

EU Declaration of Conformity

Certificate No. DOC-25022001-EN

Manufacturer Name	Carilex Medical, Inc.
Manufacturer Address	No. 77, Keji 1st Rd., Guishan Dist., Taoyuan City, 333, Taiwan
SRN (Single Registration Number)	TW-MF-000002145
EU REP	Emergo Europe B.V. AR Actor ID: NL-AR-000000116
EU REP Address	Westervoortsedijk 60,6827 AT Arnhem, The Netherlands
Device List	Refer to Appendix II
MDA Code	0318
MDN Code	1214
MDS Code	1009
MDT Code	2004 / 2010 / 2011
Classification Rule	Class I (in accordance with Rule 13 of Annex VIII of MDR (EU) 2017/745)
Conformity assessment route	Conformity assessment based on the description on Annex IX, (Chapter I&III) of Regulation (EU) 2017/745 on medical device

This declaration of conformity is issued under the sole responsibility of Carilex Medical, Inc. We hereby declare that the medical devices covered by the present declaration are in conformity with Medical Device Regulation 2017/745 (MDR). The products are designed, manufactured, inspected, tested, and released according to the approved Quality System established in accordance with EN ISO 13485:2016 and Article 10—General Obligation of Manufacturer in MDR.

All supporting documentation is retained at the premises of the manufacturer.

Issued by

K.K Liao_ the Director of R&D division

Handwritten signature in blue ink and the date 2025.2.20.

February 20 2025

Taoyuan

APPENDIX I

Standard(s) to which Conformity is Declared:

- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23 : Tests for skin irritation

Harmonized Standard(s) to which Conformity is Declared:

- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971:2019 Medical devices - Application of risk management to medical devices.
- EN ISO 20417:2021 Medical devices--Information to be supplied by the manufacturer
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes
- EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
- EN 60601-1:2006+A1:2013 Medical electrical equipment- Part 1: General requirement for basic safety and essential performance
- EN 60601-1-2:2015 Medical electrical equipment- Part 1- 2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic disturbances – Requirements and tests
- EN 60601-1-6:2010+A1:2015 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 60601-1-11:2015 applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems for use in the home healthcare environment.
- EN ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

CS to which Conformity is Declared: None



Carilex Medical, Inc.
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Taoyuan City, 333, Taiwan

APPENDIX II

Product: Anti-decubitus Air Alternating Pressure Device and System with Accessories_ Medical Electrical Air Pump, Mattress/Cushion		
Trade Name: Carilex		
Intended Purpose: Anti-decubitus Air Alternating Pressure Mattresses/Cushion System is designed for patients who endure pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer. The device is intended to prevent and manage pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area.		
Product List		
Catalogue No.	Product Description	UDI-DI
S2809-3015	DomestiCare P.U. EU	04713616096171
S2809-2010	DomestiCare M-set 90x200cm TDX	04713616096164