

PRODUCT BROCHURE



EN ISO 13485 : 2016
MFG/MD/2023/000673
MFG/MD/2024/000113
UA/TEH/MD42/2023/000004

FIBER OPTIC LIGHT GUIDES

Illumination Light Guides: - Medical & Industrial Use

For the connection of the endoscopy light source with any endoscope an illumination light guide of medical cable is being used. Long life-time is being ensured by using autoclavable materials. Available in size 3.5, 4.5, 4.8mm & 2.3, 3mtr in length.

All types of fitting available such as Storz, Olympus, wolf, Stryker etc.

- High temperature 350rc epoxy used with fiber, easily used to xenon, led & halogen light source.
- Autoclavable, Steris & Sterrad tested.
- Fiber Type :-LF5 (Scott Germany).
- Ergonomic grips for easy handling with gloves.
- Private labeling available.

Fiber Type :- A2 Fiber Large angle
 Fiber Numeric aperture :- 0.66
 (Theoretical value at 587nm)
 Effective acceptance angle 2α at V :- $> 80^\circ$
 For 1m length (Measured for 40um fiber)
 Optical attenuation of single fiber :- $< 300\text{db/km}$
 At 553nm :- (measured for 401.1m fiber)
 Typical field of application :- Lighting sensor and medical Technology.



LIGHT GUIDE FOR FLEXIBLE ENDOSCOPE



Welfo Fiber optics is a leading manufacturer and OEM supplier of premium quality, ready to install illumination bundles for the following flexible endoscope brands and types:-

◆ Olympus ◆ Pentax ◆ Fujinon ◆ Karl Storz

Our high performance illumination bundles are made of small diameter, fast transmission fibers drawn in-house at our facility. Surrounding the bundle is a USP Class VI, thin wall silicone sheathing treated with Molykote inside and out for durability and ease of installation.

We offer more than 300 different styles. No minimum order requirement. Most prototypes are created in 2-4 days.

Most bundles are in stock and ready to ship same day to minimize turn time for your customers. Don't see what you need? Call us today. We can make it.

Welfo Fiber optics is a contract supplier to global instrument manufacturers. Contact us to discuss custom illumination bundles for your project.

HIGH POWER SILICA FIBER CABLES

Fiber Optic Laser cables are the best for laser power delivery with high brightness and beam quality. High power silica cables secure long term use for industrial and medical applications.

Main features:

- Special laser fiber structures
- Cool high power connectors HP-SMA and D80
- Flexible and robust for high power & bright laser beams



LED LIGHT SOURCE 120 WATT

This 120W endoscopy led light source is a product which represents the latest technology for the led development, which achieves the same effect as traditional 350W, xenon light source through endoscope, a perfect alternative product for xenon and halogen, it is widely used in endoscopy, microscopy, quality insurance, system test, industrial bore scopes, inspection systems, image process, machine vision, lab equipment, etc.

- ◆ High Brightness is comparable to 350W traditional xenon light source, could be used for laparoscopy without any problem.
- ◆ Long life, it could last 60,000 hours max, 120 times of xenon, so you do not need to replace the bulb for years.
- ◆ Wide range power from 100-240V/AC: 50/60Hz.
- ◆ Perfect color temperature 5000K to 6500k.
- ◆ Does not emit light in UV or IR.
- ◆ Customized connector, it accepts fiber light guides with active areas ranging from 3mm to 10mm diameter.
- ◆ It saves energy for more than 50%.
- ◆ Environmentally friendly.
- ◆ Friendly design, easy operation.



LED LIGHT SOURCE 50 WATT

This 30/60 Watt and industrial use led light source is a product which represents the latest technology for the led development. A perfect alternative product widely used in ENT, endoscopy, microscopy, industrial bore scopes, inspection systems, image process, machine vision, lab equipment, etc.

