PRODUCT CATALOGUE

ELECTROSURGERY

PENCILS
ELECTRODES
GROUNDING PADS
ELECTROCAUTERIES
NERVE LOCATOR

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Date: 2026.07.30 17:26:14 EEST
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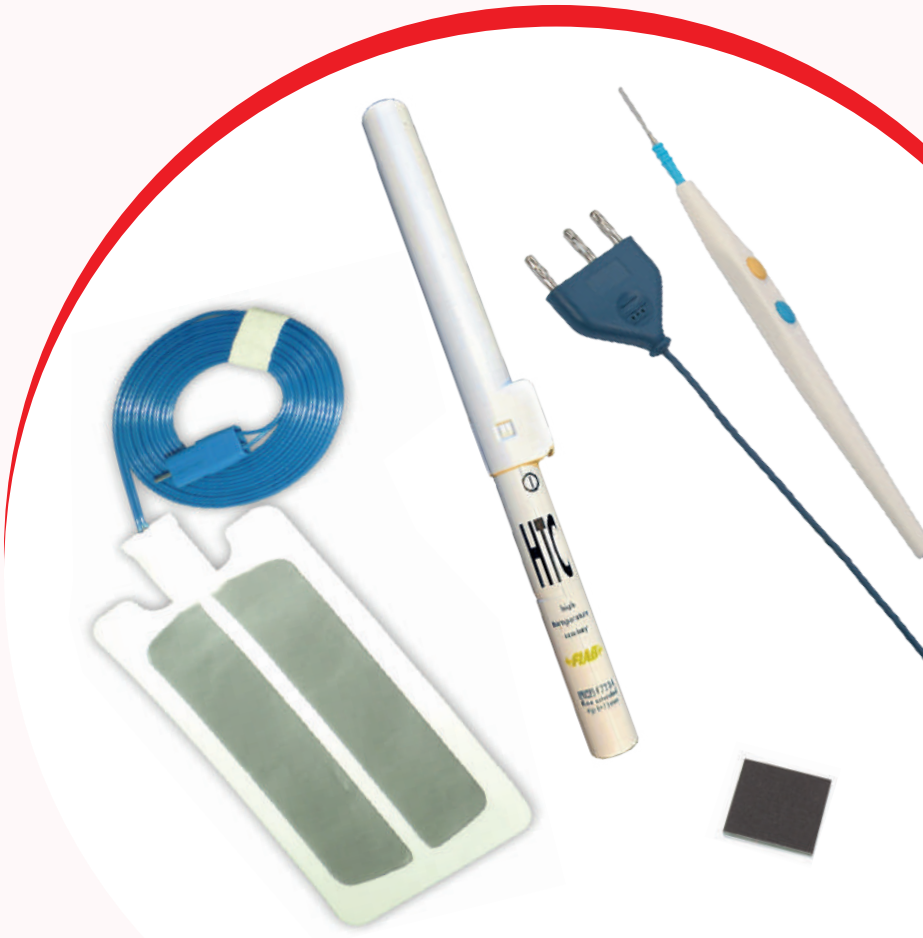
Location: Moldova
MOLDOVA EUROPEANĂ



PENCILS

Our comprehensive range of disposable and reusable electrosurgical pencils is designed to meet the diverse needs and preferences of surgeons. Available in push-button, rocker switch, and foot-controlled models, each pencil can be paired with a choice of stainless steel or anti sticking teflon coated electrodes to suit various surgical applications.

SINGLE USE PENCILS

F4797 FIAB SERIES

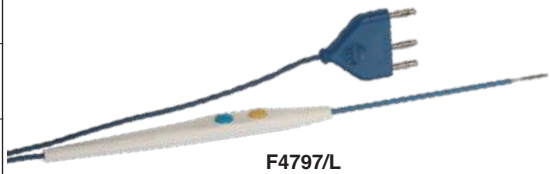
F4799 FIAB PVC FREE SERIES

NEW

ESSENTIAL SAFETY FEATURES:

- Hexagonal hub design compatible with standard 2,38" electrodes, ensuring secure fit and preventing accidental rotation during procedures
- Sealed activation controls offer reliable protection against fluid penetration
- Responsive touch sensation, designed to deliver an enhanced feel during activation supporting controlled and intuitive use
- Ergonomic, non-slip grip enhances surgical precision and helps prevent unintentional activation

BUTTON SWITCH PENCILS WITH INTERNATIONAL STANDARD CONNECTOR (VALLEYLAB TYPE)

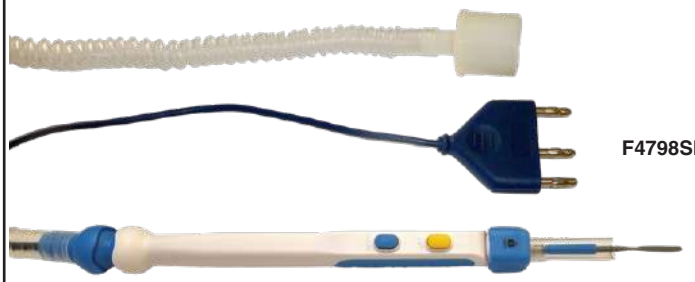
Electrode Type	320 cm cable	500 cm cable	picture
BLADE	**F4797** **F4799** (with F4046)	**F4797/5** **F4799/5** (with F4046)	 F4797/L
	F4797TEF **F4799TEF** (with F4046/TEF)	**F4797/5TEF** **F4799/5TEF** (with F4046/TEF)	
	F4797/L **F4799/L** (with F4050)	**F4797/5L** **F4799/5L** (with F4050)	
	F4797T **F4799T** (with F4046T)		
SPHERE	**F4797/PL** **F4799/PL** (with F4067)		
	F4797/P **F4799/P** (with F4044)		
NEEDLE	**F4797/AL** **F4799/AL** (with F4052)		 F4797TEF
	F4797/A **F4799/A** (with F4048)	**F4797/5A** **F4799/5A** (with F4048)	
NO ELECTRODE	**F4797/WB** **F4799/WB**	**F4797/5WB** **F4799/5WB**	

BUTTON SWITCH PENCILS WITH ERBE NON INTERNATIONAL CONNECTOR

Electrode Type	320 cm cable	500 cm cable	picture
BLADE	**F4797/ERB** **F4799/ERB** (with F4046)	**F4797/5ERB** **F4799/5ERB** (with F4046)	 F4797/ERB
SPHERE	**F4797/P/ERB** **F4799/P/ERB** (with F4044)	**F4797/5P/ERB** **F4799/5P/ERB** (with F4044)	
NEEDLE	**F4797/A/ERB** **F4799/A/ERB** (with F4048)		

