



# NSAI

## Certificate of Registration of Quality Management System to ISO 13485:2003

The National Standards Authority of Ireland  
A CMDCAS Recognized Registrar certifies that:

**Lake Region Medical**  
**340 Lake Hazeltine Dr.**  
**Chaska, MN 55318**  
**USA**

has been assessed and deemed to comply with the requirements  
of the above standard in respect of the scope of operations given  
below:

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**The Design, Development, Manufacture and  
Distribution of Sterile and Non-Sterile Guidewires  
for the areas of Gastroenterology/Urology and  
Vascular Guidewires for Peripheral and Cardiac  
use.**

**Additional sites covered under this multi-site certification are listed on the Annex  
(File No. CM19.4406)**

Approved by:  
Kevin D. Mullaney  
Chief Executive Officer

Approved by:  
John Bier  
Operations Manager

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Certificate Number: CM19.4406  
Certification Granted: Oct 08, 2008  
Effective Date: Sep 09, 2015  
Expiry Date: Jul 24, 2016



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National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800  
National Standards Authority of Ireland, 20 Trafalgar Squaret, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



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**Annex to Certificate number: CM19.4406**

## **Scope of Registration :**

**The Design, Development, Manufacture and Distribution of Sterile and Non-Sterile Guidewires for the areas of Gastroenterology/Urology and Vascular Guidewires for Peripheral and Cardiac use.**

### **Activity**

### **Location**

Design and Development,  
Manufacturing, Distribution

Lake Region Medical  
340 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: CM19.4406

Manufacturing, Distribution

Lake Region Medical  
305 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: CM19.4406/A

Manufacturing

Lake Region Medical  
307 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: CM19.4406/B

Manufacturing, Distribution

Lake Region Medical  
304 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: CM19.4406/C

Manufacturing, Distribution,  
Warehouse, Service

Lake Region Medical  
1234 Lakeview Dr.  
Chaska, MN 55318  
USA  
File No.: CM19.4406/D



**NSAI**