



सत्यमेव जयते

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/2024/000211

1. M/s PHOTOTRONIC ENGINEERS, OPP KALA MANDIR, NEAR AJANTA COMPLEX, DHEBAR, ROAD SOUTH, RAJKOT, GUJRAT, 360002 RAJKOT, Rajkot, Gujarat (India) - 360002 Telephone No.: 9714144444 FAX: 9714144444 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PHOTOTRONIC ENGINEERS, OPP KALA MANDIR, NEAR AJANTA COMPLEX, DHEBAR ROAD SOUTH, Rajkot, Gujarat (India) - 360002 Telephone No.: 9824056590 FAX: 9824056590

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	<p>Generic Name:Laparoscope Model No.:NIL Intended Use:Laparoscope is inserted through an incision in the abdominal wall and is used to examine visually the interior of the peritoneal cavity. Class of medical device:Class B Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers Dimension(if any):Manufacturing of various diameters, angles of view and lengths Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>
2	<p>Generic Name:Endoscope Model No.:NIL Intended Use:An endoscope is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs and canals. Class of medical device:Class B Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers Dimension(if any):Manufacturing of various diameters, angles of view and lengths Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>

3	<p>Generic Name: Hysteroscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended used for the visual examination of the cervix and interior of the uterus.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>
4	<p>Generic Name:Cystoscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended for the visual examination of the bladder and the urinary tract.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>
5	<p>Generic Name:Urethroscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended for the visual examination of the urethra.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>
6	<p>Generic Name:Ureterorenoscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended for the visual examination of the ureter and the renal pelvis.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>

7	<p>Generic Name:Otoscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended for visual examination of the outer ear canal and tympanic membrane (eardrum) by direct viewing through the ear opening.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>
8	<p>Generic Name:Laryngoscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended for visual examination of the larynx (voice box).</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>
9	<p>Generic Name:Bronchoscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended for the visual examination of the trachea, primary bronchi and upper regions of the lungs.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>
10	<p>Generic Name:Nephroscope</p> <p>Model No.:NIL</p> <p>Intended Use:Intended for visual examination of the kidney, renal pelvis, major calyces and minor calyces by percutaneously inserting scope into the renal pelvis.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 (1.4301) , Victrex PEEK 450, epoxy, glass optics, glass fibers</p> <p>Dimension(if any):Manufacturing of various diameters, angles of view and lengths</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): ENDO OPTICS / PHOTOTRONIC ENGINEERS</p>

Place: GANDHINAGAR

Date 27-Mar-24

State Licensing Authority