SMOKE EVACUATOR PENCILS
WITH INTERNATIONAL STANDARD CONNECTOR (VALLEYLAB TYPE)

FIAB SMOKE EVACUATOR PENCIL WITH TEFLON-COATED TELESCOPIC TIP F4798SE/TEF



F4798SE/TEF

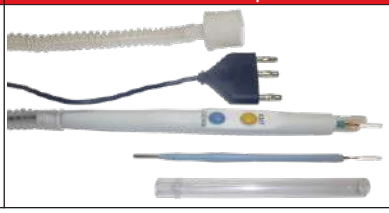
ESSENTIAL FEATURES:

- Suction cannula with the electrode is telescopic and is equipped with a ring mechanism that assures its locking

- A 360 degree swivel allows for fluid hand movement and free range of motion

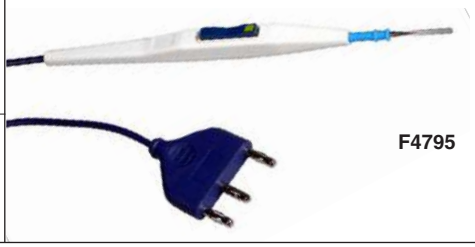
- Teflon coating makes the electrode "antisticking" so that the cleaning during the procedure results easier

Electrode Type	320 cm cable	500 cm cable
TELESCOPIC TEFLON COATED BLADE	F4798SE/TEF	F4798SE/5TEF

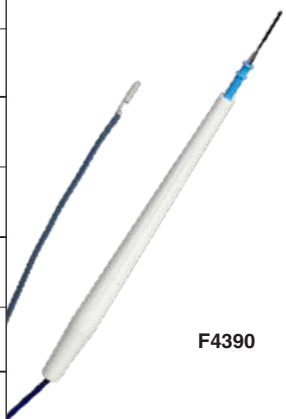
Electrode Type	320 cm cable	500 cm cable	picture
BLADE F4046 AND F4050 (NON TELESCOPIC)	F4797SE	F4797/5SE	 F4797SE

ALTERNATIVE DISPOSABLE PENCILS SOLUTIONS

ROCKER SWITCH PENCILS WITH INTERNATIONAL CONNECTOR (VALLEYLAB TYPE)

Electrode Type	320 cm cable	500 cm cable	picture
BLADE	**F4795** (with F4046)	**F4795/5** (with F4046)	 F4795
	F4795TEF (with F4046/TEF)		

FOOT SWITCH PENCILS

Electrode Type	320 cm cable	500 cm cable	320 cm cable	picture
BLADE	**F4390** (with F4046)	**F4390/5** (with F4046)	**F4390/AM** (with F4046)	 F4390
	F4390/L (with F4050)			
SPHERE	**F4390/P** (with F4044)			
	F4390/PL (with F4067)			
NEEDLE	**F4390/A** (with F4048)			
	F4390/AL (with F4052)			
NO ELECTRODE	**F4390/WB**	**F4390/5WB**		
CONNECTION	3,2MM PLUG		4MM PLUG	

REUSABLE PENCILS

CE 2797

BUTTON SWITCH PENCILS WITH INTERNATIONAL STANDARD CONNECTOR (VALLEYLAB TYPE)

Electrode and Shaft	300 cm cable	320 cm cable	500 cm cable	n° sterilization	picture
BLADE F4060 2.38mm SHAFT		F4141	F4151	30	 F4141
	F4242	F4243	F4252	100	
BLADE F4060/4 4mm SHAFT	F4246		F4256	100	

BUTTON SWITCH PENCILS WITH ERBE NON INTERNATIONAL CONNECTOR

Electrode Type	320 cm cable	n° sterilization	picture
BLADE F4060 2.38mm SHAFT	F4141/ERB	30	 F4141/ERB

FOOT SWITCH PENCILS WITH 4MM PLUG CONNECTOR

Electrode Type	320 cm cable	n° sterilization	picture
BLADE F4060 2.38mm SHAFT	F4812	100	 F4812

REUSABLE ADAPTERS

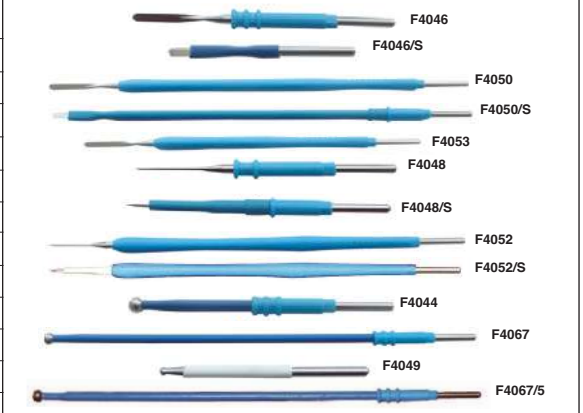
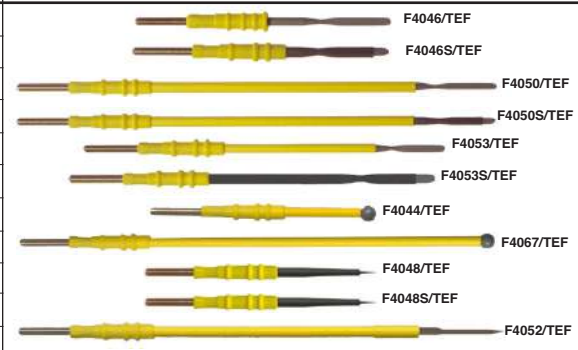
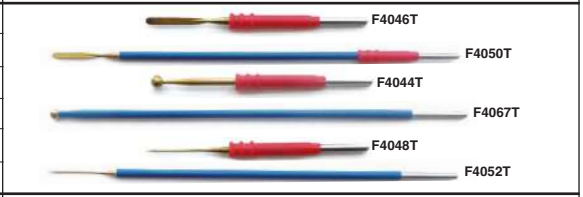
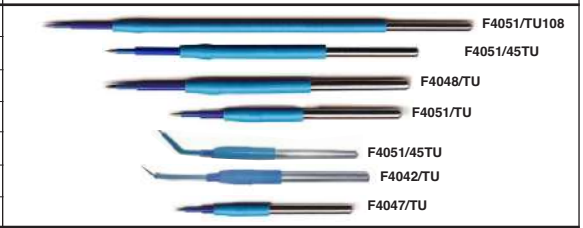
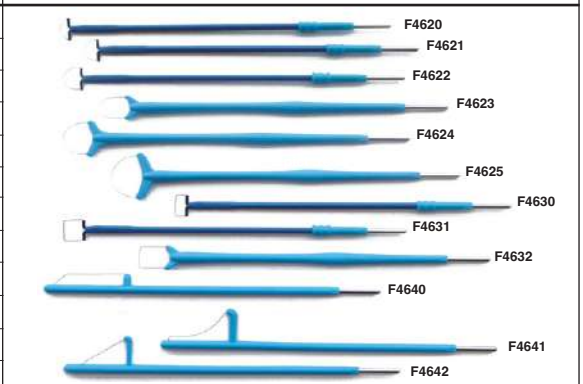
CE

