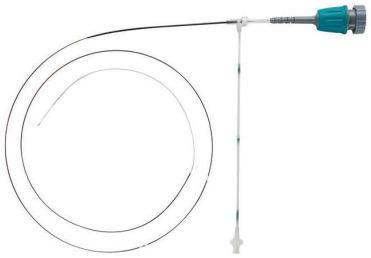
Dragonfly™ OPTIS™

Imaging Catheter

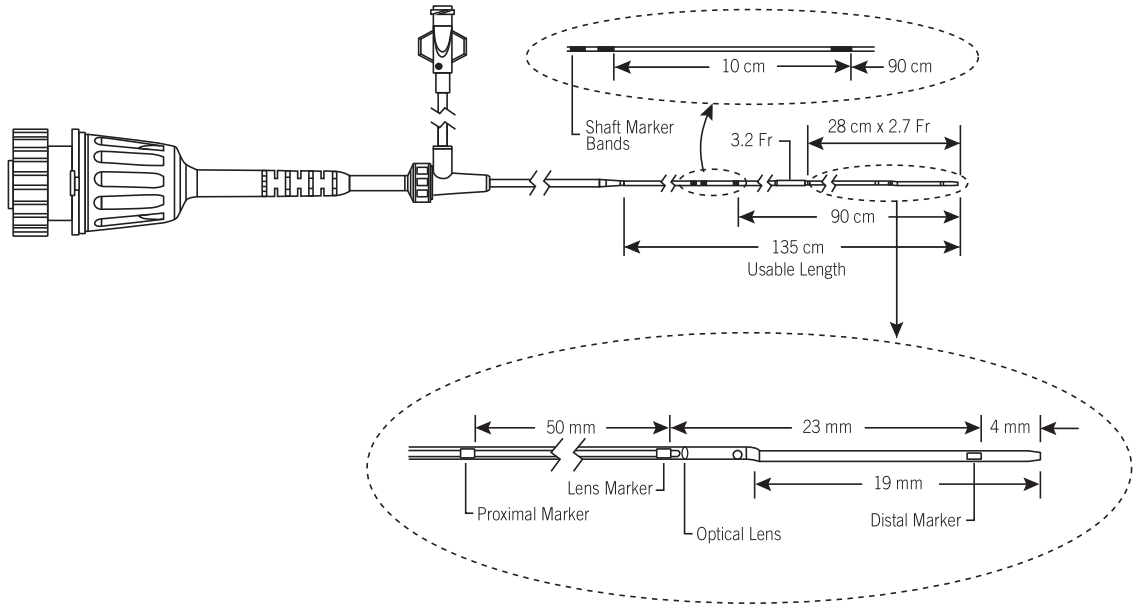


PRODUCT FEATURES

- OCT imaging catheter for OPTIS™ Integrated System*, ILUMIEN™ OPTIS™ and ILUMIEN™ PCI Optimization™ Systems
- Radiopaque markers at the distal tip, imaging lens and 50 mm proximal to the lens for aligning the OCT pullback to region of interest
- Proprietary sheath design provides continuous calibration throughout pullback
- Dual lumen rapid exchange tip for easier guidewire loading
- Lens marker <2 mm proximal to optical lens
- Proximal shaft marker bands at 90 mm and 100 mm
- 2.7 F low-profile tip
- Hydrophilic coating
- Simple setup
- Compatible with standard 0.014" guidewires

SPECIFICATIONS

Usable length:	135 cm
Outer diameter:	2.7 F (distal)
Wire lumen:	0.014"



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*Available only in geographies with appropriate regulatory approvals

ORDERING INFORMATION	
Reorder Number	**Description**
C408646	Dragonfly OPTIS Imaging Catheter, Sterile DOC Cover and 1 Sterile 3 ml Syringe are provided with the catheter
200-700-00	Sterile DOC Cover
C408655	Sterile 3 ml Syringe

St. Jude Medical Inc.
Global Headquarters
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ILUMIEN.com
SJMprofessional.com

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Rx Only

Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark.

Dragonfly OPTIS catheter, OPTIS integrated system and ILUMIEN system

ID-2001610 A EN (08/14)

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 565565**

Issued To: **Lightlab Imaging Inc.**
4 Robbins Road
Westford
Massachusetts
01886
USA

In respect of:

Optical Coherence Tomography, Sterile Cardiovascular Imaging Catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2010-09-28** Date: **2018-07-31** Expiry Date: **2023-08-05**

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EC Design-Examination Certificate

Supplementary Information to CE 565565

Issued To:

Lightlab Imaging Inc.
4 Robbins Road
Westford
Massachusetts
01886
USA

In respect of:

