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/2019/000057

Endorsement No. 1

1. M/s KAMAL ENCON INDUSTRIES LIMITED, 56 INDUSTRIAL ESTATEYAMUNA NAGAR, --, Haryana (India) - 135001 Telephone No.: 1123351365 FAX: 1123721657 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s KAMAL ENCON INDUSTRIES LIMITED, Plot No. 917, IMT Faridabad, Sector- 68, Faridabad, Haryana (India) - 121001 Telephone No.: 11-23723158, 11-23351369 FAX: 11-23721657

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	Generic Name:Sirolimus Eluting Coronary Stent System Model No.:NIL Intended Use:Sirolimus Eluting Coronary Stent System is intended for use in the patient eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA). Sirolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete de novo lesions of length 40 mm in native coronary arteries with a reference vessel diameter of 2.00 to 4.50 mm and those who are eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA). Class of medical device:Class D Material of construction:1. Cobalt Chromium L605 Stent 2. Sirolimus Drug 3. PTCA Rapid Exchange Balloon Catheter & 4. Biodegradable Polymers Dimension(if any):Stent Diameter (mm): 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 4.00 & 4.50 AND Stent Length (mm): 8, 9, 12, 13, 15, 16, 18, 20, 23, 24, 28, 32, 33, 36, 38, 40, 43 & 47 Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Trackflex (TM under process) & Stenoflex (TM under process)

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Date: 2019.11.20 15:50:27 +05'30'

2	Generic Name:Everolimus Eluting Coronary Stent System Model No.:NIL Intended Use:Everolimus Eluting Coronary Stent System is intended for use in the patient eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA). Everolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete de novo lesions of length 40 mm in native coronary arteries with a reference vessel diameter of 2.00 to 4.50 mm and those who are eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA). Class of medical device:Class D Material of construction:1. Cobalt Chromium L605 Stent 2. Everolimus Drug 3. PTCA Rapid Exchange Balloon Catheter & 4. Biodegradable Polymers Dimension(if any):Stent Diameter (mm): 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 4.00 & 4.50 AND Stent Length (mm): 8, 9, 12, 13, 15, 16, 18, 20, 23, 24, 28, 32, 33, 36, 38, 40, 43 & 47 Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Everoshine (TM under process) & Trackmaster (TM under process)

Place:

Date20-Nov-19

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Central Licensing Authority