Electrode And Shaft	Ref	Pencil Connector	Esu Connector	Compatibility	picture
REUSABLE ADAPTERS FOR HAND SWITCH PENCILS	F4831	Valleylab	protected 4mm plug	Berchtold, Martin	 F4831 F4832 F4833
	F4832	Valleylab	5mm plug	Erbe ACC/ICC	
	F4833	Valleylab	4mm plug	Erbe T series	
REUSABLE ADAPTERS FOR FOOT SWITCH PENCILS	F4830	4mm plug	8mm plug	Bovie, Soxil, Bard,Valleylab, Burdick	 F4830 F4834 F4835 F4836 F4837 F4838
	F4834	4mm plug	6mm plug	Alsatom	
	F4835	3,2mm plug	8mm plug	Bovie, Soxil, Bard, Danieli, Ag e Cvs, Neomed, Valleylab, Burdick, Ems	
	F4836	3,2mm plug	4mm plug	Martin, Siemens, Erbe, Alsa, Laser	
	F4837	3,2mm plug	4mm plug	Martin, Blendtorne, Emc,Acmicron, Erbe, Cobi	
	F4838	3,2mm plug	8mm plug	Alsatom, EBSS4/MMSB	

ELECTRODES

A very wide range of disposable and reusable electrodes allows to match every customer need. Stainless steel electrodes can be supplied also with teflon or titanium antisticking coating; tungsten electrodes are available both with ultrasharp needle for microdissection as well as in different loop sizes and shapes.

DISPOSABLE ELECTRODES

Material	Shape	Ref.	Length	Picture
STAINLESS STEEL	BLADE	F4046	70mm	
		F4046/S	50mm (44mm insulation)	
		F4050	153mm	
		F4050/S	153mm (147mm insulation)	
		F4053	100mm	
	NEEDLE	F4048	70mm	
		F4048/S	69mm (63mm insulation)	
		F4052	152mm	
		F4052/S	152mm (146mm insulation)	
	4MM SPHERE	F4044	70mm	
		F4067	156mm	
	2MM SPHERE	F4049	54mm	
	LONG SPHERE 5MM	F4067/5	157mm	
STAINLESS STEEL WITH TEFLON COATING	BLADE	F4046/TEF	70mm	
		F4046S/TEF	70mm (65mm insulation)	
		F4050/TEF	150mm	
		F4050S/TEF	150mm (145mm insulation)	
		F4053/TEF	100mm	
		F4053S/TEF	100mm (95mm insulation)	
	SPHERE 4MM	F4044/TEF	70mm	
		F4067/TEF	150mm	
	NEEDLE	F4048/TEF	70mm	
		F4048S/TEF	70mm (65mm insulation)	
		F4052/TEF	150mm	
STAINLESS STEEL WITH TITANIUM COATING	BLADE	F4046T	70mm	
		F4050T	153mm	
	SPHERE 4MM	F4044T	70mm	
		F4067T	156mm	
	NEEDLE	F4048T	70mm	
		F4052T	152mm	
TUNGSTEN	ULTRASHARP MICRODISSECTION NEEDLE	F4051/TU108	108mm (104mm insulation)	
		F4051/45TU	55mm (51mm insulation)	
		F4048/TU	65mm (61mm insulation)	
		F4051/TU	55mm (51mm insulation)	
		F4051/45TU	55mm (51mm insulation)	
		F4042/TU	55mm (51mm insulation)	
		F4047/TU	45mm (41mm insulation)	
LOOP TUNGSTEN	ROUND	F4620	10x3mm	
		F4621	10x5mm	
		F4622	10x7mm	
		F4623	10x10mm	
		F4624	15x10mm	
		F4625	20x10mm	
	SQUARE	F4630	10x4mm	
		F4631	10x8mm	
		F4632	10x10mm	
	TRAPEZOIDAL	F4640	30x5mm	
	REVERSED CURVED	F4641	23x13mm	
	TRIANGULAR	F4642	17x12mm	
EXTENSIONS		F4902	102mm	
		F4903	150mm	
		F4904	182mm	

ELECTRODES

REUSABLE ELECTRODES

Shape	Ref.	Length	Picture	Shaft
BLADE	F4053R	100mm		2,38mm SHAFT
	F4060	69mm		
	F4065	153mm		
CURVED BLADE	F4062	150mm		
SPHERE 2,5MM	F4064	150mm		
SPHERE 4MM	F4068	70mm		
	F4045	156mm		
SPHERE 4MM 10°	F4045/10	156mm		
SPHERE 4MM 20°	F4045/20	156mm		
SPHERE 4MM 30°	F4045/30	156mm		
SPHERE 4MM 40°	F4045/40	156mm		
0,75MM NEEDLE	F4084	69mm		
0,78MM NEEDLE	F4063	152mm		
1,30MM NEEDLE	F4066	152mm		
	F4086	69mm		
ROUND NEEDLE 20°	F4061	100mm		
BLADE	F4064/4	55mm (51mm sleeve)		4mm SHAFT
	F4065/4	160mm		
SPHERE 4MM	F4068/4	50mm		
NEEDLE 0,8MM	F4084/4	55mm		
EXTENSIONS	F4952	102mm		
	F4953	150mm		
	F4954	182mm		

