

[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:	506040783SlideSheetsYG
Name of the Device:	Slide Sheets
Intended Purpose:	Slide Sheets are intended to be used for transferring, moving, or repositioning a patient which can include lateral transfers, turning a patient, transferring from bed.
Device variants:	Different colour options (Appendix I)
Classification:	Class 1
EMDN:	V0805
GMDN code:	37163

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 ISO 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 Code	GMDN
187	Emergency Transfer Sheet	5056387401607	V0805	37163
B-FLAT	Silva Supreme Flat Slide Sheets 200 x 150cm (pair)	5056387405117	V0805	37163
FLATBAR	Silva Supreme ® Flat Slide Sheets Royal 200 x 150cm (Pair)	5056387413204	V0805	37163
FLATBAR2	Flat Sheet Bariatric 198cm x 100cm (pair) 2oz Nylon	5056387413211	V0805	37163
FLATHAN1	Flat Sheet with Handles 152cm x 91cm (Pair)	5056387413228	V0805	37163
FLATHAN4	Flat Sheet with Handles 173cm x 73cm (Pair)	5056387413235	V0805	37163
FLATHAN5	Flat sheet With handles 198 cm x 71 cm (Pair)	5056387413242	V0805	37163
SCE-SLD1	Slide Sheet Size: 68 x 198cm	5056387426402	V0805	37163
SCE-SLD2	Slide Sheet 90 x 200cm (90cm Doubled)	5056387426419	V0805	37163
SCE-SLD3	Slide Sheet 140 x 200 cm (140cm doubled)	5056387426426	V0805	37163
SLDB-P	Cylindrical Slide Sheet Wide Poly (120 x 100cm)	5056387429021	V0805	37163
SLDBT	Cylindrical Slide Sheet with Taped Edges Wide 120 x 100cm	5056387429038	V0805	37163
SLDC	Cylindrical Slide Sheet Compact (70 x 68cm)	5056387429045	V0805	37163
SLDL-P	Cylindrical Slide Sheet Long Poly (145 x 68cm)	5056387429052	V0805	37163
SLDLT	Cylindrical Slide Sheet with Taped Edges Long 145 x 68cm	5056387429069	V0805	37163
SLDMINI	Cylindrical Slide Sheet Mini (60 x 41cm)	5056387429076	V0805	37163
SLDMITT	Silva Slide Mitt (Each)	5056387429083	V0805	37163
SLDSND-P	Cylindrical Slide Sheet Standard Poly (122 x 68cm)	5056387429090	V0805	37163
SLDSNDT	Cylindrical Slide Sheet with Taped Edges Yellow 122 x 68cm	5056387429106	V0805	37163
SLDUNI-P	Cylindrical Slide Sheet Universal Poly (87 x 68cm)	5056387429113	V0805	37163
SLDXL	Cylindrical Slide Sheet Xlong (198 x 68cm)	5056387429120	V0805	37163
TILBLUESLD9	Slide Sheet Blue 100cm x 70cm	5056387430508	V0805	37163
TILBLUESLD BAR1	Slide Sheet Bariatric Size 1 (175cm x 150cm)	5056387430515	V0805	37163
TILGREYSLD	Slide Sheet Grey 120 (Doubled) x 100cm	5056387430850	V0805	37163
TILNAVYSLD	Slide Sheet Navy 120 (Doubled) x 100cm	5056387430867	V0805	37163
TILNSSL	Non Slip Square for American Sling Large	5056387430874	V0805	37163
TILRDBSLD	Slide Sheet Red/Blue Tag 120cm x 100cm	5056387430881	V0805	37163
TILRDSLD	Slide Sheet Red 210cm x 100cm	5056387430898	V0805	37163
TILRDSLD1	Slide Sheet Red 90cm x 110cm	5056387430904	V0805	37163
TILREDSLD	Slide Sheet Red 87cm x 68cm	5056387430911	V0805	37163
TILREDSLD2	Slide Sheet Red 180cm x 150cm	5056387430928	V0805	37163
TILREDSLD3	Slide Sheet Red 120cm x 100cm	5056387430935	V0805	37163
TILREDSLD4	Slide Sheet Red 140cm x 110cm	5056387430942	V0805	37163
TILREDSLD5	Slide Sheet Red 122cm x 68cm	5056387430959	V0805	37163
TILREDSLD6	Slide Sheet Red 210cm X 100cm	5056387430966	V0805	37163
TILYELSLD2	Slide Sheet Yellow 120cm x 100cm	5056387431062	V0805	37163
TILYELSLD3	Slide Sheet Yellow 210cm x 100cm	5056387431079	V0805	37163
TILYELSLD4	Slide Sheet Yellow 152cm x 94cm	5056387431086	V0805	37163
TILYELSLD5	Slide Sheet Yellow 122cm x 68cm	5056387431093	V0805	37163
TILYELSLD6	Slide Sheet Yellow 144cm x 94cm	5056387431109	V0805	37163
TILYLBSLD	Slide Sheet Yellow/Blue Tag 210cm x 100cm	5056387431116	V0805	37163
TILYLBSLD2	Slide Sheet Yellow/Blue Tag 120cm x 100cm	5056387431123	V0805	37163

WFLAT	Wide Flat Sheets (Pair) 198 x 88cm	5056387433479	V0805	37163
WSLDLRG	One-Way Slide Sheet Large	5056387434711	V0805	37163
WSLDMED	One-Way Slide Sheet Medium	5056387434728	V0805	37163
WSLDSM	One-Way Slide Sheet Small	5056387434735	V0805	37163

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).