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.
8300 Dow Circle
Suite 400
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/A)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Registration Number: MD19.4787/A
Certification Granted: March 26, 2013
Effective Date: June 26, 2020
Expiry Date: December 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/A

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

Verified by:
Operations Manager