

# Declaration of Conformity

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
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
Dual Tip Skin Marker	2777
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

MANUFACTURER		
Name of company	Address	Representative
Aspen Surgical Products, Inc.	6945 Southbelt Drive SE Caledonia, Michigan 49316 USA	Kerry Turner

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax EmergoEurope@ul.com

NOTIFIED BODY	
Notified Body and ID #	CE certificate number
BSI Say Building, John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797	CE 571159

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class 1s Rule 1	Annex V of MDD 93/42/EEC Council Directive	ISO 13485: 2016

Aspen Surgical Products Inc. declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Kerry Turner

**TITLE:** Vice President of Quality Assurance and Regulatory Affairs **SIGNATURE:**



**DATE:** 11 Dec 2020