# DECLARATION OF CONFORMITY

EU MDR 2017/745 | UK MDR 2002 (as amended)

*CE Marking & UKCA Marking*

This Declaration of Conformity is issued under the sole responsibility of the manufacturer named below. It covers both CE marking (for the EU and Republic of Ireland market under Regulation (EU) 2017/745) and UKCA marking (for the Great Britain market under The Medical Devices Regulations 2002, SI 2002/618, as amended). Lisclare Limited is established in Northern Ireland and holds dual market access under the Windsor Framework.

## 1. Manufacturer Details

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| **Legal Manufacturer** | Lisclare Limited |
| **Registered Address** | 38 Montgomery Road, Belfast, BT6 9HL, Northern Ireland, United Kingdom |
| **Company Registration No.** | NI031180 (Companies House, Northern Ireland) |
| **Website** | www.lisclare.com |
| **EUDAMED Manufacturer ID** | Single Registration Number (SRN): XI-MF-000031978 |
| **MHRA Manufacturer ID** | Account Number: 2126 |

## 2. Manufacturing

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| **Manufacturing Arrangement** | These products are manufactured under contract by a third-party manufacturer operating a Quality Management System certified to ISO 13485:2016. Lisclare Limited retains full legal and regulatory responsibility as the placing-on-market manufacturer. |
| **Supplier Documentation** | The identity, address, and full qualification details of the contract manufacturer are held within the Lisclare Limited Technical File and Quality Management System records. These documents are available for inspection by competent authorities (MHRA / national market surveillance authorities) upon formal request. |

## 3. Product Identification

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| **Brand Name** | MySling |
| **Product Description** | Non-rigid body-support units: Patient Slings (non-launderable). |
| **Product Ranges** | Styles such as High-Back and Universal covering a variety of applications with both loop and clip attachments. |
| **Available Sizes** | XXS, XS, S, M, L, XL, XXL (range varies by product type) |
| **Intended Purpose** | Non-rigid body-support units designed to safely transfer and/or support a person with limited mobility. Intended for use in combination with a patient hoist or standing aid using loop-to-hook attachments with 2 or 4 connection points. |
| **EMDN Code & Term** | V0805038002 - Rigid supports for lifts (harnesses) |
| **GMDN Code & Term** | 37480 - General-purpose patient lifting system sling/harness |
| **Basic UDI-DI** | **506075020MYSLINGLR** |
| **Device Classification** | Class I - MDR 2017/745, Annex VIII Class I<br>- UK MDR 2002 (as amended) |

## 4. Regulatory Framework & Conformity Assessment

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| **CE Marking — European Union** | |
| **Regulation** | Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices (EU MDR) |
| **Conformity Assessment** | Class I - Self-declaration by manufacturer in accordance with Article 52(7) and Annex IV of EU MDR 2017/745. No Notified Body involvement required. |
| **EUDAMED Actor Identification** | XI-MF-000031978. |
| **UKCA Marking — Great Britain** | |
| **Regulation** | The Medical Devices Regulations 2002 (SI 2002/618), as amended by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and subsequent amendments. |
| **Conformity Assessment** | Class I — Self-declaration by manufacturer. No Approved Body involvement required. |
| **MHRA Account Number** | 2126 |
| **Northern Ireland — Windsor Framework** | |
| **Dual Market Access** | Lisclare Limited is established in Northern Ireland and operates under the Windsor Framework. The CE mark is valid for the Northern Ireland market and the EU single market. The UKCA mark is valid for Great Britain. |

## 5. Applied Harmonised & Designated Standards

The following standards have been applied to demonstrate conformity with the General Safety and Performance Requirements (GSPRs) of EU MDR 2017/745 (Annex I) and the equivalent Essential Requirements of UK MDR 2002. The harmonised standards listed below are cited in the Official Journal of the European Union (OJEU). The corresponding UK designated standards are substantially identical in technical content.

