DECLARATION OF CONFORMITY
FIBRE LIGHT CABLES & CONNECTORS

BOLTON SURGICAL
Optical Supply.Repair.Exchange.

Bolton Surgical Fibre Light Cables are designed to transmit illumination from a light source with a power rating up to 300-watt Xenon to an endoscope, surgical instrument or surgical headlight.

Bolton Surgical Limited declares that the reusable **Fibre Light Cables** listed and coded within the Company catalogue are classified as:

Class I reusable surgical devices conforming to the requirements of UK Medical Device Regulations UK MDR 2002

Bolton Surgical Fibre Light Cables are manufactured in accordance with our Quality Management System certified to ISO13485:2016 in accordance with the requirements of UK Medical Device Regulations UK MDR 2002. Manufacturing processes and materials used are suitable for sterilization and as appropriate, products are manufactured and supplied in accordance with the requirements of one or more of the recognised standards and guidance documents listed below:

Standard:	*Details:*
BS EN ISO 13485:2016	Medical Devices – Quality Management Systems - Requirements for regulatory purposes
UK MDR 2002	UK Medical Device Regulations
BS EN ISO 7153-1:2016 (BS 5194:Part 1:1991)	Surgical Instruments – Metallic materials part 1 - Stainless Steel
BS EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices
BS EN ISO 17664-2017	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices.
BS EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.
HTM 01-01	Management and decontamination of re-usable surgical instruments (medical devices) used in acute care
AS/NZ 4187-2014	Cleaning, disinfecting & sterilising of re-usable surgical instruments

For and on behalf of Bolton Surgical Limited: L J Bolton *Date:* 11/10/2021

Name of person authorised to sign: Lyndsey J Bolton

Position in Company: Commercial Director

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Registered in England. Reg No. 1638982

Pride.Precision.Performance.

MEDILINK MEMBER

CE

bsi. FM 500657

UKAS MANAGEMENT SYSTEMS 003