

## “Coolview®” – CLED53 New Generation LED Examination Light

**Coolview CLED53** LED Examination Lights from Brandon Medical are the perfect light source for a wide range of procedures. Providing a high intensity, bright natural looking light, Coolview CLED53 is perfect for medical consultations and examinations in primary care and medical clinics.

### **Powerful, variable Light Intensity**

Coolview CLED53 emits a powerful 50,000 Lux of light at 0.5Metres, providing an intense, clear light source for excellent visualization. The easily accessible and intuitive controls offer 5 levels of brightness



CLED53FX Rail Mounting (illustrated)

### **Perfect Colour**

The powerful light source is matched with an selectable colour temperature feature, which can be adjusted between 3,300, 3,800 and 4,400°Kelvin. This provides the Clinician with accurate representation and visualization of the site under examination.

Coolview CLED53 offers a high CRI Ra of  $\geq 93$  which describes the exceptionally high quality of white Light and excellent overall colour rendition, whilst the high CRI R9 value of  $\geq 90$  can help to enhance visualization of areas where red is more predominant.

### **Infection Control**

The fully enclosed light head is sealed to protect from dust and light liquid ingress.

### **Mountings**

The **CLED53 Examination Light** operates on a spring balanced rigid arm offering optimum reach, positioning and stability. The Light can be specified for mounting on the Wall (with or without Backplate), Desk, “Medirail” or on a Mobile Wheeled Base



For fuller details on features and specifications please refer to the Technical Data overleaf or contact Brandon Medical

## “Coolview®” – CLED53 New Generation LED Examination Light

### Technical Data

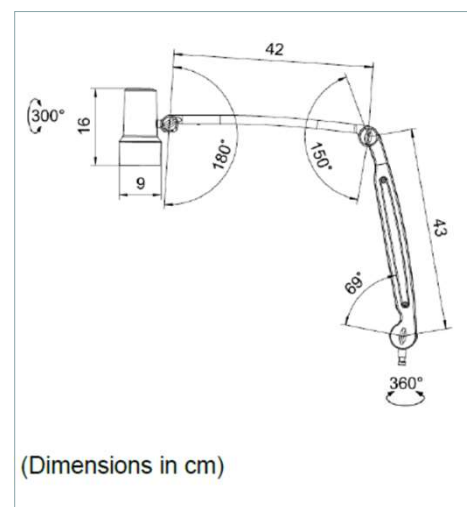
General Information	CLED53	Protection Class II
	Degree of Protection as per IEC 60529	IP20 (lamphead)
	Classification according to EU-Regulation 2017/745 (MDR), Article 51	Class I
	Electrical Safety and EMC Approvals	EN/IEC 60601-1, EN/IEC 60601-1-2, BS EN 60601-2-41
	Type of luminaire (according to BS EN60601-2-41)	Luminaire for Diagnosis
	Light Intensity Control	Lamphead Keypad (5 step dimming)
	Lamphead On/Off switch	Spring Arm Switch
	Maximum Total System Weight (kg) [approx.]	1.7 kg
	Total Arm Reach (mm) [approx.]	850mm
	Rotation About Central Axis of mount (max)	360°
	Arm Angle bottom joint (max)	69°
	Lamphead Roll (Rotation about arm) (max)	300°
	Mains Power Supply Lead	1.8m lead
Electrical Data	Rated Input Voltage	100-240 V
	Frequency Range	50/60Hz
	Nominal Power Consumption	12-18W (15-22VA)
Photometric Data*	Number of Light Sources (LED Bulb)	7
	Type of Light Source	LED
	Central Illuminance E <sub>c</sub> (Light Intensity) @ 0.5m	50,000 Lux *
	Light Field Diameter	(d10 Distance of 0.5m) 180 mm
		(d50 Distance of 0.5m) 90 mm
	Colour Temperature	4400K / 3800K / 3300K
	Colour rendering index Ra	93
	Colour rendering index R9	90
	Total Irradiance E <sub>e</sub> at maximum intensity	<180 mW/m²
	LED Life	50,000 Hours

\*-10% / +20%

As part of Brandon Medical policy of continuous improvement, Brandon Medical reserves the right to change specifications as and when product improvements become available.  
Brandon Medical Co Ltd | Elmfield Road | Morley | Leeds | LS27 0EL Tel: 0113 277 7393 Fax: 0113 272 8844 Email: [enquiries@brandon-medical.com](mailto:enquiries@brandon-medical.com)

