Clear Surgical

Oplight™

The Oplight

Clear Surgical have developed an innovative enabling technology, the **Oplight.** The **Oplight** is a patented, LED, sterile, lighting cartridge which fits on to existing flat blade medical retractors to light up the surgical cavity area of an operation. This solves the existing problem of shadows, light reflection and cables currently suffered by surgeons.

This information pack will provide you with all technical information you require to assist in the evaluation of the **Oplight** technology.

Frequently Asked Questions

- What class of medical device is the Oplight?

It is a Class 1s (sterile). See SGS (UK) Ltd certificate GB19/963717 Directive 93/42/EEC on medical devices, Annex V.

- What is the shelf life of the Oplight?

The Oplight has a shelf life of 3 years, as determined by the sterility process and packaging. We will always supply items for sale with at least 24 months shelf life. Samples may have a shorter shelf life.

- What size is the Oplight?

The Oplight measures 55.96mm by 27.3mm by 4.7 mm and weights 26.6g

- How will the Oplight be packed?

The Oplight is packed in single units. The Oplight will be presented in a sterile double pouched pack

- Can I switch the Oplight off and on during a procedure?

Yes. The Oplight has a single off/on switch that is accessible during use.

- Can the Oplight be taken from one retractor and placed on another during a procedure?

No. We do not advise removing the Oplight from one retractor as this may reduce the adhesion properties.

- Does the Oplight contain any latex?

The Oplight has been manufactured to be free of latex

Oplight compatible retractors

Below is a list of surgical retractors which will accommodate the Oplight during surgical interventions. Whilst this is a comprehensive list there may be additional “flat blade” retractors that will be compatible with the Oplight.

- Langenbeck Retractor
- Phyris Retractor
- St Marks Retractor
- Norfolk and Norwich Retractor
- Obwegeser Retractor
- Simon Vaginal Retractor OB/GYN
- Pryor-Pean Retractor OB/GYN
- Doyen Vaginal Retractor OB/GYN
- Heaney Hysterectomy Retractor OB/GYN
- Guttman OB/GYN
- Lateral Vaginal Wall Retractor OB/GYN
- Reinhoff Retractor
- Heaney-Simon Retractor
- Piling Multipurpose blade
- Davidson Scapula Retractor
- Harrington Extra Deep
- Deep Deaver Retractor
- DeBakey- Cooley Retractor
- Taylor Retractor
- Horizontal Retractor
- Kocher Retractor
- Tudor Edwards Scapula Retractor
- Cloward Style Retractor
- Bookler Right Angle Retractor
- Jackson Burrows Retractor
- Hibbs Retractor
- Taylor Spinal Retractor
- Meyerding Retractor
- Lamina Spreader
- Fakuda Shoulder Retractor
- Tuffier Retractor
- Lemmon Extra Deep Deaver Retractor
- Yu Holtgreve Malleable Blade
- Blafour Center Blades
- Wexler Expandable Blade
- Beckman-Eaton Retractor
- Davis Brain Spatula
- Sauerbruch Retractor
- Wishbone Splachnic Retractor

Oplight Surgeries

The Oplight has been used in number of surgeries which have been included below. This list is not exhaustive.

Vascular

Adominal aortic endarterectomy

Fem-pop bypass in a deep popliteal fossa

Nerogenic thoracic outlet syndrome

Vascular thoracic outlet syndrome

Popliteal aneurism

ENT

Parotidectomy

Thyroidglossal Cysts

Branchial Cysts

Tonsillectomy

Colorectal

Anal fissures

Anal fistula

Others

Breast & axillary access

Axillary node dissection

Mastectomy; depending on approach used

Plastic Surgery

Cardiac TAVI surgery

Deep posterior capsule release

Anterior Lumbar Interbody Fusion (ALIF)

Lumbar posterior fusion (PLIF)

Open Cholecystectomy

Open Appendectomy

Hernia

Carpal Tunnel

Anterior Hip Arthroplasty

Oplight Specification Rev 1.1

Disposable single-use, sterile cartridge incorporating LED technology to provide light source to directly illuminate the interior cavity of an incision during surgery.

