Covidien llc

15 Hampshire Street
Mansfield
Massachusetts
02048

2024/07/31

Notified Body Confirmation Letter

Reference: EU2023-607/812648

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:

Covidien LLC
15 Hampshire Street
Mansfield, MA 02048 USA

SRN Number (if available): US-MF-000028763

Note the date of the written agreement between Covidien and BSI was made effective 2019/12/18, and the contract surrounding the application to regulation 2017/745 was made 2019/12/18.

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Graeme Tunbridge
Senior Vice President, Medical Devices

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
Valleylab hex-locking reusable blade electrode (E1020)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Edge Blade Monopolar Single-use Electrodes (E1450-4, E1450-4NSB, E1450-6, E1450-6NSB, E1450G, E1450GNSB, E1450X, E1450XNSB, E1475X)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Single Use Pencils - Edge Electrodes (E2450H, E2450H-GNSB, E2350HGNSB, E2350H, E2350HDB, E2350HDBNSB, E2350HNSB, E2450HDBNSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Smoke Attachment (E3815, E3810)	Class IIa	N/A	CE 00500; expiry date 2024-05-26, NB 2797
ValleyLab Rocker Switch Electrosurgical Pencil (E2515, E2515-NSB, E2515-GNSB, E2516, E2516-NSB, E2516-GNSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
ValleyLab Rocker Switch Electrosurgical Pencil Holster (E2515H, E2515H-DB, E2515H-DB-NSB, E2515H-GNSB, E2516H, E2516H-NSB, E2516H-DA, E2516H-GNSB, E2515HDA, E2516H,	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Edge Needle Monopolar Single-use Electrodes (E1452, E1452-6, E1452NSB, E1455, E1455B, E1455-4, E1455-4NSB, E1455-6, E1455-6NSB, E1455-NSB, , E1455B-4, E1465, E1465-4, E1465-6, E1465B, E1465BNSB, E1465B-4, E1475X, E1650, E1651, E1652, E1653, E1654B, E1465-4NSB E1455B-4NSB, E1465NSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Edge Insulated Blade Electrodes (E1455G)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Edge Footswitching monopolar coagulator single-use with suction (E2505-10FR, E3305, E3310,	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Edge Handswitching monopolar coagulator single-use with suction (E2608-6)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Edge/Accuvac footwitching electrosurgical pencil, holster (E3250H, E3504, E3504H	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Edge/Accuvac footwitching electrosurgical pencil, holster, non-sterile bulk; (E3250HNSB, E3504NSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797

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Valleylab Straight Extension reusable (E1502, E1504)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Endoscopic monopolar electrodes single-use (E1550, E1551X, E1551XNSB, E1551-6, E1551G, E1551-6NSB, E1552, E1552NSB, E1552-6)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
ValleyLab reusable electrosurgical pencil (E2100, E2100E)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
ValleyLab Rocker Switch Electrosurgical Pencil (E2515, E2515-NSB, E2515H, E2515H-DB, E2515H-DB-NSB, E2515-GNSB, E2515H-GNSB, E2516, E2516-NSB, E2516H, E2516H-NSB, E2516H-DA, E2516-GNSB, E2516H-GNSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Force Triverse Electrosurgical Monopolar Pencils (FT3000, FT3000DB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Electrosurgical Pencil (VL2610, VL2610DB, VL2610E)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Reliant Button Switch Pencils, Blades, and Holsters (VL2615, VL2615DB, VL2615E)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Reliant Button Switch Pencils, Blades, and Holsters - Non-sterile bulk (VL2610NSB, VL2615NSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-2, NB 27976
Valleylab and CleanCoat Laparoscopic Electrodes (E3770-36, E3771-36, E3771-45, E3772-36, E3773-36, E3773-45, E3774-36, E3774-45, E3770-36C, E3771-36C, E3771-45C, E3772-36C, E3773-36C, E3773-45C, E3774-36C, E3774-45C)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Laparoscopic Electrodes (E3780-28, E3781-28, E3782-28, E3783-28, E3786-28)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Laparoscopic Electrodes with aspiration holes (E3781R-28ASP, E3782R-28ASP, E3783R-28ASP, E3783R-36-ASP, E3784R-28ASP)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Laparoscopic Handsets (E2750)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Laparoscopic Handsets non-sterile bulk (E2750NSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
BiZact Sealing bipolar dividers, single-use (BZ4212)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Ligasure Impact Curved, Large Jaw, Open Sealer/Divider, with or without Nano-coating (LF4418)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797

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LigaSure Curved Small Jaw Open Seal/Divider (LF1212, LF1212A)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
LigaSure Exact Dissector (LF2019)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
LigaSure™ Retractable L-hook Laparoscopic Sealer/Divider (LF5637, LF5644)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
LigaSure Blunt Tip Open and Laparoscopic Sealer/Divider (LF1823, LF1837, LF1844)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
LigaSure Maryland Jaw Open and Laparoscopic Sealer/Divider, with Nano Coating (LF1923, LF1937, LF1944, LF1930T)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab FT10 Energy Platform General-purpose electrosurgical diathermy system generator (VLFT10GEN)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Electrosurgical Return Electrodes, Single-use (E7507, E7507DB, E7508, E7509, E7509B, E7510-25, E7510-25DB, E7512)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Telescoping Smoke Evacuation RockerSwitch Pencil (SEP6000, SEP6015)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Valleylab Telescoping Smoke Evacuation Rocker Switch Pencil, Non-Sterile Bulk (SEP6000NSB, SEP6015NSB)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
ValleyLab Bipolar Coagulation Forceps (E4051-CT, E4052-CT, E4053-CT, E4054-CT, E4055-CT, E4056-CT, E4057-CT, E4058-CT, E4059-CT, E4060-CT, E4062-CT, E4073-CT)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Sonicision Cordless Ultrasonic System Generator-(SCGAA) and battery (SCBA)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797
Curved Jaw Cordless Ultrasonic Dissectors for 5mm Open & laparoscopic (SCDA26, SCDA39, SCDA48); Open (SCDA13)	Class IIb - Non-Implantable - non-WET- non-Rule 12	N/A	CE 00500; expiry date 2024-05-26, NB 2797

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Single Use Electrosurgical Cords (E0510)	Class Is	N/A	CE 01948; expiry date 2024-05-26, NB 2797
FT single use electrosurgical cords (FT0510)	Class Is	N/A	CE 01948; expiry date 2024-05-26, NB 2797
electrode holsters (E2400)	Class Is	N/A	CE 01948; expiry date 2024-05-26, NB 2797
Smoke Evacuator Tubing Sets (SEL7010, SEA3705, SEA3710, SEA3715, SEA3720, SEA3725)	Class Is	N/A	CE 01948; expiry date 2024-05-26, NB 2797
Single Use Tip Cleaners (E2401)	Class Is	N/A	CE 01948; expiry date 2024-05-26, NB 2797
Bipolar Cords (E0512)	Class Is	N/A	CE 01948; expiry date 2024-05-26, NB 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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	Action
2024/03/21	Initial issue
2024/05/20	Addition of ValleyLab reusable electrosurgical pencil (E2100, E2100E) Removal of Valleylab Endoscopic monopolar electrodes single-use (E1560, E1561, E1562, E1563, E1564, E1565, E1567)
2024/05/24	Correction of typo regarding Valleylab Laparoscopic Electrodes
2024/07/31	Addition of E1020 Valleylab Hex Locking reusable blade electrode Correction of certificate reference for SEP6000, SEP6015, SEP6000NSB, SEP6015NSB