	60 W-100 Ω
Working frequency	600 kHz	600 kHz	600 kHz
Patient circuit	F	F	F
Selectable input voltage	115 - 230 Vac	115 - 230 Vac	115 - 230 Vac
Mains frequency	50 - 60 Hz	50 - 60 Hz	50 - 60 Hz
Electrical input power	230 VA	300 VA	350 VA
Size WxHxD mm	254x104x288	254x104x288	254x104x288
Weight	5 kgs	5 kgs	5 kgs
Controls:	Patient/Plate circuit monitoring, Output power monitoring, Self check control		
Safety:	EN60601-1, EN60601-1-2, EN60601-2-2, Electrical Class: I CF, MDD 93/42/EC Class: II b		

STANDARD ACCESSORIES

MB single use two button handle
 MB waterproof foot switch 30577 (usable as alternative to handle)
 MB flat neutral plate with cable (30564)
 Kit of 10 short autoclavable electrodes, Ø 2.4 mm (30500). Power cable: 2 m
 User manual: GB, IT, available on request FR, ES, PL

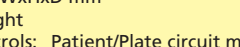
MONOPOLAR ELECTROSURGERY UNITS 50W AND 80W



DENTISTRY
 DERMATOLOGY
 OUT PATIENT SURGERY
 FIRST AID
 VETERINARY*
 VASCULAR SURGERY*
 *Diatermo 80 only

- 30625 DIATERMO 50 - monopolar
- 30626 DIATERMO 80 - monopolar

30625



Diatermo 50 and 80 are radiofrequency electro-surgical units suitable for minor monopolar surgery.

Diatermo 50 through the function selection makes pure cut, cut coagulation (CUT 1 - CUT 2) and pure coagulation possible. Diatermo 80 has a multifunction selector which makes cutting (CUT), cut coagulation (BLEND), coagulation (COAG) and micro-coagulation (MICRO) possible. The one-board microcontroller and digital display guarantee high safety and reliability under any conditions. They offer outstanding professional surgical results due to their ergonomic and superior safety features.

TECHNICAL SPECIFICATIONS

	50	80
Max output power CUT	50 W-400 Ω	80 W-400 Ω
Max output power CUT/COAG1	45 W-400 Ω	-
Max output power CUT/COAG2	40 W-400 Ω	-
Max output power BLEND	-	60 W-400 Ω
Max output power COAG	40 W-400 Ω	50 W-400 Ω
Max output power MICRO	-	20 W-600 Ω
Working frequency	600 kHz	700 kHz
Patient circuit	F	F
Selectable input voltage	115 - 230 Vac	115 - 230 Vac
Mains frequency	50 - 60 Hz	50 - 60 Hz
Electrical input power	200 VA	230 VA
Size WxHxD mm	190x85x239	190x85x239
Weight	2.5 kg	2.5 kg
Controls:	Patient/Plate circuit monitoring, Output power monitoring, Self check control	
Safety:	EN60601-1, EN60601-1-2, EN60601-2-2, Electrical Class: I CF, MDD 93/42/EC Class: II b	

STANDARD ACCESSORIES

Single use handle
 MB waterproof foot switch (30577)
 MB flat neutral plate with cable (30564)
 Kit of 6 short autoclavable electrodes, Ø 2.4 mm, length 5 cm (30501/2/4/7/9/10) see page 229
 Power cable 2 m - Schuko plug
 User manual: GB, IT, available on request FR, ES



MONO-BIPOLAR ELECTROSURGICAL UNIT 200W



OUTPATIENT SURGERY
ENDOSCOPY
FIRST AID
GASTROENTEROLOGY
GENERAL SURGERY
GYNAECOLOGY
NEUROSURGERY
ORTHOPEDICS
OTORHINOLARYNGOLOGY
PEDIATRIC SURGERY
PLASTIC SURGERY
PNEUMOLOGY
UROLOGY
VASCULAR SURGERY
VETERINARY

MADE IN ITALY

• 30630 DIATERMO MB 200D - 200 W

MB 200D is a high frequency electrocautery equipment suitable for light and medium surgery, allows minimally invasive surgical procedure of resection, evaporation and coagulation. MB 200D allows pure CUT, Cut-Coagulation BLEND, incision with reduced production of eschar ENHANCED, superficial coagulation FORCED COAG, deep coagulation in absence of necrosis SOFT COAG and BIPOLAR coagulation. Digital reading of delivered power and surveillance through microcontroller of the operational functions, assure absolute reliability of working conditions.

MB 200D allows a highly professional surgery through ergonomic and safety features. The connection of neutral electrode is constantly monitored. Safety control of patient/plate contact using split neutral electrode. Possibility to control the output functions and the delivery of output power by the handle, allows the surgical operation without diverting attention from the surgical field.

- patient-to-plate contact control

STANDARD ACCESSORIES

- MB two-button autoclavable handle (30536)
- MB waterproof foot-switch (30577)
- Flex steel neutral plate with cable (30555 + 30560)
- Kit 10 short standard electrodes, Ø 2.4 mm (30500)
- 3 needle + 3 blade + 3 ball electrodes 7 cm
- Power cable 5 m
- Manual: available in GB, IT

- split return electrode use
- minimally invasive surgical treatment allowed
- monopolar and Bipolar independent output
- auto Start/Stop in Bipolar Coag
- working condition planning
- power delivery by pedal and/or handle
- digital regulation and indication of the output power
- sound level control
- adjustable power increment



TECHNICAL SPECIFICATIONS

Maximum output power CUT	200W - 250Ω
Maximum output power ENHANCED	120W - 250Ω
Maximum output power BLEND	120W - 200Ω
Maximum output power FORCED COAG	150W - 150Ω
Maximum output power SOFT COAG	90W - 100Ω
Maximum output power BIPOLAR COAG	80W - 50Ω
Working frequency	600 kHz
Patient circuit	F
Mains voltage	115-230 Vac
Mains frequency	50-60 Hz
Electrical input power	350 VA
Size WxHxD mm	370x144x319
Weight	6 kgs
Controls:	Patient/Plate circuit monitoring, Output power monitoring, Self check control
Safety:	EN60601-1, EN60601-2-2, EN60601-1-2, EN60601-2-2, Electrical Class: I CF, MDD 93/42/EC Class: II b

DIATERMO MB 200 - MONO-BIPOLAR - 200W



30542



MADE IN ITALY

STANDARD ACCESSORIES

- MB two-button autoclavable handle (30536)
- MB waterproof foot-switch 30577 (usable in alternative to handle)
- MB flat neutral metal plate with cable (30564)
- Kit 10 short standard electrodes, Ø 2.4 mm (30500)
- Power cable 2 m
- Manual: available in GB, IT

• 30542 DIATERMO MB 200 - 200 W

HF electrocautery unit suitable to perform middle monopolar or bipolar electrocautery. The available waveforms and peak voltage value, as well as the accurate HF leakage current operation allows use for polypectomy, TURP, intrauterine resections, endometriosis excision, etc. The units allow the accurate preset of the output power with as low as 1 Watt resolution and to perform coagulation by high crest factor current, to get an elevated thermal effect, as well as with low voltage low crest factor current, to get coagulation in absence of carbonization. Ten different programs related to ten different operative conditions could be stored and easily recalled by the surgeon. The use of either split or normal neutral plates are allowed. A special electronic circuit (Skin Plate Electronic Control) continuously checks if the plate is safely connected to the patient and detects unwanted short circuit in the connecting cable. An over time warning (OVT) is provided to prevent excessive heating of the tissue around the surgical target due to too long current delivery time.

TECHNICAL SPECIFICATIONS

Maximum output power CUT (W)	200	250Ω	Crest factor	Weight kg	8
Maximum output power CUT 90% (W)	200	250Ω	1.5	Size LxHxD mm	360x150x265
Maximum output power CUT 80% (W)	200	250Ω	1.6	Selectable mains power(Vac)	115 -230
Maximum output power CUT 70% (W)	200	250Ω	1.7	Mains frequency (Hz)	50-60
Maximum output power BLEND (W)	120	200Ω	1.8	Fuses 115Vac - 230Vac (5x20) TIMED	2x 6.3A - 2x 3.15A
Maximum output power COAG FORCED (W)	150	150Ω	2.0	Power accuracy output warning system	•
Maximum output power COAG SOFT (W)	90	100Ω	1.7	Split or not split patient plate allowed	•
Maximum output power BIPOLAR COAG (W)	100	100Ω	1.5	Electrical Class (EN60601 - 1)	I CF
Maximum output power BIPOLAR CUT (W)	120	250Ω	1.5	MDD 93/42/EEC Class	II b
Working frequency	600 kHz			Patient circuit	F
				Duty cycle (action/pause) in seconds	10/30

MB 200 TOUCH MONO-BIPOLAR ELECTROSURGICAL UNIT 200W

• 30693 DIATERMO MB 200 T - 200W

High Frequency electrosurgical equipment suitable for precision mono and bipolar surgery and micro-surgery, without tissue alterations. It can also supply HF operative powers for programmable time as short as hundredths of a second. The unit allows pure CUT, cut-coagulation BLEND, incision with reduced production of eschar ENHANCED, superficial coagulation FORCED COAG, deep coagulation in absence of necrosis SOFT COAG, bipolar CUT, COAG and SEALING, FULGURATION.

The digital reading of delivered power and the operational functions overseen through microcontroller, assure absolute reliability of work conditions. Diatermo MB 200 T allows a highly professional surgery due to user-friendly and safety solutions normally used.

The neutral electrode and patient/plate safety control are constantly monitored. The possibility of output functions and output power delivery control, by handle, allows to perform surgery avoiding the surgeon to take his eyes off the operational field.

Software

Developed to provide a simple, functional and intuitive work experience. Through one finger touch, you can customize screen, work settings, change cut or coagulation power and manage each device function.

STANDARD ACCESSORIES

- Flex steel neutral plate with cable (30555+30560)
- Kit 10 short standard electrodes Ø 2.4 mm (30500)
- Power cable 5 m
- Holder for handle and electrodes
- Reusable handle with switches (30536)
- Waterproof footswitch (30577)



30693

CASUALTY (R)	NEUROSURGERY (R)	PNEUMOLOGY (R)
ENDOSCOPY (R)	ORTHOPAEDICS (U)	TRANS URETHRAL RESECTION TUR (U)
FIRST AID (R)	OTORHINOLARYNGOLOGY (R)	UROLOGY (R)
GASTROENTEROLOGY (R)	PAEDIATRIC SURGERY (U)	VASCULAR SURGERY (R)
GENERAL SURGERY (U)	PLASTIC SURGERY (U)	VETERINARY (R)
GYNECOLOGY (R)		

R = recommended U = usable



MADE IN ITALY

TECHNICAL SPECIFICATIONS

Max power:			
PURE CUT	200 W - 300 Ω	FULGURATION	100 W - 1000 Ω
BLEND	150 W - 300 Ω	BIPOLAR SEALING	200 W - 50 Ω
ENHANCED	150 W - 300 Ω	BIPOLAR COAG	120 W - 50 Ω
FORCED COAG	150 W - 200 Ω	BIPOLAR CUT	120 W - 50 Ω
SOFT COAG	100 W - 200 Ω		
RF power pulse:		emission time	10 ms - 30 sec, interval 1-30 F
Patient circuit:		Selectable input voltage:	100 - 240 Vac - 750 VA
Selectable input voltage:		Working frequency:	360 kHz
Working frequency:		Size (WxHxD) - Weight:	370x145x300 mm - 6 kg
Size (WxHxD) - Weight:		Controls:	Patient/Plate circuit monitoring Output power monitoring, Self check control
Controls:		Safety:	EN60601-1; EN60601-1-2; EN60601-2-2
Safety:		Electrical classification:	I CF MDD 93/42 / EC: II b
Electrical classification:			

