# EC Certificate
## Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.: **10749-2017-CE-RGC-NA-PS Rev. 1.0**

Project No.: **PRJC-224189-2010-PRC-TWN**

Valid Until: **06 December 2022**

This is to certify that the quality system of:

**Carilex Medical, Inc.**
No.77, Keji 1st Rd., Guishan Dist., Taoyuan City (333), Taiwan (R.O.C.)

For design, production and final product inspection/testing of:

**Anti-decubitus devices, cushions & pumps, air flotation mattresses**

Has been assessed with respect to:

**The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
**Høvik, 31 January 2018**

NORWEGIAN ACCREDITATION
**PROD 021**
**Notified Body No.: 2460**

For:
**DNV GL NEMKO PRESAFE AS**

**Villy Rønneberg**

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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### Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Issue Date |
|---|---|---|
| 0.0 | Initial certificate | 2017-12-06 |
| 1.0 | Changed EU Representative | 2018-01-31 |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|---|---|---|
| Anti-decubitus devices, cushions & pumps, air flotation mattresses | S2XXX series (XXX only change in size, color, brand) | IIa |

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

| Site Name | Address |
|---|---|
| Carilex Medical, Inc. | No.77, Keji 1st Rd., Guishan Dist., Taoyuan City (333), Taiwan (R.O.C.) |

### EU Representative

| Name | Address |
|---|---|
| Carilex Medical GmbH | Hanauer Landstraße 291 B 60314 Frankfurt am Main, Germany |

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| **10749-2017-CE-RGC-NA-PS Rev. 1.0** | **PRJC-224189-2010-PRC-TWN** | **06 December 2022** |

### Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

### Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate