



America

CERTIFICATE

No. QS 090035 0007 Rev. 02

Certificate Holder: Venusa de Mexico S. de R.L. de C.V.
a Lake Region Medical Company
Calle Hertz 1525
Parque Industrial Antonio J. Bermudez
Chihuahua
32470 Ciudad Juarez
MEXICO

Certification Mark:



Scope of Certificate: Manufacturing and Distribution of Sterile and Non-Sterile Fluid Delivery Disposables with Associated Sterile Adapters, Disposable Endoscopic Biopsy Forceps and Snares, Transurethral Thermotherapy Probes, Tubal Occlusion Devices, Urological Retrieval Coils, Organ Perfusion and Transport Systems, Wound Dressings, Lens Delivery System, Catheters, Electrosurgical Devices, Sterile Guidewires for Vascular and Non-Vascular Use, Tubing Subassemblies; Production of Metal Stamped Medical Device Components; Laser Cutting Manufacturing Processes; Hydrophilic and PTFE Coating of Subassemblies and Finished Medical 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.: 72169274

Effective Date: 2021-10-18

Expiry Date: 2022-09-13

Page 1 of 2

Date of Issue: 2021-11-17

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS2 090035 0007 Rev. 02

Facility(ies):

**Venusa de Mexico S. de R.L. de C.V.
a Lake Region Medical Company**

Calle Hertz 1525, Parque Industrial Antonio J. Bermudez
Chihuahua, 32470 Ciudad Juarez, MEXICO

Facility Scopes:

Manufacturing and Distribution of Sterile and Non-Sterile Fluid Delivery Disposables with Associated Sterile Adapters, Disposable Endoscopic Biopsy Forceps and Snares, Transurethral Thermotherapy Probes, Tubal Occlusion Devices, Urological Retrieval Coils, Organ Perfusion and Transport Systems, Wound Dressings, Lens Delivery System, Catheters, Electrosurgical Devices, Sterile Guidewires for Vascular and Non-Vascular Use, Tubing Subassemblies; Production of Metal Stamped Medical Device Components; Laser Cutting Manufacturing Processes; Hydrophilic and PTFE Coating of Subassemblies and Finished Medical Devices

Facility(ies):

Venusa LTD a Lake Region Medical Company

31 C Butterfield Trail, El Paso TX 79906, USA

Facility Scopes:

Warehousing and Distribution of Sterile and Non-Sterile Fluid Delivery Disposables with Associated Sterile Adapters, Disposable Endoscopic Biopsy Forceps and Snares, Transurethral Thermotherapy Probes, Tubal Occlusion Devices, Urological Retrieval Coils, Organ Perfusion and Transport Systems, Wound Dressings, Lens Delivery System, Catheters, Electrosurgical Devices, Sterile Guidewires for Vascular and Non-Vascular Use, Tubing Subassemblies

Page 2 of 2

Date of Issue: 2021-11-17

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services