MONO-BIPOLAR ELECTROSURGICAL UNITS 120W AND 200W



• 30631 DIATERMO MB 120 FLASH
• 30633 DIATERMO MB 200 FLASH

30631

Professional High Frequency ElectroSurgical equipment suitable for precision monopolar and bipolar surgery and micro-surgery without tissue alterations. Surgical treatments with programmable timer operations up to milliseconds or with traditional mode. MB FLASH allow pure CUT, cut-coagulation BLEND, incision

TECHNICAL SPECIFICATIONS

	MB 120F	MB 200F
Max output power CUT	120 W-250 Ω	200 W-250 Ω
Max output power BLEND	90 W-200 Ω	120 W-200 Ω
Max output power ENHANCED	90 W-250 Ω	120 W-250 Ω
Max output power FORCED COAG	80 W-150 Ω	150 W-150 Ω
Max output power SOFT COAG	60 W-100 Ω	90 W-100 Ω
Max output power BIPOLAR COAG	60 W-50 Ω	80 W-50 Ω
Working frequency	600 kHz	600 kHz
RF power pulse emission time	10ms - 30sec	10ms - 30sec
RF power pulse interval	1 - 9	1 - 9
Patient circuit	F	F
Selectable input voltage	115 - 230 Vac	115 - 230 Vac
Mains frequency	50 - 60 Hz	50 - 60 Hz
Electrical input power	300 VA	350 VA
Size WxHxD mm	370x144x319	370x144x319
Weight	6 kg	6 kg
Controls:	Patient/Plate circuit monitoring, Output power monitoring, Self check control	
Safety:	EN60601-1, EN60601-1-2, EN60601-2-2, Electrical Class: I CF, MDD 93/42/EC Class: II b	

OUTPATIENT SURGERY	PEDIATRIC SURGERY**	PODIATRY**
DERMATOLOGY	FIRST AID	PNEUMOLOGY**
VASCULAR SURGERY	PLASTIC SURGERY**	UROLOGY**
GYNECOLOGY	ENDOSCOPY	VETERINARY
DENTAL*	OPHTHALMOLOGY	GASTROENTEROLOGY
OTORHINOLARYNGOLOGY	NEUROSURGERY**	ORTHOPEDICS**
	*Diatermo MB 120 only	**Diatermo MB 200 only

MADE IN ITALY

with reduced production of eschar ENHANCED, superficial coagulation FORCED COAG, deep coagulation in absence of necrosis SOFT COAG and BIPOLAR coagulation.

Digital reading of delivered power and the surveillance through microcontroller of the operational functions, assure absolute reliability of the working conditions. Connection of neutral electrode is constantly monitored. Safety control of patient/plate contact using split neutral electrode.

Possibility to control the output functions and the delivery of output power by handle, allows surgical operation without diverting attention from the surgical field.

Features:

- patient to plate contact control
- split return electrode use allowed
- minimally invasive surgical treatment allowed
- monopolar and Bipolar independent output
- auto Start/Stop in Bipolar Coag
- working condition planning
- power delivery by pedal and/or handle
- digital regulation and indication of the output power
- sound level control
- adjustable power increment
- RF power pulse emission time setting and interval setting

STANDARD ACCESSORIES

MB two-button autoclave handle (30536)	2 disposable rem ground pads (30493)
Flex steel neutral plate with cable (30555-30560)	Power cable 5m
MB waterproof footswitch (30577)	Microsurgery handle (30552)
Kit 10 short standard electrodes Ø 2.4 mm	Microsurgery needles 10 pieces
3 needle + 3 blade + 3 ball electrodes 7 cm	Manual: GB, IT



HIGH POWER ELECTROSURGICAL UNITS 300 AND 400 WATT



- 30634 DIATERMO MB 300D
- 30635 DIATERMO MB 400D

DIATERMO MB300D and MB400D are high frequency electro-surgical equipments suitable to supply power for monopolar cut and coagulated cut (with different levels of coagulation), bipolar cut and coagulation.

TWIN OPERATIVE ACTIVITY

- two output channels for monopolar cutting
- two independent setting and output channels for the most frequent monopolar coagulation

CONTROLLED CUTTING PROCEDURES

- enhanced cutting current for eschar free incision
- cutting current with selectable coagulating property for bleeding controlled dissection
- low capacitive coupling by slow BLEND current for endoscopic procedures

TWIN CONTROLLED COAGULATION PROCEDURES

- SPEEDY coagulation and DEEP coagulation available to two operators
- SPRAY coagulation by hand switch or foot switch controls

EXTENSIVE BIPOLAR FEATURES

- bipolar cutting current with selectable bleeding control

- slow BLEND cutting current
 - automatic start/stop coagulation functions
- SURGEON AND PATIENT TOTAL SAFETY**
- acceptability of contact impedance between patient body and return electrode continuously monitored by Skin Plate Electronic Control (SPEC)
 - H.F. Leakage currents continuously monitored
 - mains fluctuation automatically compensated before delivery of HF power

PERSONALIZED PROCEDURES

- independent choice of coagulation currents and power levels by each of two operators
- up to 10 procedures can be configured and re-called

EXTENSION DRIVER AND INTERLOCK SIGNALS

- driven output connection to external Argon Plasma unit and Smoke Evacuator unit

AUTOMATIC SELF DIAGNOSIS

- automatic diagnostic control of the complete functionality of electronic unit and connected accessories with coded report of failures

MADE IN ITALY



30634

OUTPATIENT SURGERY
GENERAL SURGERY
PAEDIATRIC SURGERY
PLASTIC SURGERY
THORAX SURGERY
VASCULAR SURGERY
DERMATOLOGY
ENDOSCOPY

GASTROENTEROLOGY
GYNAECOLOGY
NEUROSURGERY
ORTHOPEDICS
OTORHINOLARINGOLOGY
PNEUMOLOGY
UROLOGY
VETERINARY

TECHNICAL SPECIFICATIONS MB300/MB400

	MB 300	MB 400
Maximum out power monopolar pure CUT	300 W - 300 Ω	400 W - 300 Ω
Maximum out power monopolar cut-coag CUT80%	250 W - 300 Ω	350 W - 300 Ω
Maximum out power monopolar cut-coag CUT60%	200 W - 300 Ω	250 W - 300 Ω
Maximum out power monopolar cut-coag CUT40%	150 W - 300 Ω	200 W - 300 Ω
Maximum out power monopolar cut ENHANCED	200 W - 500 Ω	250 W - 500 Ω
Maximum out power monopolar cut-coag BLEND	200 W - 300 Ω	250 W - 300 Ω
Maximum out power monopolar coag SPEEDY	100 W - 500 Ω	120 W - 500 Ω
Maximum out power monopolar coag DEEP	100 W - 200 Ω	120 W - 200 Ω
Maximum out power monopolar coag SPRAY	70 W - 2000 Ω	100 W - 2000 Ω
Maximum out power monopolar coag SPRAY ARGON	70 W - 2000 Ω	100 W - 2000 Ω
Maximum out power bipolar CUT	95 W - 150 Ω	95 W - 150 Ω
Maximum out power bipolar cut-coag CUT80%	95 W - 150 Ω	95 W - 150 Ω
Maximum out power bipolar cut-coag CUT60%	95 W - 150 Ω	95 W - 150 Ω
Maximum out power bipolar cut-coag CUT40%	60 W - 150 Ω	60 W - 150 Ω
Maximum out power bipolar cut-coag BLEND	90 W - 150 Ω	90 W - 150 Ω
Maximum out power bipolar cut-coag BLEND	70 W - 100 Ω	70 W - 100 Ω
Working frequency monopolar / bipolar	425 kHz / 525 kHz	425 kHz / 525 kHz
Patient circuit	F	F
Selectable input voltage	115-230 Vac	115-230 Vac
Mains frequency	50-60 Hz	50-60 Hz
Electrical input voltage	1000 VA	1000 VA
Size WxHxD mm	470x150x400	470x150x400
Weight	17.5 Kgs	17.5 Kgs
Controls:	Patient/Plate circuit monitoring, Output power monitoring, Self check control	
Safety:	EN60601-1, EN60601-1-2, EN60601-2-2, Electrical Class: I CF, MDD 93/42/EC Class: II b	

STANDARD ACCESSORIES

- 1 - Power supply cord 5 m
- 1 - Two-button autoclavable handle (30536)
- 5 - Two-button cold sterilizable handle (30551)
- 1 - Flex steel neutral plate (30555)
- 1 - Cable for flex plate (30560)
- 5 - Rem disposable ground pads (30493)
- 2 - HP double Water proof foot switch (30604)
- 3 - Short, general surgery blade electrode 7 cm
- 3 - Long, general surgery blade electrode 16 cm
- 3 - Short, general surgery ball electrode Ø 4 mm, 6 cm
- 1 - Electrode brush
- 1 - User manual (IT, GB)



ELECTROSURGICAL UNITS TOUCHSCREEN 300 AND 400 WATT



USE	300	400
DERMATOLOGY	R	U
ENDOSCOPY	R	U
GASTROENTEROLOGY	R	R
GENERAL SURGERY	R	R
GYNECOLOGY	R	U
NEUROSURGERY	R	R
ORTHOPAEDICS	U	R
OTORHINOLARYNGOLOGY	R	U
PAEDIATRIC SURGERY	R	R
PLASTIC SURGERY	R	R
PNEUMOLOGY	R	U
THORAX SURGERY	U	R
TRANS URETHRAL RESECTION (TUR)	U	R
UROLOGY	R	R
VASCULAR SURGERY	U	U
VETERINARY	R	U

R= recommended U= usable



• **30695 DIATERMO MB 300 T**
 • **30697 DIATERMO MB 400 T**
 Diatermo MB 300 T and MB 400 T, the new generation of electrosurgery, that allows two surgeons to work simultaneously.

A radiofrequency generator suitable for microsurgery and precise surgery in monopolar and bipolar modality. The simplicity of new Diatermo MB 300 T and MB 400 T allows you to use it without learning time, resulting in time savings. The initial setup and setting adjustments, during a surgery, can be easily selected through the large touchscreen.

- Performance, usability, design and reliability**
- simultaneous activation of monopolar and bipolar
 - power control depending on impedance
 - activating power with pedal and / or handpiece
 - neutral-patient electrode contact control
 - cutting function under saline solution TUR
 - modular cut in wet conditions BLEND
 - vessel sealing to clamp vessels up to 7 mm
 - possibility of use for minimally invasive surgery
 - monopolar / bipolar functions
 - auto-start / auto-stop in bipolar modality
 - adjusting sound intensity

An intuitive and logic work environment
 Particularly basic and intuitive work environment. Horizontal matching between monitors, RGB light indications and connectors provide a clear and easy-to-read overview. The large 9" capacitive touchscreen, designed with a sleek flat front, ensures faster and more efficient cleaning in the operating room.

State of the art device
 Highly professional surgery with ergonomic and safety solutions. Neutral electrode connection is constantly monitored: if a split neutral plate is used, the device will monitor the contact between the patient and the electrode. The possibility to switch the functions and active the power

STANDARD ACCESSORIES	
Flex steel neutral plate with cable (30556+30560)	
3 blade electrodes - 7 cm	Reusable handle with switches (30536)
3 blade electrodes - 16 cm	MB waterproof foot switch (30608)
3 ball Ø 4 mm electrodes - 6 cm	Power cable 5 m

supply from the handpiece, allows surgical procedures without divert attention from operation field.

