SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS2 090035 0007 Rev. 00

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:

TÜV SÜD ISO 13485

Scope of Certificate:

Production 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, Ablation Catheters, Electrosurgical Medical Devices; Production of Metal Stamped Medical Device Components. Laser-Cutting Manufacturing Processes for Medical Devices

Standard(s): **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.: **M4457**

Effective Date: **2018-09-14**

Expiry Date: **2021-09-13**

Date of Issue: 2018-09-14

(Arie Henkin)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
US-Letter / 07.17

SCC Accredited CB-MS
OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS2 090035 0007 Rev. 00

Facility(ies):

Venusa de Mexico S. de R.L. de C.V. a Lake Region Medical Company
1525 Parque Industrial Antonio J. Bermudez, Ciudad Juarez, Chihuahua, 32470, 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, Ablation Catheters, Electrosurgical Medical Devices; Production of Metals Stamped Medical Device Components. Laser-Cutting Manufacturing Processes for Medical Devices

Facility(ies):

Lake Region Medical
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, Ablation Catheters, Electrosurgical Medical Devices

Date of Issue: 2018-09-14

(Arie Henkin)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
US-Letter / 07.17