



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/2019/000078

1. M/s Hospi Line Equipments Pvt. Ltd., F-15A, 3rd Floor Jindal Complex Subhash Chowk, Laxmi Nagar, DelhiDelhi, --, Delhi (India) - 110092 Telephone No.: 9810021997 FAX: 01122460362 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Hospi Line Equipments Pvt. Ltd., G-439, 440, 441 & 442, UPSIDC, Phase-II, M.G. Road, (Near Coca-Cola), Hapur, Ghaziabad Uttar Pradesh (India) - 201015 Telephone No.: 120-4150332 FAX: 120-4150332

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:Aspiration and Injection Needle Model No.:A-B-XXXX - Custommade-Device Intended Use:The standard TBNA technique uses 21-gauge cytology needles or 19-gauge histology needles together with a flexible bronchovideoscope. To localise the mass or node to be aspirated the bronchoscopist uses chest radiographs and CT scan. The needle is then advanced to the sampling area and moved out of the sheath. The target tissue is pierced with the needle and aspiration is started. After aspiration, the needle is fully retracted into the sheath and withdrawn through the working channel. Class of medical device:Class B Material of construction:PTFE Tube, ABS/Nylon Handle, Medical Grade SS Needle, Medical Grade Glue, Heatshrink Tube Dimension(if any):O.D. - 1.8, 2.3mm and length - 100, 160, 230cms Shelflife:3yrs. Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>

2	<p>Generic Name:Endoscopic Ligation Device  Model No.:G-PXXXX - Custommade-Device ,G-H-XXXX - Custommade-Device  Intended Use:Band Ligator Set Under direct visualization through an endoscope, elastic bands are applied to Esophageal or Gastric Varices. When Varices are bleeding, this procedure provides a means of hemorrhage control. When Varices are not bleeding, Ligation Therapy may be performed for therapeutic prevention of future hemorrhage via Variceal Ablation.  Class of medical device:Class B  Material of construction:Silicon &amp; Crystal Part, Nylon Thread, Silicon (Latex Free) "O" Rings, TPU Tube,  Dimension(if any):O.D. - 8.9mm-11mm and Lenght - 165cms.  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>
3	<p>Generic Name:Forceps Endoscopic  Model No.:H-X-XXX D-X-XXX F-X-XXXX - Custommade-Device  Intended Use:For removing the foreign body these forcep are passes through the endoscope and grip over the foreign body and remove it. For difference type of foreign body endoscopist has to decide which design/type of foreign body removing forcep has to use. For marbel/denture type of foreign bodies, net snare has to use, for bone pcs. 2/3/4 prongs are required and for coin rat teeth/alligator forcep required. If doctor found any polyps or tumors during endoscopy or other colorectal exam, and they are too big to be removed on the spot, then doctor will pass the biopsy through the channel of the endoscope, will take small samples of the tissue and test it for cancer before ordering another test. The tissue is generally examined under a microscope by a pathologist, and can also be analyzed chemically.Same process will be used for the Brush Biopsy.  Class of medical device:Class B  Material of construction:ABS/Nylon Handle, Medical Grade Spring and SS Wire/PTFE, Medical Grade SS Rod/Netcloth/Magnet/Nylon Brush, Medical Grade Glue, Heatshrink Tube.  Dimension(if any):O.D. - 1, 1.8, 2.3mm and Length - 100, 160, 230cms  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>
4	<p>Generic Name:Gastro-Enterostomy Tube  Model No.:C-PEG-XX - Custommade-Device  Intended Use:Patients who are unable to move food from their mouth to their stomach are the ones who commonly need PEG tube placement. This includes those with neurologic disorders such as stroke, cerebral palsy, brain injury, amyotrophic lateral sclerosis, and impaired swallowing. In addition, patients who have trauma, cancer, or recent surgery of the upper gastrointestinal or the respiratory tract may require this procedure to maintain nutrition intake.  Class of medical device:Class B  Material of construction:Silicon/PU feeding Tube, Nylon thread, Nylon Tube, Connector &amp; Tip  Dimension(if any):O.D. - 6.7, 8mm and Length - 80-90cms.  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>