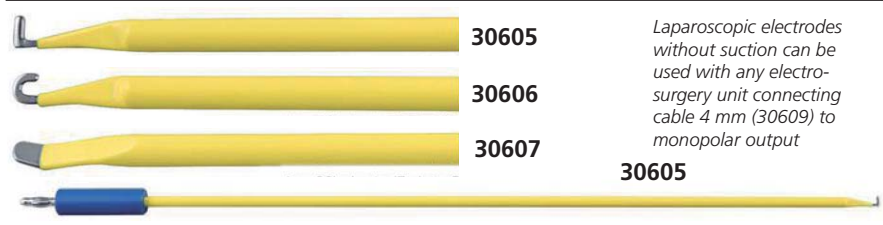
Software
 Provide a simple, functional and intuitive work experience. Through one finger touch, you can customize and save your work settings, change the cut or coagulation power and manage each device function.



	TECHNICAL SPECIFICATIONS	
	MB 300 T	MB 400 T
Maximum output power PURE CUT	300 W - 300 Ω	400 W - 300 Ω
Maximum output power BLEND	200 W - 300 Ω	250 W - 300 Ω
Maximum output power ENHANCED	200 W - 300 Ω	250 W - 300 Ω
Maximum output power FORCED COAG	120 W - 150 Ω	150 W - 150 Ω
Maximum output power SOFT COAG	120 W - 200 Ω	150 W - 200 Ω
Maximum output power FULGURATION	80 W - 500 Ω	100 W - 500 Ω
Maximum output power BIPOLAR TUR	250 W - 200 Ω	300 W - 200 Ω
Maximum output power BIPOLAR CUT	150 W - 100 Ω	150 W - 100 Ω
Maximum output power BIPOLAR COAG	150 W - 50 Ω	150 W - 50 Ω
Maximum output power BIPOLAR SEALING	250 W - 50 Ω	250 W - 50 Ω
Working frequency	360 kHz	360 kHz
Patient circuit	F	F
Selectable input voltage	100-240 Vac	100-240 Vac
Mains frequency	50-60 Hz	50-60 Hz
Electrical input voltage	1000 VA	1000 VA
Size WxHxD mm	450x200x420	450x200x420
Weight	15.5 kg	15.5 kg

Controls: Patient/Plate circuit monitoring, Output power monitoring, Self check control, HF leakage currents control, Compensation of mains fluctuation
Safety: EN60601-1, EN60601-1-2, EN60601-2-2, Electrical Class: I CF, MDD 93/42/EC Class: II b


LAPAROSCOPIC STERILE ELECTRODES



Laparoscopic electrodes without suction can be used with any electro-surgery unit connecting cable 4 mm (30609) to monopolar output


GIMA code	LAPAROSCOPIC ELECTRODES - sterile
30605	L-Hook electrode - 36 cm
30606	J-Hook electrode - 36 cm
30607	Spatula electrode - 36 cm
30609	Monopolar cable - 4 mm - M - F - 3 m

LOOP ELECTRODES Ø 2.4 mm - AUTOCLAVABLE OR DISPOSABLE



AUTOCLAVABLE 20 TIMES

GIMA code	LOOP ELECTRODES - Ø 2.4 mm autoclavable at 134°C - non sterile	Shaft length	Electrode width	Electrode depth
30686	Square loop electrode	13 cm	10 mm	8 mm
30687	Loop electrode	13 cm	15 mm	8 mm
30688	Loop electrode	13 cm	20 mm	10 mm

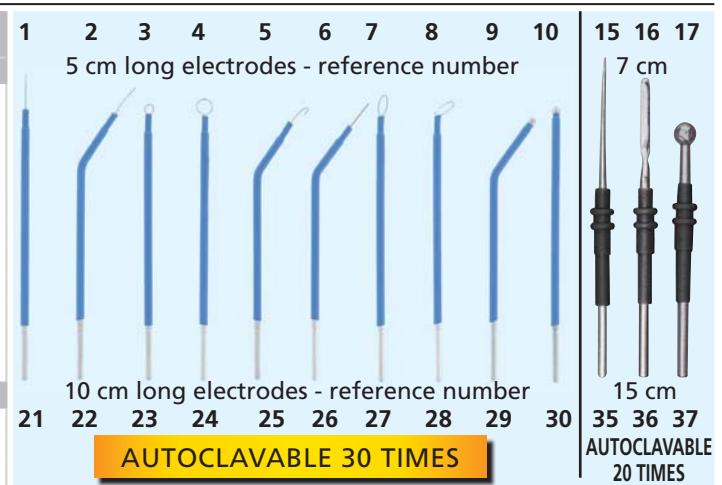


STERILE

GIMA code	LOOP ELECTRODES - Ø 2.4 mm disposable - sterile	Shaft length	Electrode width	Electrode depth	Minimum order
30677	Square loop electrode	13 cm	10 mm	8 mm	box of 10
30678	Loop electrode	13 cm	15 mm	8 mm	box of 10
30679	Loop electrode	13 cm	20 mm	10 mm	box of 10

AUTOCLAVABLE ELECTRODES Ø 2.4 mm

GIMA code	Reference number	AUTOCLAVABLE ELECTRODES Ø 2.4 mm	Reference number	GIMA code
length 5 cm		minimum order: 6 pcs.	length 10 cm	
30501	1	Electrode wire 0.2 - straight	21	30521
30502	2	Electrode wire 0.2 - angled 45°	22	30522
30503	3	Electrode bend - Ø 4 - straight	23	30523
30504	4	Electrode bend - Ø 8 - straight	24	30524
30505	5	Electrode hook - angled 45°	25	30525
30506	6	Electrode wire 1 mm.- angled 45°	26	30526
30507	7	Electrode straight slip-knot - straight	27	30527
30508	8	Electrode angled slip-knot - straight	28	30528
30509	9	Electrode ball point - Ø 3 mm - angled 45°	29	30529
30510	10	Electrode ball point - Ø 3 mm - straight	30	30530
30500	SET	Set of 10 electrodes	SET	30531
length 7 cm		minimum order: 10 pcs.	length 15 cm	
30511	15	Needle electrode	35	30532
30512	16	Blade electrode	36	30533
30513	17	Ball electrode Ø 4 mm	37	30534



5 cm long electrodes - reference number

10 cm long electrodes - reference number

7 cm

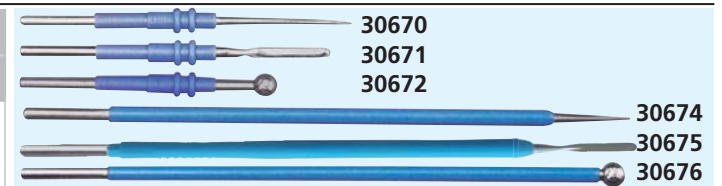
15 cm

AUTOCLAVABLE 30 TIMES

AUTOCLAVABLE 20 TIMES

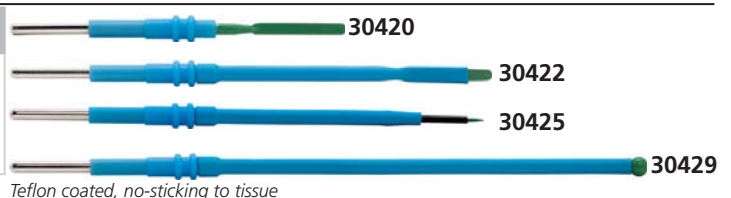
SINGLE USE STERILE ELECTRODES Ø 2.4 mm

Length		SINGLE USE ELECTRODES Ø 2.4 mm
7 cm	15 cm	Sterile electrode - box of 24
30670	30674	Needle electrode - sterile
30671	30675	Blade electrode - sterile
30672	30676	Ball Ø 4 mm electrode - sterile



SINGLE USE NON-STICK STERILE ELECTRODES Ø 2.4 mm


GIMA code	NON-STICK SINGLE USE ELECTRODE Ø 2.4 mm	Length
30420	Blade electrode - sterile	7 cm
30422	Blade electrode - sterile	10 cm
30425	Needle electrode - sterile	10 cm
30429	Ball electrode - sterile	13 cm



Teflon coated, no-sticking to tissue

SINGLE USE STERILE TUNGSTEN NEEDLE ELECTRODES Ø 2.4 mm

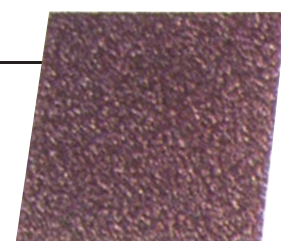
Straight	Angled	TUNGSTEN MICRO NEEDLE ELECTRODES	Length
30370	30371	Tungsten electrode - sterile	5 cm
30372	30373	Tungsten electrode - sterile	6 cm
30374	30375	Tungsten electrode - sterile	7 cm



Tungsten needle has extremely high melting point (> 3400°C) which helps maintain sharpness.

ELECTRODE CLEANING PAD

• 30537 ELECTRODE CLEANING PAD - 50x50 mm - box of 100
Disposable sterile radiopaque abrasive tip cleaner pad.



30537

3-PIN MONOPOLAR HANDLE AND ELECTRODES Ø 4 mm

• 30480 AUTOCLAVABLE MB HANDLE Ø 4 mm - 100 times

Autoclavable handle up to 100 times for Ø 4 mm shaft electrodes with 3 m silicone cable and blade electrode.

• 30482 NEEDLE ELECTRODE Ø 4 mm

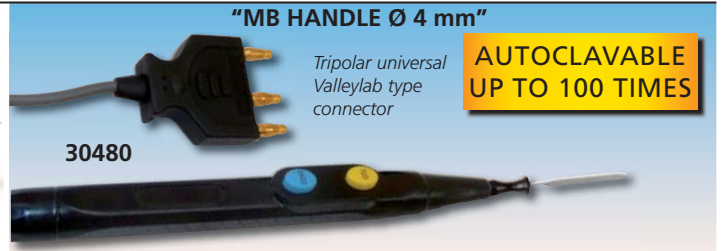
• 30483 BLADE ELECTRODE Ø 4 mm

• 30484 BALL ELECTRODE Ø 4 mm

S/S electrodes autoclavable 100 times.

Sold in box of 5.

Length 5.5 cm.



3-PIN MONOPOLAR HANDLES FOR ELECTRODES Ø 2.4 mm

VALLEYLAB CONNECTOR HANDLES with 2 "click" push-buttons GIMA autoclavable electrosurgery pencils with CUT-COAG switch offer maximum reliability and functionality to the operator.

Provided with a 3 Pin plug Valleylab type fitting all Gima monopolar Diatermo MB (80, 120, 122, 132, 160, 200, 240, 300, 380, 400) and most of bipolar electrosurgical units: Aspen Lab, ES Generator, EMC Statome, Danieli, Braun, Berchtold, Ohmeda, Ritter, Conmed, Eschmann, Bovie, Martin, Kontron, Bard, Birtcher 771, Cobi, Valleylab, Led, Erbe...

■ AUTOCLAVABLE HANDLES

• 30554 MB AUTOCLAVABLE HANDLE - 100 times

Autoclavable handle with 2 large "click" push-buttons, provided with a 3 meter long silicone cable and a blade electrode. It can be autoclaved up to 100 times (electrode 20 times).

• 30545 MB AUTOCLAVABLE HANDLE - 100 times

Same as code 30554 but with a 5 m long silicone cable

• 30548 STAR AUTOCLAVABLE HANDLE - 30 times

Same as code 30554 but autoclavable up to 30 times (electrode is autoclavable up to 20 times).

• 30539 ORION PLUS AUTOCLAVABLE HANDLE - 100 times

Same as 30554, but with a screw clamp locking system ensuring a safe contact and adapting to slightly different electrode diameters. High insulation to prevent liquid damage.

• 30536 SURGEON AUTOCLAVABLE HANDLE - 100 times

Autoclavable, waterproof handle with ergonomic grip. Coloured ring that indicates CUT and COAG push buttons. Provided with 3 m cable and blade electrode.

