



Certificate

No. Q6 090035 0009 Rev. 00

Holder of Certificate: **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:

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, Catheters, Electro-surgical Medical Devices, Sterile and Non-Sterile Guidewires for vascular and non-vascular use, tubing sub-assemblies. Production of Metals Stamped Medical Device Components. Laser-cutting manufacturing processes for Medical devices. Hydrophillic coating of guidewires and subassemblies, PTFE coating of subassmblies, manufacturing aids, guidewires, catheters, hypotubes, cable wires, and mandrels for medical applications.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72150583

Valid from: 2020-07-07

Valid until: 2021-12-03

Date, 2020-07-08



Christoph Dicks

Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

Venusa LTD a Lake Region Medical Company
31 C Butterfield Trail, El Paso TX 79906, USA

Lake Region Medical (Corporate)
100 Fordham Road, Wilmington MA 01887, USA

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