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| **Product Safety & Performance** | |
| **ISO 10535:2021** | Assistive products - Hoists for the transfer of persons - Requirements and test methods. Covers body-support units (slings) including structural integrity, load capacity, attachment systems, and labelling requirements. Primary product standard. |
| **Risk Management** | |
| **EN ISO 14971:2019 + A11:2021** | Medical devices - Application of risk management to medical devices. Harmonised standard under EU MDR. Demonstrates conformity with GSPRs 3, 4, 5, 8 and 9. A11 amendment provides Annex Z mapping to MDR GSPRs. |
| **Information Supplied by Manufacturer (Labelling & IFU)** | |
| **ISO 20417:2021** | Medical devices - Information to be supplied by the manufacturer. Replaces EN 1041:2008+A1:2013 (withdrawn). Sets requirements for labelling, Instructions for Use (IFU), and all accompanying information. |
| **EN ISO 15223-1:2021** | Medical devices - Symbols to be used with information to be supplied by the manufacturer. Harmonised under EU MDR. Defines standardised symbols used on device labels and packaging. |
| **Care Labelling (Textile)** | |

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| **ISO 3758:2012** | Textiles - Care labelling code using symbols. Referenced within ISO 10535:2021 for care and maintenance instructions applicable to fabric sling components. |

## 6. Declaration

Lisclare Limited hereby declares, under its sole responsibility, that the products identified in Section 3 of this document meets all applicable requirements of:

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| **(a) EU Market** | Regulation (EU) 2017/745 on Medical Devices (EU MDR), including all applicable General Safety and Performance Requirements set out in Annex I. The device is CE marked accordingly. |
| **(b) GB Market** | The Medical Devices Regulations 2002 (SI 2002/618, as amended). The device is UKCA marked accordingly. |

*This declaration is supported by a Technical File held at the manufacturer's registered address. The Technical File is available for inspection by competent authorities upon request.*

## 7. Authorised Signatory

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| **Signed on behalf of** | Lisclare Limited |
| **Registered Address** | 38 Montgomery Road, Belfast, BT6 9HL, Northern Ireland, UK |
| **Date of Issue** | 01 Sep 2025 |
| **Date of First Declaration** | 08 Dec 2017 |
| **Document Reference** | DOC-MS-01 Version 3.0 |

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| **Signature:** | |
| **Name:** | Stephen **Hall** |
| **Position:** | Managing Director |
| **Date:** | 01 Sep 2025 |

## Annex A - Product Reference List

*The following product ranges and sizes are covered by this Declaration of Conformity.*

| Style | Product Code | Description |
|---|---|---|
| ActiveSling | 2500053 | MySling ActiveSling (loop), S |
| | 2500054 | MySling ActiveSling (loop), M |
| | 2500055 | MySling ActiveSling (loop), L |
| | 2500056 | MySling ActiveSling (loop), XL |
| | 2500057 | MySling ActiveSling (loop), XXL |
| | 2500058 | MySling ActiveSling (loop), XXXL |
| Amputee | 2500020 | MySling Amputee (loop), S |
| | 2500021 | MySling Amputee (loop), M |
| | 2500022 | MySling Amputee (loop), L |
| | 2500023 | MySling Amputee (loop), XL |
| | 2511030 | MySling Amputee (clip), S - with aperture |
| | 2511031 | MySling Amputee (clip), M - with aperture |
| | 2511032 | MySling Amputee (clip), L - with aperture |
| | 2511033 | MySling Amputee (clip), XL - with aperture |
| Amputee No Ap | 2511130 | MySling Amputee, no commode aperture (clips) -S |
| | 2511131 | MySling Amputee, no commode aperture (clips) -M |
| | 2511132 | MySling Amputee, no commode aperture (clips) -L |
| | 2511133 | MySling Amputee, no commode aperture (clips) -XL |
| Hammock | 2501010 | MySling Hammock (loop), S |
| | 2501011 | MySling Hammock (loop), M |
| | 2501012 | MySling Hammock (loop) ,L |
| | 2501013 | MySling Hammock (loop), XL |
| | 2501014 | MySling Hammock (loop), XXL |
| Hammock (no aperture) | 2501110 | MySling Hammock Sling, no comm. aperture (loop) -S |
| | 2501111 | MySling Hammock Sling, no comm. Aperture (loop) -M |
| | 2501112 | MySling Hammock Sling, no comm. aperture (loop) -L |
| | 2501113 | MySling Hammock, no comm. aperture (loop) -XL |
| | 2501114 | MySling Hammock, no comm. aperture (loop) -XXL |
| High-Back | 2500005 | MySling High-Back (loop), S |
| | 2500006 | MySling High-Back (loop), M |
| | 2500007 | MySling High-Back (loop), L |
| | 2500008 | MySling High-Back (loop), XL |
| | 2500009 | MySling High-Back (loop), XXL |
| | 2500051 | MySling HB paediatric (loop), XXS |
| | 2500052 | MySling HB paediatric (loop), XS-P |
| | 2510005 | MySling High-Back (clip), S |
| | 2510006 | MySling High-Back (clip), M |
| | 2510007 | MySling High-Back (clip), L |
| | 2510008 | MySling High-Back (clip), XL |
| | 2510009 | MySling High-Back (clip), XXL |
| | 2510051 | MySling HB paediatric (clip), XXS |
| | 2510052 | MySling HB paediatric (clip), XS-P |
| High-Back Supports | 2500105 | MySling HB sling w/ HS plastic insert (loop) -S |

| Style | Product Code | Description |
|---|---|---|
| | 2500106 | MySling HB sling w/ HS plastic insert (loop) -M |
| | 2500107 | MySling HB sling w/ HS plastic insert (loop) -L |
| | 2500108 | MySling HB sling w/ HS plastic insert (loop) -XL |
| | 2510104 | MySling HB sling w/ HS plastic insert (clips) -XS |
| | 2510105 | MySling HB sling w/ HS plastic insert (clips) -S |
| | 2510106 | MySling HB sling w/ HS plastic insert (clips) -M |
| | 2510107 | MySling HB sling w/ HS plastic insert (clips) -L |
| | 2510108 | MySling HB sling w/ HS plastic insert (clips) -XL |
| Hygiene | 2500040 | MySling Hygiene (loop), S |
| | 2500041 | MySling Hygiene (loop), M |
| | 2500042 | MySling Hygiene (loop), L |
| | 2500043 | MySling Hygiene (loop), XL |
| Limb Lifter | 2501120 | MySling Limb Lifter Sling, (loop) |
| | 2501121 | MySling Limb Lifter Sling, reg (loop) |
| | 2501122 | MySling Limb Lifter Sling, bari (loop) |
| RehabSling | 2500035 | MySling RehabSling (loop), S |
| | 2500036 | MySling RehabSling (loop), M |
| | 2500037 | MySling RehabSling (loop), L |
| | 2500038 | MySling RehabSling (loop), XL |
| Sit-to-stand | 2500030 | MySling Sit-to-stand (loop), S |
| | 2500031 | MySling Sit-to-stand (loop), M |
| | 2500032 | MySling Sit-to-stand (loop), L |
| | 2500033 | MySling Sit-to-stand (loop), XL |
| | 2500034 | MySling Sit-to-stand (loop), Mix (1S,4M,4L) |
| | 2510030 | MySling Sit-to-stand (clip), S |
| | 2510031 | MySling Sit-to-stand (clip), M |
| | 2510032 | MySling Sit-to-stand (clip), L |
| | 2510033 | MySling Sit-to-stand (clip), XL |
| | 2510039 | MySling Sit-to-stand (clip), Mix (1S,4M,4L) |
| Ultra Sling | 2500210 | MySling - Ultra Sling XXL, 600kg |
| | 2500220 | MySling - Ultra Sling XXXL, 600kg |
| Universal | 2500000 | MySling Universal (loop), S |
| | 2500001 | MySling Universal (loop), M |
| | 2500002 | MySling Universal (loop), L |
| | 2500003 | MySling Universal (loop), XL |
| | 2500004 | MySling Universal (loop), XXL |
| | 2500011 | MySling Universal (loop), XXS |
| | 2500012 | MySling Universal (loop), XS |
| | 2512001 | MySling Universal (clip), XXS |
| | 2512002 | MySling Universal (clip), XS |
| | 2512003 | MySling Universal (clip), S |
| | 2512004 | MySling Universal (clip), M |
| | 2512005 | MySling Universal (clip), L |
| | 2512006 | MySling Universal (clip), XL |
| | 2512007 | MySling Universal (clip), XXL |

| Style | Product Code | Description |
|---|---|---|
| Universal (NI) | 2501201 | MySling Plus Universal Sling - XS |
| | 2501202 | MySling Plus Universal Sling - S |
| | 2501203 | MySling Plus Universal Sling - M |
| | 2501204 | MySling Plus Universal Sling - L |
| | 2501205 | MySling Plus Universal Sling - XL |