■ SINGLE USE HANDLE WITH PUSH-BUTTONS OR ROCKER SWITCH

• 30549 KIRKY SINGLE-USE HANDLE - STERILE - box of 50

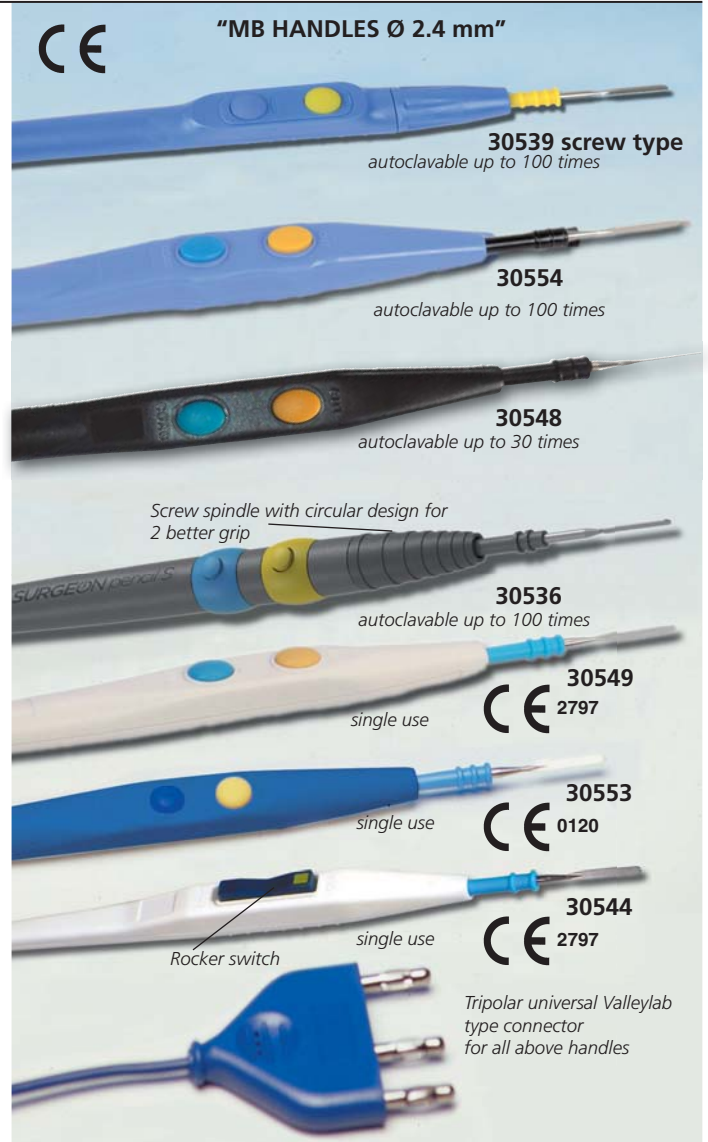
Single-use handle with "click" push-buttons for cut and coag. Includes blade electrode and 3.20 m cable. Multilingual instructions: GB, FR, IT, ES, PT, DE, NL, PL, RO, HU, DK, SE, FI, EE, LV, RU, SK, CZ, HR, SI, GR, BG, TR, Arabic.

• 30553 GIMA SINGLE-USE HANDLE - STERILE

Handle with "click" push-buttons for cut and coag. With 3 m cable.

• 30544 ROCKER SINGLE USE HANDLE - STERILE - box of 50

Single-use handle with rocker-switch for cut and coag. Includes blade electrode and 3.20 m cable. Multiling. instructions as 30549.



1-PIN MONOPOLAR HANDLES FOR ELECTRODES Ø 2.4 mm

1 pin plug HANDLES for diatermo 50, 80, 106, 108

These handles are provided with a 1 Pin socket (4 mm) fitting all Gima Diatermo and most of electrosurgical units in the market. These handles **do not have push-buttons**.

• 30515 SURGEON 1 PIN AUTOCLAVABLE HANDLE - 100 times

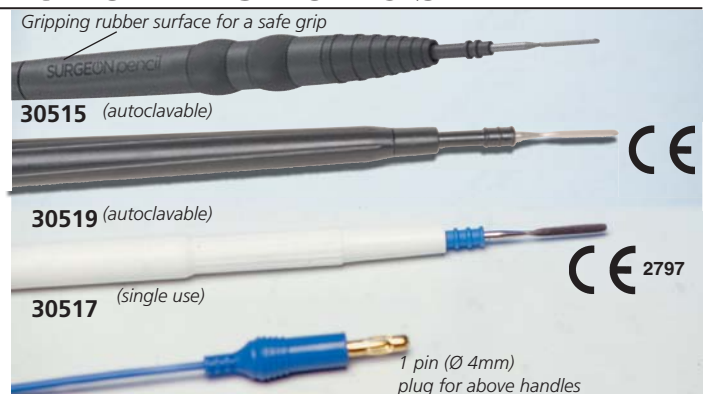
Autoclavable, waterproof handle with ergonomic grip. Provided with 3 m cable and blade electrode

• 30519 AUTOCLAVABLE 50-80-106-108 HANDLE - 100 times

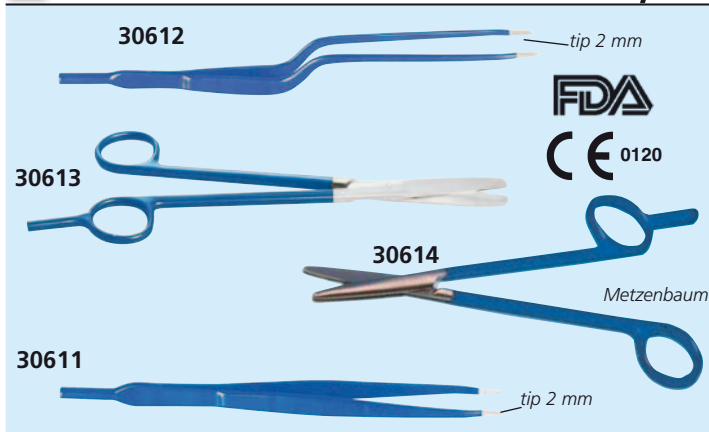
Autoclavable handle without buttons, provided with a 3 meter long cable and a blade electrode.

• 30517 KIRKY SINGLE-USE 50-80-106-108 HANDLE - STERILE - box of 50

Single-use handle without button with blade electrode with 4 mm PIN connection. Multilingual instructions as 30549.



MONOPOLAR FORCEPS, SCISSORS AND CABLES



Monopolar forceps and scissors are provided with a 4 mm connection for standard monopolar cables. These can be used with all Gima, LED, Erbe and many other electro-surgical units in the market.

GIMA code	INSULATED MONOPOLAR INSTRUMENTS
30610	Monopolar cable - 4 mm pin - 3 m
30611	Mc INDOE straight monopolar forceps 15 cm (6")
30612	Bayonet monopolar forceps - 20 cm (7 1/2")
30613	Monopolar scissors - straight - 18 cm (7")
30614	Metzenbaum monopolar scissors - straight - 18 cm (7")
30615	Metzenbaum monopolar scissors - curved - 18 cm (7")

3M ELECTROSURGICAL GROUNDING PADS WITH SAFETY RING

- 30496 3M 9160 SPLIT GROUNDING PAD - box of 100
 - 30497 3M 9160F SPLIT GROUNDING PAD - box of 200 (40 pouches of 5 pieces)
 - 30498 3M 9165 SPLIT GROUNDING PAD - precorded - box of 40
- The 3M Universal Grounding Pads all have a conductor area of 15 square inches and come with the patented 3M Green Safety Ring technology which allows them to perform the same as grounding pads that are up to 33% larger in conductor area. Green Ring allows adult and pediatric use.

They have fluid resistance, non-woven backing which allows heat to pass through up to 25% faster than foam, and they have no minimum age or weight limit.



30496, 30497
(3M 9160)

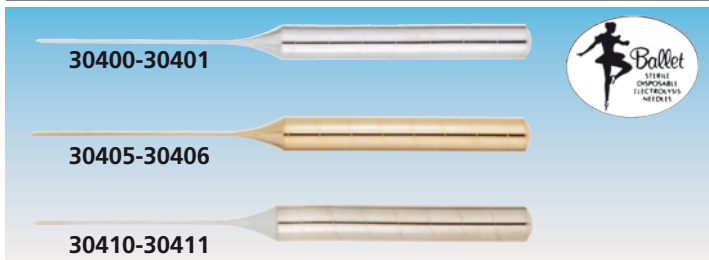
HANDLES FOR ELECTROLYSIS NEEDLES

Needle handles for all GIMA Diatermo and electro-depilators

- 30552 HANDLE for electrolysis needles
- 30415 PROFESSIONAL HANDLE for electrolysis needles



BALLET STERILE DISPOSABLE ELECTROLYSIS NEEDLES



Stainless steel	Gold plated	Insulated	ELECTROLYSIS NEEDLES - STERILE	Minimum order
30400	30405	30410	K2 needle - 0.055 mm (0.002")	box of 50
30401	30406	30411	K3 needle - 0.075 mm (0.003")	box of 50

Ballet needles

Manufactured with a precise point and a mirror-like surface polish. The rounded tapered point of the needle assists the electrologist in locating the follicle opening and upon insertion the needle will slide smoothly and accurately to the base of the follicle.

Stainless steel needles

Ideal for patients with strong healthy skin who respond well to electrolysis treatment.

Insulated needles

Suggested for patients with high sensitivity to discomforts of electrolysis.

24 carat gold plated needles

For clients who suffer from allergies and sensitive skin.



ELECTRODEPILATOR

• 28340 ELECTRO-DEPILATOR 400

This device ensures a definitive depilation with thermolytic method. It delivers a current of radiofrequency to cause the heating and consequent coagulation of the papilla, reached through the introduction of a needle into the follicle of the hair. Provided with highly reliable electronic integrated components, with RF intensity adjustable with continuity and luminous working signal. It comes complete with footswitch, handpiece for depilation, depilation needle and power cable (2 m).

TECHNICAL SPECIFICATIONS

RF output frequency: 1.9 ±10% MHz
 Modulation: sinusoidal
 Maximum output power: 7 ±2Watt
 Size: 260x265x110 mm Weight: 4 kg
 Operating voltage: 115/230 V - 50/60 Hz switchable
 Norms: CEI 62-39 Class: I-BF

- 30552 HANDPIECE FOR DEPILATION
- 30577 FOOTSWITCH

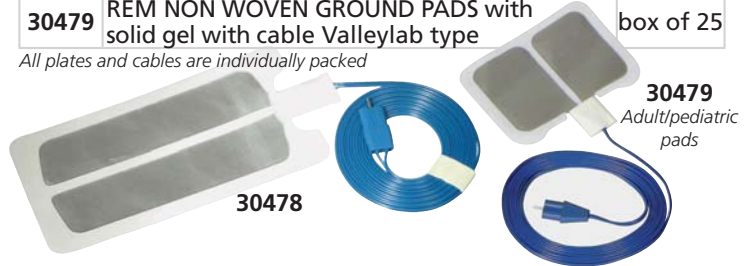


DISPOSABLE GROUND PADS - WITH/WITHOUT CABLE



GIMA code	DISPOSABLE GROUND PADS WITH SOLID GEL - need cable 30563	Minimum order
30491	REM GROUND PADS - pediatric	box of 25
30487	REM GROUND PADS - pediatric	box of 100
30492	GROUND PADS - adult	box of 25
30489	GROUND PADS - adult	box of 100
30493	REM GROUND PADS - adult	box of 25
30488	REM GROUND PADS - adult	box of 100
30495	REM NON WOVEN GROUND PAD - ad/ped	box of 100
30563	CABLE FOR PADS - 5 m	box of 1
DISPOSABLE GROUND PADS WITH CABLE - 3m		
30476	PADS WITH CABLE Ø 6.3 mm plug	box of 25
30478	PADS WITH CABLE Valleylab type	box of 25
30479	REM NON WOVEN GROUND PADS with solid gel with cable Valleylab type	box of 25

All plates and cables are individually packed



CONNECTION CABLES FOR DISPOSABLE GROUND PADS

CABLES TO CONNECT GROUND PADS TO ELECTROSURGERY UNITS

The bipolar universal connection cables are supplied with a bipolar clamp for connection to disposable ground pads with a tab (dimensions 22-25 mm).