- ◆ High Brightness is comparable to 30/60 Watt could be used for laparoscopy without any problem.
- ◆ Long life, it could last 60,000 hours max, so you do not need to replace the bulb for years.
- ◆ Wide range power from 240V/AC: 50/60Hz.
- ◆ Perfect color temperature 5000K to 6500k.
- ◆ Does not emit light in UV or IR.
- ◆ Environmentally friendly.
- ◆ Friendly design, easy operation.
- ◆ ISO 13485 certified.



VIDEO HD CAMERA

- ◆ 1/1.8" or 1/2.8 " SONY CMOS.
- ◆ Video : 1920*1080P 50/60fps.
- ◆ Output : 2*HDMI+1 *DVI+1 *SDI+1 *CVBS+2*USB.
- ◆ CAMERA 4 *BUTTONS : AWB, FREEZE, RECORD, CAPTURE
- ◆ CCU BUTTONS : MENU, AWB, FREEZE, BRIGHT +RECORD, CAPTURE, SURGICAL, COLOR
- ◆ RECORD : MP4
- ◆ CAPTURE :JPG
- ◆ User defined : Color, shortcut button, surgical scenes.
- ◆ Support PLAYBACK VIDEO AND PHOTO.
- ◆ Support HDMI LCD Touch Screen (RS232).
- ◆ Support HD recording by USB.
- ◆ Support customize : LOGO, Language, Menu.etc.



RECHARGEABLE ENT HEADLIGHT

Maximum excellent LED headlight. Headband makes this LED headlight easy to wear for long periods of time. Our new headlight is engineered to outperform any portable LED light surgical headlight system available today. Providing an exceptionally bright, cool white, clear spot light.

Features:-

- Light Source :- LED Technology.
- Illumination Spot Size :- 3.5" approx.
- Lights working distance from 10"- 15" approx.
- Power of light :- 5w LED.
- Recharge time :- 1.5 hour.
- Adaptable voltage :- 100-240V, 50-60Hz.
- Life of light :- 20,000 hours
- Brightness :- High power
- LED Color :- Cool white
- Light weight :- 268gm(9.45ounce)
- Preferred for comfort.
- Compact optical system
- Fully adjustable



SURGICAL HEADLIGHT



We are offering a wide range of quality medical equipment fiber optic headlight. This headlight is used in various medical applications like checking the true tissue color of a human body using high illuminating lights provided by these headlights. It can be also used in cardio and spine surgery.

Fiber Optic Headlight is available in variable 5-80mm light spot or fixed 80mm light spot at the distance of 16". At 19.5" the spot size is 100mm for fixed or variable type headlight. This is virtually shadow free.

ENT HEAD LIGHT WITH LOUPE

Surgical LED Headlight with Intensity Controller Galilean Loupe (Surgical)

Lens Type	: Galilean
Suitable for	: Surgical
Frame Material	: Plastic
Mounting Type	: Headband
Type	: Through the lens
Recharge time	: 1.5 hour.
Life of light	: 20,000 hours
Magnification	: 3.5x
Working length	: 350mm
Weight	: 300gm
Warranty	: 1 year manufacturing defect
Fully adjustable	



FIBER OPTIC LARYNGOSCOPE

Laryngoscopes & allied anesthesia products offered by our firm include Fiber Optic Laryngoscope, Flexible Blade Laryngoscope, Laryngoscope Set Adult, Laryngoscope Set Pediatrics, Disposable Laryngoscope, Laryngoscope Blades, Macintosh Type Blades, Miller Type Blades, Laryngoscope Battery Handle, Laryngoscope Bulb, Magill Forceps etc.

These products are well-known in the market for their durability, longer service life, corrosion-resistance, reliability, sturdy design and ease of use.

- ◆ Laryngoscope handle with inbuilt LED Bulb, White light, Standard handle with modular.
- ◆ Reusable Fiber Optic Laryngoscope Blade with detachable Fiber Optic tube.
- ◆ 60,000 hours LED life.
- ◆ Large Quartz for Maximum Light. Incomparable Intense, bright LED light handles.
- ◆ Surgical Stainless steel, Brass, Aluminum & Export Quality material is used to make this Device.



RIGID ENDOSCOPE

Specifications :

- 0 / 30 / 70 Degree Sinuscope, Cystoscope, endoscope
- Adopt high quality stainless steel material
- Endoscope adopts German optic glass, light fiber and light cone
- Degree :- 0 / 30 / 70 Degree
- Sapphire cover for lens, never abrasion
- Endoscope can stand of temperature of 134°C/273° F for sterilization
- New optic system, clearfield of view
- Comes with storz adapter for light cable input



Welfo offers a wide range of repair services including:

- ◆ Rod Lens Replacements
- ◆ Stainless Steel Tubing Replacement
- ◆ Objective Replacement
- ◆ Eye Cup Replacement
- ◆ Rigid Camera Repair

Total Scope is the perfect choice for rigid endoscope repair services. Our technicians are professionally trained and have years of experience executing both major and minor repairs on a broad range of rigid endoscopes.



ENT PORTABLE LED LIGHT PEN

Portable SW LED light source. Very small, easy to carry, easy to use stick LED light source. Can be connected to both rigid and flexible endoscopes. For in clinic usage. Charger and rechargeable batteries are included.

Working hours : 2 hours continuously

Charging time : 1.5 hours.



FIBER OPTIC PHOTOTHERAPY PAD

We are providing Glass Optical Fiber pad for phototherapy which is the most premium modality for the treatment of neonatal jaundice in terms of safety and comfort. Optical fiber based light therapy allows to deliver healing light only to the skin without polluting into surroundings thereby increases comfort to both patient and care-taker. Flexible fiber optic pad allows to wrapped around the baby such that mother could hold while breast feeding.

Advantages over conventional Phototherapy system : -

Adjustable irradiance	: up to 601.1 W /cm ² /nm
Spectrum	: 450-470nm with peak at 455nm
Larger surface area	: illumination area (20cmX34cm)
Innovative optical design	: Provides uniform Illumination
Flexible Pad	: allows to wrap over the baby



PHOTOTHERAPY LIGHT SOURCE

Features :

Adjustable irradiance	: up to 60uW/cm ² /nm	Spectrum	: 450-470 nm with peak at 455nm
Larger surface area	: illumination area (25cm x 40cm)	Quiet operation	: Very low noise operation
Innovative optical design	: Provides uniform illumination	Flexible Blanket	: Allows to wrap over the baby
Device Timer	: Monitor treatment time & LED usage	Long life LED source	: 50,000 hours

Safety : ♦ No UV/IR emission ♦ Automatic cut off for overheating

Electrical specifications

- ♦ Voltage: 180 – 260 AC
- ♦ Power (max): 45 Watts
- ♦ Fuse: 3.15A

Electrical Classification

- ♦ Type of shock protection: IEC Class 1
- ♦ Degree of shock protection: Type B
- ♦ Mode of operation: continuous



USB ENDOSCOPY CAMERA

- ♦ 1/4" CCIQ III DIGITAL CMOS Sensor
- ♦ Variable Focal Range Couplers Available
- ♦ 5.0 Mega Pixel, Full HD
- ♦ 2.0 HI-Speed USB Data Transfer
- ♦ Driver Free
- ♦ Focusable Video Coupler Included
- ♦ Compact, Light Weight Body
- ♦ Windows 10 and Mac OS (macOS) compatible!



OESOPHAGOSCOPE RIGID SET WITH FIBER OPTIC LIGHT CARRIER

Fiber Optic Oesophagoscope offer the finest in design and craftsmanship to provide optimal clinical performance. Oesophagoscope with fiberoptic light carrier, for Child, Adolescent and Adults, graduated in centimeters. Esophageal Speculum available in Polished metal or Mat finishes metal in case. Fiber optics provide a cool distal ring of light with no reflections, no obstructions. Made from autoclavable stainless steel for convenience and durability. Graduated tube with removable tip for fiber cleaning.

- ◆ F.O. Oesophagoscope Adult Length 45cm Dia 16mm
- ◆ F.O. Oesophagoscope Medium Length 35cm Dia 12mm
- ◆ F.O. Oesophagoscope Child Length 25cm Dia 8mm



DIGITAL OTOSCOPE

The digital Otoscope is intended to allow inspection of the external ear, ear canal, and tympanic membrane under magnification.

Technical features and Specification :-

Dimension	: 43*43*175 mm
Weight	: Approximate 140 g
Display	: 1.5"full color TFT-LCD
Probe size	: 3.9mm*43mm (L)
Resolution	: Full HD resolution
Focus Type	: Mixed focus
Light Source	: High Luminance White LED
File Format	: JPEG, MP4
Interface	: USB type C
Memory	: Micro SD card 32G
WIFI standard	: 802.11
Power	: Built-in rechargeable lithium battery 3.7V/2600mAh/ (6 hours runtime)



DISPOSABLE PROCTOSCOPE

A proctoscopy (rigid sigmoidoscopy) is a procedure to examine the insides of the rectum and the anus. A proctoscopy is a hollow tube, usually with a tiny light at the end that can also be used to take tissue samples for biopsies as a cancer screening tool. The procedure also helps your gastroenterologist find other causes of rectal and anal bleeding, such as hemorrhoids.

- ◆ Detect disease in the rectum or anus.
- ◆ Find the source of anal bleeding.
- ◆ Find the cause of diarrhea or constipation.
- ◆ Remove or monitor the development of existing polyps or growths.
- ◆ Screen for colon cancer or monitor rectal cancer that has already been treated.



LED OT LIGHT

Highest intensity, Feather touch digital touch panel integrated with high definition Optical system. Flare is a revolutionary product in surgical lighting division. The streamlined Shape minimize disruption of laminar airflow in the operation theatre, and the light weight of the lamp enables easy setting of the lamp and its stable positioning.

Technical Data :

Intensity: 2,00,000 Lux

Intensity Control: 10~100 Digital Touch

Spot Diameter: 100-150 mm

Diameter of Light: 749 mm

Special Function: Dual memory function

LED Average life: >50000 Hrs.

Colour Rendering Index: 93 Ra

No. of LED's: 84

Depth Diameter: 10-25 cm

Power Supply: 220V/50Hz AC

Power Consumption: 67.2 wa

Colour Temp.: 3800 - 4800k

Focusing: Manual



HYDRAULIC OT TABLE

FEATURES

- ◆ Hydraulic and Mechanical Operated.
- ◆ Centric base made from high quality stainless steel.
- ◆ Leg & Head section are interchangeable.
- ◆ Centric pillars, Stainless flitting.
- ◆ Detachable head, leg and pelvic section.
- ◆ Inbuilt kidney bridge.
- ◆ Base and cover made of attractive, easy to clean stainless steel.
- ◆ Sophisticated mechanics provide smooth, stepless articulation of the table top for precise patient positioning.



LED PHOTOTHERAPY STAND



- ◆ Easy to operate.
- ◆ Low power consumption (12 W) compared to any conventional phototherapy system (120 W).
- ◆ LED's emitting blue light in 450-470 nm. Spectrum matching peak absorption wavelength (458 nm.) at which bilirubin is broken down. Do not emit light in infrared radiation range reducing the risk of fluid loss.
- ◆ Long life > 20,000 hrs.
- ◆ Negligible Maintenance cost.
- ◆ Intensity: > 25 $\mu\text{W} / \text{cm}^2 / \text{nm}$.
- ◆ Heavy duty mobile stand with height adjustment facility & easy swivelling box when stand is to be used in conjunction with radiant warmer or infant trolley.
- ◆ Mounted on castors for easy mobility.
- ◆ M.S. Fabrication with powder coated paint

ECG MACHINE

Equipped with High-resolution thermal printing array system, the offered one channel ECG machine is used for screening of different cardiac abnormalities. Manufactured by using latest machinery, the one channel ECG machine is known for its frequency response as high as 150 Hz.

Features:

- ◆ Capable of printing continuously on channel trace and annotations including lead mark and parameter such as sensitivity, paper speed and filter operation status.
- ◆ High resolution digital filter inhibits baseline drift without affecting ECG waveform
- ◆ One-touch operation
- ◆ Concept of floating input circuit meets IEC safety standard
- ◆ Rechargeable battery supporting more than 50 patient examinations
- ◆ Lead Standard: 12 leads.



OXYGEN CONCENTRATOR

Oxygen concentrator consisted of air compressor, adsorption tower of molecular sieve, sensor and flow meter. With the molecular sieve to be absorbent, the machine adopts PSA (pressure swing absorbers) method to directly concentrate medical oxygen with high concentration from the air. It is small and portable. The machine takes the advantages of small volume, light in weight, convenient in moving (it has turning truckle), stable in performance, high in safety, easy in operating, low in noise, safe in working which complies with requirements of medical device. The machine can also realize the measurement and display of SpO₂ and pulse rate by connecting accessories. The machine has a wide applications, including hospital, clinic, oxygen bar, plateau outpost, gym center etc.



CO2 INSUFFLATOR

- ◆ Digital indication of instantaneous flow
- ◆ Auto cut off at set pressure.
- ◆ Auto disinflation (safety features)
- ◆ Smart bottle level indication.
- ◆ Data Memory inside (Micro controller technology)
- ◆ Pressure :- Pre-selection : 0-24 mm HG
- ◆ Pressure accuracy : ± 1 mm HG
- ◆ Pressure sensor :- Made in Germany
- ◆ Pulsatile flow of gas in verses mode.
- ◆ Non-pulsatile flow of gas in trocar mode.
- ◆ Auto cut-off and restart on abdominal pressure reaching set value.
- ◆ Universal regulator to accept any size of CO₂ cylinder.
- ◆ Safety valve in regulator acting as an auto blow-off for excess CO₂ pressure in cylinder.
- ◆ Cylinder gas indicator in console (empty/full)
- ◆ Feather touch switch to change on to air mode.
- ◆ Feather touch tactile switch.
- ◆ Dual system operation (manual and through remote control).
- ◆ Inbuilt stabilizer.



FLEXIBLE VIDEO BRONCHOSCOPE & LARYNGOSCOPE

Multi-function Buttons : Capture, record, freeze, zoom in/out.

CMOS + LED Technology : CMOS image sensor delivers a high quality image.

No fiber : durable and easy maintenance.

Application : Pneumology : bronchoscopy, peripheral observation and interventional therapy.



Model	Insertion Tube	Working Channel	Working Length	Bending (up/down)	Rotation (left/right)	View Angle	Depth of View	Image Processor
LTEF23A	2.8mm	1.2 mm	610mm	210°/130°	120°/120°	120°	3-50 mm	Standard : 8 inches portable Monitor
LTEF23B	4.2mm	2 mm						Optional : 10 inches portable monitor
LTEF23C	4.8mm	2 mm						HD image Standard : 10 inches
LTEF23D	5.8mm	2 mm		180°/130°				portable monitor

RAW GLASS FIBER BUNDLE



We are manufacturing world class glass optical fiber, basic raw material such as glass tube & glass rod imports from Germany {Schott}. We are providing different size glass fiber bundles as per customer's requirement for their own manufacturing.

S. No.	Fiber Bundle Dia	Bundle Length	Single Fiber Dia
1	4mm	10mtr	30 to 40 micron
2	5mm	10mtr	30 to 40 micron
3	6mm	10mtr	30 to 40 micron

Core Refractive Index	1.5814
Clad Refractive Index	587.6
Wave Length	380 to 1500nm maximum transmission
Glass Code	581409.322
Core & Clad Ratio	80:20
Numeric Aperture	0.64

FIBER OPTIC BAND PIPE & ATTACHMENTS

New technology which simultaneously retracts the tissue and illuminates the operating field. Reliable, safe and cost effective solution to non-autoclavable cables which require special sterilization and care.

These instruments are available with fiber optic attachments such as Deaver, Right angle, Cusco, Sigmoid Scope, Proctoscope, ENT Laryngoscope, Bronchoscope etc.