ACCESSORIES AND KITS

F4545 STERILE HOLSTER FOR PENCILS	F4798/75H COMPLETE KIT	F7520 STERILE TIP CLEANER 50X50MM RADIOPAQUE ADHESIVE BACKING
		
KIT PENCIL + HOLSTER	**KIT PENCIL + HOLSTER + TIP CLEANER**	**PENCIL + TIP CLEANER**
F4798/H (with F4797)	**F4798/75H** (with F4797)	**F4797/75** (with F4797)
F4798/5H (with F4797/5)	**F4798/5-75H** (with F4797/5)	**F4797/5-75** (with F4797/5)
F4798/HTEF (with F4797TEF)	**F4797T/75H** (with F4797T)	**F4390/75** (with F4390)
F4798/5HTEF (with F4797/5TEF)	**F4798/5ERB-75H** (with F4797/5ERB)	**F4390/5-75** (with F4390/5)
F4390/H (with F4390)	**F4390/75H** (with F4390)	
F4390/5H (with F4390/5)	**F4390/5-75H** (with F4390/5)	

Non-Sterile versions for Procedural Packs For clarity and ease of consultation, only sterile electrosurgical items are listed in this catalog.
Non-sterile versions for procedural packs are available. To identify the non-sterile REF, simply replace the initial “F” with “FCB”. Example: Sterile F4797 / Non-sterile FCB4797.

GROUNDING PADS

Grounding pads are available adult, paediatric and neonatal. Disposable models have tab or cable connection. Reusable grounding pads, connection cables and adapters complete the range.

DISPOSABLE GROUNDING PADS

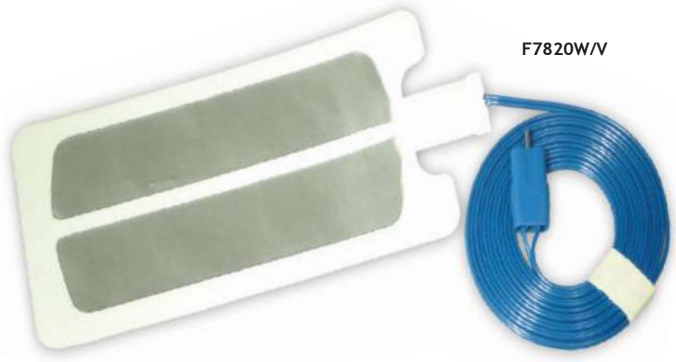
ADULT

WITH REM FEATURE

ref.	*dimensions*	*baking*	*active surface*	*REM*	*cable*	*connection*
F7820	202X101mm	FOAM	118cm²	YES	NO	Tab Connection
F7820W/V	202X101mm	FOAM	118cm²	YES	300cm	Valleylab connector
F7820W/6.3	202X101mm	FOAM	118cm²	YES	300cm	Ø6.3mm bipolar connector

F7820

F7820W/V



ONLY FOR "HIGH CURRENT MODE" PROCEDURES

ref.	length	*shape*	*active surface*	*REM*	*cable*	*connection*
F7805	202 x 105 mm	FOAM	132cm²	NO	NO	Tab Connection
F7805 W/V	202 x 105 mm	FOAM	132cm²	NO	300cm	Valleylab connector
F7805W/6.3	202 x 105 mm	FOAM	132cm²	NO	300cm	Ø6.3mm Bipolar connector
F7805W/6.3-5	202 x 105 mm	FOAM	132cm²	NO	500cm	Ø6.3mm Bipolar connector

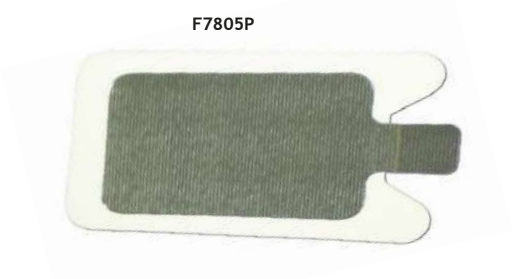
F7805

PAEDIATRIC

ref.	length	*shape*	*active surface*	*REM*	*cable*	*connection*
F7805P	148x90mm	FOAM	78cm²	NO	NO	Tab Connection
F7805PW/V	148x90mm	FOAM	78cm²	NO	300cm	Valleylab connector
F7820P	148x90mm	FOAM	72cm²	YES	NO	Tab Connection
F7820PW/V	148x90mm	FOAM	72cm²	YES	300cm	Valleylab connector

F7820P

F7805P



NEONATAL

ref.	dimensions	baking	active surface	REM	cable	connection
F7805N	88x74mm	FOAM	36cm²	NO	NO	Tab Connection
F7820N	88x74mm	FOAM	33cm²	YES	NO	Tab Connection
F7820NW/V	88x74mm	FOAM	33cm²	YES	300cm	Valleylab connector

CE 2797

F7805N

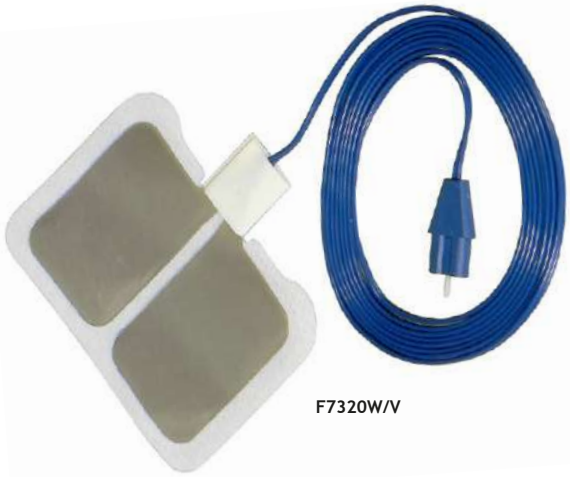
F7820N

F7820NW/V

VERSATILE

ref.	dimensions	baking	active surface	REM	cable	connection
F7320	164x117mm	FOAM	107cm²	YES	NO	Tab Connection
F7320W/V	150x108mm	NON WOVEN	107cm²	YES	300cm	Valleylab connector

CE 2797



F7320W/V

F7320

CONNECTION CABLES FOR DISPOSABLE GROUNDING PADS

ref.	connector	length	picture
F7902	Universal 6.3mm mono Jack	500cm	CE
F7902/4	4mm plug	500cm	
F7902/24	Double 4mm plug	500cm	
F7903	Valleylab type (ESU with REM)	500cm	
F7903/F	Valleylab type (ESU without REM)	500cm	
F7904	Special 6.3mm mono jack for ERBE: ACC, ICC, VIO, T	500cm	

F7902

REUSABLE ADAPTERS FOR DISPOSABLE GROUNDING PADS

ref.	connector	picture
F4828	from Vallylab to 4mm plug	CE
F4829	from Valleylab to 6.3mm plug	

F4828

F4829

REUSABLE GROUNDING PADS

GROUNDING PADS

ref.	dimensions	baking	active surface	REM	cable	connection
F7930	200x150mm	Silicone	250cm²	YES	NO	4 mm Socket

CE 2797

F7930

CONNECTION CABLES FOR REUSABLE GROUNDING PADS

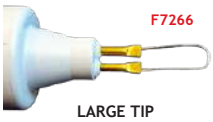
ref.	connector	cable length	picture
F7922	 Universal 6,3 mm MONO JACK	500cm	CE  F7922
F7922/WB	 Universal 6.3mm MONO JACK without derivation box	500cm	
F7922/24	 DOUBLE 4 MM PLUG	500cm	
F7923	 VALLEYLAB TYPE (ESU WITH REM)	500cm	
F7924	 6,3 mm MONO JACK (ESU WITHOUT REM)	500cm	

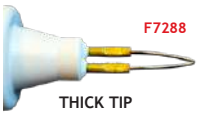
ELECTROCAUTERIES

FIAB cauteries are sterile battery-powered devices designed for the effective cauterization of small blood vessels. Lightweight and easy to handle, they ensure precision during use. They are available in a wide range of models, that can differ in operating temperature (1200°C, 700°C), as well as in tip shape, thickness, and length, allowing clinicians to select the most suitable option for each specific procedure.

DISPOSABLE MODELS

TIPS


F7266
LARGE TIP


F7288
THICK TIP


F7234, F7277,
F7244, F7255
FINE TIP


F7255UF
ULTRA FINE TIP

Breaking Point Detail

Pre-cut shaft allows the extraction of the batteries and their separate disposal

REF	F7234	F7277	F7244	F7266	F7288	F7255	F7255UF
LENGTH (cm)	23,5	29	18	18	18	12,5	12,5
TIP SHAPE	FINE	FINE	FINE	LARGE	THICK	FINE	ULTRA FINE
TEMPERATURE (°C)	800 / 1200						600 / 1100
ACTIVE PRESSURE (GR)	200					200	
POWER SUPPLY (V)	3,0					1,5	
DIAMETER (MM)	16					16	
WEIGHT (GR)	78	70	65	65	65	45	45
SERIES	HIGH TEMPERATURE CAUTERIES					LOW TEMPERATURE CAUTERIES	

MDR 2017/745 approved

REUSABLE MODELS

PRODUCT TYPE	REUSABLE CAUTERY	DISPOSABLE TIP	DISPOSABLE TIP	DISPOSABLE TIP	REUSABLE CAUTERY	DISPOSABLE TIP
REF	F7299	F7298F	F7298L	F7298FG	F7297	F7298F
LENGTH (cm)	12	318	3	12	16,5	3
TIP SHAPE	--	LARGE	THICK	FINE	--	FINE
TEMPERATURE (°C)	800 / 1200				600 / 1100	
ACTIVE PRESSURE (GR)	200				200	
POWER SUPPLY (V)	3,0				1,5	
DIAMETER (MM)	16				16	
WEIGHT (GR)	78	70	65	65	65	45
	HIGH TEMPERATURE CAUTERIES				LOW TEMPERATURE CAUTERIES	

NERVE LOCATOR

NEUROPACER is a sterile battery operated disposable device. It has been developed for identification of exposed motor nerves during microsurgery operations, in order to protect them by any damage. Neuropacer is particularly intended for plastic surgery and surgery of head, neck and hands. The device is supplied complete with an active electrode and a subcutaneous reference needle. A safety system allows the device to be switched on just immediately before use. An alternating and pulsating current guarantees a safe and effective stimulation.

F1745 NEUROPACER

Disposable, sterile, battery operating nerve locator complete with active electrode and grounding needle

FIAB SpA
Via Costoli, 4 - I-50039 Vicchio (Florence) - Italy
Tel. +39 0558497999
export@fiab.it - www.fiab.it

ISO 13485 Quality Management Systems CERTIFIED
MD 77846

52501287BR4C

SERIE F783x / F783x SERIES

CAVO SOGLIA PER STIMOLAZIONE CARDIACA, STERILE MONOUSO

THRESHOLD CABLE FOR CARDIAC STIMULATION, STERILE DISPOSABLE

F7830S

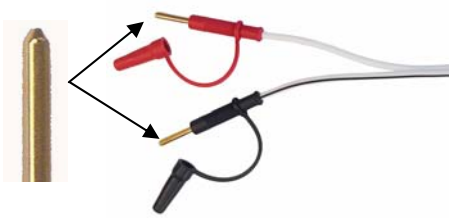
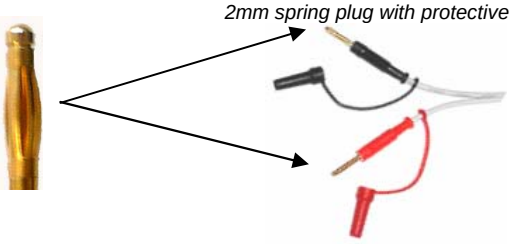
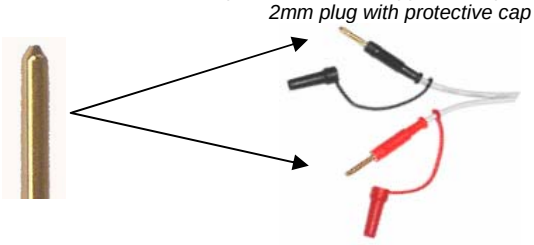
Cavo soglia destinato al sensing dell'attività atriale o alla stimolazione del cuore con impulsi elettrici quando è connesso ad un analizzatore di soglia (PSA) da una estremità e all'elettrocatetere cardiaco dall'altra.
I prodotti vengono forniti sterili per un immediato e sicuro utilizzo. Grazie alla lunghezza del cavo l'analizzatore di soglia può essere collocato lontano dal campo sterile. I prodotti sono senza lattice.