Various connectors make the cables compatible with numerous electrosurgical devices.

The cable can be fixed to the surgical sheet during the operation thanks to a metal sliding clamp. Latex free. Individually packed in sealed polyethylene pouch compliance to 93/42/EEC. MD Class I.

30563



Connection to electronic unit

Connection to disposable ground plates

COMPATIBLE ELECTROSURGERY UNITS

• 30563 CONNECTION CABLE FOR PADS - 5 m - Universal jack mono plug 6.3 mm

Aesculap: TM, TM401
Alexandra: D205, E300, 500D, 102/201, 2020/E, 202, MICRO180
ALSA: All
 MF100, MF360/A360, 380100, 180
Berchold: Elektrotom 200, 390, 400, 540
Birtcher: 772, 773, 737, 737XL, 774

Bovie: Bovie CSV, URO, BS, 400/400, 400SR, X10, X10L
Burdick: U-7, SU-8
Cameron-Miller: 26-1290
Cobe: TS-403
Concept: 9600, 9700, 9800, 9900
Dolley: COBII 203T, 502, 503T, 505T
Ems Davol: System 2000, 5000

Faset: Serie COBI
Gima: all models
GPS: all models
I Cuatro: Megeri1
Lamidey: Series Subtilec: All
 Series Surgilec: All
Led: all models
Martin: all models

Neomed: Series 3000, 3000A, 3002, 3006; 3010, 3020
Philips: TS-403
Ritter/Mdt: Solide State 400, 400B, 400SR
Sidevan: Seb2
Soxil: BP 2000, X10
Thackray: T3005
Torry: Lem 300 CST

• 30546 CONNECTION CABLE FOR PADS - plug with spacer - 5 m - Universal jack mono plug 6.3 mm



Erbe: ACC, ICC, VIO, T

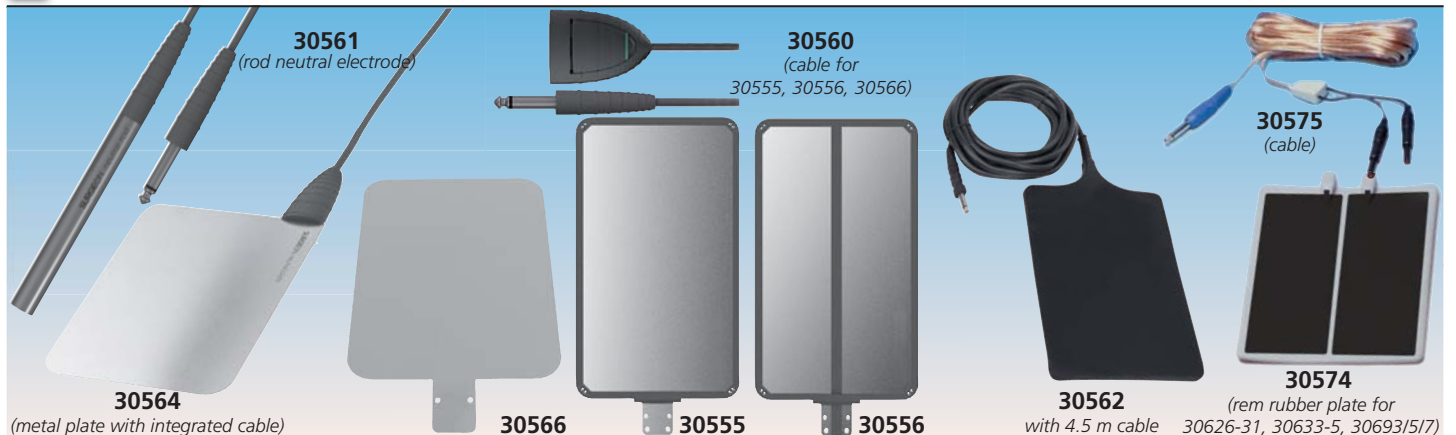
• 30547 CONNECTION CABLE FOR PADS VALLEYLAB TYPE - 5 m - Universal Valleylab connection



Aspenlabs: Excalibur
 Valleylab: REM type devices
 Bowa

Conmed
 Erbe ICC International
 Erbe ACC International

AUTOCLAVABLE METAL AND RUBBER PLATES



- 30566 METAL PLATE - needs cable 30560
- 30560 CABLE FOR RUBBER STEEL PLATES 30555, 30556, 30566
- 30564 SURGEON NEUTRAL PLATE 16x12 cm - with cable
- 30561 ROD NEUTRAL ELECTRODE with cable for 30625*
- 30562 FLEXIBLE RUBBER PLATE 15x8 cm with cable 4.5 m
- 30565 FLEXIBLE RUBBER PLATE 25x15 cm with cable 4.5 m

*Available on request for other electrocautery

- 30555** FLEXI STEEL RUBBER PLATE 18x21 cm - needs cable 30560
- 30556*** FLEXI STEEL REM RUBBER PLATE - needs cable 30560
- 30560 CABLE FOR RUBBER STEEL PLATES 30555, 30556, 30566
- 30574 REM RUBBER PLATE 20x15 cm - needs cable 30575
- 30575 CABLE FOR RUBBER PLATES 30573 and 30574

**Compatible with all Gima diatermo

***Compatible with all Gima diatermo except 30516, 30625



BIPOLAR CABLES FOR MAJOR BRANDS

Quality highly flexible silicone bipolar cables 3 m long (10").
Autoclavable at 134°C for minimum 20 times.
Recommended EtO sterilization for max extended life.

Suitable for most generators, with connector for European or US forceps. Multilingual box and manual: GB, FR, IT, ES, PT, DE, SE PL, RO,GR, HR, Arabic

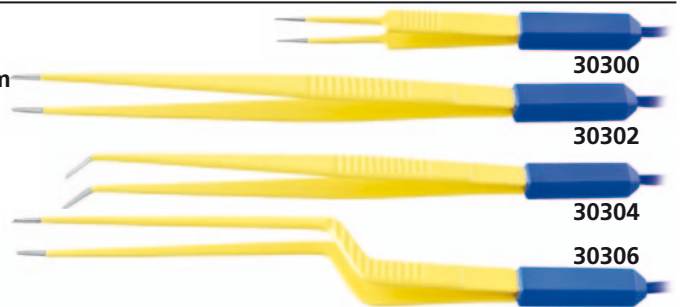
<p>30642 BIPOLAR CABLE ADAPTOR</p>	<p>Connector to forceps</p>	<p>Connector to electro-surgical unit</p>	<p>Connector to forceps</p>	<p>Connector to electro-surgical unit</p> <p>Pin distance 29 mm</p>						
	GIMA Code	30632	30618	30640	30637	30643	30618+ 30642	30617	30644	30639
Connector to forceps	EU	US	EU	US	EU	US	EU	US	EU	EU
Compatibility brand/model	GIMA: MB 240, MB 380 VALLEYLAB, CONMED, CODMAN, OLYMPUS		GIMA: MB 120 F, MB 200 F, MB 200 D, MB 200T, MB 300 D, MB 400 D, MB 300T, MB 400T LED: SURTRON 120, 200, 200T, 300, 300T, 400, 400T VALLEYLAB, EMC, DOLLEY		GIMA: MB 122, MB 160, MB 200, MB 202		GIMA: MB 80 D, MB 120 D, MB 160 D LED: SURTRON 80, 120, 160		MARTIN, BERCHTOLD, AESCULAP, WOLF	ERBE, SELECT, DOWNS, SIEMENS

DISPOSABLE BIPOLAR FORCEPS - VALLEYLAB CABLE

- 30300 DISPOSABLE JEWELER FORCEPS - 11.5 cm - tip 0.5 mm
 - 30302 DISPOSABLE STRAIGHT FORCEPS - 20 cm - tip 1.0 mm
 - 30304 DISPOSABLE STRAIGHT FORCEPS - 15 cm - angled tip 1.0 mm
 - 30306 DISPOSABLE BAYONET FORCEPS - 20 cm - tip 1.0 mm
- Disposable bipolar forceps are supplied with 3 m cable.

Valleylab plug (same connector and compatibility as 30640).

Sterilization by Ethylene Oxide (EtO).



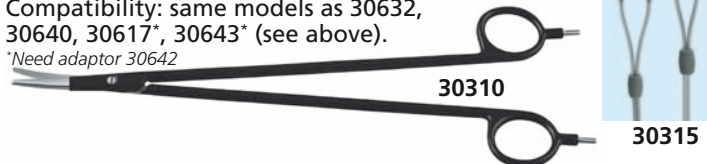
BIPOLAR SCISSORS

- 30310 BIPOLAR SCISSORS - 18 cm (7") - curved
Needs bipolar cable 30315

- 30315 SILICONE BIPOLAR CABLE - 3 m (10')
with Ethicon type connector

For bipolar scissors. Connector 2.5 mm
Compatibility: same models as 30632, 30640, 30617*, 30643* (see above).

*Need adaptor 30642



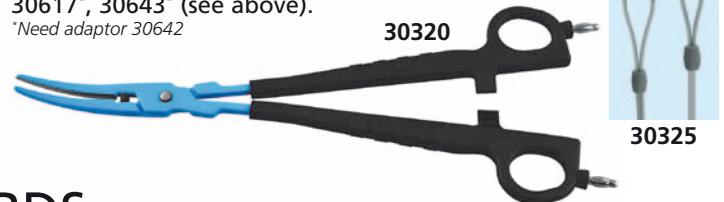
BIPOLAR ARTERY SEALER

- 30320 BIPOLAR ARTERY SEALER - 26 cm (10.5")
Needs bipolar cable 30325

- 30325 SILICONE BIPOLAR ARTERY SEALER CABLE - 3 m (10')

Connector 4 mm, Banana plug.
Compatibility: same models as 30632, 30640, 30617*, 30643* (see above).

