EU Declaration of Conformity to MDR

MANUFACTURER		
Name of company	**Address**	**SRN**
Aspen Surgical Products, Inc.	6945 Southbelt Drive SE Caledonia, Michigan 49316, USA	US-MF-000008255

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Cautery Tip Cleaner (35/box)	032001PBX
Cautery Tip Cleaner (100/box)	TC-100
Cautery Tip Cleaner (25/box)	TC-100A
Cautery Tip Cleaner (240/box)	TC-100B
Cautery Tip Cleaner (50/box)	300-50CE
Intended Purpose	**Basic UDI-DI**
Intended to assist in cleaning and removing material from cautery tips during surgical procedures	0840113211000ST36

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	1s	ISO 13485:2016 issued by BSI Group America Inc.
Rule:	1	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
BSI Say Building, John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands	2797	Annex XI Part A of MDR 2017/745 Regulation	MDR 755274

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. Aspen Surgical Products, Inc. declares that the above-mentioned products meet the relevant requirements of the EU Medical Device Regulation 2017/745.

COMPANY REPRESENTATIVE: Stephanie Sullivan

TITLE: Regulatory Affairs Manager **SIGNATURE:** Stephanie Sullivan

Digitally signed by Stephanie Sullivan
Date: 2024.01.23 17:22:44 -05'00'

PLACE: Caledonia, Michigan USA **DATE:** January 23, 2024