[Issue 4]

Declaration of Conformity

Manufacturer Details:	Silvalea Limited, Units 1-4 Silverhills Buildings, Silverhills Road, Decoy Industrial Estate, Newton Abbot, Devon, UK, TQ12 5LZ
Authorised Representative:	Advena Limited, Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013. Malta
Authorised Representative SRN:	MT-AR-000000234
UDI-DI:	506040783LiftingSlings33
Name of the Device:	Patient Lifting Sling
Device variants:	Different fabric and colour options, additions: head support, waist/chest support, hip tapes (Appendix I)
Classification:	Class 1
Notified Body Details:	MHRA, 10 South Colonnade, Canary Wharf, London, UK, E14 4PU
MHRA Number:	224
GMDN Codes:	37163, 37164, 37480, 40538, 45382

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.'

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.

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.

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, UK

Date: 24.1.2024

Tel: +44 (0)1626 331 655
Email: sales@silvalea.com
Website: www.silvalea.com

VAT Reg No. GB 797 412786 Company No: 04350939
Silverhills Buildings, Decoy Ind. Estate, Newton Abbot, Devon, TQ12 5LZ, UK
EC REP ADVENA Ltd. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013. Malta

Cert No. 6982B3K