



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. **10**

1. **M/s KAMAL ENCON INDUSTRIES LIMITED, 56 INDUSTRIAL ESTATEYAMUNA NAGAR, --, Haryana (India) - 135001 Telephone No.: -- Haryana 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.: Faridabad Haryana 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 : Dental Implant with Abutment and Prosthesis Model No. : I-Series - Diameter (mm) 2.75, 3.0, 3.5, 4.0, 4.5, 5.0 and Length (mm): 6.5, 7.5, 8.5, 10, 11.5, 13, 15, IP-Series - Diameter (mm) 2.75, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 and Length (mm): 6.5, 7.5, 8.5, 10, 11.5, 13, 15, 18, 20, S-Series - Diameter (mm) 3.0, 3.6, 4.0, 4.5, 5.0, 5.5, 6.0 and Length (mm) 6.75, 7, 8, 10, 12, 14, 16, 18, 20, SP-Series - Diameter (mm) 3.0, 3.6, 4.0, 4.5, 5.0, 5.5, 6.0 and Length (mm): 6.75, 7, 8, 10, 12, 14, 16, 18, 20, ZE-Series - Diameter (mm) 4.3, 4.6 and Length (mm) 30, 35, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, 62.5, ZI-Series - Diameter (mm) 3.0, 3.5, 4.0, 4.2, 4.5, 5.0, 5.5, 6.0 and Length (mm) 8, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, B-Series - Diameter (mm) 2.75, 3.0, 3.6, 4.5, 5.5 and Length (mm): 8, 10, 12, 14, 16, 17, 18, 20, 22, 23, 24, 26, C-Series - Diameter (mm): 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 and Length (mm): 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, AP-Series (Apex Konnect) - Diameter (mm) 2.75, 3.0, 3.5, 3.75, 4.0, 4.2, 4.5, 5.0, 5.5, 6.0 and Length (mm) 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, AK-Series (Apex Konnect) - Diameter (mm) 2.75, 3.0, 3.5, 3.75, 4.0, 4.2, 4.5, 5.0, 5.5, 6.0 and Length (mm): 6.5, 7, 7.5, 8, 8.1, 8.5, 8.6, 9, 9.1, 9.5, 9.6, 10, 10.1, 10.5, 10.6, 11, 11.1, 11.5, 11.6, 12, 12.1, 12.5, 12.6, 13, 13.1, 13.5, 13.6, 14, 14.1, 14.5, 14.6, 15, 15.1, 15.5, 15.6, 16, 16.1, 16.5, 16.6, 17.1, 17.5, 17.6, 18.1 Intended Use : Dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. Class of medical device : Class C Material of construction : Titanium Alloy, Ti-6Al-4V Dimension(if any) : I-Series: Diameter (mm) 2.75, 3.0, 3.5, 4.0, 4.5, 5.0 and Length (mm): 6.5, 7.5, 8.5, 10, 11.5, 13, 15 IP-Series: Diameter (mm) 2.75, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 and Length (mm): 6.5, 7.5, 8.5, 10, 11.5, 13, 15, 18, 20 S-Series: Diameter (mm) 3.0, 3.6, 4.0, 4.5, 5.0, 5.5, 6.0 and Length (mm) 6.75, 7, 8, 10, 12, 14, 16, 18, 20 SP-Series: Diameter (mm) 3.0, 3.6, 4.0, 4.5, 5.0, 5.5, 6.0 and Length (mm): 6.75, 7, 8, 10, 12, 14, 16, 18, 20 ZE-Series: Diameter (mm) 4.3, 4.6 and Length (mm) 30, 35, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, 62.5 ZI-Series: Diameter (mm) 3.0, 3.5, 4.0, 4.2, 4.5, 5.0, 5.5, 6.0 and Length (mm) 8, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26, 26.5, 27, 27.5, 28, 28.5, 29, 29.5, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60 B-Series: Diameter (mm) 2.75, 3.0, 3.6, 4.5, 5.5 and Length (mm): 8, 10, 12, 14, 16, 17, 18, 20, 22, 23, 24, 26 C-Series: Diameter (mm): 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 and Length (mm): 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 AP-Series (Apex Konnect): Diameter (mm) 2.75, 3.0, 3.5, 3.75, 4.0, 4.2, 4.5, 5.0, 5.5, 6.0 and Length (mm) 14, 14.5, 15, 15.5, 16, 16.5, 17, 17.5, 18, 18.5, 19, 19.5, 20, 20.5, 21, 21.5, 22, 22.5, 23, 23.5, 24, 24.5, 25, 25.5, 26 AK-Series (Apex Konnect): Diameter (mm) 2.75, 3.0, 3.5, 3.75, 4.0, 4.2, 4.5, 5.0, 5.5, 6.0 and Length (mm): 6.5, 7, 7.5, 8, 8.1, 8.5, 8.6, 9, 9.1, 9.5, 9.6, 10, 10.1, 10.5, 10.6, 11, 11.1, 11.5, 11.6, 12, 12.1, 12.5, 12.6, 13, 13.1, 13.5, 13.6, 14, 14.1, 14.5, 14.6, 15, 15.1, 15.5, 15.6, 16, 16.1, 16.5, 16.6, 17.1, 17.5, 17.6, 18.1 Shelflife : 5 Years Sterile or Non sterile : Sterilized Brand Name(if registered under the Trade Marks Act, 1999) : I-Fix
2	Generic Name : PTFE Guidewire Model No. : PTFE Guide wire - J tip - Diameter: 0.018"/0.021/0.025"/0.032"/0.035"/0.038" and Length 50 to 300cm, PTFE Guide wire - Straight tip - Diameter: 0.018"/0.025"/0.032"/0.035"/0.038" and Length 50 to 300cm Intended Use : Guidewires are intended for use in the percutaneous introduction of catheters. Class of medical device : Class D Material of construction : Platinum nickel alloy, SS 304, Nitinol, Polyvinylpyrrolidone (PVP), PP, LDPE Dimension(if any) : Diameter: 0.018"/0.021/0.025"/0.032"/0.035"/0.038" and Length 50 to 300cm Shelflife : 2 Years Sterile or Non sterile : Sterilized Brand Name(if registered under the Trade Marks Act, 1999) : Kayak

Place:

Date: 21-Nov-25

Central Licensing Authority

