



America

CERTIFICATE

No. QS1 14 11 90011 001

Certificate Holder: Lake Region Medical
31 C Butterfield Trail
El Paso TX 79906
USA

Certification Mark:



Scope of Certificate: Assembly and Packaging of Sterile and Non-Sterile Fluid Delivery Disposables with Associated Sterile Adapters, Disposable Endoscopic Biopsy Forceps and Snares, Transurethral Thermotherapy Probes, Tubal Occlusion Devices, Permanent Birth Control Delivery System and Accessories, Urological Retrieval Coils, Organ Perfusion and Transport Systems, Wound Dressing, Lens Delivery System, and Ablation Catheters; Production of Metal Stamping of Medical Device Components

Standard(s): ISO 13485:2003

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.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M4457

Effective Date: 2014-11-17

Expiry Date: 2017-09-15

Gary Minks
Vice President, Regulatory Affairs

Page 1 of 2

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA



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UCB_F_12.04 2012-02



America

CERTIFICATE

No. QS1 14 11 90011 001

Lake Region Medical
31-C Butterfield Trail
El Paso, TX 79906
USA

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, Permanent Birth Control Delivery System and Accessories, Urological Retrieval Coils, Organ Perfusion and Transport Systems, Wound Dressings, and Lens Delivery System

Venusa de Mexico S.A. de C.V.
a Lake Region Medical Company
1525 Hertz Street,
Industrial park J Bermudez,
Ciudad Juárez, 32470 Chihuahua
Mexico

Assembly and Packaging of Sterile and Non-Sterile Fluid Delivery Disposables with Associated Sterile Adapters, Disposable Endoscopic Biopsy Forceps and Snares, Transurethral Thermotherapy Probes, Tubal Occlusion Devices, Permanent Birth Control Delivery System and Accessories, Urological Retrieval Coils, Organ Perfusion and Transport Systems, Wound Dressings, and Lens Delivery System; Production of Metal Stamped Medical Device Components

Lake Region Medical
100 Fordham Road
Wilmington, MA 01887
USA

Headquarters, Administrative Functions, Design Control

Effective Date: 2014-11-17
Expiry Date: 2017-09-15

Gary Minks
Vice President, Regulatory Affairs

Page 2 of 2

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