EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
C542168 NoMA TWN	23 December 2022	22 December 2027

This is to certify that the quality system of

Carilex Medical, Inc.

No. 77, Keji 1st Rd., Guishan Dist., Taoyuan City, 333, Taiwan

SRN: **TW-MF-000002145**

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

Anti-decubitus Air Alternating Pressure Device and System with Accessories_ Medical Electrical Air Pump, Mattress/Cushion

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 24 May 2023

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2704686	23 December 2022
1.0	EAR Address Change	2896074	24 May 2023

Products covered by this Certificate:

Product Description	Product Name	Class*
Anti-decubitus Air Alternating Pressure Device and System with Accessories, Medical Electrical Air Pump, Mattress/Cushion Basic UDI-DI: 471987369S2XXXS4	Anti-decubitus Air Alternating Pressure Device (1). Model Name: TheraFlo AP Accessories - Medical Electrical Air Pump Catalogue Number: S2002-3055 - Mattress: Catalogue Number: S2001-2440 (2). Model Name: TheraFlo AP 7&9 Accessories - Medical Electrical Air Pump Catalogue Number: S2002-3115 - Mattress: Catalogue Number: S2001-2580 S2001-2590 S2001-2600 S2001-2610 S2001-2620 S2001-2630 S2001-2640 S2001-2650 (3). Model Name: Dual GT Accessories - Medical Electrical Air Pump Catalogue Number: S2103-3035 S2103-3073	IIa

	S2103-3087 S2103-3103 S2103-3117 - Mattress: Catalogue Number: S2103-2010 S2103-2020 S2103-5020 (4). Model Name: Centrius Accessories - Medical Electrical Air Pump Catalogue Number: S2106-3107 S2106-3083 S2106-3123 S2106-3157 - Mattress: Catalogue Number: S2101-2320 (5). Model Name: Entrix NX Accessories - Medical Electrical Air Pump Catalogue Number: S2202-3115 - Mattress: Catalogue Number: S2202-2010 S2202-2030 S2202-2070 S2202-2210 S2202-2340 S2202-2430 S2202-2440 S2202-2450 S2202-2520 S2202-5080 S2202-5090 (6). Model Name: CariChair Accessories - Medical Electrical Air Pump Catalogue Number: S2303-3042	

	- Cushion: Catalogue Number: S2303-2050 S2303-2060 (7). Model Name: CozinyPlus Accessories - Medical Electrical Air Pump Catalogue Number: S2304-3022 S2304-3042 - Mattress: Catalogue Number: S2302-2010 S2302-2020 S2302-2030 S2302-5010 Anti-decubitus Air Alternating Pressure System (1). Model Name: DualPlus Catalogue Number: S2102-0C15 S2102-0C25 Accessories - Medical Electrical Air Pump Catalogue Number: S2102-3065 S2602-3063 - Mattress Catalogue Number: S2102-2010 S2102-2020 S2602-2040 (2). Model Name: RevoPlus Catalogue Number: S2205-0C15 S2205-0C25 S2205-0C26 S2205-0C27 Accessories - Medical Electrical Air Pump Catalogue Number:	

	S2205-3025 - Mattress Catalogue Number: S2205-2010 S2205-2020	

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

EU Representative
Emergo Europe B.V. AR Actor ID: NL-AR-000000116 Westervoortsedijk 60, 6827 AT Arnhem,The Netherlands

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

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

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

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