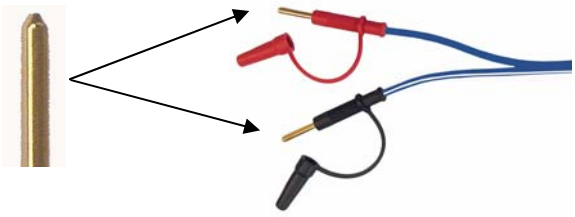
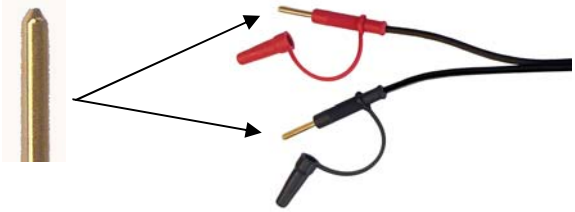
Threshold cable intended to sense the heart activity or pace the heart with electrical impulses when connected to a threshold analyzer (PSA) on one side and to cardiac lead on the other side.
The cables are supplied in sterile packaging for a safe and immediate use. The cable length allows to place the threshold analyser far from the sterile field. The products are Latex free.

CARATTERISTICHE TECNICHE – *TECHNICAL FEATURES*	
DESCRIZIONE ***DESCRIPTION***	Cavo soglia, sterile monouso, per sensing attività atriale o stimolazione cardiaca *Threshold cable, sterile disposable, intended to sense the cardiac activity or pacing*
MATERILE CONDUTTORE ***CONDUCTOR MATERIAL***	Rame *Copper*
MATERIALE ISOLANTE ***INSULATION MATERIAL***	Vedi lista REF *See REF list*
LUNGHEZZA CAVO ***CABLE LENGTH***	200 (*) cm
ATTACCO ALL'ELETTROCATETERE ***CONNECTION TO LEADS***	Coccodrillo isolato rosso e nero *Red and black insulated alligator*
STERILIZZAZIONE ***STERILISATION***	Ossido di Etilene *EO gas*
CONFORMITÀ ALLA NORMATIVA ***COMPLIANCE TO STANDARDS***	Regolamento (UE) 2017/745. Dispositivo medico in classe I sterile *Regulation (EU) 2017/745. Class I Sterile medical device*

CONFEZIONAMENTO – PACKAGING	
CONFEZIONE PRIMARIA ***PRIMARY PACKAGING***	Singolo in doppia busta: interna PE + esterna carta PE termosaldata *Singly in double bag, internal PE + external paper - PE heat-sealed*
CONFEZIONE DI VENDITA ***SALE PACKAGING***	10 confezioni primarie in scatola di cartone *10 primary packages in carton box*
IMMAGAZZINAMENTO ***STORAGE***	Temperatura: 0°C ÷ +50°C – Umidità relativa: 20% ÷ 80% *Temperature: 0°C ÷ +50°C – Relative humidity: 20% ÷ 80%*
SCADENZA ***EXPIRY***	4 anni dalla data di produzione riportata sulla confezione *4 years from production date printed on packaging*

REF	LATO STIMOLATORE *PACEMAKER SIDE*	LATO PAZIENTE *PATIENT SIDE*
F7830S **COLORE / *COLOUR*** **GRIGIO / *GREY***	2 spinotti 2mm maschio tipo “touch proof” (E-DIN 428802-2) ROSSO/NERO *2 “Touch proof” (E-DIN 428802-2) 2mm plug - RED/BLACK*  ISOLANTE / *INSULATION*: PVC	
F7830SL **COLORE / *COLOUR*** **GRIGIO / *GREY***	2 spinotti 2mm maschio tipo “touch proof” (E-DIN 428802-2) ROSSO/NERO *2 “Touch proof” (E-DIN 428802-2)* *2mm plug - RED/BLACK*  ISOLANTE / *INSULATION*: PVC *Con etichetta “monouso”* *With “disposable” label* 	
F7830DIN **COLORE / *COLOUR*** **GRIGIO / *GREY***	DIN 1.5mm rosso e nero *DIN 1.5mm red and black*  *ISOLANTE / INSULATION: Poliuretano / Polyurethane*	
F7830/MED **COLORE / *COLOUR*** **GRIGIO / *GREY***	Connettore tipo Medtronic / Medtronic type connector  *ISOLANTE / INSULATION: PVC*	
F7831S **COLORE / *COLOUR*** **BLU / *BLUE***	2 spinotti 2mm maschio tipo “touch proof” (E-DIN 428802-2) ROSSO/NERO *2 “Touch proof” (E-DIN 428802-2) 2mm plug - RED/BLACK*  *ISOLANTE / INSULATION:* PVC	
F7832S **COLORE / *COLOUR*** **GRIGIO / *GREY*** (*) **Lunghezza 400cm** ***Length 400cm***	2 spinotti 2mm maschio tipo “touch proof” (E-DIN 428802-2) ROSSO/NERO *2 “Touch proof” (E-DIN 428802-2) 2mm plug - RED/BLACK*  *ISOLANTE / INSULATION: Poliuretano / Polyurethane*	

F7832/MED **COLORE / *COLOUR*** **GRIGIO / *GREY*** (*) **Lunghezza 400cm** ***Length 400cm***	Connettore tipo Medtronic / Medtronic type connector  *ISOLANTE / INSULATION: PVC*	
F7833 **COLORE / *COLOUR*** **GRIGIO / *GREY***	Spinotti 2mm con cappuccio di protezione *2mm plug with protective cap*  *ISOLANTE / INSULATION:* PVC	
F7833L **COLORE / *COLOUR*** **GRIGIO / *GREY***	Spinotti 2mm con cappuccio di protezione *2mm plug with protective cap*  *ISOLANTE / INSULATION:* PVC *Con etichetta "monouso"* *With "disposable" label* 	
F7833E **COLORE / *COLOUR*** **GRIGIO / *GREY***	*Spinotti 2mm elastici con cappuccio di protezione* *2mm spring plug with protective cap*  *ISOLANTE / INSULATION: Poliuretano / Polyurethane*	
F7833/4 **COLORE / *COLOUR*** **GRIGIO / *GREY*** (*) **Lunghezza 400cm** ***Length 400cm***	Spinotti 2mm con cappuccio di protezione *2mm plug with protective cap*  *ISOLANTE / INSULATION: Poliuretano / Polyurethane*	

F7834 **COLORE / *COLOUR*** **BLU / *BLUE***	Spinotti 2mm con cappuccio di protezione *2mm plug with protective cap*  *ISOLANTE / INSULATION:* PVC	
F7837S **COLORE / *COLOUR*** **NERO / *BLACK***	2 spinotti 2mm maschio tipo “touch proof” (E-DIN 428802-2) ROSSO/NERO *2 “Touch proof” (E-DIN 428802-2) 2mm plug - RED/BLACK*  ISOLANTE / *INSULATION*: PVC	
F7838 **COLORE / *COLOUR*** **NERO / *BLACK***	Spinotti 2mm con cappuccio di protezione *2mm plug with protective cap*  ISOLANTE / *INSULATION*: PVC	