5	<p>Generic Name:Oesophageal Sengstaken Tube  Model No.:K-S-XXXX - Custommade-Device  Intended Use:It is used in like threatening upper GI bleed from ruptured oesophageal/gastric varices when traditional treatment with band ligaton or glue injection has failed or are not available. This is only temporary method to buy time for more definitive procedures to stop the bleeding.  Class of medical device:Class B  Material of construction:Latex / Silicon Balloon (Small &amp; Big), Triple Lumen Silicon Tube, PU Connectors, Medical Grade Glue/Nylon Thread, Heatshrink Tube  Dimension(if any):O.D. - 6.7, 8mm and Length - 80-90cms  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>
6	<p>Generic Name:PERCUTANEOUS NEPHROSTOMY DRAINAGE CATHETER  Model No.:NIL  Intended Use:Percutaneous Nephrostomy Set: Used for external urine drainage from the renal pelvis. Nephrostomy is performed whenever a blockage keeps urine from passing from the kidneys, through the ureter and into the urinary bladder. Without another way for urine to drain, pressure would rise within the urinary system and the kidneys would be damaged.  Class of medical device:Class B  Material of construction:Fluroscopic PU Tube &amp; Connector  Dimension(if any):O.D. - 2.6mm-10mm and Length - 30cms.  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>
7	<p>Generic Name:Sclerotherapy Needle /Catheter  Model No.:A-G-XXXX A-C-XXXX - Custommade-Device  Intended Use:Indications for endoscopy to introduce a sclerosing agent or vasoconstrictor into selected sites to control actual or potential bleeding lesions in the digestive system; and the injection of saline to aid in Endoscopic Mucosal Resection (EMR), polypectomy procedures and to control non-variceal hemorrhage  Class of medical device:Class B  Material of construction:PTFE Tube, ABS/Nylon Handle, Medical Grade SS Needle, Medical Grade Glue, Heatshrink tube.  Dimension(if any):  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>

8	<p>Generic Name:Billiary Stone Retrieval Basket  Model No.:X-E-XXXXXX S-E-XX - Custommade-Device  Intended Use:Billiary Stone Retrieval Baskets and balloon are usually used for the removal of common bile duct stones. Baskets are generally used for stone extraction, but balloon extraction catheters are also used for this purpose, especially to remove small stones and biliary track. 1. After Endoscopic sphincterotomy, remove the wire guide with the sphincterotome but beginners can leave the wire guide in the bile duct. 2. Capturing the Stone the most basic technique of capturing a stone with a standard 4-wire basket is to advance the catheter until upstream of the stone, then pull the catheter back slowly after opening the basket. Stone capture is accomplished  Class of medical device:Class B  Material of construction:PTFE Tube, Latex / Silicon Balloon, Medical Grade SS Wire, ABS/Nylon Handle &amp; Connector, Medical Grade Glue  Dimension(if any):O.D. - 1-2.85mm and Length - 100, 160, 230cms.  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>
9	<p>Generic Name:Urethral/Uretic Catheter  Model No.:U-U-XXXXX - Custommade-Device  Intended Use:One of the most common types is the uretic or urinary catheter, which is used to drain urine from the urinary bladder of a man or woman.Drainage of urine from the kidney.  Class of medical device:Class B  Material of construction:PU/PTFE Tube  Dimension(if any):O.D. - 1mm-2.3mm and Length - 70cms  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>
10	<p>Generic Name:Endoscopy Mucosal Ressection Catheter  Model No.:M-E-XXXX - Custommade-Device ,Q-E-XXXX - Custommade-Device  Intended Use:A snare is a self-contained metal ring that is opened over the polyp and then closed entrapping polyp tissue for resection by closing the ring. Before pulling the snare out of the scope, the polyp should be brought to the six o'clock position. Once the polyp is captured in the snare, the snare plastic sheath should be advanced moving the polyp away from the scope tip if electrocautery is to be used to avoid electrical damage to the scope. When snaring a pedunculated polyp, the snare should be placed about half way up the stalk, so that after cutting, a stalk remnant is left which can be grabbed or clipped if hemorrhage occurs. The polyp is pulled away from its base into the lumen tenting the colon wall to avoid burning the adjacent deep colon layers. Needle-knife sphincterotomy or needle-knife papillotomy is a cutting method that uses a straight, fine, wire-type needle, referred to as a needle knife, to incise the papilla as well as the overlying and deeper tissues, opening the sphincter itself. The needle knife utilizes electrocautery to aid in cutting. The purpose of needle knife sphincterotomy is to cut into the sphincter area and facilitate entry into either the common bile duct or pancreatic duct. direct needle-knife entry and release of the stone is a much-preferred method that is used by many endoscopists.  Class of medical device:Class B  Material of construction:Handle (ABS/Nylon), Single/Double Lumen PTFE Tube, Medical Grade Braided SS wire &amp; tube, Electrical connector, Heatshrink Tube.  Dimension(if any):O.D. - 1, 1.8, 2.3mm and Length - 100, 160, 200, 230cms.  Shelflife:3yrs.  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>

Place: Lucknow

Date 21-May-19

State Licensing Authority

Uttar Pradesh

