



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

The National Standards Authority of Ireland certifies that:

**Lumitex, LLC**

**6611 W Snowville Road  
Brecksvilles, OH 44141  
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 Production of Components and Finished  
Medical Illumination and Phototherapy Devices.**

**Additional sites covered under this multi-site certification are listed on the  
Annex (File No. MD19.4788)**

Approved by:  
Kevin Mullaney  
Director of Certification

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Registration Number: MD19.4788  
Certification Granted: March 26, 2013  
Effective Date: February 14, 2025  
Expiry Date: June 25, 2026





**Annex to Certificate Number: MD19.4788**

**Scope of Registration:**

**The Production of Components and Finished Medical Illumination and Phototherapy Devices.**

**Activity**

**Location**

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

Lumitex, LLC  
6611 W Snowville Road  
Brecksvilles, OH 44141  
USA  
File No.: MD19.4788

Production

Lumitex, LLC  
Carr. Celaya a Salvaterra Km.17  
Guanajuato 38150  
Mexico  
File No.: MD19.4788/B

**Verified by:  
Director of Certification**