



America

CERTIFICATE

No. QS2 083867 0009 Rev. 04

Certificate Holder: Roechling Medical Lancaster, LLC
44 Denver Rd
Denver PA 17517
USA

Certification Mark:



Scope of Certificate: Design and Development, Manufacturing and Packaging of Sterile Bifurcated Needles for Vaccinating and Allergy Skin Testing;

Contract Manufacture, Assembly and Packaging of Electro-Mechanical, Ophthalmic, Infusion, Endoscopic, Orthopedic, Drug Delivery, Spinal Fixation Implants, General and Cardiovascular Surgery Products, and Aspiration and Injection Needle Devices

Standard: ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: 72199218

Effective Date: 2024-10-17

Expiry Date: 2027-10-16

Page 1 of 2

Date of Issue: 2024-09-06

(Renee Walker)
Director, US Certification Body, MHS



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No. QS2 083867 0009 Rev. 04

Facility(ies): **Roechling Medical Lancaster**
44 Denver Rd, Denver PA 17517, USA

Facility Scopes: Design and Development, Manufacturing and Packaging of Sterile Bifurcated Needles for Vaccinating and Allergy Skin Testing;

Contract Manufacture, Assembly and Packaging of Electro-Mechanical, Ophthalmic, Infusion, Endoscopic, Orthopedic, Drug Delivery, Spinal Fixation Implants, General and Cardiovascular Surgery Products, and Aspiration and Injection Needle Devices

Facility(ies): **Roechling Medical Lancaster**
Bay 11 360 Steel Way, Lancaster PA 17601, USA

Facility Scopes: Overflow Storage of Maintenance, Repair and Operating Supplies and Inventory Items excluding Finished Medical Devices, Medical Device Components, and Materials Contacting Medical Devices

Page 2 of 2
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(Renee Walker)
Director, US Certification Body, MHS