FIAB SpA
Via P. Costoli 4,
Vicchio
Firenze
50039
Italy
06 June 2023

Notified Body Confirmation Letter

Reference: EU2023-607/634403

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

FIAB SpA
Via P. Costoli 4,
Vicchio
Firenze
50039
Italy
SRN Number: IT-MF-000005988

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 BSI Group The Netherlands B.V.,

Giorgia Romeo

Digitally signed by Giorgia Romeo
Date: 2023.06.06 17:20:13 +02'00'

Giorgia Romeo

BSI Scheme Manager

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
Esophageal Leads Esophageal leads for transesophageal electrophisiology studies and cardioversion	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
External cardiac stimulator "Easypace" single chamber	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
External temporary pacemaker – dual chamber (model "1797")	Class III	N/A	CE01906, exp 10 May 2023, NB # 2797
Single chamber external temporary pacemaker "1748"	Class III	N/A	CE01906, exp 10 May 2023, NB # 2797
Sterile single use electrosurgical electrodes Sterile single use electrosurgical pencils Reusable extensions for electrosurgery Reusable electrodes for electrosurgery Sterile single use electrosurgical kits- Reusable electrosurgical pencils Non-sterile single-use electrosurgical pencils Non-sterile single-use electrosurgical electrodes Non-sterile single-use electrosurgical kits	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
Sterile single use tips for reusable cauteries Sterile single use electrocauteries Reusable electrocauteries	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
Sterile single use epicardial wires "Myopace" (mono and bipolar, quadripolar)	Class III	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 CE 649635 (Annex II.4) exp 26 May 2024, NB # 2797

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
Rostock Filter	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
Nerve stimulator "Neuropacer" single use, sterile	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
Needles for EMG and EEG, single use Needles for EMG and EEG, reusable	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
Esophageal temperature monitor Connection cable for esophageal temperature monitor and probe Esophageal temperature probe	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797 (MDR 747884 issued on 23 Jan, 2023, NB # 2797)
Single use electrosurgical neutral electrodes, single section Single use electrosurgical neutral electrodes, dual section Reusable electrosurgical neutral electrodes	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906, exp 10 May 2023, NB # 2797
Temporary cardiac pacing leads "Spike" – bipolar, tripolar, tetrapolar, multipolar	Class III	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 CE 649635 (Annex II.4) exp 26 May 2024, NB # 2797
Sterile lead introducer set peel-away Sterile hemostasis valve introducer kit	Class IIa	N/A	CE01906, exp 10 May 2023, NB # 2797
"Extra Safe" dilator sheaths	Class III	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 CE 720326 (Annex II.4) exp 26 May 2024, NB # 2797
External cardioversion defibrillation electrodes	Class IIb excluding Class IIb implantable non-WET	N/A	CE01906 (Annex II.3), exp 10 May 2023, NB # 2797 (MDR 747884 issued on 6 Apr, 2023, NB # 2797)

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/06/06	Initial issue

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Fiab SpA
Via P. Costoli, 4
Vicchio (FI)
50039
Italy

Holds Certificate Number: MD 77846

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, servicing and retail of the following medical devices and accessories:
- Electronic devices for electrophysiology and temporary cardiac stimulation.
- Catheters, leads, wires and accessories for electrophysiology and heart pacing (permanent and temporary, including esophageal leads).
- Accessories for electrocardiography, electrosurgery, oxygen therapy, electrotherapy, electroencephalography (EEG) and electromyography (EMG).
- Introducer kits for percutaneous use.
- Devices for the extraction of permanent intravenous and subcutaneous leads.

The stockholding and supply of medical devices, with lot traceability.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2004-02-25
Latest Revision Date: 2024-07-26

Effective Date: 2024-08-01
Expiry Date: 2027-07-31

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Certificate No: MD 77846

Location	Registered Activities
Fiab SpA Via P. Costoli, 4 Vicchio (FI) 50039 Italy	Manufacture of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes; non sterile ECG reusable electrodes, electrotherapy reusable accessories, packaging of oxygen therapy accessories. Warehousing and distribution of oxygen therapy accessories, ECG reusable electrodes, electrotherapy reusable accessories.
Fiab SpA Via Passerini 2,3,4,6 Vicchio (FI) 50039 Italy	Via Passerini 2-4-6 – MAIN SITE: Administrative, Design and Development of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes, temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths; non sterile ECG reusable electrodes, electrotherapy reusable accessories, oxygen therapy accessory, external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables, defibrillation electrodes, electrostimulation electrodes and ECG single use electrode. Manufacture of sterile temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths, non-sterile external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables. Final packaging, warehousing and distribution of percutaneous introducers sterile products, sterile temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths. Servicing activities of non-sterile external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor. Via Passerini 3: - LOGISTIC Warehousing and distribution of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes, temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths; non sterile ECG reusable electrodes, electrotherapy reusable accessories, oxygen therapy accessory, external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables, defibrillation electrodes, electrostimulation electrodes and ECG single use electrode.
Fiab SpA Via Della Resistenza, 18 Vicchio (FI) 50039 Italy	Manufacture of non sterile defibrillation electrodes, Storage of oxygen therapy accessories and electrosurgical neutral electrodes and raw material for defibrillation electrodes. Warehousing and distribution of non sterile defibrillation electrodes

Original Registration Date: 2004-02-25

Effective Date: 2024-08-01

Latest Revision Date: 2024-07-26

Expiry Date: 2027-07-31

Certificate No: MD 77846

Location	Registered Activities
Fiab SpA Via Costoli 6 Vicchio (FI) 50039 Italy	Storage of components and assemblies for oxygen therapy and electrosurgery.
Fiab SpA Via Barducci 13 Vicchio (FI) 50039 Italy	Storage of components and assemblies for oxygen therapy and electrosurgery.
Fiab SpA Via Giugni 8 Vicchio Firenze 50039 Italy	Design and Development of sterile electrosurgery accessories and electrocauteries, EMG needle electrodes, temporary pacing leads, esophageal leads, epicardial wires, percutaneous introducers, dilator sheaths; non sterile ECG reusable electrodes, electrotherapy reusable accessories, oxygen therapy accessory, external temporary pacemaker, esophageal cardiac stimulator, pacing-sensing analyser, esophageal temperature monitor, ECG patient cables and electrostimulation cables, defibrillation electrodes, electrostimulation electrodes and ECG single use electrode. Manufacture of non-sterile electrostimulation electrodes and ECG single use electrodes. Warehousing and distribution of non-sterile electrostimulation electrodes and ECG single use.

