



NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Lumitex, LLC
8443 Dow Circle
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:

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. CM19.4788)

Approved by:
Kevin Mullaney
Director of Certification

Registration Number: CM19.4788
Certification Granted: March 26, 2013
Effective Date: September 23, 2024
Expiry Date: June 25, 2026



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: CM19.4788

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
8443 Dow Circle
Strongsville, OH 44136
USA
File No.: CM19.4788

Quality Assurance, Regulatory
Affairs, Production

Lumitex, LLC
8300 Dow Circle, Suite 400
Strongsville, OH 44136
USA
File No.: CM19.4788/A

Production

Lumitex, LLC
Carr. Celaya a Salvaterra Km.17
Guanajuato 38150
Mexico
File No.: CM19.4788/B

**Verified by:
Director of Certification**