



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 used in 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: November 08, 2022
Expiry Date: June 25, 2023



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: MD19.4788

Scope of Registration:

The Production of Components used in Medical Illumination and Phototherapy Devices.

Activity

Location

Headquarters, Administration,
Quality Assurance, Regulatory
Affairs, Production, 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.: 19.4788/B

**Verified by:
Director of Certification**