[Issue 4]

Declaration of Conformity EU

Manufacturer Details:	Silvalea Limited, Units 1-4 Silverhills Buildings, Silverhills Road, Decoy Industrial Estate, Newton Abbot, Devon, UK, TQ12 5LZ
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:	Different fabric options (Appendix I)
Classification:	Class 1
EMDN:	V0805
GMDN codes:	40538, 37163, 37164, 37480

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
Director, Newton Abbot TQ12 5LZ, UK.
On Behalf of Silvalea Limited

Date: 24.1.2024

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Cert No. 6982B3K