



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
217008-2017-AQ-RGC-NA-PS Rev. 3.0

Initial certification date:
05 July 2010

Valid:
09 February 2022 – 08 February 2025

This is to certify that the management system of

Carilex Medical, Inc.

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

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Development, Manufacturing, Sales and Distribution of Anti-Decubitus Devices, Cushions & Pumps, Alternating Air Pressure Mattresses, NPWT-Negative Pressure Wound Therapy and Sterile Wound Dressings.

Place and date:
Høvik, 30 August 2021



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer