



Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Lumitex Medical Devices, Inc.

**8443 Dow Circle
Strongsville
Ohio 44136
USA**

to the Product Family

Surgical instrument fibreoptic light (LightMat)

GMDN Code: 48036

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex
II, excluding (4)*

*The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product family is hereby authorised.*

Registration Number: 252.914

Original Approval: 14 November 2013

Last Amended on: 28 August 2018

Remains valid until: 13 November 2018

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.