



Certificate of Registration of Quality Management System to 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:

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: February 14, 2025
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



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
6611 W Snowville Road
Brecksvilles, OH 44141
USA
File No.: CM19.4788

Production

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

**Verified by:
Director of Certification**