# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 01906**

Issued To: **Fiab SpA**
**Via P. Costoli, 4**
**Vicchio**
**Firenze**
**50039**
**Italy**

In respect of:

**The design, development and manufacture of sterile leads for transoesophageal cardiac and temperature monitoring, cardiac stimulation, cardiac defibrillation and electrophysiological studies; percutaneous introducers; electronic equipments for oesophageal temperature monitoring, electrophysiological studies and emergency cardiac stimulation; sterile and non sterile electrosurgical electrodes and related accessories; electrodes for defibrillation/pacing; sterile single use neuropacers; sterile single use and reusable electrocauteries and associated accessories; sterile and non sterile, single use and reusable needle electrodes for EEG and EMG.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Albert Roossien, Regulatory Lead

First Issued: **1998-05-11** Date: **2019-03-12** Expiry Date: **2023-05-10**

...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<br>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<br>Sterile single use electrosurgical pencils<br>Reusable extensions for electrosurgery<br>Reusable electrodes for electrosurgery<br>Sterile single use electrosurgical kits-<br>Reusable electrosurgical pencils<br><br>Non-sterile single-use electrosurgical pencils<br>Non-sterile single-use electrosurgical electrodes<br>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<br>Sterile single use electrocauteries<br>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<br>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<br>Needles for EMG and EEG, reusable | Class IIa | N/A | CE01906, exp 10 May 2023, NB # 2797 |
| Esophageal temperature monitor<br>Connection cable for esophageal temperature monitor and probe<br>Esophageal temperature probe | Class IIb excluding Class IIb implantable non-WET | N/A | CE01906, exp 10 May 2023, NB # 2797<br><br>(MDR 747884 issued on 23 Jan, 2023, NB # 2797) |
| Single use electrosurgical neutral electrodes, single section<br>Single use electrosurgical neutral electrodes, dual section<br>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<br>CE 649635 (Annex II.4) exp 26 May 2024, NB # 2797 |
| Sterile lead introducer set peel-away<br>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<br>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<br><br>(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 |