CERTIFICATE OF COMPLIANCE



INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the

MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEM of

WELFO FIBER OPTICS

Forest Road, Industrial Area, Dhalwala Rishikesh, Uttarakhand - 249201, India.

has been assessed and registered as complying with the requirements of the following International Standard:

ISO 13485 : 2016

The Medical Devices - Quality Management System applicable to:

Scope : Manufacturing, Sales and Distribution of Rigid Endoscope, Fiber Optics Phototherapy Pad, Fiber Optics Light Guide Cable, Fiber Optic Light Guide Bundle, LED (Light - Emitting Diode) Light Source, ENT (Ear, Nose, and Throat) Headlight, ENT Portable Torch, Retractors with Optical Fiber Attachments & Optical Glass Fiber and Trading of Intubation Laryngoscope & Fiber Carrier Attachment.

Registration No. : RQMD91/11703
Registered Date : 12th February, 2024
Issue Date : 20th February, 2024
Expiry Date : 11th February, 2027



QMS 009



Amnir

Director (Technical)

International Certification Services Pvt. Ltd.

Accredited by National Accreditation Board For Certification Bodies, India.

Validity of this certificate is based on periodic audits of the management system defined by the above scope and is contingent upon prompt, written notification of significant changes to the management system and/or its components thereof shall be immediately communicated to ICS. Further certifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained at www.icsindia.com or www.icspl.org

2373, Gopal Prastha, Swasti Estate, 178 CST Road, Kalra, Sarbajit (S) Mumbai - 400 046, Maharashtra, India. Tel: 022-42200400



FORM MD-42

[See sub-rule(4) of rule 87A and sub-rule (1) of rule 87C]

REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE

Registration no: UA/TEH/MD42/2023/000004 /864

1. M/s WELFO FIBRE OPTICS situated at FOREST ROAD DHALWALA TEHRI GARHWAL UTTARAKHAND 249201, Tehri Garhwal, Uttarakhand-249201, India Telephone No.: 01353550465, FAX: 01353550465, E-mail: saleswelfofiber@gmail.com, has been registered to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device under the Medical Devices Rules, 2017.
Constitution: Proprietary

2. Name and qualification of competent person:

S.No.	Name	Qualification	Experience
1	Sanjay Bhatt	12th	5 Years

3. This registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: Tehri Garhwal, Uttarakhand

Date: 15-Apr-2023

Tajbir Singh
15/4/2023
State Licensing Authority
(Tajbir Singh)
Drug Controlling & Licensing Authority
Uttarakhand



FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2024/000113 /2576

1. M/s Welfo Fiber Optics, Forest Road, Industrial Area/Varenda Nagar, Tehri Garhwal, Uttarakhand (India) - 249201 Telephone No.: 9567870167 FAX: 01353550465 has been licensed to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s WELFO FIBER OPTIC, FOREST ROAD, INDUSTRIAL AREA, DHALWALA, RISHIKESH, Tehri Garhwal, Uttarakhand (India) - 249201 Telephone No.: 0135-3550465 FAX: 0135-3550465

