FORM MD-15

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

Licence to Import Medical Device

Licence No. : IMP/MD/2024/000818

1. M/s RIFA PHARMA, SHOP NO 1, FIRST FLOOR, PRUTHVI CORNER, JAKAT NAKA,N.H NO 8, VAPI TAL PARD , Valsad, Gujarat (India) - 396195 Telephone No.: 9619494942 FAX: 9619494942 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

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 France, Country: France Telephone No.: 330471611309 FAX: 330471662664 E-Mail : union-plastic@omerin.com	Actual Manufacturing Site : M/s Union Plastic, Union Plastic Division Ape, Zone Industrielle - Route de Souppes 77570 Chateau-Landon, France, Country: France Telephone No.: 33 0 164785109 FAX: 33 0 164785109 E-Mail : contact@ape-medical.fr

3. Details of medical device(s):

S.No	Medical Device Details
1	**1. Generic Name :**Vial Adaptor **2. Brand Name(if registered under the Trade Marks Act, 1999) :**NIL **3. Class of Medical Device :**Class B **4. Shelf Life :**5 years **5. Sterile/Non-sterile:**Sterilized **6. Intended Use :**Vial Adapter is sterilized single used, indicated for the transfer and mixing of drugs contained in vials. The Vial Adapter is packed in a rigid solid blister. **7. Material of Construction:** Body - Polycarbonate medical grade, Filter - Polyethylene high density(in case of vials with filter)) Hallow spike - Siloxanes and silicones dimethyl **8. Dimension:** NA **9. Model No. :**1MVA0004 - Ø 13mm ,1MVA0011 - Ø 13mm with filter 5m ,1MVA0014 - Ø 13mm with filter 15m ,1MVA0017 - Ø 20mm ,1MVA0008 - Ø 20mm with filter 5m ,1MVA0020 - Ø 20mm with filter 15m **10. Accessory/Components :**NIL

RAJEEV SINGH RAGHUVANSHI

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DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, 2.5.4.20=42d7189b1c0981bbb5a263a4a73d025ff4b11b680a91f08773480400a43ee361b, postalCode=110002, st=Delhi, serialNumber=657f5e47d940985d8f03bdc902d0e1fe73cfa12a1a126ea94fa5701124a19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.09.26 15:25:34 +05'30'

4. The authorised agent M/s RIFA PHARMA, SHOP NO 1, FIRST FLOOR, PRUTHVI CORNER, JAKAT NAKA,N.H NO 8, VAPI TAL PARD , Valsad, Gujarat (India) - 396195 Telephone No.: 9619494942 FAX: 9619494942will 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.

RAJEEV SINGH RAGHUVANSHI

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Date: 2024.09.26 15:25:40 +05'30'

Place: New Delhi

Central Licensing Authority