EU MDR Declaration of Conformity (DoC) # 603A

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
Contract Manufacturer:	Linemaster Switch Corp. 29 Plaine Hill Road Woodstock, CT 06281 USA
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:	Class I
Classification Rule:	Rule 1
Intended Purpose:	This product is intended to activate monopolar electrosurgical energy from the generator to an instrument to be used with Covidien's line of electrosurgical generators.

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
E6008, E6008L, E6009, E6009L, E6019, FT6003, FT6009, LF0500, LS0300	
RoHS DIRECTIVE 2015/863	RE00267600
REACH (EC) No 1907/2006 and Directive 2019/1194	RE00236973
REGULATION (EU) 2017/745	RE00194763

Place: Boulder, Colorado, USA

Name: Ben Cordileone

Title: Sr. Regulatory Affairs Manager

Signature: Ben Cordileone

Date: 12-Apr-2022

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI	GMDN Code	CND Code	Reference to External Standards List (optional)	Quality Certificates
Valleylab™ Monopolar Footswitch	E6008	0763000B000016075	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Bipolar Standard Footswitch	E6009	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Bipolar Dome Footswitch	E6019	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Three-Pedal Footswitch	FT6003	0763000B000016075	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
ForceTriad™ FT Series Bipolar Resection Footswitch	FT6009	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
LigaSure™ Tissue Fusion Footswitch, Orange	LF0500	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and	RE00208898	Not Applicable

				Bipolar - Accessories		
LigaSure™ Tissue Fusion Footswitch, Purple	LS0300	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Monopolar Footswitch	E6008L	0763000B000016075	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable
Valleylab™ Bipolar Footswitch	E6009L	0763000B000016177	36336, Footswitch, electrical	K020180, Electrosurgical Devices, Mono - and Bipolar - Accessories	RE00208898	Not Applicable

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Certificate No.: C2019-02785	30-Sep-2019	RE00181210: Linemaster ISO 13485 Certificate