



NSAI

Certificate of Registration of Quality Management System to ISO 13485:2003

The National Standards Authority of Ireland
A CMDCAS Recognized Registrar 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:

**Design and Development, Production, Contract
Manufacturing 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
Attachment (File No. CM19.4787)**

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Eoin Banville
Operations Manager,
Medical Devices

Certificate Number: CM19.4787
Certification Granted: Mar 26, 2013
Effective Date: Aug 11, 2017
Expiry Date: Dec 31, 2018



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



Attachment 1 to Certificate Number: CM19.4787

Scope of Registration :

Design and Development, Production, Contract Manufacturing 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.
8443 Dow Circle
Strongsville, OH 44136
USA
File No.: CM19.4787

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

Lumitex Medical Devices, Inc.
8300 Dow Circle
Suite 400
Strongsville, OH 44136
USA
File No.: CM19.4787/A

**Verified by:
Operations Manager**