

EST. 1993

Sling & Hoist Compatibility - Jan 2018

Our Standards as a Manufacturer of Medical Devices. Silvalea has manufactured replacement slings and manual handling products for many hoist manufacturers, within the UK, Europe and North America for many years.

Throughout the years, interchangeable slings have been an issue for many healthcare professionals. This is an understandable concern with the growing number of sling manufacturers within the market. There may be reluctance by certain hoist manufacturers to accept the interchange-ability of slings or hoists; however, with a thorough written risk assessment conducted by a competent assessor (LOLER 1998/PUWER 1998), the use of interchanging slings can provide the right solution for a client's specific need.

Further guidance on risk assessments and competency can be found under the Provision and Use of Work Equipment Regulations (PUWER 5 Dec 1998)

Silvalea is governed and conducts its manufacturing and design towards the guidelines set out in 'International Standard 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 based manufacturer our guidelines are set out under the **BS EN ISO 10535:2006** testing requirements.

All testing and design technical information is carefully stored and documented and although this information is commercially sensitive if required Silvalea has a legal and ethical obligation to release technical information to our governing body The Medicines and Healthcare Products Regulatory Agency (MHRA) and any other relevant authority body.

Silvalea manufactures all its products following the internal British standard directive BS EN ISO 9001; which covers both manufacturing and design quality standards. Silvalea's certification number is FM35946.

Alongside these standards all products, where applicable, carry a CE (Conformity European) mark '(Silvalea CE Certificate Number: CA001159)' following guidelines set out by the Medicines and Healthcare Products Regulatory Agency (MHRA) under the 'Medical Devices Directive 93/42/EEC (13 June 2002)'.

Unique Device Identification (UDI) Protocol

There are a number of worldwide rulings to help improve the identification of medical devices in order to ensure the identity of the manufacturer or distributor of medical devices along with ensuring the specific details of the devices are easily and quickly identifiable, these measures have been introduced to improve patient safety and ensure medical devices are correctly labelled within the global marketplace.

These measures are part of a new objective to safeguard patient safety and are being adopted by many governing bodies such as MHRA within the UK, FDA within the United States and many others worldwide.

Silvalea take our responsibilities as a manufacturer very seriously and we endeavor to uphold the protocols to ensure that our distributors, contractors, hospitals and end users receive products clearly labelled.

Silvalea products are classified as a Class 1 medical device. In order for healthcare professionals to identify medical devices in the field, Silvalea products fall under the GMDN (Global Medical Device Nomenclature) Number: 40535 – Lift Patient Transfer: Sling/Harness/Strap.

In order to comply with current and on-going unique device identification (UDI) regulations, Silvalea can confirm our registration under GS1 and our company prefix number is 506040783.

Supply chain labels will be issued in order to comply with the GS1 labelling requirements to ensure compliance for organizations such as the NHS.

Following guidelines by 'Lifting Operations and Lifting Equipment Regulations (LOLER 5 Dec 1998)' Silvalea Ltd ensure that each product manufactured is safe and fit for purpose, visibly marked with any relevant information required for a safe transfer, including information of the style of the replacement sling, the maximum weight limit, inspection instructions and unique serial numbers for identification. Under the LOLER regulations periodic 6-monthly checks should be undertaken and Silvalea Ltd were one of the first manufacturers to add a 'Service Label' onto their replacement slings to help identify LOLER checks.

Public and Product Liability

Silvalea insurers provide a combined Public and Products Liability cover to the sum of £10 million in respect of injury or damage in the use of slings supplied by our company, for use on hoists manufactured by major companies. They state that:

'They are aware that slings and other equipment, manufactured by Silvalea are designed for and used on hoists and other equipment manufactured by independent companies. This will not prejudice the cover provided and Silvalea's legal liability for damage, accident or injury resulting from defects in manufacture or operation of equipment is provided.'

Silvalea are able to provide a copy of our latest insurance certificate upon request.

Silvalea conducts regular research and testing to ensure that Silvalea Ltd replacement slings meet with the requirements of the market leading hoists. Some of these hoists are listed below as a guide. However, this list is not exhaustive nor is it specific to a particular sling.

Most slings are only suitable for a group of specific hoists such as hoists with stud fixings or alternatively those hoists with a loop fixing spreader bar only. The interchangeability of Silvalea slings across different hoist manufacturers should not be **ASSUMED** but should be tested and a risk assessment conducted by a competent assessor (LOLER 1998/PUWER 1998). All of our slings carry an 'attachment type' guide and also an 'installation options' guide to help identify compatible hoists. PLEASE check each individual sling attachment type and installation options before ordering.

As stated above 'compatibility' is very much dependent on sling type and hoist, however there are a number of things to be considered apart from fixing type, such as attachment type/spreader bar configuration (loop straight/coat or stud fixing spreader bar), end user distance from attachment, end user angle, end user posture, size, security and stability of fixing.

Allegro, Arjo, BHM, Caricare Nopac, Carters Invacare, Chiltern Invadex, Days Healthcare (DMA), Doherty, Ergolet, Faaborg, Freeway, Guldmann, Helping Hands, Horcher, Hoyer® (Joerns), Huntleigh (HNE), Invacare, Liftech, Liko, Locomotor, Molift, Moorcare, Nordic Care, Opemed, Osprey, Oxford, Park-Lite Range, Prism, Promed, Romedic, Spectra Group, Talley, Taylors, Wessex, Westholme