*Need adaptor 30642



FOOTSWITCHES AND BOARDS

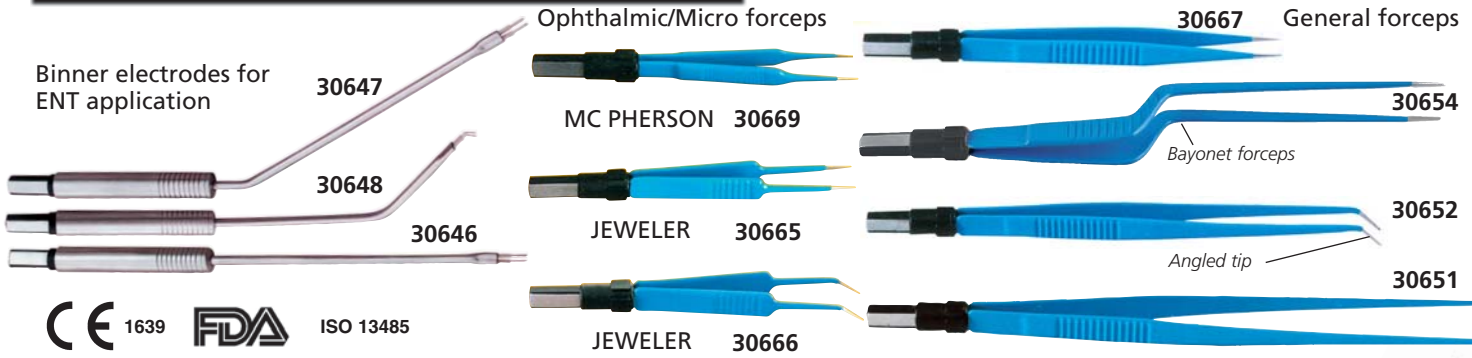
GIMA code	FOOTSWITCHES FOR 50, 80, 106, MB 80D, 120D, 120F, 122, 132, 160, 160D, 200, 200D, 200F, 200 T, 202
30577	MB waterproof footswitch - 2m cable
30578	MB waterproof footswitch - 3m cable
	ANTIEXPLOSION FOOTSWITCH FOR MB 120D, 120F, 122, 132, 160, 160D, 200, 200D, 200F, 202
30602	Double antiexplosion, water proof MB footswitch
	ANTIEXPLOSION FOOTSWITCHES FOR MB 240, 300D, 300T, 380, 400, 400D, 400T
30603	Double antiexplosion, water proof footswitch - MB240-380
30604	Double antiexplosion, water proof footswitch - MB250-400-300D-400D
30608	Double antiexplosion, water proof footswitch - MB300-400 TOUCH
	MAIN BOARD
30557	Main board - specify model and serial number of diatermo with order
30558	Output board for MB 240, 250, 380, 400 - specify as above



It allows selection from pedal of CUT and COAG functions
Antiexplosion and waterproof.

UNIVERSAL HIGH QUALITY INSULATED BIPOLAR FORCEPS

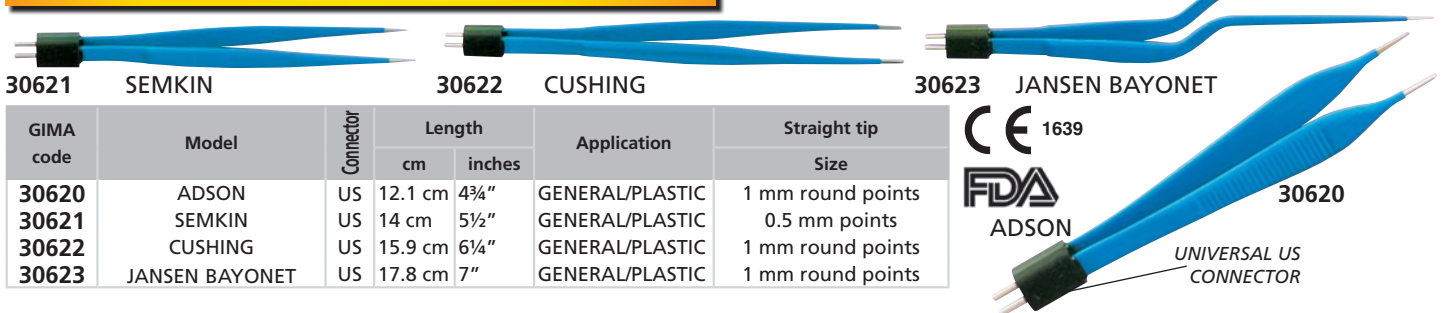
EUROPEAN CONNECTOR BIPOLAR FORCEPS



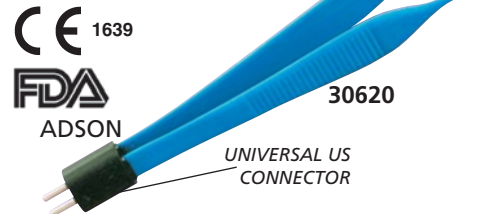
GIMA code	Model	Connector	Length		Tip style	Application	Tip size
			cm	inches			
30645	BINNER	EU	22 cm	8½"	ANGLED	ENT	-
30646	BINNER	EU	18 cm	7"	STRAIGHT	ENT	-
30647	BINNER	EU	18 cm	7"	ANGLED	ENT	-
30648	BINNER	EU	19 cm	7¾"	ANGLED 45°	ENT	-
30650	STRAIGHT	EU	18 cm	7"	STRAIGHT	GENERAL	1 mm round points
30656	STRAIGHT with irrigation	EU	18 cm	7"	STRAIGHT	GENERAL	1 mm round points
30651	STRAIGHT	EU	20 cm	7¾"	STRAIGHT	GENERAL	1 mm round points
30658	STRAIGHT	EU	20 cm	7¾"	STRAIGHT	GENERAL	2 mm round points
30652	STRAIGHT	EU	18 cm	7"	ANGLED	GENERAL	1 mm round points
30653	STRAIGHT	EU	20 cm	7¾"	ANGLED	GENERAL	1 mm round points
30657	BAYONET	EU	16.5 cm	6½"	STRAIGHT	GENERAL	1 mm round points
30654	BAYONET	EU	18 cm	7"	STRAIGHT	GENERAL	1 mm round points
30655	BAYONET	EU	20 cm	7¾"	STRAIGHT	GENERAL	1 mm round points
30659	BAYONET	EU	22 cm	8¾"	STRAIGHT	GENERAL	1 mm round points
30663	BAYONET	EU	24 cm	9½"	STRAIGHT	GENERAL	1 mm round points
30660	STRAIGHT	EU	18 cm	7"	ANGLED	GENERAL	0.3 mm points
30661	STRAIGHT	EU	18 cm	7"	STRAIGHT	GENERAL	0.3 mm points
30662	STRAIGHT	EU	20 cm	7¾"	STRAIGHT	GENERAL	0.3 mm points
30664	ADSON	EU	12.1 cm	6"	STRAIGHT	GENERAL	1 mm round points
30665	JEWELER 5	EU	11.5 cm	4½"	STRAIGHT	OPHTHALMIC/MICRO	0.25 mm points
30666	JEWELER 5	EU	11.5 cm	4½"	ANGLED	OPHTHALMIC/MICRO	0.25 mm points
30667	STRAIGHT	EU	15 cm	6"	STRAIGHT	OPHTHALMIC/MICRO	0.5 mm points
30668	STRAIGHT	EU	15 cm	6"	ANGLED	OPHTHALMIC/MICRO	0.5 mm points
30669	Mc PHERSON	EU	10.2 cm	4"	STRAIGHT	OPHTHALMIC/MICRO	0.5 mm points



US CONNECTOR BIPOLAR FORCEPS



GIMA code	Model	Connector	Length		Application	Straight tip Size
			cm	inches		
30620	ADSON	US	12.1 cm	4¾"	GENERAL/PLASTIC	1 mm round points
30621	SEMKIN	US	14 cm	5½"	GENERAL/PLASTIC	0.5 mm points
30622	CUSHING	US	15.9 cm	6¼"	GENERAL/PLASTIC	1 mm round points
30623	JANSEN BAYONET	US	17.8 cm	7"	GENERAL/PLASTIC	1 mm round points



EUROPEAN NON-STICK BIPOLAR FORCEPS

NON-STICK BIPOLAR FORCEPS

Thanks to new Ag-Tech non-stick technology, the forceps stay clean, virtually eliminating the need for cleaning during

coagulation. A tip material with excellent thermal properties prevents the sticking of tissues. The non-stick effect is permanent and will not reduce with the use of forceps.

GIMA code	Model	Connector	Length		Tip style	Tip size
			cm	inches		
30460	STRAIGHT	EU	15	6"	STRAIGHT	1 mm
30461	STRAIGHT	EU	18	7"	STRAIGHT	1 mm
30462	STRAIGHT	EU	20	7¾"	STRAIGHT	1 mm
30464	STRAIGHT	EU	18	7"	ANGLED	1 mm
30465	STRAIGHT	EU	20	7¾"	ANGLED	1 mm
30468	BAYONET	EU	18	7"	STRAIGHT	1 mm
30469	BAYONET	EU	20	7¾"	STRAIGHT	1 mm
30472	JEWELER	EU	11.5	4.5"	STRAIGHT	0.7 mm
30473	JEWELER	EU	11.5	4.5"	ANGLED	0.7 mm
30474	ADSON	EU	12.1	4¾"	STRAIGHT	1 mm



SMART CARTS FOR ELECTROSURGICAL UNITS

- 27895 SMART CART - 2 shelves 40x36 cm + base
 - 27889 SMART CART - 2 shelves 50x42 cm + base
 - 27890 SMART CART - 2 shelves 60x42 cm + base
- Sturdy carts with painted powder steel base and aluminium frame. 2 shelves with protection edge on back, adjustable at different height.
Suitable for all Gima electrosurgical units.
Illustrated assembly instructions. Medical Devices Class I.

	TECHNICAL SPECIFICATIONS		
	27895	27889	27890
Total load:	80 kg	80 kg	80 kg
Load x shelf:	15 kg	15 kg	15 kg
Size mm:	482x500xh 780	582x500xh 780	682x500xh 780
Weight:	13 kg	15 kg	17 kg



CARTS FOR ELECTROSURGICAL UNITS

Ergonomic trolley designed to hold and carry electrosurgical units (including Argon units). The height of 915 mm with inclined top shelf allows easy reading of the unit's display. The trolley is provided with a second shelf with antiskid raised edges, two drawers placed at the base and a rear space with securing straps to hold two Argon cylinders. Upright stands can hold optional accessories. Made of epoxy-painted, tempered steel and aluminium. Available version with 4 socket group, fuses box, independent grounding plug, power cable 3m.

	TECHNICAL SPECIFICATIONS	
Load capacity:	- Total load 200 kg	- Inclined shelf 50 kg
Inclined shelf:	42x45 cm (27864/6)	50x36 cm (27865/7)
Drawers and shelf:	42x36 cm (27864/6)	50x36 cm (27865/7)

GIMA code	CARTS FOR ELECTROSURGICAL UNITS
27864	DIATERMO CART - medium
27865	DIATERMO CART - large
27866	DIATERMO CART with power - medium
27867	DIATERMO CART with power - large



ELECTROSURGERY SMOKE EVACUATOR

• 30450 SMOKE EVACUATOR
An aspiration and filtering system for the smokes produced during the surgical procedures. The smokes, generated during the surgical procedures, have a bad, strong and persistent smell. These smokes consist of water vapour, organic gas, visible or invisible solid particles and viral parts. So a good aspiration and filtration eliminates bad smells, reduce the bacteriological and/or viral risks, and improves vision of the zone of the operation area during the laparoscopic procedures.

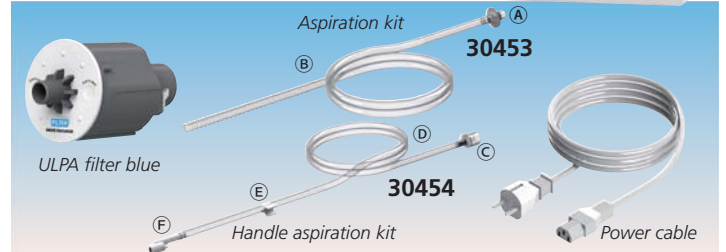
Activation of the aspiration can be:
- **Automatic**, through the remote electronic system of automatic survey of the activation of the high frequency electrosurgical unit
- **Manual**
- **Through a foot switch (optional)**
The aspiration flow can be adjusted to suit the specific needs. For laparoscopic procedures there is a specific function L, quickly selectable. Smoke evacuator has an electronic control of the aspiration with the indication of the wearing status of

TECHNICAL SPECIFICATIONS	
Mains voltage:	230 V (115 V on request)
Mains frequency:	50/60 Hz
Electrical input power:	800 VA
Max vacuum flow rate:	1000 LPM (35 CFM)
Max static suction:	250 mbar (83 in H ₂ O)
Filter type:	ULPA with active carbons
Filter efficiency:	99,999%
Particles diameter:	0.12 micron
Size:	370x144x319 mm
Weight:	4 kg

STANDARD ACCESSORIES	
ULPA filter (5 hours) blue	
Aspiration kit (A) filter + (B) pipe Ø 22 mm, length 2.4 m)	
handle aspiration kit (C) adapter 10 mm / 22 mm (D), pipe Ø 10 mm, length 1.8 m,	
(E) clip to fix the pipe to the handle, (F) adapter to the handle)	
Power cable	

the filters. There are two different kinds of quickly replaceable ULPA type filters, with active carbons: the BLUE filter is the first filter and it is included with the unit for an initial time of use (5 hours), the RED filter is an optional spare part, developed for a long time use (20 hours). They have connector of 7/8".

