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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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