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name: Rigid Endoscope Model No. Welfo - Rigid Endoscope RE/1301 Intended Use: An endoscope with a rigid inserted portion intended for the visual examination and treatment in minimally invasive surgical procedures like (minimally invasive surgery, cystoscopy (urinary bladder), and laparoscopy (abdomen)). Class of medical device: Class B Material of construction: Objective Lens Assembly, Rod lenses, Light fiber, light post, light cable, focusing, coupler window, ocular system, retainer/ marker plate, housing, optical tubing, inner tubing, outer tubing, as pipe, peek rod, as rod Dimension (if any): (2.9mm length: 175mm - 45°, 30°, 45°, 70°, 90°) (2.9mm length: 302mm - 45°, 30°, 45°, 70°, 90°) (4mm length: 175mm - 45°, 30°, 45°, 70°, 90°) (4mm length: 302mm - 45°, 30°, 45°, 70°, 90°) (5mm length: 335mm - 45°, 30°, 45°, 70°, 90°) (10mm length: 325mm - 45°, 30°, 45°, 70°, 90°) Shelf life: 3 YEARS Sterile or Non sterile: Non-Sterilized Brand Name (if registered under the Trade Marks Act, 1999): Welfo
2	Generic Name: Fiber Optic Phototherapy Pad (Blanket) Model No. Welfo - Fiber Optic Phototherapy Pad/ Blanket PTP/1219 Intended Use: A device designed to emit a blue light in the visible wavelength of around 425-475 nm to treat neonatal jaundice (or hyperbilirubinemia). It consists of a fiber optic light source that connects through a flexible fiber optic cable to a transparent blanket-like wrap or pad which emits the light and covers or reduces the neonate's body. Exposure to this device will alter the bilirubin through photo-oxidation and configurational and structural isomerization allowing the body function to dispose of it naturally. This device can be suitable for home-use. Class of medical device: Class B Material of construction: 3mm paper, PU Cover, Inner Sleeve (Plastic), Fiber holder, Gray Silicon sleeve, (A3 size paper synthetic), 3mm plain sticker sheet, Silver paper, Outer Cover, Optical fiber. Dimension (if any): 400mm x 250mm, 260mm x 180mm Shelf life: 2 YEARS Sterile or Non sterile: Non-Sterilized Brand Name (if registered under the Trade Marks Act, 1999): Welfo

Place:
Date: 26-Feb-24

Tajbir Singh
26/2/2024
State Licensing Authority
(Tajbir Singh)
Drug Controlling & Licensing Authority
Uttarakhand



FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2023/000673 /2534

1. M/s Welfo Fiber Optics, Forest Road, Industrial Area/Varenda Nagar, Tehri Garhwal, Uttarakhand (India) - 249201 Telephone No.: 9567870167 FAX: 01353550465 has been licensed to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s WELFO FIBER OPTIC, FOREST ROAD, INDUSTRIAL AREA, DHALWALA, TEHRI GARHWAL, Tehri Garhwal, Uttarakhand (India) - 249201 Telephone No.: 0135-3550465 FAX: 0135-3550465

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name: Fiber Optic Light Guide Model No.: STZ/1240 - Fiber Optic Light Guide 3.5 MM X 2.3 METER, STZ/1241 - Fiber Optic Light Guide 3.5 MM X 2.5 METER, STZ/1242 - Fiber Optic Light Guide 3.5 MM X 3 METER, STZ/SSP/1243 - Fiber Optic Light Guide 4.5 MM X 2.3 METER, STZ/1245 - Fiber Optic Light Guide 4.5 MM X 2.5 METER, STZ/1246 - Fiber Optic Light Guide 4.5 MM X 3 METER, STZ/1247 - Fiber Optic Light Guide 4.8 MM X 2.3 METER, STZ/1248 - Fiber Optic Light Guide 4.8 MM X 3 METER, STZ/1249 - Fiber Optic Light Guide 4.8 MM X 2.5 METER, MCR/1263 - Fiber Optic Light Guide 6 MM X 4 FEET, ZZ/1264 - Fiber Optic Light Guide 6 MM X 4 FEET, PT/1265 - Fiber Optic Light Guide 3.5 MM X 5.5 FEET Intended Use: USED FOR RIGID ENDOSCOPE Class of medical device: Class A Material of construction: GLASS FIBER OPTIC Dimension (if any): PROVIDED IN MODEL NO & SPECIFICATION COLUMN Shelf life: 5 YEARS Sterile or Non sterile: Non-Sterilized Brand Name (if registered under the Trade Marks Act, 1999): WELFO

Place:
Date: 20-Jul-23



Tajbir Singh
20/7/2023
State Licensing Authority
(Tajbir Singh)
Drug Controlling & Licensing Authority
Uttarakhand

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WF[®] Welfo Fiber Optics

Manufacturer of Fiber Optic Light Guides & Medical Devices

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