

EU Quality Management System Certificate

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

MDR 724712 R000

Manufacturer: Covidien Ilc

Address:

15 Hampshire Street
Mansfield
Massachusetts
02048
USA

Single Registration Number: US-MF-000028763

EU Authorised Representative: Medtronic B.V.

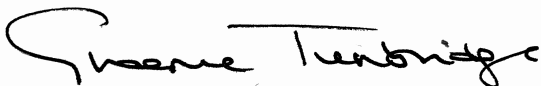
Address:

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

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: **2021-08-12**

Current Issue Date: **2025-06-27**

Starting Validity Date: **2025-06-27**

Expiry Date: **2026-08-11**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Edge Blade Monopolar Single-use Electrodes (E1450-4, E1450-6, E1450G, E1450X, E1452, E1452-6, E1455, E1455B, E1455B-4, E1455-4, E1455-6, E1465, E1465-4, E1465-6, E1465B, E1465B-4, E1475X)	Tissue dissection and vessel coagulation
Edge Blade Monopolar Single-use Electrodes bulk non-sterile (E1450-4NSB, E1450-6NSB, E1450GNSB, E1450XNSB, E1452NSB, E1455BNSB, E1455-4NSB, E1465B-NSB, E1455-6NSB, E1455NSB, E1465-4NSB, E1465NSB)	Tissue dissection and vessel coagulation
Valleylab hex-locking reusable blade electrode (E1020)	Tissue dissection and vessel coagulation
ValleyLab reusable electrosurgical pencil (E2100, E2100E)	Tissue dissection and vessel coagulation
Valleylab Straight extension reusable electrode (E1502, E1504)	Tissue dissection and vessel coagulation
Valleylab Bipolar Forceps (E4051-CT, E4052-CT, E4053-CT, E4054-CT, E4055-CT, E4057-CT, E4058-CT, E4059-CT, E4060-CT, E4062-CT, E4073-CT)	Tissue dissection and vessel coagulation
Edge Blade Monopolar Single-use Electrodes with Holster (E2450H, E2350H, E2350HDB)	Tissue dissection and vessel coagulation
Edge Insulated Blade Electrodes (E1455G)	Tissue dissection and vessel coagulation
Valleylab Monopolar Single-use Electrodes (E1650, E1651, E1652, E1653, E1654B)	Tissue dissection and vessel coagulation
Valleylab Endoscopic monopolar electrodes single-use (E1550, E1551X, E1551-6, E1551G, E1552, E1552-6)	Tissue dissection and vessel coagulation
Valleylab Endoscopic monopolar electrodes single-use bulk non-sterile (E1551XNSB, E1551-6NSB, E1552NSB)	Tissue dissection and vessel coagulation
Edge Footswitching monopolar coagulator single-use with suction bulk non-sterile (E2505-10FRNSB, E3310NSB)	Tissue dissection and vessel coagulation
Edge Footswitching monopolar coagulator single-use with suction (E2505-10FR, E2608-6, E3305, E3310)	Tissue dissection and vessel coagulation
Edge/Accuvac footswitching electrosurgical pencil, holster (E3250H)	Tissue dissection and vessel coagulation
Valleylab footswitching electrosurgical pencil (E3504, E3504H)	Tissue dissection and vessel coagulation
Edge Electrosurgical Pencil non-sterile bulk (E2350HDBNSB, E2350HGNSB, E2350HNSB, E2450HDBNSB, E2450HGNSB, E2450HNSB)	Tissue dissection and vessel coagulation
Edge/Accuvac footswitching electrosurgical pencil, holster, non-sterile bulk; (E3250HNSB)	Tissue dissection and vessel coagulation