Power Source:

Li-MnO2 Battery - CP162235/160mAh/3.0V

Material:

Resin - ALTUGLAS SG7 Adhesive – Avery Dennison MED 6361U

Light Source

NSSW206 White LED

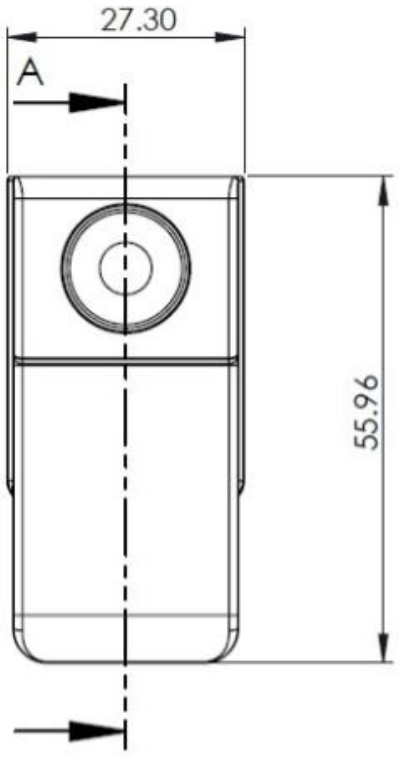
Storage

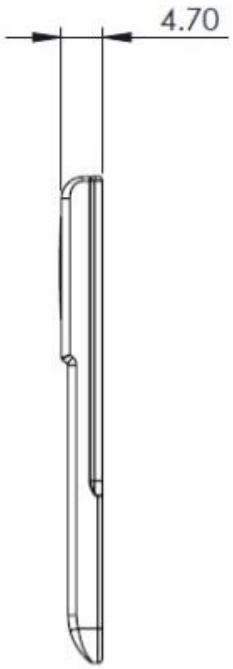
Storage Temperature Range: 15ºC to 27ºC

Storage Humidity Range: 30% to 60% relative humidity (RH)

Atmospheric pressure: 97kPa to 104 kPa

Sizes and Codes
SLC5525DT - Sterile





Caution

- Ensure there is no damage to sterile barrier packaging.
- Do not use if packaging is damaged.
- Only to be used by appropriately trained individuals.
- Do not misuse.
- Do not use after use by date.
- Single use only.
- Do not re-sterilise.
- Dispose of Cartridge as a contaminated medical device containing a lithium battery.
- No modification of this equipment is allowed.

Product Weight

Light Cartridge 26.6g

Performance Characteristics

The average illumination over 45mins - 1132 Lux.

Guidance and Manufacturer's declaration – electromagnetic emissions		
Oplight is intended for use in the electromagnetic environment specified below. The user of Oplight should assure that it is used in such an environment		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	Oplight uses RF energy only for its internal function. Therefore its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Oplight is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose
Harmonic Emissions IEC6100-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC6100-3-2	Not Applicable	

Guidance and Manufacturer's declaration – electromagnetic immunity			
Oplight is intended for use in the electromagnetic environment specified below. The user of Oplight should assure that it is used in such an environment			
Immunity Test	IEC 60601 test level	Compliance Level	**Electromagnetic Environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst	+/- 2kV for power supply lines	Not Applicable	

IEC 61000-4-4	+/- 1kV for input/output lines		
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle <5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 0.5 s	Not Applicable	
Power Frequency(50/60Hz) Magnetic Field IEC 61000-4-8	3A/m	3A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial hospital or environment
NOTE U_T is the a.c. mains voltage prior to application of the test level			

The device was tested under Classification 4 Group 1 Class B of EN 60601-1-2:2007 and was tested to the following standards:

EN 60601-1-2:2007
EN 60601-2-41: 2009

Emissions
EN 55011 Class B Radiated Disturbance

Immunity
EN61000-4-3 Radiated RF electromagnetic fields
EN61000-4-2 Electrostatic Discharge (ESD)
EN61000-4-8 Power frequency magnetic fields

Iver Macdonald

Technical & Regulatory Manager Date: 18th October 2019

Oplight EC Declaration of Conformity Issue 1.7

This is to confirm that the Oplight is classified as a Class Is medical device in accordance with Annex IX Rule 7 and Rule 12 of the Medical Device Directive 93/42/EEC of June 1993 and amending Directive 2007/47/EEC. The Oplight complies with the essential requirements as detailed in Annex I of the Directive and is CE marked in accordance with Annex II of the Directive.

EC Certificate Full Quality Assurance System: Certificate GB19/963717

The product will be marketed in the European Economic Area (EEA) as:

Oplight

The manufacturer responsible for placing the Oplight on the Market is Clear Surgical Ltd, Glenbervie Business Centre, Ramoyle House, Glenbervie Business Park, Larbert, FK5 4RB, United Kingdom.

The route to conformity has been assessed by SGS United Kingdom Ltd, Unit 202b, Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom.

Notified Body Number 0120

Signed: Dated: *11/10/2019*

Michelle Ward
Chairman & CEO

Clear Surgical Ltd. Glenbervie Business Centre, Ramoyle House, Glenbervie Business Park Larbert, FK5 4RB, United Kingdom

BS EN 556-1:2001
Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices.

BS EN 1041:2008+A1:2013
Information supplied by the manufacturer of medical devices.

BS EN ISO 10993-1:OCTOBER 2009
Biological evaluation of medical devices –
Part 1: Evaluation and testing (ISO 10993-1:2003)

BS EN ISO 11135:2014
Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices.

BS EN ISO 11607-1:2009+A1:2014
Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging.

BS EN ISO 11737-1:2006
Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products.

BS EN ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes.

BS EN ISO 14155:2011
Clinical investigation of medical devices for human subjects. Good clinical practice.

BS EN ISO 14937:2009
Sterilization of health care products. General requirements for characterization of a sterile agent and the development, validation and routine control of sterilization process for medical devices.

BS EN ISO 14971:2012
Medical devices – application of risk management to medical devices.

BS EN ISO 15223-1:2016
Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.

BS EN ISO 15883-1:2009+A1:2014
Washer – disinfectors. General requirements, terms and definitions and tests.

BS EN 60601-1:2006+A12:2014
Medical electrical equipment. General requirements for basic safety and essential performance

BS EN 60601-1-2:2007
Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.

BS EN 60601-2-41:2009
Medical electrical equipment. Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis.

BS EN 55011:2009+A1:2010
Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement.

BS EN 61000-4-3:2006+A2:2010
Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test.

BS EN 61000-4-2:2009
Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test.

BS EN 61000-4-8:2010
Electromagnetic compatibility (EMC). Testing and measurement techniques. Power frequency magnetic field immunity test.

BS EN 62366-1:2015
Medical devices. Application of usability engineering to medical devices.

BS EN ISO 17664:2004
Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices.

Clear Surgical ISO 13485 Certificate

Certificate GB14/92322

The management system of

Clear Surgical Limited

Glenbervie Business Centre, Ramoyle House,
Glenbervie Business Park, Larbert, FK5 4RB, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Development and Manufacture of sterile disposable surgical instruments and non sterile reusable surgical instruments.

This certificate is valid from 05 December 2018 until 04 December 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 October 2020
Issue 3. Certified since 04 December 2014

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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UKAS MANAGEMENT SYSTEMS
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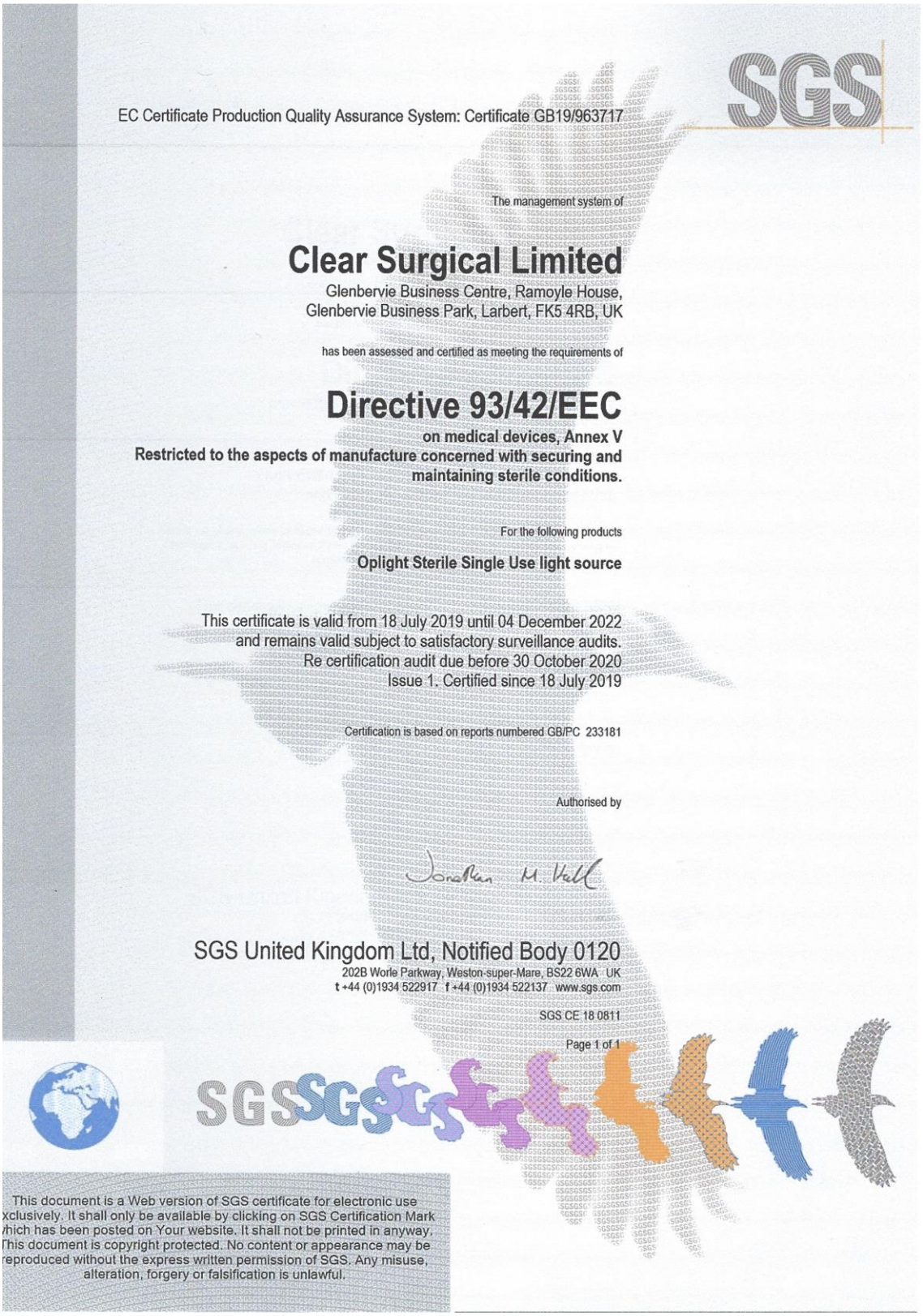
Oplight Directive 93/42/EEC certificate

CE Mark



EC Certificate Production Quality Assurance System: Certificate GB19/963717

SGS

The management system of

Clear Surgical Limited

Glenbervie Business Centre, Ramoyle House,
Glenbervie Business Park, Larbert, FK5 4RB, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

For the following products

Oplight Sterile Single Use light source

This certificate is valid from 18 July 2019 until 04 December 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 October 2020
Issue 1. Certified since 18 July 2019

Certification is based on reports numbered GB/PC 233181

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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