### Product Variants -

<b>CLED53FXBP</b>	CLED53 FX Back Plate (Wall) Mounted Examination Light
<b>CLED53FXDP</b>	CLED53 FX Desk (Clamp) Mounted Examination Light
<b>CLED53FXMP</b>	CLED53 FX Mobile Examination Light
<b>CLED53FXRP</b>	CLED53 FX MediRail Mounted Examination Light
<b>CLED53FXWP</b>	CLED53 FX Wall Mounted Examination Light



To: Whom It May Concern

Date: 06/06/2023.

### Authorization

We, Company-manufacturer **BRANDON MEDICAL COMPANY LTD.**, of ELMFIELD ROAD, MORLEY, LEEDS, LS27 0EL

U.K., hereby appoint following company:

F.C.P.C. "DataControl" S.R.L.,

17/6, N.Testimiteanu street,

MD-2025, Chişinau, Republic of Moldova,

to be our official Representative at the responsible authorities of the Republic of Moldova for registration, renewal,  
variation of registration etc. .

Signature for and on behalf of Manufacturer, title of the authorized person, seal



**Arthur Loftus**  
**Regional Director, EMEA**

## EU Declaration of Conformity



### Brandon Medical Company Limited (BMCL)

Elmfield Road, Morley, Leeds, West Yorkshire, LS27 0EL, UK

SRN (Non-EU Manufacturer): GB-MF-000005501

SRN (European Authorised Representative): IE-AR-000003999

Declares that under our sole responsibility, the product: **Coolview 50**  
**Coolview 53**  
(Refer to end of declaration for variant UDI-DI & Basic UDI-DI)

With intended purpose of: **Examination Lamp**

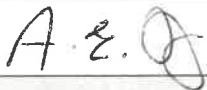

Is in conformity to the general safety and performance requirements of the following EC Regulation:

- **2017/745 – Medical Device Regulation** Risk Classification as per Annex VIII
- **Class I Self-Declaration Medical Device**
- **Conformity assessment route: Class I:** EC conformity self-declaration according to MDR 2017/745 Article 19, and Annexes II and III.

The following standards were applied in full:

- EN ISO 13485:2016 Medical devices Quality management systems - Requirements for regulatory purposes
- ISO 9001:2015 Quality management systems - Requirements
- BS EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN60601-1:2006+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- BS EN60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
- BS EN 60601-2-41 2009+A11:2011 Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
- EN 60601-6:2010+A1:2015
- Waste from Electrical and Electronic Equipment (WEEE) Directive

This product has been developed, tested and verified in accordance with the international standards listed above.

Person Responsible for Regulatory Compliance (PRRC)	Signature	Date
Annette Hemmings Head of Quality Assurance Brandon Medical Company Limited		17 MAY 2022
Countersignature	Signature	Date
Tom Partington Product Manager Brandon Medical Company Limited		17-05-22

European Authorised Representative: European Healthcare & Device Solutions (Ireland) Ltd. Stratton House,  
Bishopstown Road, Bishopstown, Cork, Ireland



## EU Declaration of Conformity

Model variant	Model description	UDI-DI (GTIN)	Basic UDI-DI
CLED50FXBP	Coolview CLED50 FX Articulated Arm Wall Mounted with Backplate Examination Lamp with UK Plug Lead	05060413447439	506041344CLED2L
CLED50FXC	Coolview CLED50FX Articulated Arm Ceiling Mounted Examination Lamp (Limited Rotation)	05060413448511	506041344CLED2L
CLED50FXDP	Coolview CLED50 FX Articulated Arm Desk Mounted Examination Lamp with UK Plug Lead	05060413447446	506041344CLED2L
CLED50FXMP	Coolview CLED50 FX Articulated Arm Mobile Mounted Examination Lamp with UK Plug Lead	05060413447453	506041344CLED2L
CLED50FXRP	Coolview CLED50 FX Articulated Arm Rail Mounted Examination Lamp with UK Plug Lead	05060413447460	506041344CLED2L
CLED50FXWP	Coolview CLED50 FX Articulated Arm Wall Mounted Examination Lamp with UK Plug Lead	05060413447477	506041344CLED2L
CLED50SXPB	Coolview CLED 50 SX Flexible Arm Wall Mounted with Backplate Examination Lamp with UK Plug Lead	05060413447484	506041344CLED2L
CLED50SXDP	Coolview CLED 50 SX Flexible Arm Desk Mounted with Lamp with UK Plug Lead	05060413447491	506041344CLED2L
CLED50SXMP	Coolview CLED 50 SX Flexible Arm Mobile Mounted with Lamp with UK Plug Lead	05060413447507	506041344CLED2L
CLED50SXRP	Coolview CLED 50 SX Flexible Arm Rail Mounted with Lamp with UK Plug Lead	05060413447514	506041344CLED2L
CLED50SXWP	Coolview CLED 50 SX Flexible Arm Wall Mounted with Lamp with UK Plug Lead	05060413447521	506041344CLED2L
CLED53FXBP	Coolview CLED53 FX Articulated Arm Wall Mounted with Backplate Examination Lamp with UK Plug Lead	05060413447545	506041344CLED2L
CLED53FXDP	Coolview CLED53 FX Articulated Arm Desk Mounted Examination Lamp with UK Plug Lead	05060413447552	506041344CLED2L
CLED53FXMP	Coolview CLED53 FX Articulated Arm Mobile Mounted Examination Lamp with UK Plug Lead	05060413447569	506041344CLED2L
CLED53FXRP	Coolview CLED53 FX Articulated Arm Rail Mounted Examination Lamp with UK Plug Lead	05060413447576	506041344CLED2L
CLED53FXWP	Coolview CLED53 FX Articulated Arm Wall Mounted Examination Lamp with UK Plug Lead	05060413447583	506041344CLED2L
CLED53FXC	Coolview CLED53FX Articulated Arm Ceiling Mounted Examination Lamp (Limited Rotation)	05060413448528	506041344CLED2L



Business Quality Assurance International

BS EN ISO 13485:2016

Certificate Number 326  
Issue 3

# Certificate of Registration

*Certificate of registration of an organisation or business of assessed capability.*

Business Quality Assurance International Ltd hereby grants to

**Brandon Medical Company Ltd.,  
Elmfield Road, Morley, Leeds, West Yorkshire,  
LS27 OEL, UK.**

(hereafter called the Business) the right and licence to be listed in the BQAI Register of Businesses of Assessed Capability in respect of the goods or services particularly described below. Goods or services shall be provided by the business, only at the address(es) given above, all in accordance with BS EN ISO 13485:2016.

The Certificate of Registration is granted subject to BQAI regulations governing the registration referred to above.

Goods or services in respect of which the business is registered:

**Design, manufacture, installation and servicing of: operating theatre lights, medical luminaires, and accessories. Distribution, installation and servicing of operating tables, accessories and medical pendants.**

Signed:

  
BQAI Governing Board Chairman, Prof. Michael J. Hynes

Signed:

  
BQAI Chief Executive Officer, Mr. Declan O'Connor

Original date of registration: **31st August 2018**

Current certification three-year cycle start date: **31st August 2021**

Date of governing board endorsement: **13th September 2021**

Current certificate expiry date: **31st August 2024**

Date of extension of scope change approval: **13th September 2021**

*The approval is subject to the supplier maintaining its Quality Management System to the required standard which will be monitored by BQAI.  
This Certificate remains the property of Business Quality Assurance International Ltd. and can be recalled at any time.*

## EU Declaration of Conformity



### **Brandon Medical Company Limited (BMCL)**

Elmfield Road, Morley, Leeds, West Yorkshire, LS27 0EL, UK

SRN (Non-EU Manufacturer): GB-MF-000005501

SRN (European Authorised Representative): IE-AR-000003999

Declares that under our sole responsibility, the product:

### **Quasar eLite Fixed Surgical Lighting**

Qe60 Basic UDI-DI: 506041344QE6023

Qe30 Basic UDI-DI: 506041344QE30ZP

UDI-DI: Refer to appended list

With intended purpose of:

### **Surgical Luminaire**


Is in conformity to the general safety and performance requirements of the following EC Regulation:

- **2017/745 – Medical Device Regulation** Risk Classification as per Annex VIII
- **Class I Self-Declaration Medical Device**
- **Conformity assessment route:** Class I: EC conformity self-declaration according to MDR 2017/745 Article 19, and Annexes II and III.

The following standards were applied in full:

- EN ISO 13485:2016 Medical devices Quality management systems - Requirements for regulatory purposes
- ISO 9001:2015 Quality management systems - Requirements
- BS EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN60601-1:2006+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- BS EN60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
- BS EN 60601-2-41 2009+A11:2011 Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
- Radio equipment directive 2014/53/EU
- BS EN 62366:2008 Medical devices. Application of usability engineering to medical devices
- BS EN1041:2008+A1:2013 Information supplied by the manufacturer of medical devices
- Waste from Electrical and Electronic Equipment (WEEE) Directive

This product has been developed, tested and verified in accordance with the international standards listed above.

Person Responsible for Regulatory Compliance (PRRC)	Signature	Date
Nigel Davill Chief Technical Officer Brandon Medical Company Limited		23 <sup>rd</sup> February 2023

**European Authorised Representative: European Healthcare & Device Solutions (Ireland) Ltd. Stratton House, Bishopstown Road, Bishopstown, Cork, Ireland**

## EU Declaration of Conformity

Product Code	Description	UDI-DI (GTIN)
Qe3010lonc	Quasar eLite Qe30 lamp head (160Klux), Qe10 satellite (100Klux), low ceiling, light spring arms, tandem bracket for ceiling mount.	5060413449631
Qe3010lotc	Quasar eLite Qe30 lamp head (160Klux), Qe10 satellite (100Klux), low ceiling, light spring arms, Titan central axis for ceiling mount.	5060413449648
Qe303030satc	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), Qe30 2nd satellite (160Klux), single cardanic, AC spring arms, Titan central axis for ceiling mount.	5060413449051
Qe3030GDsvtc	Quasar eLite Qe30 lamp (160Klux), Qe30 satellite (160Klux), 1.5-21Kg monitor arm, cabled with stops, single cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390541
Qe3030lonc	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), low ceiling, light spring arms, tandem bracket for ceiling mount.	5060413449655
Qe3030lotc	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), low ceiling, light spring arms, Titan central axis for ceiling mount.	5060413449662
Qe3030LTJ	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), single cardanic, tandem bracket for ceiling mount.	5060413446852
Qe3030sanc	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), single cardanic, AC spring arms, tandem bracket for ceiling mount.	5060413449679
Qe3030sanc	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), single cardanic, AC spring arms, tandem bracket for ceiling mount.	5060413449679
Qe3030satc	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), single cardanic, AC spring arms, Titan central axis for ceiling mount.	5060413449242
Qe3030svtc	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449686
Qe3030TJ	Quasar eLite Qe30 lamp head (160Klux), Qe30 satellite (160Klux), single cardanic, light spring arms, tandem bracket for ceiling mount.	5060413449556
Qe30looc	Quasar eLite Qe30 lamp head (160Klux), low ceiling, light spring arms, light horizontal for ceiling mount.	5060413449693
Qe30lvtc	Main Qe30 Lamp head (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449709
Qe30svtc	Main Qe30 Lamp head (160kLux) -Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449716
Qe3C10svtc	Quasar eLite Qe30 lamp (160Klux) with camera and stops, Qe10 satellite (100Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449723
Qe3C30GDsvtc	Quasar eLite Main Qe30 Lamphead with HD Fixed Focus Camera and stop (160kLux), Satellite Qe30 Lamphead (160kLux), Satellite Accessory Arm 21kg Stopped-Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060928390695
Qe3C30svtc	Quasar eLite Qe30 lamp (160Klux) with camera and stops, Qe30 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449730
Qe3C60svtc	Quasar eLite Qe30 lamp (160Klux) with camera and stops, Qe60 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449747
Qe3Csvtc	Quasar eLite Qe30 lamp (160Klux) with camera and stops, single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449754
Qe3H10svtc	Main Qe30 Lamp head with HD Fixed Focus Camera 360° (160kLux) Satellite Qe10 Lamp head Lamp (100kLux) -Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449761
Qe3H30sanc	Quasar eLite Main Qe30 Lamp head with HD Fixed Focus Camera 360° (160kLux) Satellite Qe30 Lamp head (160kLux)-Single Cardanic-AC Spring-Arm-Tandem (45mm Stem) Ceiling Mounted	5060413449778
Qe3H30svtc	Main Qe30 Lamp head with HD Fixed Focus Camera 360° (160kLux) Satellite Qe30 Lamp head (160kLux) -Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449785
Qe3Hlvtc	Main Qe30 Lamp head with HD Fixed Focus Camera 360° (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449792
Qe3Hsvtc	Main Qe30 Lamp head with HD Fixed Focus Camera 360° (160kLux) -Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449808
Qe603010dvtc	Main Qe60 Lamp head (160kLux) Satellite Qe30 Lamp head (160kLux) Satellite Qe10 Lamp head Lamp (100kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449815
Qe603010svtc	Main Qe30 Lamp head with HD Fixed Focus Camera 360° (160kLux) Satellite Qe30 Lamp head (160kLux) Satellite Qe10 Lamp head Lamp (100kLux) -Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449822
Qe603030dvtc	Quasar eLite Qe60 lamp head (160Klux), Qe30 satellite (160Klux), Qe30 2nd satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449839
Qe603030svtc	Quasar eLite Qe60 lamp head (160Klux), Qe30 satellite (160Klux), Qe30 2nd satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449846
Qe6030dvtc	Quasar eLite Qe60 lamp head (160Klux), Qe30 satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449006
Qe6030GDdvtc	Quasar eLite Qe60 lamp (160Klux), Qe30 satellite (160Klux), 1.5-21Kg monitor arm, cabled with stops, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390602
Qe6030GDsvtc	Quasar eLite Qe60 lamp (160Klux), Qe30 satellite (160Klux), 1.5-21Kg monitor arm, cabled with stops, single cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390558
Qe6030lvtc	Quasar eLite Main Qe60 Lamp head (160kLux) Satellite Qe30 Lamp head (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449037
Qe6030svtc	Quasar eLite Qe60 lamp head (160Klux), Qe60 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449143
Qe606030dvtc	Quasar eLite Qe60 lamp head (160Klux), Qe60 satellite (160Klux), Qe30 2nd satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449853



## EU Declaration of Conformity

Qe606030svtc	Quasar eLite Qe60 lamp head (160Klux), Qe60 satellite (160Klux), Qe30 2nd satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449860
Qe606060dvtc	Quasar eLite Qe60 lamp head (160Klux), Qe60 satellite (160Klux), Qe60 2nd satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449877
Qe606060svtc	Quasar eLite Qe60 lamp head (160Klux), Qe60 satellite (160Klux), Qe60 2nd satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449884
Qe6060dvtc	Quasar eLite Qe60 lamp head (160Klux), Qe60 satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449013
Qe6060lvtc	Quasar eLite Main Qe60 Lamp head (160kLux) Satellite Qe60 Lamp head (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449167
Qe6060svtc	Quasar eLite Qe60 lamp head (160Klux), Qe60 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449150
Qe60dvtc	Quasar eLite Qe60 lamp head (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449112
Qe60GAdvtc	Quasar eLite Qe60 lamp (160Klux), 1.5-21Kg monitor arm, 3P with 360° power connectors, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390725
Qe60GDdvtc	Quasar eLite Qe60 lamp (160Klux), 1.5-21Kg monitor arm, cabled with stops, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390480
Qe60lvtc	Quasar eLite Main Qe60 Lamp head (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449136
Qe60svtc	Quasar eLite Qe60 lamp head (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449129
Qe6C30GDdvtc	Quasar eLite Main Qe60 Lamp head with HD Camera and Stop (160kLux) Satellite Qe30 Lamp head (160kLux) Satellite Accessory Arm 21kg Stopped-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449891
Qe6C30svtc	Quasar eLite Qe60 lamp (160Klux) with camera and stops, Qe30 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449075
Qe6C60dvtc	Quasar eLite Main Qe60 Lamp head with HD Camera and Stop (160kLux) Satellite Qe60 Lamp head (160kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449907
Qe6C60svtc	Quasar eLite Qe60 lamp (160Klux) with camera and stops, Qe60 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449914
Qe6Clvtc	Quasar eLite Main Qe60 Lamp head with HD Camera and Stop (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449921
Qe6Csvtc	Quasar eLite Qe60 lamp (160Klux) with camera and stops, single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449938
Qe6H3010LCCT	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe30 Lamp head (160kLux) Satellite Qe10 Lamp head (100kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413448832
Qe6H3030dvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe30 Lamp head (160kLux) Satellite Qe30 Lamp head (160kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449563
Qe6H3030svtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe30 Lamp head (160kLux) Satellite Qe30 Lamp head (160kLux), single Cardanic, V Spring-Arm, Titan Central Axis Ceiling Mounted	5060928390312
Qe6H30dvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe30 satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449228
Qe6H30GAdvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe30 satellite (160Klux), 1.5-21Kg monitor arm, 3P with 360° power connectors, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449945
Qe6H30GDdvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe30 satellite (160Klux), 1.5-21Kg monitor arm, cabled with stops, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449464
Qe6H30HDdvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe30 satellite (160Klux), 26Kg monitor arm, cabled with stops, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449952
Qe6H30lvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe30 Lamp head (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449235
Qe6H30svtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe30 satellite (160Klux), single cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449020
Qe6H6030dvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe60 Lamp head (160kLux) Satellite Qe30 Lamp head (160kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449969
Qe6H6030svtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe60 Lamp head (160kLux) Satellite Qe30 Lamp head (160kLux)-Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060928390848
Qe6H6060dvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe60 Lamp head (160kLux) Satellite Qe60 Lamp head (160kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449976
Qe6H60dvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe60 satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449068
Qe6H60GAdvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe60 satellite (160Klux), 1.5-21Kg monitor arm, 3P with 360° power connectors, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449983
Qe6H60GDdvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe60 satellite (160Klux), 1.5-21Kg monitor arm, cabled with stops, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060413449600
Qe6H60HDdvtc	Quasar eLite Qe60 lamp (160Klux) with camera, Qe60 satellite (160Klux), 26Kg monitor arm, cabled with stops, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390008
Qe6H60lvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe60 Lamp head (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449211
Qe6H60svtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) Satellite Qe60 Lamp head (160kLux) -Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449204

## EU Declaration of Conformity

Qe6Hdvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) -Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449174
Qe6HGDdvtc	Quasar eLite Qe60 lamp (160Klux) with camera, 1.5-21Kg monitor arm, cabled with stops, double cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390015
Qe6Hlvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) -Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449181
Qe6Hsvtc	Quasar eLite Main Qe60 Lamp head with HD Camera 360° (160kLux) -Single Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449198
Qe6P30dvtc	Quasar eLite Main Qe60 Lamp head with Camera Preparation (160kLux) Satellite Qe30 Lamp head (160kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449426
Qe6P60dvtc	Quasar eLite Qe60 lamp (160Klux) with camera provision, Qe60 satellite (160Klux), double cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390022
QeGA0vtc	Quasar eLite 1.5-21Kg monitor arm, 3P with 360° power connectors, no bracket, V spring arms, Titan central axis for ceiling mount.	5060413449440
QeGA60dvtc	Quasar eLite Accessory Arm 21kg 3 Pole 360° Satellite Qe60 Lamphead (160kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060928390770
QeGC60dvtc	Quasar eLite Accessory Arm 21kg 5P + 360° video connections Satellite Qe60 Lamp head (160kLux)-Double Cardanic-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449570
QeGDvtc	Quasar eLite 1.5-21Kg monitor arm, cabled with stops, VESA twin monitor bracket, V spring arms, Titan central axis for ceiling mount.	5060413449372
QeGDvvtc	Quasar eLite Accessory Arm 21kg Stopped -with Single Symposia-view VESA Monitor Bracket (fixed) -V Spring-Arm -Titan Central Axis Ceiling Mounted	5060413449259
QeHDvtc	Quasar eLite 26Kg monitor arm, cabled with stops, VESA twin monitor bracket, V spring arms, Titan central axis for ceiling mount.	5060413449471



Business Quality Assurance International

ISO 9001:2015

Certificate Number 325

Issue 2

# Certificate of Registration

*Certificate of registration of an organisation or business of assessed capability.*

Business Quality Assurance International Ltd hereby grants to

**Brandon Medical Company Ltd.**

**Elmfield Road, Morley, Leeds, West Yorkshire, LS27 0EL, UK.**

(hereafter called the Business) the right and licence to be listed in the BQAI Register of Businesses of Assessed Capability in respect of the goods or services particularly described below. Goods or services shall be provided by the business, only at the address(es) given above, all in accordance with ISO 9001:2015.

The Certificate of Registration is granted subject to BQAI regulations governing the registration referred to above.