Original Registration Date: 2004-02-25

Effective Date: 2024-08-01

Latest Revision Date: 2024-07-26

Expiry Date: 2027-07-31

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Manufacturer: Fiab SpA

Address:
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

Single Registration Number: IT-MF-000005988

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-11-17**

Current Issue Date: **2024-10-09**

Starting Validity Date: **2024-10-09**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Esophageal temperature monitoring system, including sterile probes and connecting cables.	Intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms.
External cardioversion defibrillation electrode pads.	Disposable multifunction electrodes intended for: - Transthoracic external defibrillation. - Transthoracic synchronized cardioversion. - Transthoracic ECG Monitoring. - Temporary transthoracic cardiac pacing (non-invasive).
Single use surgical instruments and neutral electrodes for use in electrosurgery.	Single use, sterile and non-sterile, handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.
Reusable surgical instruments and neutral electrodes for use in electrosurgery.	Reusable handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.
Instruments for diathermocoagulation.	Reusable and sterile single-use handpieces and electrodes, intended for cauterisation of soft tissues and small blood vessels in surgical procedures.

First Issue Date: **2021-11-17**

Current Issue Date: **2024-10-09**

Starting Validity Date: **2024-10-09**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Accessories for oxygentherapy and aerosoltherapy.	Class IIa
Transesophageal arrhythmology devices.	Class IIa
Non implantable cardiac stimulators – hardware	Class Is
Cleaning pads and holsters for electrosurgery	Class Is
Accessory for percutaneous dilator sheaths	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issue Date: **2021-11-17**

Current Issue Date: **2024-10-09**

Starting Validity Date: **2024-10-09**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-17	3415341	Issued
2023-01-23	3792161	Amended – Removal of subcontractor pages. Supplemented – addition of device group "Esophageal temperature monitoring system, including sterile probes and connecting cables". Supplemented – addition of device category "Accessories for oxygentherapy and aerosoltherapy.".
2023-04-06	3872133	Supplemented – addition of device group "External cardioversion defibrillation electrode pads.".
Current	30076890	Amended – Editorial amendment, with no change in scope, to the wording of the intended use of device group "External cardioversion defibrillation electrode pads". Supplemented – Addition of device group "Single use surgical instruments and neutral electrodes for use in electrosurgery". Supplemented – Addition of device group "Reusable surgical instruments and neutral electrodes for use in electrosurgery". Supplemented – Addition of device category "Instruments for diathermocoagulation". Supplemented – Addition of device category "Transesophageal arrhythmology devices".

First Issue Date: **2021-11-17**

Current Issue Date: **2024-10-09**

Starting Validity Date: **2024-10-09**

Expiry Date: **2026-11-16**

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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Manufacturer: Fiab SpA

Address:
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

Single Registration Number: IT-MF-000005988

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-11-17**

Current Issue Date: **2025-08-20**

Starting Validity Date: **2025-08-20**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
External temporary cardiac stimulators dual chamber External temporary cardiac stimulators single chamber	See MDR 823996
MYOPACE® - epimyocardial pacing wires for temporary cardiac stimulation	See MDR 747885
Endocardial Leads for Temporary Pacing and Electrophysiological Studies	See MDR 823997

Class IIb	Intended purpose
Esophageal temperature monitoring system, including sterile probes and connecting cables.	Intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms.
External cardioversion defibrillation electrode pads.	Disposable multifunction electrodes intended for: - Transthoracic external defibrillation. - Transthoracic synchronized cardioversion. - Transthoracic ECG Monitoring. - Temporary transthoracic cardiac pacing (non-invasive).
Single use surgical instruments and neutral electrodes for use in electrosurgery.	Single use, sterile and non-sterile, handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.
Reusable surgical instruments and neutral electrodes for use in electrosurgery.	Reusable handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.

First Issue Date: **2021-11-17**

Current Issue Date: **2025-08-20**

Starting Validity Date: **2025-08-20**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Instruments for diathermocoagulation.	Reusable and sterile single-use handpieces and electrodes, intended for cauterisation of soft tissues and small blood vessels in surgical procedures.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Accessories for oxygentherapy and aerosoltherapy.	Class IIa
Transesophageal arrhythmology devices.	Class IIa
Cardiocirculatory introducers	Class IIa
Non implantable cardiac stimulators – hardware	Class Is
Cleaning pads and holsters for electrosurgery	Class Is
Accessory for percutaneous dilator sheaths	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

First Issue Date: **2021-11-17**

Current Issue Date: **2025-08-20**

Starting Validity Date: **2025-08-20**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-17	3415341	Issued
2023-01-23	3792161	Amended – Removal of subcontractor pages. Supplemented – addition of device group "Esophageal temperature monitoring system, including sterile probes and connecting cables". Supplemented – addition of device category "Accessories for oxygentherapy and aerosoltherapy.".
2023-04-06	3872133	Supplemented – addition of device group "External cardioversion defibrillation electrode pads.".
2024-10-09	30076890	Amended – Editorial amendment, with no change in scope, to the wording of the intended use of device group "External cardioversion defibrillation electrode pads". Supplemented – Addition of device group "Single use surgical instruments and neutral electrodes for use in electrosurgery". Supplemented – Addition of device group "Reusable surgical instruments and neutral electrodes for use in electrosurgery". Supplemented – Addition of device category "Instruments for diathermocoagulation". Supplemented – Addition of device category "Transesophageal arrhythmology devices".
2025-03-27	30377373	Supplemented – Addition of External temporary cardiac stimulators dual chamber and MYOPACE® - epimyocardial pacing wires for temporary cardiac stimulation. Addition of device category - Cardiocirculatory introducers.

First Issue Date: **2021-11-17**

Current Issue Date: **2025-08-20**

Starting Validity Date: **2025-08-20**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

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Date	Reference Number	Action
Current	30447766	Supplemented – Addition of Endocardial Leads for Temporary Pacing and Electrophysiological Studies and External Temporary Cardiac Stimulators Single Chamber.

First Issue Date: **2021-11-17**

Current Issue Date: **2025-08-20**

Starting Validity Date: **2025-08-20**

Expiry Date: **2026-11-16**

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