

Life Changing Innovation

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Aspen Medical Products, LLC	6481 Oak Canyon, Irvine, CA 92618 USA	US-MF-000001571

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/email
Emergo Europe	Prinsessegracht 20	NL-AR-000000116	+31.70.345.8570 - phone
	2514 AP The Hague		EmergoEurope@ul.com
	The Netherlands		

PRODUCT IDENTIFICATION		
Generic Device Group (GDG)		
SI		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Evergreen SI	See attached list	081824901 SI SK
Intended Purpose		
To provide Sacral stabilization.		

RISK CLASS FOR MEDICAL	DEVICES
Device Classification	Common Specifications
Class I	None
Rule 1	

Aspen Medical Products, LLC declares that the above-mentioned products meet the provision of the following EU legislation:

• MDR (EU) 2017/745

COMPANY REPRESENTATIVE: John Hamilton

TITLE: Vice President, Quality and Strategic Initiatives

SIGNATURE:

Mh

DATE: May 13, 2021

PLACE: Irvine, CA USA

6481 Oak Canyon Irvine, CA 92618

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REF	Description	UDI
36-2102	EVERGREEN SI, SMALL	818249012315
36-2104	EVERGREEN SI, MEDIUM	818249012322
36-2106	EVERGREEN SI, LARGE	818249012339