



सत्यमेव जयते

## FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2018/000082

1. 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 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. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
4. 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:Wire (Self Expendable Metal Stent)</p> <p>Model No.:L-E-XXXX - Custommade-Device</p> <p>Intended Use:The vast majority of SEMS are used to alleviate symptoms caused by cancers of the gastrointestinal tract that obstruct the interior of the tube-like (or luminal) structures of the bowel — namely the esophagus, duodenum, common bile duct and colon. SEMS are designed to be permanent and, as a result, are often used when the cancer is at an advanced stage and cannot be removed by surgery.</p> <p>Class of medical device:Class C</p> <p>Material of construction:PU/PTFE Tube, Nitinol Wire, ABS/Nylon Moulded Handle and connector, Silicon Sleeves, Heatshrink Tube</p> <p>Dimension(if any):</p> <p>Shelflife:3yrs.</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>

2	<p>Generic Name:Stent (Urology/Biliary/Pancreatic)</p> <p>Model No.:V-E-XXXX - Custommade-Device,U-U-XXXX - Custommade-Device</p> <p>Intended Use:The ureteral stent is intended to provide drainage from the kidney to the bladder, serving as an internal indwelling catheter, in the case of stone obstruction in ureter. This stent provide the bypass track for urine flow from Kidneyto bladder. The Biliary Stents are indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms. It is required to bypass the bile juice from gallbladder to intestine when there is blockage because of stone in billiary track.</p> <p>Class of medical device:Class C</p> <p>Material of construction:PU/PTFE Tube (Fluroscopic)</p> <p>Dimension(if any):</p> <p>Shelflife:3yrs.</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):HOSPILINE</p>
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Place:

Date:15-Nov-18

Central Licensing Authority