- 30451 ULPA FILTER (20 hours) RED for 30450 since S.N. 0216383
- 30452 ULPA FILTER (20 hours) RED for 30450 up to S.N. 0216382
- 30453 ASPIRATION KIT - box of 6
- 30454 HANDLE ASPIRATION KIT - sterile - box of 12
- 30577 MB WATERPROOF FOOTSWITCH - 2 m



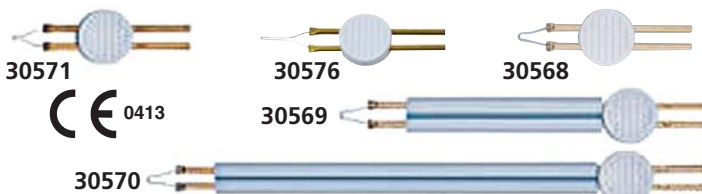
CHANGE-A-TIP™ CAUTERIES WITH HIGH TEMPERATURES

BOVIE CAUTERIES

Improved battery-operated cautery with a safety-enhanced design and a recessed button to reduce the potential for inadvertent activation.

It also allows the practitioner to "snapped off" the end of the cautery for safe and effective battery removal.

- interchangeable sterile tips (non sterile tips for 30584 and 30590)
- replaceable batteries
- reusable handles
- no sterilization necessary.



GIMA code	CAUTERY HANDLE AND INTERCHANGEABLE STERILE TIPS	Recommended for:	Minimum order
30590	Cautery handle "AA" (tip included)	All tips	1
30568	High temp loop tip	DER/ENT	box of 10
30569	High temp 2" flex loop tip	GYN/ENT	box of 10
30570	High temp 5" loop tip - long size	GYNAECOLOGY	box of 10
30571	High temp fine tip	DER/CARDIO	box of 10
30576	High temp elongated tip	VASECTOMY	box of 10
30584	High temp cautery kit (1 handle + 4 non sterile tips)		

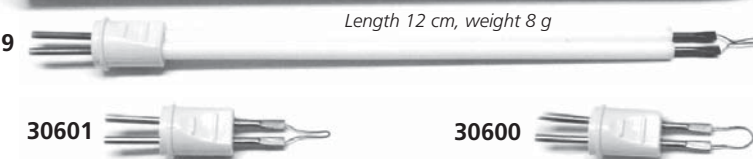
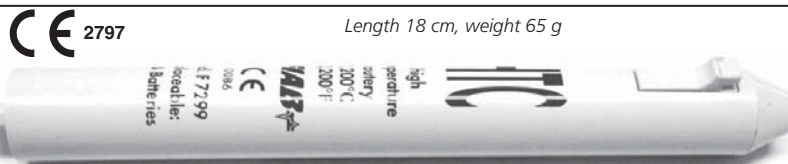
REUSABLE HIGH TEMPERATURE CAUTERY WITH REPLACEABLE TIP

CAUTERIES - 1,200°C (2,200°F)

- interchangeable tips with nickel-chrome wire
- replaceable batteries
- reusable handles

Wide application in gynaecology, orthopedy, ear/nose/throat, dermatology and urology.

GIMA code	INTERCHANGEABLE TIP CAUTERIES MINIMUM ORDER: 10 TIPS
30598	Cautery handle "AA" (tip not included)
30599	High temp long fine tip - sterile - box of 10
30600	High temp large tip - sterile - box of 10
30601	High temp fine tip - sterile - box of 10



DISPOSABLE HIGH/MEDIUM/LOW TEMPERATURE CAUTERIES

• 30700 ELECTROCAUTERY - 1,200°C - fine tip - box of 10

Electrocautery is a sterile bipolar battery operated disposable device for the cauterization of small vessels. With a fine tip required in most of the surgeries.

• 30701 ELECTROCAUTERY - 1,200°C - large tip - box of 10

Same as 30700, but with a large tip.

• 30702 LONG SHAFT ELECTRO CAUTERY - 1,200°C - fine tip - box of 10

Same as 30700 but with the tip fixed on a 12 cm long shaft. Precise cauterization even in difficult access sites.

• 30703 EMERGENCY ELECTROCAUTERY - 800°C - thick tip - box of 10

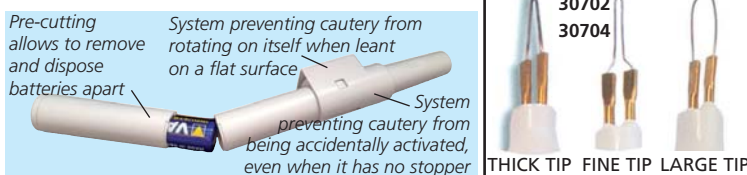
Same as 30700 but with "thick tip" for the perforation of nails in case of haematoma.

• 30704 ELECTROCAUTERY - 600°C - fine tip - box of 10

Same as 30700 but with lower temperature 600°C. Especially designed for ophthalmology.



Applications	30700	30701	30702	30703	30704
Cardiovascular, thoracic surgery	x				
Proctology	x	x	x		
General surgery			x		
Gynaecology	x				
Surgical gynaecology			x		
Neurosurgery	x	x	x		
Orthopedic	x	x			
Urology	x				
Obstetrics	x				
Emergency ward				x	
Otolaryngology	x	x	x		
Plastic and reconstructive	x	x			
Ophthalmology	x				x
Dermatology	x				
Dental surgery	x				



Features	HTC (High Temperature Cautery)			MTC (Med. Temp. Cautery)	LTC (Low. Temp. Cautery)
	30700	30701	30702	30703	30704
Tip shape	Fine	Large	Fine	Thick	Fine
Tip length	28mm	28mm	125mm	28mm	28mm
Temperature °C/°F	1200/2200	1200/2200	1200/2200	800/1400	600/1100
Weight	65g	65g	78g	65g	45g

HISTOFREEZER® CRYOSURGICAL SYSTEM

- **30591 HISTOFREEZER® - kit with applicator 2 mm**
Two 80 ml aerosol bottles and 60 applicators 2 mm.
- **30592 HISTOFREEZER® - kit with applicator 5 mm**
Two 80 ml aerosol bottles and 52 applicators 5 mm.
- **30589 HISTOFREEZER® - large kit mixed applicators**
Two 80 ml aerosol bottles, 24 applicators 2 mm, 36 applicators 5 mm.
- **30585 HISTOFREEZER® - mini kit mixed applicators**
One 80 ml aerosol bottle, 16 applicators 2 mm, 16 applicators 5 mm.

The Histofreezer® portable cryosurgical system is a low cost, highly effective cryosurgical agent that provides safe and effective treatment for warts and other common benign skin lesions. This therapeutic treatment makes use of local freezing for the controlled destruction or removal of living tissue. Suitable for adults and children.

Multilingual box and manual in: GB, FR, IT, DE, ES, NL, PL. From web you can download: GR, PT, TH, Arabic. For professional use only.

9 types of benign lesions	% of resolution*
Verruca Vulgaris (Common Warts)	94%
Verruca Plantaris (Plantar Warts)	86%
Molluscum Contagiosum	100%
Lentigo (Age Spots)	100% - facial 99% - non facial
Condyloma (Genital Warts)	89%
Seborrheic Keratosis	95%
Acrochordon (Skin Tags)	100%
Verruca Plana (Flat Warts)	93%
Actinic keratosis (Facial and Non-Facial)	91% - facial 87% - non facial

*Summary of resolution rates by type of lesion from a number of clinical trials obtained with histofreezer + post-treatment of 27% salicylic acid / 17% lactic acid

Saturated 2 mm applicators will stay cold for 90 seconds.



30591



30591

Saturated 5 mm applicators will stay cold for 120 seconds.



30592



30585



30589



2 mm
5 mm

2 mm disposable applicator for small lesions
5 mm disposable applicator for large lesions

CHARGE
custom applicator press valve until droplets start to form.

INVERT
canister for 15 seconds for optimal freezing temperature.

APPLY
a frozen applicator to lesion for 15-40 seconds.

CRYOMEGA® AND CRYOCLEAR® MULTI-USE CRYOSURGICAL DEVICES

• **30586 CRYOMEGA® with 16 g cartridge - non-refillable**
CryoOmega® dispenses liquid nitrous oxide (-89°C) the coldest portable cryogen and it is cleared for 16 common lesions including verrucae, skin tags, and seborrheic keratoses. Ideal choice in portable cryosurgery for physician offices looking for convenience and great first-time outcomes. It provides clinically effective freezing with pinpoint precision. No contact device for use on different patients at 1 cm distance. Up to 300 seconds treatment time per device (approx 30 treatments of 10 seconds). For medical healthcare professionals.



Type of Lesion	Freeze time range (sec)*
Verruca Vulgaris	10-20
Verruca Plantaris	10-20
Molluscum Contagiosum	3-10
Skin Tags	5-10
Lentigo	2-5
Actinic Keratosis	5
Verruca Plana	5-15
Seborrheic Keratosis	5-10
Genital Lesions	5-12

N₂O
-89°C

30586



Multilingual pack and instructions (GB, FR, IT, ES, DE, NL, PL, FI).

*Suggested freezing time as reported in literature 237

• **30587 CRYOCLEAR® with 16 g cartridge - non-refillable**
CryoClear® uses Carbon Dioxide which freezes at -79°C to a depth of no more than 2 mm into the skin, delivering a safe and clinically effective treatment to superficial skin indications. Over 95% high efficacy combined with less destruction of healthy tissue makes it perfect for treating age spots, sun spots, and skin tags. It offers a better and faster cryotherapy solution, even as combination treatment to chemical peels, facials, micro-needling or dermaplaining. No contact device for use on different patients at 0.5 cm distance. Up to 300 seconds treatment time per device (approx 60 treatments of 5 seconds). Suggested for use at aesthetics and cosmetic sites.



Indication	Freeze time range (sec)*
Actinic Keratosis (sun spots)	5-10
Lentigo (Age Spots)	5-10
Skin Tags	5-10

CO₂
-79°C

30587



Multilingual pack and instructions (GB, FR, IT, ES, DE, NL, PL, FI).

*Suggested freezing time as reported in literature

GIMA S.P.A.
VIA TOMMASO GROSSI, 2 20121 MILANO

2024.01.04

Notified Body Confirmation Letter
Reference: 000126369

To whom it may concern,

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 (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, ICIM SPA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 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:

GIMA S.P.A.
VIA TOMMASO GROSSI, 2 20121 MILANO

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) 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 MDD/AIMDD certificate expiry; 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 the 20 Mar 2023 for the relevant devices.

