

NSAI

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

The National Standards Authority of Ireland certifies that:

Lumitex, Inc.

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)**

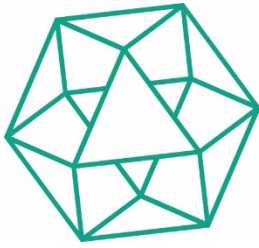
Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Eoin Banville
Operations Manager,
Medical Devices

Certificate Number: CM19.4788
Certification Granted: Mar 26, 2013
Effective Date: Sep 14, 2018
Expiry Date: Jun 25, 2020



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 Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



NSAI

Annex to Certificate Number: CM19.4788

Scope of Registration:

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

Activity

Headquarters, Administration,
Quality Assurance, Regulatory
Affairs, Production, Design and
Development

Quality Assurance, Regulatory
Affairs, Production, and Design
and Development

Location

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

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

**Verified by:
Operations Manager**