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Class IIb	Intended purpose
Edge/Accuvac footwitching electrosurgical pencil, non-sterile bulk; (E3504NSB)	Tissue dissection and vessel coagulation
ValleyLab Rocker Switch Electrosurgical Pencil (E2515, E2516)	Tissue dissection and vessel coagulation
ValleyLab Rocker Switch Electrosurgical Pencil Holster (E2515H, E2515HDB, E2515HDA, E2516H, E2516HDA)	Tissue dissection and vessel coagulation
ValleyLab Rocker Switch Electrosurgical Pencil Holster bulk non-sterile (E2515NSB, E2515GNSB, E2515HNSB, E2515HDANSB, E2515HDBNSB, E2515HGNSB, E2516NSB, E2516GNSB, E2516HNSB, E2516HGNSB)	Tissue dissection and vessel coagulation
Force Triverse Electrosurgical Monopolar Pencils (FT3000, FT3000DB)	Tissue dissection and vessel coagulation
Reliant Button Switch Pencils, Blades, and Holsters (VL2610, VL2610DB, VL2610E, VL2615, VL2615DB, VL2615E)	Tissue dissection and vessel coagulation
Reliant Button Switch Pencils, Blades, and Holsters non-sterile bulk (VL2610NSB, VL2615NSB)	Tissue dissection and vessel coagulation
CleanCoat Laparoscopic Electrodes (E3770-36C, E3771-36C, E3771-45C, E3772-36C, E3773-36C, E3773-45C, E3774-36C, E3774-45C)	Tissue dissection and vessel coagulation
Valleylab Laparoscopic Electrodes (E3770-36, E3771-36, E3771-45, E3772-36, E3773-36, E3773-45, E3774-36, E3774-45)	Tissue dissection and vessel coagulation
Valleylab Laparoscopic Electrodes (E3780-28, E3781-28, E3782-28, E3783-28, E3786-28)	Tissue dissection and vessel coagulation
Valleylab Laparoscopic Electrodes with aspiration holes (E3781R-28ASP, E3782R-28ASP, E3783R-28ASP, E3783R-36ASP, E3784R-28ASP)	Tissue dissection and vessel coagulation
Valleylab Laparoscopic Handsets (E2750)	Tissue dissection and vessel coagulation
Valleylab Laparoscopic Handsets non-sterile bulk (E2750NSB)	Tissue dissection and vessel coagulation
BiZact Sealing bipolar dividers (BZ4212)	Tissue dissection and vessel coagulation
LigaSure Curved Small Jaw Open Seal/Divider (LF1212, LF1212A)	Tissue dissection and vessel coagulation
Ligasure Impact Curved, Large Jaw, Open Sealer/Divider, with Nano-coating (LF4418)	Tissue dissection and vessel coagulation
LigaSure Retractable L-hook laparoscopic sealer/divider (LF5637, LF5644)	Tissue dissection and vessel coagulation
LigaSure Exact Dissector (LF2019)	Tissue dissection and vessel coagulation
LigaSure Blunt Tip Open and Laparoscopic Sealer/Divider (LF1823, LF1837, LF1844)	Tissue dissection and vessel coagulation

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Class IIb	Intended purpose
LigaSure Maryland jaw open and laparoscopic sealer/dividers (LF1923, LF1937, LF1944, LF1930T)	Tissue dissection and vessel coagulation
Ligasure Robotically Assisted Surgical (RAS) Maryland jaw vessel sealer/divider (MRASILF19)	Tissue dissection and vessel coagulation
LigaSure XP Maryland jaw open and laparoscopic sealer/dividers (LXMJ23S, LXMJ37S, LXMJ44S, LXMJ23L, LXMJ37L, LXMJ44L)	Tissue dissection and vessel coagulation
Valleylab FT10 Energy Platform (VLFT10GEN, VLFT10FXGEN, VLFT10LSGEN)	Tissue dissection and vessel coagulation
Patient Return Electrodes (E7507, E7507DB, E7508, E7509, E7509B, E7510-25, E7510-25DB, E7512)	RF energy dispersion
Valleylab Telescoping Smoke Evacuation Rocker Switch Pencil, Non-Sterile Bulk (SEP6000NSB, SEP6015NSB)	Tissue dissection and vessel coagulation
Valleylab Telescoping Smoke Evacuation Rocker Switch Pencil (SEP6000, SEP6015)	Tissue dissection and vessel coagulation
Valleylab Smoke Evacuation Pencil (VSMP10, VSMP15)	Tissue dissection and vessel coagulation
Valleylab Smoke Evacuation Pencil non-sterile bulk (VSMP10NSB)	Tissue dissection and vessel coagulation
Cordless ultrasonic dissector system generator and reusable battery pack (SCGAA, SCG7AA, SCG7AB, SCBA)	Tissue dissection and vessel coagulation
Curved jaw cordless ultrasonic dissectors (SCDA13, SCDA26, SCDA39, SCDA48, SCD7A13, SCD7A26, SCD7A39, SCD7A48)	Tissue dissection and vessel coagulation