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 (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
 ICIM SPA
 Piazza Don Enrico Mapelli, 75
 2099 Sesto San Giovanni MI
 Identificazione su NANDO CE0425

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Physiological parameters measuring devices (Scales – ASTRA)	Class IM	N/A	Certificate nr. MED 26036-1, released Kiwa Cermet Italia spa
Physiological parameters measuring devices (Height meter - Skinfold caliper - Baby measuring meter)	Class IM	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Sterile single use surgical instrument	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Blood pressure measuring devices (Aneroid Sphygmomanometers)	Class IM	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Blood pressure measuring devices (Digital Sphygmomanometers)	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Body temperature measuring devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Respiratory care and resuscitation devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Aerosol therapy devices	Class IIb	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Oxygen saturation measuring devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Sterile Single use gynaecology and ENT devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa
Active substances and liquids suctioning devices	Class IIa	N/A	Certificate nr. MED 26036, released by Kiwa Cermet Italia spa

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Multiparameters patient monitors	Class IIa	N/A	Certificate nr. MED 26036B, released by Kiwa Cermet Italia spa

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.04.01	000126369	Initial issue

Remaining at your disposal for any clarification on the content of this offer, we take this opportunity to extend our best regards.

Dott. Edoardo Dossena
Product Sales Manager Certificazione
Prodotto, Ispezioni e Direttive
ICIM S.p.A.


Dott. Dario Bruno
Direttore Commerciale
ICIM S.p.A.


Note:

The following documents are available at www.icim.it

- Certification Regulations related to the services covered by this tender.
- Certification scheme Regulation (EU) 2017/745 (0209CS)
- ICIM Certification Mark User Manual (0260CR)
- ICIM General Rules for the provision of services (0001CR)
- Rules for the Certification of Management Systems (0002CR)
- Product and Service Regulations (0003CR)



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

Pagina / Page 1 di / of 12

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

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

GIMA S.p.A.

Sede Operativa / Operational Headquarter:

Via Marconi, 1
20060 Gessate, MI - Italia

Sede Legale / Registered Headquarter

Via Tommaso Grossi, 2
20121 Milano, MI - Italia

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

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

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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

Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



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

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi attivi per l'aspirazione di sostanze e liquidi / Active substances and liquids suctioning devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1104

Marca / Brandname:

VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / Model:

Aspiratori chirurgici / Surgical aspirators

Codici / Codes:

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

Tipologia / Medical Devices:

Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

Chief Operating Officer

Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:11:56



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it





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

Pagina / Page 3 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Modello / Model:

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

Codici / Codes:

29745 ; 29748-29749

Modello / Model:

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

Codici / Codes:

29991

Modello / Model:

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

Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

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

Codici / Codes:

29987

Modello / Model:

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

Codici / Codes:

29995

Modello / Model:

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

Codici / Codes:

29986

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:12:15



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Modello / Model:

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

Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di trasporto in plastica sterile / Sterile plastic transport swab

Codici / Codes:

29753

Marca / Brandname:

Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Codici / Codes:

29735 ;29736 ; 29737

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Proctoscopio adulti / Adult proctoscope

Codici / Codes:

25957

CERTIFICATE



Reg. Numero /
Reg. Number

MED 26036

Revisione /
Revision

23

Primo rilascio /
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2021-05-24

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per aerosolterapia / Aerosol therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1102

Modello / Model:

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

Codici / Codes:

28091 ; 28092

Marca / Brandname:

EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / Brandname:

MISTRAL

Modello / Model:

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

Codici / Codes:

28102

CERTIFICATE

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40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
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Organismo Notificato n. 0476
Notified Body nr. 0476



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

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della pressione sanguigna / Blood pressure measuring devices

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 0104

Marca / Brandname:

BOSTON / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TECNICO PROFEXIONAL / DAYTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

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

Marca / Brandname:

SIRIO

Modello / Model:

Manometro Aneroido / Aneroid manometer

Codici / Codes:

32904

Marca / Brandname:

YTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

32720; 32703; 32693; 32701

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MDS 7010

Chief Operating Officer
Giampiero Belcredi

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

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della pressione sanguigna / Blood pressure measuring devices

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital Sphygmomanometers WRIST / ARM

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / Brandname:

DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

Tipologia / Medical Devices:

Dispositivi per la misurazione della saturazione di ossigeno / Oxygen saturation measuring devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Codici / Codes:

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

Kiwa Cermet Italia S.p.A.
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di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476



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

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della temperatura corporea / Body temperature measuring devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Marca / Brandname:

DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

Marca / Brandname:

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

Modello / Model:

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

Codici / Codes:

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

Marca / Brandname:

FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / Brandname:

PBpharma /GIMA

Modello / Model:

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

Codici / Codes:

25580 ; 25585

Chief Operating Officer

Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:13:57



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Kiwa Cermet Italia S.p.A.
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Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione di parametri fisiologici / Physiological parameters measuring devices

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 1301, MD 0104

Modello / Model:

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

Codici / Codes:

27335 ; 27344; 27331

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0101, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Codici / Codes:

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

Modello / Model:

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

Codici / Codes:

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

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Codici / Codes:

34424; 34425, 34426, 34427, 34428, 34429

Chief Operating Officer
Giampiero Belcredi

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit

Codici / Codes:

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

Modello / Model:

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

Codici / Codes:

34257; 34258; 34275; 34279

Modello / Model:

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

Codici / Codes:

34227 ; 34228 ; 34259 ; 34256

Tipologia / Medical Devices:

Dispositivi per terapia termica / Thermic therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack

Codici / Codes:

34110 ; 34111



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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Kit di strumentario chirurgico monouso sterile / Sterile single use surgical instrument kit

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Modello / Model:

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

Codici / Codes:

38950 ; 38951

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Modello / Model:

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

Codici / Codes:

388xx

Modello / Model:

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

Codici / Codes:

388xx

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Chief Operating Officer
Giampiero Belcredi

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Data: 25/05/2021 10:15:40



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE



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

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Modello / Model:

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

Codici / Codes:

388xx ; 389xx

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

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:16:08



Organismo Notificato n. 0476
Notified Body nr. 0476





CERTIFICATO N.
CERTIFICATE No.

ICIM-13485-050862-00

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

GIMA S.P.A.

SEDE CENTRALE / HEADQUARTER

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO
FOR OPERATIVE UNITS SEE ATTACHMENT

È CONFORME ALLA NORMA

UNI CEI EN ISO 13485:2021

IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Gestione della progettazione e della produzione, confezionamento ed assistenza di: Dispositivi medici generali non attivi e non impiantabili (eccetto: iniezione, infusione, trasfusione, dialisi; disinfezione, pulizia, risciacquo; IVF e ART; ingestione), Dispositivi per la cura delle ferite, Dispositivi dentali non attivi ed accessori (eccetto impianti dentali), Dispositivi medici generali attivi (eccetto: circolazione extracorporea, infusione, emaferesi; stimolazione o inibizione; riabilitazione e protesi attive; IVF e ART; software; sistemi di gas medicali e relative parti); Dispositivi di monitoraggio; Dispositivi per immagini e termoterapia (eccetto: radiazioni ionizzanti, litotripsia); Diagnostici in Vitro (IVD). Commercializzazione e assistenza di: Dispositivi medici generali non attivi e non impiantabili (eccetto: IVF e ART; ingestione), Dispositivi per la cura delle ferite, Dispositivi dentali non attivi e accessori (eccetto impianti dentali), Dispositivi medici generali attivi (eccetto: IVF e ART), Dispositivi per acquisizione immagini (eccetto: radiazioni ionizzanti), Dispositivi di monitoraggio, Dispositivi per radioterapia e termoterapia (eccetto: radiazioni ionizzanti, litotripsia), Diagnostici in vitro (IVD).

Management of the design and production, packaging and assistance of: Non-active and non-implantable general medical devices (except: injection, infusion, transfusion, dialysis; disinfection, cleaning, rinsing; IVF and ART; ingestion), Wound care devices, Non-active dental devices and accessories (except dental implants), Active general medical devices (except: extracorporeal circulation, infusion, hemapheresis; stimulation or inhibition; active rehabilitation and prosthetics; IVF and ART; software; medical gas systems and parts thereof); Monitoring devices; Imaging and thermotherapy devices (except: ionizing radiation, lithotripsy); In Vitro Diagnostics (IVD). Marketing and support of: Non-active and non-implantable general medical devices (except: IVF and ART; ingestion), Wound care devices, Non-active dental devices and accessories (except dental implants), Active general medical devices (except: IVF and ART), Imaging devices (except: ionizing radiation), Monitoring devices, Radiotherapy and thermotherapy devices (except: ionizing radiation, lithotripsy), In vitro diagnostics (IVD).

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE
FIRST ISSUE
15/10/2012

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17/06/2024

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14/10/2024


Vincenzo Delacqua
Rappresentante Direzione / Management Representative

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



MS N° 0004



www.cisq.com

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



CISQ is a member of



The International Certification Network
www.iqnet-certification.com

Allegato al CERTIFICATO N.
Attachment to CERTIFICATE No.

ICIM-13485-050862-00

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

GIMA S.P.A.

Comprende oltre la Sede Centrale citata sul Certificato, anche le seguenti Unità Operative:
In addition to the Headquarter mentioned on the Certificate, it also includes the following Operative Units:

VIA MARCONI, 1 20060
GESSATE MI IT - Italia

Management of the design and production, packaging and assistance of: Non-active and non-implantable general medical devices (except: injection, infusion, transfusion, dialysis; disinfection, cleaning, rinsing; IVF and ART; ingestion), Wound care devices, Non-active dental devices and accessories (except dental implants), Active general medical devices (except: extracorporeal circulation, infusion, hemapheresis; stimulation or inhibition; active rehabilitation and prosthetics; IVF and ART; software; medical gas systems and parts thereof); Monitoring devices; Imaging and thermotherapy devices (except: ionizing radiation, lithotripsy); In Vitro Diagnostics (IVD). Marketing and support of: Non-active and non-implantable general medical devices (except: IVF and ART; ingestion), Wound care devices, Non-active dental devices and accessories (except dental implants), Active general medical devices (except: IVF and ART), Imaging devices (except: ionizing radiation), Monitoring devices, Radiotherapy and thermotherapy devices (except: ionizing radiation, lithotripsy), In vitro devices (IDV).

VIA TOMMASO GROSSI, 2
20121 MILANO MI IT - Italia

Sede Legale.



MS N° 0004



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CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale. CISQ
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Certification Bodies.

Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

For Operative Units see Annex/Annexes

has implemented and maintains a/an

Quality Management System

for the following scope:

Management of the design and production, packaging and assistance of: Non-active and non-implantable general medical devices (except: injection, infusion, transfusion, dialysis; disinfection, cleaning, rinsing; IVF and ART; ingestion), Wound care devices, Non-active dental devices and accessories (except dental implants), Active general medical devices (except: extracorporeal circulation, infusion, hemapheresis; stimulation or inhibition; active rehabilitation and prosthetics; IVF and ART; software; medical gas systems and parts thereof); Monitoring devices; Imaging and thermotherapy devices (except: ionizing radiation, lithotripsy); In Vitro Diagnostics (IVD). Marketing and support of: Non-active and non-implantable general medical devices (except: IVF and ART; ingestion), Wound care devices, Non-active dental devices and accessories (except dental implants), Active general medical devices (except: IVF and ART), Imaging devices (except: ionizing radiation), Monitoring devices, Radiotherapy and thermotherapy devices (except: ionizing radiation, lithotripsy), In vitro diagnostics (IVD).

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2024-06-17**

First issued on: **2012-10-15**

Expires on: **2024-10-14**

Registration Number:

IT-149833 ICIM-13485-050862-00



Alex Stoichitoiu
President of IQNET



Mario Romersi
President of CISQ



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

IQNET Members*:

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Annex 1 to IQNET Certificate Number:
IT-149833 ICIM-13485-050862-00

GIMA S.P.A.

VIA MARCONI, 1 20060 GESSATE MI IT - Italia

List of additional locations:

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