Dragonfly Optical Coherence Tomography Imaging Catheter

Model	Alternate Model Number	Device Name
100-100-00	13751	C7 Dragonfly™ Imaging Catheter
C408644	-	Dragonfly™ DUO Imaging Catheter
C408645	-	Dragonfly™ OPTIS™ Imaging Catheter

First Issued: **2010-09-28** Date: **2018-07-31** Expiry Date: **2023-08-05**

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EC Design-Examination Certificate

Supplementary Information to CE 565565

Issued To:

Lightlab Imaging Inc.
4 Robbins Road
Westford
Massachusetts
01886
USA

Certificate History

Date	Reference Number	Action
28 September 2010	10118245	First Issue, traceable to CE 76816
27 October 2011	10131410	Reissue due to change of company address
15 October 2012	10132846	Addition of Dragon Fly II "OCT" Imagewire Catheter and packaged kits.
26 March 2013	10140482	Review and addition of Dragonfly Duo and Dragonfly Duo kit box
05 August 2013	10143338	Certificate renewal
24 July 2014	10146897	Review of Inner Shell Design Change
23 September 2014	10150295	Review of design changes made to current CE marked device Dragonfly II. Note: also as part of this review, the manufacturer wishes to change the device name from "Dragonfly II" to "Dragonfly OPTIS"
12 January 2015	10153161	Extension of device shelf life to 2 years.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
09 June 2016	10162988	Retrospective Manufacturing Transfer review of the Dragonfly Catheter to Robbins Road Facility.

First Issued: **2010-09-28** Date: **2018-07-31** Expiry Date: **2023-08-05**

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EC Design-Examination Certificate

Supplementary Information to CE 565565

Issued To:

Lightlab Imaging Inc.
4 Robbins Road
Westford
Massachusetts
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USA

Certificate History

Date	Reference Number	Action
19 December 2017	8845914	Deleted obsolete part numbers (13751, 100-100-KT) and issued mirror certificates with Abbott Medical name, CE 682144.
Current	8903805	Addition of St. Jude Medical Costa Rica as a manufacturing facility and Synergy Health Costa Rica as a sterilization site for the DragonFly OPTIS Imaging Catheter. "Coherent" replaced by "Coherence" in the scope of the certificate.
	8956499	Certificate Renewal. Clarification of Scope from "ImageWire" to "Imaging Catheter." Removal of kit model numbers. Correction to reinstate Dragonfly Imaging Catheter model and alternate model number to certificate.

First Issued: **2010-09-28** Date: **2018-07-31** Expiry Date: **2023-08-05**

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Abbott Declaration of Conformity DragonFly™ OPTIS™

Abbott Medical (Abbott) hereby declares that the following Abbott facilities and products conform to the applicable provisions of Annex II of Council Directive 93/42/EEC. All supporting documentation is retained under the premises of Abbott. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	Abbott Medical 4 Robbins Road Westford, MA 01886 USA
European Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Optical Coherence Tomography, Sterile Cardiovascular Imaging Catheter
Product Name(s):	DragonFly™ OPTIS™ Imaging Catheter
Model Number(s):	C408645
Classification:	Class III per Annex IX, Rule 6
GMDN Code(s):	47491, Coronary optical coherence tomography system catheter
Original CE Mark Date:	23 September 2014
Certificate No and expiration date:	Certificate No: CE 682109 (FQA) Expiration Date: 02 October 2023 Certificate No: CE 682144 (Annex II.4) Expiration Date: 05 August 2023
Applicable Quality System Standards:	ISO 13485:2003 & EN ISO 13485:2012
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP UK
Notified Body Number:	0086

Signature:

Marlene Peterson
Manager, Regulatory Affairs

September 21, 2018
Issue Date

Abbott Declaration of Conformity DragonFly™ OPTIS™

Manufacturing Facilities:

Abbott Medical
4 Robbins Road
Westford, MA 01886 USA

ISO Certificate No: MD 682145
Expiration Date: 07 October 2018

Additional Manufacturing Facility for Dragonfly OPTIS only:
St. Jude Medical Costa Rica, Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela, Costa Rica

ISO Certificate No: MD 639058
Expiration Date: 28 February 2019

Signature:

Marlene Peterson
Marlene Peterson
Manager, Regulatory Affairs

September 21, 2018
Issue Date

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical
4 Robbins Road
Westford
Massachusetts
01886
USA

Holds Certificate No: **FM 701294**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture, and servicing of Optical Coherent Tomography Imaging Systems, including embedded software and sterile Imaging Catheters. The distribution of syringes, sterile bags, inflation devices and accessories. Design of Diagnostic Guidewire, Computer, Signal Transmission and Diagnostic software and accessories.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2018-10-01
Effective Date: 2018-10-01
Latest Revision Date: 2018-10-01
Expiry Date: 2021-10-07

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