

[Issue 5]

Declaration of Conformity EU

Manufacturer Details:	Unit C, Heltor Business Park, Old Newton Road, Heathfield, Newton Abbot Devon, TQ12 6RW, United Kingdom
Single Registration Number:	GB-MF-000003832
Authorised Representative:	Advena Limited, Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013. Malta
Authorised Representative SRN:	MT-AR-000000234
Basic UDI-DI:	506040783DisposablesAJ
Name of the Device:	Disposable Patient Lifting Slings
Intended Purpose:	Disposable Slings are intended to be used to transfer patients between bed, chair and/or wheelchair and provide head and torso support to patients.
Device variants:	Please see Appendix 1
Classification:	Class 1
EMDN:	V0805
GMDN code:	37408

Silvalea Limited are governed and conducts its manufacturing and design towards the guidelines set out in the International Standard ISO EN 10535 'Hoists for the transfer of disabled persons – Requirements and test methods', EN ISO 3758:2012, LOLER:1998.

This standard sets out the requirements for testing both the materials and the overall design of a sling to ensure conformity of the standards exacting requirements. As a UK manufacturer our guidelines are set out under the BS EN ISO 10535:2021 testing requirements.

The other harmonised standards used to comply with the Medical Device Regulation (EU) 2017/745 are ISO 13485:2016, ISO 14971:2019, EN 15223-1:2021 and 20417:2021.

Silvalea are pleased to advise that this international standard also covers the Australian Standard AS/NZS ISO 10535:2011. Silvalea are registered with the FDA, registration number: 3008720499. The conformity assessment route followed by Silvalea involved drawing up the Technical Documentation according to Annex II and Annex III of the (EU) 2017/745, issuing the Declaration of Conformity according to Annex IV and finally assigning the CE marking.

Declaration:

This declaration of conformity is issued under the sole responsibility of Silvalea Limited. We hereby declare that the medical device specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO:9001. All supporting documentation is retained at the premises of the manufacturer.

Approved by:

Gary Bevan
President, Silvalea Ltd

Place: Newton Abbot, United Kingdom

Date: 12.3.2025

Savaria, trading as Silvalea Ltd

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**EC REP**

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ISO 9001
ISO 14001

Cert No: 6982B3K

Appendix I – Device Variants

Code	Name	UDI Code	EMDN	GMDN
AV-DHECL	Disposable Sling High Easy Clips Large	5056387403984	V0805	37480
AV-DHECM	Disposable Sling High Easy Clips Medium	5056387403991	V0805	37480
AV-DHECS	Disposable Sling High Easy Clips Small	5056387404004	V0805	37480
AV-DHECXL	Disposable Sling High Easy Clips Extra Large	5056387404011	V0805	37480
DHEA-L-C	Disposable Sling Amputee High Easy Clip Large	5056387410364	V0805	37480
DHEA-L-L	Disposable Sling Amputee High Easy Loops Large	5056387410371	V0805	37480
DHEA-M-C	Disposable Sling Amputee High Easy Clip Medium	5056387410388	V0805	37480
DHEA-M-L	Disposable Sling Amputee High Easy Loops Medium	5056387410395	V0805	37480
DHEA-XL-C	Disposable Sling Amputee High Easy Clip Extra Large	5056387410401	V0805	37480
DHEA-XL-L	Disposable Sling Amputee High Easy Loops Extra Large	5056387410418	V0805	37480
DHECL	Disposable High Easy Clips Large	5056387410425	V0805	37480
DHECM	Disposable High Easy Clips Medium	5056387410432	V0805	37480
DHECS	Disposable High Easy Clips Small	5056387410449	V0805	37480
DHECXL	Disposable High Easy Clips Extra Large	5056387410456	V0805	37480
DHELL	Disposable High Easy Loops Large	5056387410463	V0805	37480
DHELM	Disposable High Easy Loops Medium	5056387410470	V0805	37480
DHELS	Disposable High Easy Loops Small	5056387410487	V0805	37480
DHELXL	Disposable High Easy Loops Extra Large	5056387410494	V0805	37480
DS-1SIZE-A	Disposable Stand-aid Sling No Fixings One Size	5056387410630	V0805	45382
DS-1SIZE-CLIP	Disposable Stand-aid Sling One Size Clips	5056387410647	V0805	45382
DS-1SIZE-LOOP	Disposable Stand-aid Sling One Size Loops	5056387410654	V0805	45382
M921505-L	Disposable High Easy LOOPS Large	5056387415864	V0805	37480
M921505-L-P	Disposable High Easy Poly LOOPS Large	5056387415871	V0805	37480
M921505-M	Disposable High Easy LOOPS MEDIUM	5056387415888	V0805	37480
M921505-M-P	Disposable High Easy Poly LOOPS Medium	5056387415895	V0805	37480
M921505-S	Disposable High Easy LOOPS Small	5056387415901	V0805	37480
M921505-XL	Disposable High Easy LOOPS Extra Large	5056387415918	V0805	37480
M921505-XS	Disposable High Easy LOOPS Extra Small	5056387415925	V0805	37480
M921505-XXL	Disposable High Easy LOOPS XXLarge	5056387415932	V0805	37480
M921512-L	Disposable High Easy CLIPS Large	5056387416250	V0805	37480
M921512-L-P	Disposable High Easy Poly CLIPS Large	5056387416267	V0805	37480
M921512-M	Disposable High Easy CLIPS Medium	5056387416274	V0805	37480
M921512-M-P	Disposable High Easy Poly CLIPS Medium	5056387416281	V0805	37480
M921512-S	Disposable High Easy CLIPS Small	5056387416298	V0805	37480
M921512-XL	Disposable High Easy CLIPS Extra Large	5056387416304	V0805	37480
M921512-XS	Disposable High Easy CLIPS Extra Small	5056387416311	V0805	37480
M921512-XXL	Disposable High Easy CLIPS Ex Ex Large	5056387416328	V0805	37480

Version History

Issue	Compiled by	Date	Description
04	J. Waszczuk	15.01.24	UDI Codes appendix added, update of EMDN codes.
05	J. Waszczuk	24.02.25	Change of manufacturer's details (address change).