



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Lumitex Medical Devices, Inc.**  
**8300 Dow Circle**  
**Suite 400**  
**Strongsville, OH 44136**  
**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 and Development, Manufacture and Distribution of Sterile and Non-Sterile Medical Illumination Devices and Non-sterile Phototherapy Devices.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4787/A)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

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Registration Number: MD19.4787/A  
Certification Granted: March 26, 2013  
Effective Date: December 26, 2020  
Expiry Date: June 25, 2023





# NSAI

**Annex to Certificate Number: MD19.4787/A**

## **Scope of Registration:**

**The Design and Development, Manufacture and Distribution of Sterile and Non-Sterile Medical Illumination Devices and Non-sterile Phototherapy Devices.**

### **Activity**

Headquarters, Quality Assurance,  
Regulatory Affairs, Production, and  
Design and Development

Administration, Quality Assurance,  
Regulatory Affairs, Production,  
Design and Development

### **Location**

Lumitex Medical Devices, Inc.  
8300 Dow Circle  
Suite 400  
Strongsville, OH 44136  
USA  
File No.: MD19.4787/A

Lumitex Medical Devices, Inc.  
8443 Dow Circle  
Strongsville, OH 44136  
USA  
File No.: MD19.4787

**Verified by:  
Operations Manager**