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**
Camera Cover	15010-1CE
Camera Cover	LT-C02
Camera Cover	LT-C02-P
Flexible O.R. Camera Cover	LT-CF02
Steris Flexible Camera Cover	LT-54
Rigid Handle	LT-R01
Light Handle Cover, 2 up	LT-F02
Light Handle Cover, 3 up	LT-F03
Light Handle Cover, 1 up	LT-F01B
ALC Plus Light Handle Cover	LT-ALC01
ALC Plus Light Handle Cover	LT-ALC01-P
Flexible Light Handle Cover	LHC-0001
Flexible Light Handle Cover, Sterile (DYNJLHS1)	MD-LTF1E
Flexible Light Handle Cover, Sterile (DYNJLHS2)	MD-LTF2E
Steris Flexible Light Handle Cover	LT-53
Intended Purpose	**Basic UDI-DI**
Surgical Light Handle and Camera Covers are intended to be used with surgical lights or cameras to provide a sterile interface with operating room personnel.	0840113212000ST3K

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	1s	ISO 13485:2016
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: 2024.01.15 13:06:53 -05'00'

PLACE: Caledonia, Michigan USA **DATE:** January 15, 2024