



NSAI

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
Brecksville, 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:

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:
Pamela Burdette Miller
Certification Manager

Registration Number: MD19.4788
Certification Granted: March 26, 2013
Effective Date: June 26, 2026
Expiry Date: June 25, 2029





NSAI

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:
Certification Manager**