EU MDR Declaration of Conformity (DoC) # 603

Manufacturer:	Covidien llc 15 Hampshire Street Mansfield, Massachusetts 02048 USA
Manufacturer SRN:	To be determined
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	Not Applicable
Conformity Assessment Certificate(s):	*Annex IX : Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation*
Conformity Assessment Procedure:	Not Applicable for Class I (non-measuring, non-sterile, non-reusable) products, only DoC in accordance with Annex IV.
Risk Class:	Refer to the Products Covered table below
Classification Rule:	Refer to the Products Covered table below
Intended Purpose:	Refer to the Products Covered table below

Statement:

We, Covidien llc, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
SCBIGA, SCSTA	
RoHS 3 DIRECTIVE 2015/863	RE00288844
REGULATION (EU) 2017/745	RE00197250
SCSTA	
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00276478
E0005-3C, E0017, E0502-1, E0507-B	
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00295055
RoHS DIRECTIVE 2015/863	RE00295120
REGULATION (EU) 2017/745	RE00183046
E0560, E0560E	
RoHS DIRECTIVE 2015/863	RE00292613
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00267106
REGULATION (EU) 2017/745	RE00181385
E0020V, E0021S, E0022W	
RoHS DIRECTIVE 2015/863	RE00312498
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00306266
REGULATION (EU) 2017/745	RE00183046
FT0021S, FT0022W	
RoHS DIRECTIVE 2015/863	RE00291385
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00294089
REGULATION (EU) 2017/745	RE00194763
SE3695, SEA3700, SEA3745	
RoHS 3 DIRECTIVE 2015/863	RE00297912
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00297339
REGULATION (EU) 2017/745	RE00183749
SEA3730, SEA3741	
RoHS 3 DIRECTIVE 2015/863	RE00316499
REACH (EC) No 1907/2006 and Directive 2006/121/EC	RE00297407

Union Legislation	Applicable Declaration of Conformity Document Number
REGULATION (EU) 2017/745	RE00183749

Place: Boulder, Colorado, USA

Name: Ben Cordileone

Title: Sr. Regulatory Affairs Manager

Signature:

Date: 12-Apr-2022

Products Covered

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Sonicision™ Reusable Battery Insertion Guide	SCBIGA	Class I	Rule 1	0763000B00004457Q	60486, Surgical instrument battery insertion guide	K020280, Electrosurgical ultrasonic devices - accessories	RE00280978	The Sonicision Reusable Battery Insertion Guide is intended to facilitate the aseptic transfer of the non-sterile Sonicision Reusable Battery Pack into the Sonicision Curved Jaw Cordless Ultrasonic Dissection Device.	Not Applicable
Sonicision™ Sterilization Tray	SCSTA	Class I	Rule 1	0763000B00004467S	13730, Sterilization container	K020280, Electrosurgical ultrasonic devices - accessories	RE00280981	The Sonicision Reusable Sterilization Tray is intended to store the generator (SCGAA), battery (SCBA), and battery insertion guide (SCBIGA) during sterilization.	Not Applicable

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Valleylab™ Active Adapter, 4 mm	E0005-3C	Class I	Rule 1	0763000B0000 21575	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The E0005-3C, Valleylab™ Active Adapter, 4mm, is intended to be inserted into a single-pin monopolar instrument receptacle of an electrosurgical hardware unit and the 4mm plug of an active accessory is plugged into the adapter.	Not Applicable
Valleylab™ Universal Monopolar Adapter	E0017	Class I	Rule 1	0763000B0000 21575	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The Universal Monopolar Adaptor, E0017, is intended to be plugged into the active accessory jack on all Covidien electrosurgical generators and designed to accept most standard active accessory plugs. Most standard foot switching active electrosurgical accessories have a connection plug which will fit into the plug receptacle of the E0017 adapter.	Not Applicable

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Valleylab™ Monopolar Adapter	E0502-1	Class I	Rule 1	0763000B0000 21575	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The Valleylab™ Monopolar Adapter, E0502-1, is intended to allow the use of Covidien electrosurgical disposable active accessories with most electrosurgical generators. These adapters are made to accept the 1/8 inch diameter pin tip cable connector used on the power cord of these active accessories	Not Applicable
Valleylab™ Multiple Return/S Cord Adapter	E0507-B	Class I	Rule 1	0763000B0000 9698X	35041, Electrosurgical cable adapter	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00219572	The adapter is intended to monitor the continuity of the return electrode cable.	Not Applicable

