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: Suture Boots	**Model/number**
Standard Yellow, Non-Sterile, 5 pairs/tray	051003BBG
Standard Yellow, Sterile, 5 pairs/tray	051003OEMDSP
Standard Yellow, Sterile, 5 pairs/tray	051003PBX
Large Pink, Non-Sterile, 5 pairs/tray	051004BBG
Large Pink, Sterile, 5 pairs/tray	051004OEMDSP
Large Pink, Sterile, 5 pairs/tray	051004PBX
Standard Red, Non-Sterile, 5 pairs/tray	051011BBG
Standard Red, Sterile, 5 pairs/tray	051011OEMDSP
Standard Red, Sterile, 5 pairs/tray	051011PBX
Standard Blue, Non-Sterile, 5 pairs/tray	051012BBG
Standard Blue, Sterile, 5 pairs/tray	051012PBX
Standard White, Non-Sterile, 5 pairs/tray	051014BBG
Standard White, Sterile, 5 pairs/tray	051014PBX
Standard Assorted, Non-Sterile, 5 pairs/tray	051015BBG
Standard Assorted, Sterile, 5 pairs/tray	051015PBX
Standard Yellow, Non-Sterile, 2 pairs/tray	052003BBG
Standard Yellow, Sterile, 2 pairs/tray	052003PBX
Large Pink, Sterile, 2 pairs/tray	052004PBX
Large Pink, Non-Sterile 2 pairs/tray	052004BBG
Standard Yellow, Non-Sterile, 3 pairs/tray	053003BBG
Standard Yellow, Sterile, 3 pairs/tray	053003PBX
X-Tra Red Mini, Sterile, 3 pairs/tray	053030PBX
Standard Yellow, Non-Sterile, 5 pairs/tray	3803BN
Standard White, Non-Sterile 5 pairs/tray	3804BN
Standard Red, Non-Sterile, 5 pairs/tray	3806BN
Standard Assorted, Non-Sterile, 5 pairs/tray	3810BN
Standard Yellow, Non-Sterile, 2 pairs/tray	3811BN
Standard Yellow, Non-Sterile, 3 pairs/tray	3812BN
Standard Yellow, Non-Sterile, 5 pairs/tray	3813BN
Standard Yellow, Non-Sterile, 3 pairs/tray	3815BN

Large Pink, Non-Sterile, 5 pairs/tray	3816BN
Large Pink, Non-Sterile, 5 pairs/tray	3817BN
Standard White, Non-Sterile, 6 pairs/tray	3824BN
Standard Assorted, Non-Sterile 6 pairs/tray	3830BN
Intended Purpose	**Basic UDI-DI**
Suture Aid Booties are intended to protect, tag and help locate sutures.	0840113270000ST5X (Sterile) 0840113270000NS5E (Non-Sterile)

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	IIa	ISO 13485:2016
Rule:	7	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
BSI Group the Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands	2797	Annex IX of MDR 2017/745 Regulation	MDR 755273

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: 2024.01.24 10:52:07 -05'00'

PLACE: Caledonia, Michigan, USA

DATE: January 24, 2024