



CERTIFICATE

Certificate Registration No: S951 13 6266

The Certification Body of
TÜV SÜD AMERICA INC.

Certifies that the organization

Lake Region Medical Ltd.

101 E Mill St
Quakertown, PA 18951 USA

for the scope

Custom Engineering and Manufacturing of Biomedical Textile Components for Medical Device Manufacturers', Including the Cardiovascular, Orthopedic, General Surgery and Neurological Device Markets

has established and applies a Quality Management System.

An audit was performed and has furnished proof that the requirements according to

ISO 13485:2016

are fulfilled.

The certificate is valid from March 1, 2025 until February 28, 2028

With a re-issue date on N/A

Michael Fernald
Head of Central Certification Body



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The validity of this certificate is contingent on the company maintaining its management system to the requirements of the indicated standard and is subject to regular monitoring by TÜV SÜD America.