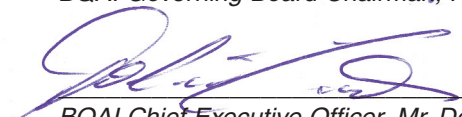
Goods or services in respect of which the business is registered:

**Design, manufacture, installation and servicing of: operating theatre lights, medical luminaries and associated control panels, medical video systems, emergency power units and earth bonding bars. Distribution of medical pendants, operating tables, UCV canopies, IPS and UPS systems.**

Signed:

  
BQAI Governing Board Chairman, Prof. Michael J. Hynes

Signed:

  
BQAI Chief Executive Officer, Mr. Declan O'Connor

Original date of registration: **31st August 2018**

Current certification three-year cycle start date: **31st August 2021**

Date of governing board endorsement: **31st August 2021**

Current certificate expiry date: **31st August 2024**

Date of extension of scope / name change approval: **N/A**

*The approval is subject to the supplier maintaining its Quality Management System to the required standard which will be monitored by BQAI.*

*This Certificate remains the property of Business Quality Assurance International Ltd. and can be recalled at any time.*



Anexa nr. 1  
*La Procedurile administrative pentru notificarea  
dispozitivelor medicale care dețin marcajul CE*

Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**  
pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale

nr. 47 din 09.06.2023

Solicitantul **FCPC „DataControl” S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: [contact@datacontrol.md](mailto:contact@datacontrol.md), solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

**Product: Examination Lamp**

**Model: COOLVIEW CLED53 FX**

CLED53FXBP  
CLED53FXDP  
CLED53FXMP  
CLED53FXRP  
CLED53FXWP  
CLED53FXC

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Actul prin care producătorul își desemnează reprezentantul
3. Declarație pe propria răspundere.

Data **09.06.2023**

Semnătura \_\_\_\_\_





**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	



Către  
Agenția Medicamentului  
și Dispozitivelor Medicale

## DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. "DataControl" S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: [contact@datacontrol.md](mailto:contact@datacontrol.md),

declar pe proprie răspundere, cunoscând prevederile art. 352<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

**Product: Examination Lamp**

**Model: COOLVIEW CLED53 FX**

CLED53FXBP  
CLED53FXDP  
CLED53FXMP  
CLED53FXRP  
CLED53FXWP  
CLED53FXC

**Sunt autentice și corespund realității**

**Alexandru Grabazei, director**



Semnătura

A handwritten signature in blue ink, written over a horizontal line. The signature is stylized and appears to be "Grabazei".

Data: **09.06.2023**



# EQUIPMENT PACKAGES FOR OPERATING THEATRES, CRITICAL CARE AREAS AND PRIMARY CARE

Medical power and control, lighting, architectural and audio video



To: Whom It May Concern

Date: 06/06/2023.

## Authorization

We, Company-manufacturer **BRANDON MEDICAL COMPANY LTD.**, of ELMFIELD ROAD, MORLEY, LEEDS, LS27 0EL

U.K., hereby appoint following company:

F.C.P.C. "DataControl" S.R.L.,

17/6, N.Testimiteanu street,

MD-2025, Chişinau, Republic of Moldova,

to be our official Representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc. .

Signature for and on behalf of Manufacturer, title of the authorized person, seal



**Arthur Loftus**  
**Regional Director, EMEA**

Brandon Medical Company Limited | Elmfield Road | Morley | Leeds | UK | LS27 0EL  
T: +44 113 277 7393 / 0845 1243 666 F: +44 113 272 8844 / 0845 1243 667  
E: [enquiries@brandon-medical.com](mailto:enquiries@brandon-medical.com) W: [www.brandon-medical.com](http://www.brandon-medical.com)  
Brandon Medical Company Limited. Registered in England & Wales No. 02827189 VAT No. GB734 591421.  
A subsidiary of Brandon Group Limited.  
Brandon Medical is always looking for opportunities to improve our products and customer service and we greatly value any feedback you can provide: [feedback@brandon-medical.com](mailto:feedback@brandon-medical.com)





## EU Declaration of Conformity



Brandon Medical Company Limited (BMCL)

Elmfield Road, Morley, Leeds, West Yorkshire, LS27 0EL, UK

SRN (Non-EU Manufacturer): GB-MF-000005501

SRN (European Authorised Representative): IE-AR-000003999

Declares that under our sole responsibility, the product: **Coolview 50**  
**Coolview 53**  
(Refer to end of declaration for variant UDI-DI & Basic UDI-DI)

With intended purpose of: **Examination Lamp**

Is in conformity to the general safety and performance requirements of the following EC Regulation:

- 2017/745 – Medical Device Regulation Risk Classification as per Annex VIII
- Class I Self-Declaration Medical Device
- Conformity assessment route: Class I: EC conformity self-declaration according to MDR 2017/745 Article 19, and Annexes II and III.

