



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:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: CM19.4788
Certification Granted: March 26, 2013
Effective Date: December 26, 2020
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

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

**Verified by:
Operations Manager**