

Declaration of Conformity EU

Manufacturer Details:	Savaria, trading as Silvalea Ltd. 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:	Please see Appendix 2
Classification:	Class 1 - Rule 1: Non-invasive devices are classified as Class1. Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical the technical documentation laid out in Annexes II and III of the EU MDR 2017 / 745.

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: 31.03.2026

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturers name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Savaria, trading as Silvalea Ltd

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EC REP

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ISO 9001
ISO 14001

Cert No: 6982B3K

Appendix 1 - Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS)

Standard / CS / Document Name	Standard / CS / Document Name
2017 / 745	Regulation (EU 2017 / 745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices
EN ISO 13485:2016+A11:2021	Medical devices - quality management systems - requirements for regulatory purposes
EN ISO 14971:2019+A11:2021	Medical devices - application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - general requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix 2 – Device Variants

Code	Name	UDI Code	EMDN Code	GMDN
187	Emergency Transfer Sheet	5056387401607	V0805	66996
B-FLAT	Silva Supreme Flat Slide Sheets 200 x 150cm (pair)	5056387405117	V0805	66996
FLATBAR	Silva Supreme ® Flat Slide Sheets Royal 200 x 150cm (Pair)	5056387413204	V0805	66996
FLATBAR2	Flat Sheet Bariatric 198cm x 100cm (pair) 2oz Nylon	5056387413211	V0805	66996
FLATHAN1	Flat Sheet with Handles 152cm x 91cm (Pair)	5056387413228	V0805	66996
FLATHAN4	Flat Sheet with Handles 173cm x 73cm (Pair)	5056387413235	V0805	66996
FLATHAN5	Flat sheet With handles 198 cm x 71 cm (Pair)	5056387413242	V0805	66996
SCE-SLD1	Slide Sheet Size: 68 x 198cm	5056387426402	V0805	66996
SCE-SLD2	Slide Sheet 90 x 200cm (90cm Doubled)	5056387426419	V0805	66996
SCE-SLD3	Slide Sheet 140 x 200 cm (140cm doubled)	5056387426426	V0805	66996
SLDB-P	Cylindrical Slide Sheet Wide Poly (120 x 100cm)	5056387429021	V0805	66996
SLDBT	Cylindrical Slide Sheet with Taped Edges Wide 120 x 100cm	5056387429038	V0805	66996
SLDC	Cylindrical Slide Sheet Compact (70 x 68cm)	5056387429045	V0805	66996
SLDL-P	Cylindrical Slide Sheet Long Poly (145 x 68cm)	5056387429052	V0805	66996
SLDLT	Cylindrical Slide Sheet with Taped Edges Long 145 x 68cm	5056387429069	V0805	66996
SLDMINI	Cylindrical Slide Sheet Mini (60 x 41cm)	5056387429076	V0805	66996
SLDMITT	Silva Slide Mitt (Each)	5056387429083	V0805	66996
SLDSND-P	Cylindrical Slide Sheet Standard Poly (122 x 68cm)	5056387429090	V0805	66996
SLDSNDT	Cylindrical Slide Sheet with Taped Edges Yellow 122 x 68cm	5056387429106	V0805	66996
SLDUNI-P	Cylindrical Slide Sheet Universal Poly (87 x 68cm)	5056387429113	V0805	66996
SLDXL	Cylindrical Slide Sheet Xlong (198 x 68cm)	5056387429120	V0805	66996
TILBLUESLD9	Slide Sheet Blue 100cm x 70cm	5056387430508	V0805	66996
TILBLUESLD BAR1	Slide Sheet Bariatric Size 1 (175cm x 150cm)	5056387430515	V0805	66996
TILGREYSLD	Slide Sheet Grey 120 (Doubled) x 100cm	5056387430850	V0805	66996
TILNAVYSLD	Slide Sheet Navy 120 (Doubled) x 100cm	5056387430867	V0805	66996
TILNSSL	Non Slip Square for American Sling Large	5056387430874	V0805	66996
TILRDBSLD	Slide Sheet Red/Blue Tag 120cm x 100cm	5056387430881	V0805	66996
TILRDSLD	Slide Sheet Red 210cm x 100cm	5056387430898	V0805	66996
TILRDSLD1	Slide Sheet Red 90cm x 110cm	5056387430904	V0805	66996
TILREDSLD	Slide Sheet Red 87cm x 68cm	5056387430911	V0805	66996
TILREDSLD2	Slide Sheet Red 180cm x 150cm	5056387430928	V0805	66996
TILREDSLD3	Slide Sheet Red 120cm x 100cm	5056387430935	V0805	66996
TILREDSLD4	Slide Sheet Red 140cm x 110cm	5056387430942	V0805	66996
TILREDSLD5	Slide Sheet Red 122cm x 68cm	5056387430959	V0805	66996
TILREDSLD6	Slide Sheet Red 210cm X 100cm	5056387430966	V0805	66996
TILYELSLD2	Slide Sheet Yellow 120cm x 100cm	5056387431062	V0805	66996
TILYELSLD3	Slide Sheet Yellow 210cm x 100cm	5056387431079	V0805	66996
TILYELSLD4	Slide Sheet Yellow 152cm x 94cm	5056387431086	V0805	66996
TILYELSLD5	Slide Sheet Yellow 122cm x 68cm	5056387431093	V0805	66996
TILYELSLD6	Slide Sheet Yellow 144cm x 94cm	5056387431109	V0805	66996
TILYLBSLD	Slide Sheet Yellow/Blue Tag 210cm x 100cm	5056387431116	V0805	66996
TILYLBSLD2	Slide Sheet Yellow/Blue Tag 120cm x 100cm	5056387431123	V0805	66996

WFLAT	Wide Flat Sheets (Pair) 198 x 88cm	5056387433479	V0805	66996
WSDLRG	One-Way Slide Sheet Large	5056387434711	V0805	66996
WSLDMED	One-Way Slide Sheet Medium	5056387434728	V0805	66996
WSLDSM	One-Way Slide Sheet Small	5056387434735	V0805	66996

Version History

Issue	Compiled by	Date	Description
01	J. Robertson	21.01.21	New issue.
02	J. Robertson	17.02.21	Correction of MHRA Registration Number.
03	J. Robertson	13.10.23	Remove BSI logo's and replace with Alcumus Isoqar logo's.
04	J. Waszczuk	15.01.24	UDI codes appendix added and update of EMDN codes.
05	J. Waszczuk	24.02.25	Change of manufacturer's details (address change).
06	J. Robertson	31.03.26	Classification update, legal <i>Person with Responsibility Statement</i> added. Applicable standards added.