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Valleylab™ REM™ Patient Return Electrode Cord	E0560	Class I	Rule 1	0763000B00001236X	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00057404	The E0560 and E0560E Cords for Patient Return Electrodes are reusable cord/clamp assemblies that are intended to be used with compatible REM Polyhesive Adult Cordless Patient Return Electrodes.	Not Applicable
Valleylab™ Cord Clamp	E0560E	Class I	Rule 1	0763000B00001236X	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00057404	The E0560 and E0560E Cords for Patient Return Electrodes are reusable cord/clamp assemblies that are intended to be used with compatible REM Polyhesive Adult Cordless Patient Return Electrodes.	Not Applicable
Valleylab™ Bipolar Forceps Cord, Reusable	E0020V	Class I	Rule 1	0763000B00001246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00133312	Cords are to electrically connect bipolar electrosurgical instruments to Covidien electrosurgical generators	Not Applicable
Valleylab™ Bipolar Forceps Cord, Storz™*	E0021S	Class I	Rule 1	0763000B00001246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00133312	Cords are to electrically connect bipolar electrosurgical instruments to Covidien electrosurgical generators	Not Applicable

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
Valleylab™ Bipolar Forceps Cord, Wolf™*	E0022W	Class I	Rule 1	0763000B00001246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00133312	Cords are to electrically connect bipolar electrosurgical instruments to Covidien electrosurgical generators	Not Applicable
ForceTriad™ Bipolar Resection Cord, Storz™*	FT0021S	Class I	Rule 1	0763000B00001246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00174174	The Bipolar Resection Cords are intended to electrically connect bipolar resectoscope electrosurgical instruments to compatible energy platforms for endoscopically controlled removal (resection) or coagulation of tissue using 0.9% NaCl solution (saline) as the irrigation medium.	Not Applicable

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
ForceTriad™ Bipolar Resection Cord, Wolf™*	FT0022W	Class I	Rule 1	0763000B00001246Z	47487, Medical device electrical cable, reusable	K020102, Electrosurgical Pads and Cables	RE00174174	The Bipolar Resection Cords are intended to electrically connect bipolar resectoscope electrosurgical instruments to compatible energy platforms for endoscopically controlled removal (resection) or coagulation of tissue using 0.9% NaCl solution (saline) as the irrigation medium.	Not Applicable

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
RAPIDVAC SMOKE EVACUATOR 220V	SE3695	Class I	Rule 1	0763000B00003377L	37861, Surgical plume evacuation system	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ Smoke Evacuator captures particulates and adsorbs gases from surgical smoke. The smoke evacuator is specifically designed to improve visibility and reduce potential health hazards associated with surgical smoke. It can be used in both open and laparoscopic procedures.	Not Applicable
RAPIDVAC 3 PORT FILTER RFID	SEA3700	Class I	Rule 1	0763000B00003377L	44979, Surgical plume evacuation system filter	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ ULPA Filter is intended **to capture the smoke plume.**	Not Applicable

Product Name	Medtronic Product Identifier CFN	Risk Class	Classification Rule	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Intended Purpose	Quality Certificates
RAPIDVAC INTERLINK CABLE	SEA3730	Class I	Rule 1	0763000B00003377L	47487, Electrical-only medical device connection cable, reusable	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ Interlink Cable is intended to attach to a generator's RF activation port and to the smoke evacuator's Remote Activator jack.	Not Applicable
REMOTE SWITCH ACTIVATOR	SEA3741	Class I	Rule 1	0763000B00003377L	47487, Electrical-only medical device connection cable, reusable	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The Remote Switch Activator (RSA) is intended to activate and deactivate the flow of the smoke evacuator when the device is in RapidVac+ mode.	Not Applicable
RAPIDVAC FOOTSWITCH	SEA3745	Class I	Rule 1	0763000B00003377L	36336, Footswitch, electrical	K02010107, SMOKE EVACUATION DEVICES	RE00230798	The RapidVac™ Footswitch is intended for **footswitching operation with the smoke evacuator** by simply plugging it into the footswitch jack on the front panel.	Not Applicable

Common Specification(s)

The following common specifications were used to demonstrate conformity. Refer to Products Covered section for Standards list:

Number	Date of Issue	Title