savaria

SILVALEA

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:	506040783ManualAidsD9
Name of the Device:	Manual Handling Aids
Intended Purpose:	Manual Handling Aids are intended to be used to transfer the patients between bed, chair and/or wheelchair.
Device variants:	Please see Appendix 2
Classific tion:	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**
Unit C, Heltor Business Park, Old Newton Road, Heathfield
Newton Abbot, Devon, TQ12 6RW, United Kingdom
E: customerservices@silvalea.com I **T**: +44 (0)330 024 1045 I **W**: silvalea.com
Registration Number: 04350939 I VAT Number: GB797412786

UK CA CE

EC REP

Advena Ltd
Tower Business Centre
2nd Floor, Tower Street
Swatar, BKR 4013, Malta

REGISTERED ISOQAR

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 Specific tions (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
062ALRG	Manual Transfer Sling Poly Large	5056387401157	V0805	40538
062AMED	Manual Transfer Sling Poly Medium	5056387401164	V0805	40538
062ASM	Manual Transfer Sling Poly Small	5056387401171	V0805	40538
062AXLRG	Manual Transfer Sling Poly Ex Large	5056387401188	V0805	40538
062AXSM	Manual Transfer Sling Poly Ex Small	5056387401201	V0805	40538
062AXXL	Manual Transfer Sling Poly Ex Ex Large	5056387401218	V0805	40538
062AXXSM	Manual Transfer Sling Poly Ex Ex Small	5056387401225	V0805	40538
062AXXXS	Manual Transfer Sling Poly Ex Ex Ex Small	5056387401232	V0805	40538
062BL	Manual Transfer Sling Mesh Large	5056387401249	V0805	40538
062BM	Manual Transfer Sling Mesh Medium	5056387401256	V0805	40538
062BS	Manual Transfer Sling Mesh Small	5056387401263	V0805	40538
062BXL	Manual Transfer Sling Mesh Extra Large	5056387401270	V0805	40538
062BXS	Manual Transfer Sling Mesh Extra Small	5056387401287	V0805	40538
062BXXS	Manual Transfer Sling Mesh Ex Ex Small	5056387401294	V0805	40538
062BXXXS	Manual Transfer Sling Mesh Ex Ex Ex Small	5056387401300	V0805	40538
062FLRG	Manual Transfer Sling Superfine Plus Large	5056387401317	V0805	40538
062FMED	Manual Transfer Sling Superfine Plus Medium	5056387401324	V0805	40538
062FSM	Manual Transfer Sling Superfine Plus Small	5056387401331	V0805	40538
062FXLRG	Manual Transfer Sling Superfine Plus Extra Large	5056387401348	V0805	40538
062FXSM	Manual Transfer Sling Superfine Plus Extra Small	5056387401355	V0805	40538
062FXXSM	Manual Transfer Sling Superfine Plus Ex Ex Small	5056387401362	V0805	40538
062FXXXS	Manual Transfer Sling Superfine Plus Ex Ex Ex Small	5056387401379	V0805	40538
062PBLK-M	Manual Transfer Sling Poly Black Medium	5056387401393	V0805	40538
062PBLK-S	Manual Transfer Sling Poly Black Small	5056387401409	V0805	40538
062-Z-L	Manual Transfer Sling S/fine Plus Turquoise Large	5056387401478	V0805	40538
062-Z-M	Manual Transfer Sling S/fine Plus Turquoise Medium	5056387401485	V0805	40538
062-Z-S	Manual Transfer Sling S/fine Plus Turquoise Small	5056387401492	V0805	40538
062-Z-XS	Manual Transfer Sling S/fine Plus Turquoise Ex Small	5056387401508	V0805	40538
062-Z-XXS	Manual Transfer Sling S/fine Plus Turquoise Ex Ex Small	5056387401515	V0805	40538
062-Z-XXXS	Manual Transfer Sling S/Fine Plus Turquoise Ex Ex Ex Small	5056387401522	V0805	40538
187	Emergency Transfer Sheet	5056387401607	V0805	37163
193GL	Deluxe Safety Grab Belt Large	5056387401614	V0805	40538
193GS	Deluxe Safety Grab Belt Small	5056387401621	V0805	40538
193GXL	Deluxe Safety Grab Belt Extra Large	5056387401638	V0805	40538
193GXS	Deluxe Safety Grab Belt Extra Small	5056387401645	V0805	40538
193GXXL	Deluxe Safety Grab Belt Ex Ex Large	5056387401652	V0805	40538
193GXXS	Deluxe Safety Grab Belt Ex Ex Small	5056387401669	V0805	40538
193M2L	Deluxe Safety Grab Belt Medium / Large	5056387401676	V0805	40538
193S2M	Deluxe Safety Grab Belt Small / Medium	5056387401744	V0805	40538
193SND	Deluxe Safety Grab Belt Standard	5056387401751	V0805	40538
201	Back & Leg Raiser	5056387401812	V0805	40538
201GT	Back/Leg Raiser	5056387401829	V0805	40538
BIRTH1	Birthing Sling Manual	5056387405148	V0805	40538
BIRTH2	Birthing Sling Hoistable Version One Size	5056387405155	V0805	40538

SIL-TL-LRG	Silva Travel Lite Superfine Double Layer Large	5056387428895	V0805	37480
SIL-TL-MED	Silva Travel-Lite Medium	5056387428901	V0805	37480
SIL-TL-SM	Silva Travel Lite Small	5056387428918	V0805	37480
SIL-TL-XSM	Silva Travel Lite Extra Small	5056387428925	V0805	37480
SIL-TL-XXSM	Silva Travel Lite Extra Extra Small	5056387428932	V0805	37480
SIL-TL-XXXSM	Silva Travel Lite XXX Small	5056387428949	V0805	37480

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 *Person with Responsibillity Statement* added. Applicable standards added.