

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
Securline Taper Tip Marker and Ruler Set	1000-00-PDG
Securline Taper Tip Marker and Ruler Set	1002-00-PDG
Securline Taper Tip Marker, Ruler and Label Set	100L-00-PDG
Fine Tip Marker, Ruler and Label Set	2630
Regular Tip Marker with Ruler and 6-Up Labels	2650
Writesite Plus Prep Resistant Skin Marker (EU), Regular Tip	2700-I
Chloraprep Resistant Marker with Ruler	2710
WriteSite Plus Multi-Ink Prep Resistant Skin/Utility Marker, Regular Tip, with Ruler and 6 Labels	2720
Modern Fine Tip Marker, Ruler and Label Set	2730
Regular Tip Marker, Ruler and Label Set	2750
Regular Style Pen with Ruler and Labels	2750OEMDSP
WriteSite Multi-Ink Marker	2755
WriteSite® Multi-Ink Marker, Marker with Ruler, and 6 Labels	2760
Dual Tip Skin Marker	2777
WriteSite® Dual Skin Marker, Marker with Ruler, and 6 Labels	2780
Taper Tip Skin Marker with Ruler and Labels	900-7019
Taper Fine Tip Pen with Ruler	AMS1000
Classic Regular Tip Marker	G2651
Modern Fine Tip Marker	G2731
Modern Style, Reg Tip, Pen & Ruler (DYNJSM01)	MD-2003
Modern Regular Tip Pen w/Ruler & 6-Up Labels (DYNJSM02)	MD-2004
Classic Style Fine Tip, Pen & Ruler (DYNJSM03)	MD-2005
Modern Fine Tip Pen, Ruler and Labels	SM0372
Modern Regular Tip Pen with Ruler	SM0572
Surgical Marking Pen Fine Tip	19004-01CE
Surgical Marking Pen Fine Tip with Ruler	19004-02CE
Surgical Marking Pen Fine Tip with Ruler and Labels	19004-03CE
Surgical Marking Pen Regular Tip	19005-01CE
Surgical Marking Pen Regular Tip with Ruler	19005-02CE
Surgical Marking Pen Regular Tip with Ruler and Labels	19005-03CE

Intended Purpose		Basic UDI-DI
Surgical Marking Pens are intended for surgical marking on intact skin.		0840113240000ST4C
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:**

PLACE: Caledonia, Michigan USA **DATE:** 18 JUNE 2024