

FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. : IMP/MD/2026/000171

1. M/s SafeEndo Dental India Private Limited, D-207, Second Floor, Abhishek Complex-1, Near Asarva Bridge, Asarva, Ahmedabad , Ahmedabad, Gujarat (India) - 380016 Telephone No.: 9904079977 FAX: 9904079977 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s Huizhou Videya Technology Co. Ltd., Factory of Songshan Villagers Group, Baishi Village, Qiuchang Street Office, Huiyang District, Huizhou 516221, Guangdong, Country: China Telephone No.: 86-755-3366447 FAX: 86-755-3366447 E-Mail : dental@videya-gd.com	Actual Manufacturing Site : M/s Huizhou Videya Technology Co. Ltd., Factory of Songshan Villagers Group, Baishi Village, Qiuchang Street Office, Huiyang District, Huizhou 516221, Guangdong, Country: China Telephone No.: 86-755-3366447 FAX: 86-755-3366447 E-Mail : dental@videya-gd.com

3. Details of medical device(s):

S.No	Medical Device Details
1	1. Generic Name :Dental Root-Canal Instruments (Rotary File) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NIL 3. Class of Medical Device :Class B 4. Shelf Life :NIL 5. Sterile/Non-sterile :Non-Sterilized 6. Intended Use :Dental Root-Canal Instruments for enlarging root canal and making smooth and flat root canal wall through grinding and polishing 7. Material of Construction : NiTi Alloy 8. Dimension : NA 9. Model No. :Super Files - Rotary File ,Engine K-Files - Rotary File ,Engine H-File - Rotary File 10. Accessory/Components :NIL

4. The authorised agent M/s SafeEndo Dental India Private Limited, D-207, Second Floor, Abhishek Complex-1, Near Asarva Bridge, Asarva, Ahmedabad , Ahmedabad, Gujarat (India) - 380016 Telephone No.: 9904079977 FAX: 9904079977 will be responsible for the bussines activities of the overseas manufacturer, in India in all respects.

5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: New Delhi

Central Licensing Authority