The following standards were applied in full:

- EN ISO 13485:2016 Medical devices Quality management systems - Requirements for regulatory purposes
- ISO 9001:2015 Quality management systems - Requirements
- BS EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN60601-1:2006+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- BS EN60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
- BS EN 60601-2-41 2009+A11:2011 Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
- EN 60601-6:2010+A1:2015
- Waste from Electrical and Electronic Equipment (WEEE) Directive

This product has been developed, tested and verified in accordance with the international standards listed above.

Person Responsible for Regulatory Compliance (PRRC)	Signature	Date
Annette Hemmings Head of Quality Assurance Brandon Medical Company Limited		17 MAY 2022
Countersignature	Signature	Date
Tom Partington Product Manager Brandon Medical Company Limited		17-05-22

European Authorised Representative: European Healthcare & Device Solutions (Ireland) Ltd. Stratton House, Bishopstown Road, Bishopstown, Cork, Ireland



## EU Declaration of Conformity

Model variant	Model description	UDI-DI (GTIN)	Basic UDI-DI
CLED50FXBP	Coolview CLED50 FX Articulated Arm Wall Mounted with Backplate Examination Lamp with UK Plug Lead	05060413447439	506041344CLED2L
CLED50FXC	Coolview CLED50FX Articulated Arm Ceiling Mounted Examination Lamp (Limited Rotation)	05060413448511	506041344CLED2L
CLED50FXDP	Coolview CLED50 FX Articulated Arm Desk Mounted Examination Lamp with UK Plug Lead	05060413447446	506041344CLED2L
CLED50FXMP	Coolview CLED50 FX Articulated Arm Mobile Mounted Examination Lamp with UK Plug Lead	05060413447453	506041344CLED2L
CLED50FXRP	Coolview CLED50 FX Articulated Arm Rail Mounted Examination Lamp with UK Plug Lead	05060413447460	506041344CLED2L
CLED50FXWP	Coolview CLED50 FX Articulated Arm Wall Mounted Examination Lamp with UK Plug Lead	05060413447477	506041344CLED2L
CLED50SXPB	Coolview CLED 50 SX Flexible Arm Wall Mounted with Backplate Examination Lamp with UK Plug Lead	05060413447484	506041344CLED2L
CLED50SXDP	Coolview CLED 50 SX Flexible Arm Desk Mounted with Lamp with UK Plug Lead	05060413447491	506041344CLED2L
CLED50SXMP	Coolview CLED 50 SX Flexible Arm Mobile Mounted with Lamp with UK Plug Lead	05060413447507	506041344CLED2L
CLED50SXRP	Coolview CLED 50 SX Flexible Arm Rail Mounted with Lamp with UK Plug Lead	05060413447514	506041344CLED2L
CLED50SXWP	Coolview CLED 50 SX Flexible Arm Wall Mounted with Lamp with UK Plug Lead	05060413447521	506041344CLED2L
CLED53FXBP	Coolview CLED53 FX Articulated Arm Wall Mounted with Backplate Examination Lamp with UK Plug Lead	05060413447545	506041344CLED2L
CLED53FXDP	Coolview CLED53 FX Articulated Arm Desk Mounted Examination Lamp with UK Plug Lead	05060413447552	506041344CLED2L
CLED53FXMP	Coolview CLED53 FX Articulated Arm Mobile Mounted Examination Lamp with UK Plug Lead	05060413447569	506041344CLED2L
CLED53FXRP	Coolview CLED53 FX Articulated Arm Rail Mounted Examination Lamp with UK Plug Lead	05060413447576	506041344CLED2L
CLED53FXWP	Coolview CLED53 FX Articulated Arm Wall Mounted Examination Lamp with UK Plug Lead	05060413447583	506041344CLED2L
CLED53FXC	Coolview CLED53FX Articulated Arm Ceiling Mounted Examination Lamp (Limited Rotation)	05060413448528	506041344CLED2L

