

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		5/12/2023

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

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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
Qe3CGDsvtc	Quasar eLite Qe30 lamp (160Klux) with camera and stops, 1.5-21Kg monitor arm, cabled with stops, single cardanic, V spring arms, Titan central axis for ceiling mount.	5060928390886
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

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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
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
Qe60GAlvtc	Quasar eLite Main Qe60 Lamphead (160Klux) Satellite Accessory Arm 21kg 3 Pole 360°-Low-Ceiling-V Spring-Arm -Titan Central Axis Ceiling Mounted	5060928391012
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

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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
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
Qe6H30GDSvtc	Quasar eLite Main Qe60 Lamphead with HD Camera 360° (160kLux) Satellite Qe30 Lamphead (160kLux) Satellite Accessory Arm 21kg Stopped, Single Cardanic, V Spring-Arm, Titan Central Axis for Ceiling Mount	5060928391203
QeGC30svtc	Quasar eLite-1.5-21Kg monitor arm-5P + 360° video connectors-Qe30 satellite (160Klux)-single cardanic-V spring arms-Titan central axis for ceiling mount	5060928391197
Qe30GDSvtc	Quasar eLite Qe30 lamp head (160kLux)-1.5-21kg monitor arm- cabled with stops-single cardanic-V spring arms-Titan central axis for ceiling mount	5060928391159