



Life Changing Innovation

EU & UK Declaration of Conformity

This European and UK 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

EU AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/email
Emergo Europe	Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

UK RESPONSIBLE PERSON			
Name of Company	Address	SRN	Telephone/email
Promedics Orthopaedics Ltd.	Port Glasgow Industrial Estate, Gareloch Road, Port Glasgow, Scotland, UK, PA14 5XH	GB-MF-000008558	01475 746400 - phone enquiries@promedics.co.uk

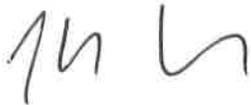
PRODUCT IDENTIFICATION		
Generic Device Group (GDG)		
SI		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Evergreen SI and Evergreen SI PRO	See attached list	081824901SISK
Intended Purpose		
To provide Sacral stabilization.		

RISK CLASS FOR MEDICAL DEVICES		
EU Device Classification	UK Device Classification	Common Specifications
Class I, Rule 1 per Annex VIII of MDR (EU) 2017/745	Class I per Part II of the UK MDR 2002, Annex IX (as modified by Part II of Schedule 2A to the UK MDR 2002)	None

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

- MDR (EU) 2017/745
- UK Medical Devices Regulations 2002

COMPANY REPRESENTATIVE: John Hamilton
TITLE: Vice President, Quality and Strategic Initiatives
PLACE: Irvine, CA USA

SIGNATURE: 

DATE: April 05, 2023

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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
36-2112	EVERGREEN SI PRO, SMALL	818249015651
36-2114	EVERGREEN SI PRO, MEDIUM	818249015668
36-2116	EVERGREEN SI PRO, LARGE	818249015675