



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/2023/000582

1. M/s Fontierz Pvt. Ltd. , C-1901,24 K OPULA, GULMOHAR PARK ROAD, VISHALNAGAR, PIMPRI CHINCHWAD, PUNE-411027, MAHARASHTRA Haveli, Pune, Maharashtra (India) - 411027 Telephone No.: 9623942932 FAX: 9623942932 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Fontierz Pvt. Ltd., 2nd Floor,Plot No.165/1/17,Priyadarshani Industrial Society, T Block,MIDC,Bhosari,Pune, Pune, Maharashtra (India) - 411026 Telephone No.: 9623942932 FAX: 9623942932

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:HIGH SPEED SURGICAL DRILL SYSTEM Model No.:NIL Intended Use:Insignia Spin is intended for cutting and shaping bone including the spine and cranium. It offers variable speed, minimal sound level. It is a high performance system and highlights minimal vibration performance, thermal energy management, neurotologists, skull base surgeons, spinal surgeons and otologists. Class of medical device:Class B Material of construction:Brushless DC Motor, Brushless DC Motor Controller TFT Touch Screen ,Aluminum ,SS, Electromechanical Components & assemblies Dimension(if any) 275(W) X 250(L) X 110(H) mm Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999) Insignia Spine</p>
2	<p>Generic Name:Arthroscopy Shaver Model No.:NIL Intended Use:Insignia Arthro System plays an indispensable role in arthroscopic surgery. The Insignia Arthro System can clean the joint space by removing soft tissue such as the synovium, and even some of the denser tissues such as degenerated cartilage fragments and dissociated cartilage, as well as the trimming of the meniscus Class of medical device:Class B Material of construction:Brushless DC Motor, Brushless DC Motor Controller TFT Touch Screen ,Aluminum ,SS, Electromechanical Components & assemblies Dimension(if any) 275(W) X 250(L) X 110(H) mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999) Insignia Arthro</p>



[Signature]
12-6-23
Joint Commissioner (Drugs)(Pune Division)
Food & Drug Administration
Maharashtra State, Pune

Place: Pune
Date: 12-Jun-23

State Licensing Authority

