

International Sling Compatibility and Safety Statement

Since 1993, Silvalea has manufactured patient lifting slings and manual handling products for lift manufacturers worldwide.

Silvalea slings are intended as replacement slings and have been designed and manufactured specifically to allow safe, secure use on a variety of lifts. Interchangeability of slings can provide critical value and flexibility to healthcare providers and individual users.

Silvalea conducts research on leading manufacturers' lifts to ensure compliance and compatibility. To ensure the highest level of safety possible, the appropriateness of any specific sling style/size with any device for a particular user should never be assumed without a full assessment by a competent assessor.

- Silvalea governs its own research, design and manufacturing following the guidelines and testing requirements set out in ISO 9001 and ISO 10535:2006 Hoists for the Transfer of Disabled Persons: Testing Requirements. Certification number is FM35946.
- All design and testing information is electronically documented for reporting purposes and available if requested by regulatory bodies including FDA, ISO, Health Canada and Medicines and Healthcare Products Regulatory Agency (UK).
- Silvalea is registered with the Food & Drug Administration within the US. Certification number is 3008720499.
- All products, where applicable and following guidelines laid out by the UK MHRA under the Medical Devices Directive 93/42/EEC (2002) carry a CE mark, and from 2021 will also carry a CA mark for products in use within the UK. Certification number is CA016767.
- Silvalea products are classified as a Class 1 Medical Device in the US, Canada and the UK.
- Silvalea products fall under the GMDN (Global Medical Device Nomenclature) database.
- GS1 labeling is available. Company prefix number is 506040783.
- Guidance on risk assessment and competency can be found from your country-specific health and safety regulators.
- Silvalea takes responsibility to uphold industry standards ensuring that distributors, contractors, healthcare providers and end users receive products that are safe and fit for purpose, and clearly labeled with the product design, spreader bar type compatibility, safe working load and washing instructions.
- Silvalea's Instructions of Use advise care providers to visibly check each sling or lifting device for general wear and tear before each use.
- All Silvalea slings carry a unique service label for quick and easy identification of semi-annual or annual sling checks.
- If the safety or integrity of a lifting device is in doubt, it must be withdrawn from use immediately in accordance with the Instructions of Use.
- A sling should always be used in conjunction with its Instructions of Use and compatibility is dependent on the lift type. For example, a 2-point loop fixing spreader bar is for those slings with loop slings only and a stud (wishbone style) spreader bar is for clip slings only.

