

FORM MD-15

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

Licence to Import Medical Device

Licence No. : IMP/MD/2026/000133

1. M/s TERRASOUL POLYMERS PRIVATE LIMITED, KHASRA NO 6/18/1 MIN, 18/3, 19/1/2, 19/2, 21/2, 22/2, 23/1, 23/2, 23/3, Safiabad , Sonipat, Haryana (India) - 131023 Telephone No.: 09896458926 FAX: 09896458926 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 UNION PLASTIC, ZA Robert - 43140 SAINT DIDIER EN VELAY, Country: France Telephone No.: 33-0471611309 FAX: 33-0471662664 E-Mail : frederic.gounon@omerin.com	Actual Manufacturing Site : M/s UNION PLASTIC, ZA Robert - 43140 SAINT DIDIER EN VELAY, FRANCE, Country: France Telephone No.: 33-0471611309 FAX: 33-0471662664 E-Mail : frederic.gounon@omerin.com

3. Details of medical device(s):

S.No	Medical Device Details
1	<p>1. Generic Name :Dosing Syringe 2. Brand Name(if registered under the Trade Marks Act, 1999) :DOS'UP 3. Class of Medical Device :Class A 4. Shelf Life :5 years 5. Sterile/Non-sterile:Non-Sterilized 6. Intended Use :Dosing Syringes are intended for dosing and dispensing pediatric syrups and oral suspensions. It is designed for individual use and shall be used only with the specific medicinal product with which it is supplied. The device may be used once or multiple times for a single patient, in accordance with the instructions for use provided in the product leaflet. 7. Material of Construction: Polypropylene and Polyethylene 8. Dimension: 0.2ml, 1ml, 5ml or 10ml 9. Model No. :Dosing Syringe DOS-UP - 0.2 ml ,Dosing Syringe DOS-UP - 1 ml ,Dosing Syringe DOS-UP - 5 ml ,Dosing Syringe DOS-UP - 10 ml 10. Accessory/Components :NIL</p>
2	<p>1. Generic Name :Vaginal Applicator 2. Brand Name(if registered under the Trade Marks Act, 1999) :Applicators APPLISIL 3. Class of Medical Device :Class A 4. Shelf Life :5 years 5. Sterile/Non-sterile:Non-Sterilized 6. Intended Use :The Vaginal Applicator is intended to dose and dispense vaginal or gynecological preparations such as medicated or cosmetic creams and pastes. It is designed for individual use and must be used only with the specific drug with which it is supplied. The device may be used once or several times by a single patient during the treatment period, following the instructions provided in the package leaflet. 7. Material of Construction: Polypropylene and Polyethylene or Polystyrene 8. Dimension: 0.5ml, 1ml, 1.5ml, 2.5ml or 5ml 9. Model No. :Applicators APPLISIL - 0.5ml ,Applicators APPLISIL - 1ml ,Applicators APPLISIL - 1.5ml ,Applicators APPLISIL - 2.5ml ,Applicators APPLISIL - 5ml 10. Accessory/Components :NIL</p>

3	<p>1. Generic Name :Pipettes</p> <p>2. Brand Name(if registered under the Trade Marks Act, 1999) :DOS'UP & DOS'UP+</p> <p>3. Class of Medical Device :Class A</p> <p>4. Shelf Life :5 years</p> <p>5. Sterile/Non-sterile:Non-Sterilized</p> <p>6. Intended Use :Pipettes are intended for dosing and dispensing pediatric syrups and oral suspensions. It is designed for individual use and shall be used only with the specific medicinal product with which it is supplied. The device may be used once or multiple times for a single patient, in accordance with the instructions for use provided in the product leaflet.</p> <p>7. Material of Construction: Polypropylene and Polyethylene or Polystyrene</p> <p>8. Dimension: 3ml, 5ml, 6ml, 8ml or 10ml</p> <p>9. Model No. :Dosing Pipette DOS-UP - 5ml ,Dosing Pipette DOS-UP - 8ml ,Dosing Pipette DOS-UP+ - 3ml ,Dosing Pipette DOS-UP+ - 5ml ,Dosing Pipette DOS-UP+ - 6ml ,Dosing Pipette DOS-UP+ - 8ml ,Dosing Pipette DOS-UP+ - 10ml</p> <p>10. Accessory/Components :NIL</p>
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4. The authorised agent M/s TERRASOUL POLYMERS PRIVATE LIMITED, KHASRA NO 6/18/1 MIN, 18/3, 19/1/2, 19/2, 21/2, 22/2, 23/1, 23/2, 23/3, Safiabad , Sonipat, Haryana (India) - 131023 Telephone No.: 09896458926 FAX: 09896458926 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

