ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 14 10 90035 002

Manufacturer:

Venusa de Mexico S.A. de C.V
a Lake Region Medical Company
Calle Hertz 1525-6
Parque Industrial J. Bermudez
Chihuahua
32470 Ciudad Juarez
MEXICO

EC-Representative:

Star Guide Ltd.
A wholly owned
subsidiary of Lake Region Medical
5 Westlink Park
Oranmore
Galway
IRELAND

Product Category(ies):

Disposable Guidewires

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: NM1409723

Valid from: 2014-11-26
Valid until: 2017-05-19

628522

Date, 2014-11-27

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

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Facility(ies):

Venusa de Mexico S.A. de C.V a Lake Region Medical Company
Calle Hertz 1525-6, Parque Industrial J. Bermudez, Chihuahua,
32470 Ciudad Juarez, MEXICO

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