



Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

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:

**Design, Development, Production and Distribution
of Medical Illumination Devices and Phototherapy
Devices**

**Additional sites covered under this multi-site certification are listed on the Annex
(File No. MD19.4788)**

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.4788
Certification Granted: Mar 26, 2013
Effective Date: Aug 11, 2017
Expiry Date: Jun 25, 2020



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



Annex to Certificate Number: MD19.4788

Scope of Registration :

**Design, Development, Production and Distribution of Medical
Illumination Devices and Phototherapy Devices**

Activity

Location

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

Lumitex, Inc.
8443 Dow Circle
Strongsville, OH 44136
USA
File No.: MD19.4788

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

Lumitex, Inc.
8300 Dow Circle
Suite 400
Strongsville, OH 44136
USA
File No.: MD19.4788/A

**Verified by:
Operations Manager**