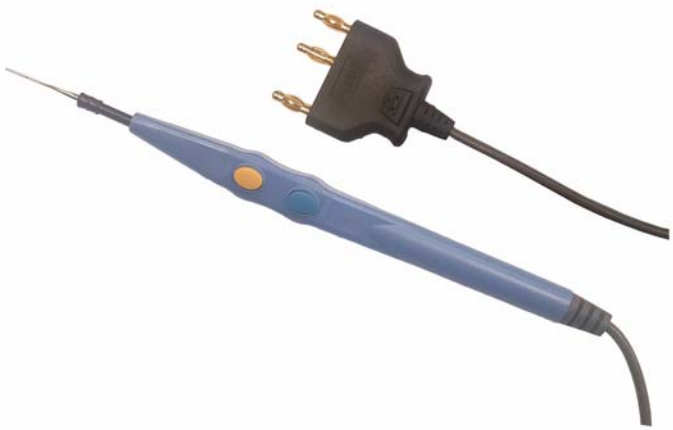
F4242 - F4252

MANIPOLO RIUTILIZZABILE PER ELETTROCHIRURGIA COMANDO MANUALE

REUSABLE HAND SWITCH ELECTROSURGICAL PENCIL



I manipoli riutilizzabili FIAB con comando manuale a doppio bottone hanno caratteristiche che li rendono del tutto affidabili nelle pratiche elettrochirurgiche. L'impermeabilità del sistema è garantita nella parte anteriore da uno speciale O-ring in silicone, nella parte posteriore da un tubetto che sigilla l'uscita del cavo.
Il connettore tipo Valleylab ne permette l'utilizzo con tutti i generatori per elettrochirurgia con questo standard. Il cavo in silicone ad alta resistenza consente ripetute sterilizzazioni in autoclave senza perdita di flessibilità.

FIAB reusable hand switch electrosurgical pencils have features that make them absolutely reliable during electrosurgical operations. The impermeability is guaranteed in the frontal part by a special silicone O-ring, At the cable end there is a tube sealing. The universal connector permits to use the pencil with all types of electrosurgical devices. The high resistance silicone connection cable permits repeated sterilisations in autoclave without loosing flexibility.

CARATTERISTICHE TECNICHE – *TECHNICAL FEATURES*		
MODELLO ***MODEL***	**F4242**	**F4252**
DESCRIZIONE ***DESCRIPTION***	Manipolo riusabile con attacco 2,38 mm (3/32"), comando manuale, con elettrodo a lama e cavo NON STERILE *Reusable hand control pencil, housing 2,38 mm (3/32") with blade electrode and cable - NOT STERILE*	
MATERIALE ***MATERIAL***	Plastico ad alta resistenza sterilizzabile. Prodotto senza lattice *Sterilisable high resistance plastic. Latex-free*	
LUNGHEZZA ***LENGTH***	168 mm	
ELETTRODO ***ELECTRODE***	Elettrodo a lama riutilizzabile, rimovibile *Removable blade electrode*	
PESO TOTALE ***TOTAL WEIGHT***	90 g ± 3%	150 g ± 3%
CAVO ***CABLE***	Tripolare ad alta flessibilità in silicone sterilizzabile *Sterilisable tripolar high flexible silicone*	
LUNGHEZZA CAVO ***CABLE LENGTH***	300 cm ± 3%	500 cm ± 3%
ATTACCO ***CONNECTOR***	Universale tripolare stampato tipo Valleylab *Tripolar universal Valleylab type*	
STERILIZZAZIONE ***STERILISATION***	Ossido di Etilene o autoclave: manipolo risterilizzabile fino a 100 volte, elettrodo fino a 20 volte E*O gas and steam: the pencil can be sterilised up to 100 times, the electrode up to 20 times*	
STERILIZZAZIONE IN AUTOCLAVE ***STERILISATION WITH STEAM***	Pre-vuoto - *Pre-vacuum*: 8 min Esposizione – *Exposition*: 134°C *(273°F)* 2,05 bar per/*for* 12 min Asciugatura – *Drying*: 9 min Oppure / *or* Pre-vuoto- *Pre-vacuum*: 8 min Esposizione - *Exposition*: 121°C *(250°F)* 1,05 bar per/*for* 20 min Asciugatura - *Drying*: 9 min	
CONFORMITA' STANDARD SICUREZZA ELETTRICA ***COMPLIANCE TO ELECTRICAL SAFETY STANDARDS***	EN 60601-1 ; EN 60601-2-2 ; EN 60601-1-2	
CONFORMITÀ ALLA DIRETTIVA ***COMPLIANCE TO DIRECTIVE***	Direttiva 93/42/CEE (D.L. 46/97) e succ. modifiche. Dispositivo medico in classe IIB *Directive 93/42/EEC and amendments. Class IIB medical device*	

CONFEZIONAMENTO – *PACKAGING*	
CONFEZIONE PRIMARIA ***PRIMARY PACKAGING***	Singola in busta termosaldata di polietilene – NON STERILE *Singly packaged in sealed polyethylene pouch – NOT STERILE*
CONFEZIONE VENDITA ***SALE PACKAGING***	5 pezzi in scatola di cartone *5 units in carton box*
IMMAGAZZINAMENTO ***STORAGE***	Temperatura: 0 ÷ +50 °C - Umidità relativa: 20 ÷ 80 % *Temperature: 0 ÷ +50 °C - Relative humidity: 20 ÷ 80 %*
SCADENZA ***EXPIRY***	5 anni dalla data di produzione se conservati correttamente *5 years from production date if correctly stored*

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

...making excellence a habit.™

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**

...making excellence a habit.™

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**

...making excellence a habit.™

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**

...making excellence a habit.™

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**

...making excellence a habit.™

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