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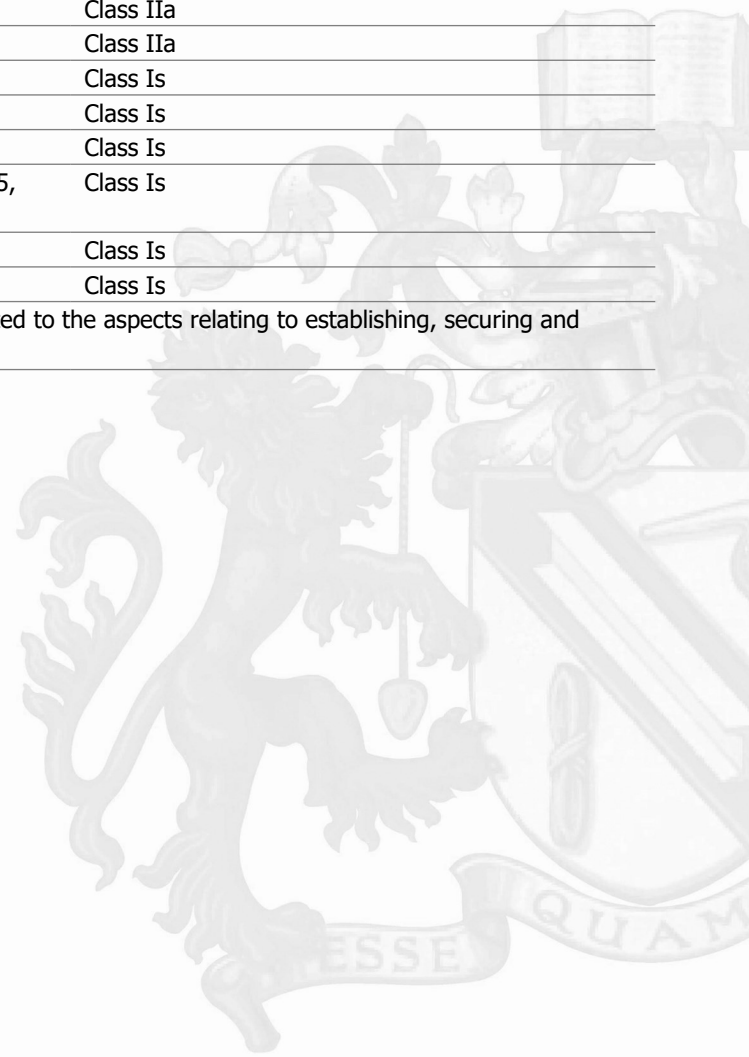
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Smoke Evacuation Attachments (E3810, E3815)	Class IIa
Smoke Evacuation Attachments bulk non-sterile (E3810NSB)	Class IIa
Valleylab Smoke Evacuation Attachment (VSMEN4, VSMEN6)	Class IIa
Single-use electrosurgical cords (E0510)	Class Is
ForceTriad single use electrosurgical cords (FT0510)	Class Is
Electrode holsters (E2400)	Class Is
Smoke evacuator tubing sets (SEL7010, SEA3705, SEA3710, SEA3715, SEA3720, SEA3725)	Class Is
Single-use tip cleaners (E2401)	Class Is
Bipolar cords (E0512)	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	



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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
2021-08-12	3150615	Issued
2022-02-23	3541340	Supplemented – Addition of Sonicision 7 ultrasonic dissector system dissector and generator part numbers, Ligasure Maryland jaw open and laparoscopic sealer/dividers, Valleylab FT10Energy Platform, Valleylap hex-locking reusable blade electrodes, Valleylab bipolar forceps, patient return electrodes. Amended – Addition of subcontractors for the added products.
2023-01-25	3811751	Amended – Addition of manufacturer SRN. Addition of subcontractors for the added devices. Removal of subcontractor pages. Administrative update to the history. Supplemented – Addition of Edge Insulated Blade Electrodes; Reliant Button Switch Pencils (sterile and bulk non-sterile), Blades, and Holsters; Valleylab Laparoscopic Handsets (sterile and bulk non-sterile); Ligasure Curved Small Jaw Sealer/Dividers; and Ligasure XP Maryland Jaw Sealer/Dividers.
2023-06-19	30001077	Supplemented – Addition of LigaSure Blunt Tip devices Amended – Addition of subcontractor for sterilization of Bizact, Ligasure, and Ultrasonic Dissector devices.

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Date	Reference Number	Action
2023-09-29	30007557	Amended – Administrative change to subcontractor address Amended – Addition of two subcontractors for manufacture and design
2024-04-26	30126729	Supplemented - Addition of Ligasure Impact, Ligasure Exact, and additional models of Valleylab FT10 Energy Platform devices.
2024-08-13	30181409	Supplemented – Addition of smoke evacuation attachments.
2024-08-30	30248314	Supplemented – Addition of further models of Edge monopolar electrodes and pencils, ValleyLab reusable electrosurgical pencils, Valleylab monopolar electrodes and pencils, Valleylab suction coagulators, CleanCoat laparoscopic electrodes, Valleylab laparoscopic electrodes, Valleylab smoke evacuation pencils, and Valleylab smoke evacuation attachments Amended – Addition of manufacturing and sterilization subcontractors for added products.
2025-02-27	30360217	Supplemented – Addition of a Valleylab Endoscopic monopolar electrode Supplemented – Addition of Force Triverse Electrosurgical Monopolar Pencils Supplemented – Addition of BiZact Sealing bipolar dividers Restricted – Removal of electrosurgical accessories (E0520) no longer placed on market
2025-05-08	30423673	Supplemented – Addition of device Valleylab Straight extension reusable electrode (E1502, E1504). Amended – Correction of Force Triverse Electrosurgical Monopolar Pencils device model number from FD3000DB to FT3000DB.

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Date	Reference Number	Action
Current	30400103	Supplemented – Addition of the device Ligasure Robotically Assisted Surgical (RAS) Maryland jaw vessel sealer/divider (MRASILF19).



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
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