# Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Lumitex Medical Devices, 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 Design and Development, Manufacture and Distribution of Sterile and Non-Sterile Medical Illumination Devices and Non-sterile Phototherapy Devices.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4787)**

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.4787
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

## Annex to Certificate Number: MD19.4787

### Scope of Registration:

The Design and Development, Manufacture and Distribution of Sterile and Non-Sterile Medical Illumination Devices and Non-sterile Phototherapy Devices.

| Activity | Location |
|---|---|
| Headquarters, Administration, Quality Assurance, Regulatory Affairs, Production, Design and Development | Lumitex Medical Devices, Inc.<br>8443 Dow Circle<br>Strongsville, OH 44136<br>USA<br>File No.: MD19.4787 |
| Quality Assurance, Regulatory Affairs, Production, and Design and Development | Lumitex Medical Devices, Inc.<br>8300 Dow Circle<br>Suite 400<br>Strongsville, OH 44136<br>USA<br>File No.: MD19.4787/A |

**Verified by:**
**Operations Manager**