

GOVERNMENT OF INDIA/भारत सरकार**MINISTRY OF RAILWAYS/रेल मंत्रालय****(RAILWAY BOARD/रेलवे बोर्ड)****No.2024/H/4/1/DP/MerckSpecialities
11.08.2025.****New Delhi dated:****Principal Chief Medical Director
Central Railway
Mumbai.****Sub:-Renewal of registration of drug/pharmaceutical products
supply firm M/s Merck Specialties Pvt. Ltd.- reg.****Ref:- E-3498853 & CR-HQ0MED(MMIS)/17/2025-O/o PCMD/HQ/CR.***********

Kind attention is invited to Zone's file cited under reference on the subject cited above. As approved by the competent authority in Railway Board, the firm **M/s Merck Specialties Pvt. Ltd.** is renewed with the validity upto **10/08/2028**.

**Digitally signed by
NITI KUMARI****Date: 11-08-2025****(Dr. Niti Kumari/डॉ. नीती कुमारी)****Joint Director/IH (संयुक्त निदेशक/औद्योगिक स्वास्थ्य)****Railway Board/ रेलवे बोर्ड****Ministry of Railways (रेल मंत्रालय)****Copy to:- PCMD(s)/PCMO(s), all Indian Railways including PUs &
RDSO.**



Date: 07.05.2025

Name: M/s. Merck Specialities Private Limited

Corporate Office Address: Godrej One, 8th Floor, Pirojshanagar, Eastern Express Highway, Vikhroli (East), Mumbai – 400079

Turnover of the Last 3 Years (Rs. In Crores): 21 – 22 - 532.35, 22 – 23 - 721.14, 23 – 24 - 840.85, Total Turnover for last 3 years: 2094.34

Request for Renewal of Registration Product List for Central Railway, Mumbai

| Sr. No. | Brand Name | Generic Name | Pack Size | Address of the Manufacturing Unit | Manufacturing Unit Inspected or Not | GST % | HSN Code |
|---------|---------------------------------|---|---|---|-------------------------------------|-------|----------|
| 1 | Erbitux 5 mg/ml 20 ml Vials | Each vial contains: Cetuximab 100 mg in 20 ml (5 mg/ml) Excipients ...q.s. | Solution for infusion, 1 vial of 20 ml | M/s. Merck Healthcare KGaA, Frankfurter Strabe 250 Darmstadt (Germany) - D- 64293 | Imported Products | 12.00 | 30021500 |
| 2 | Erbitux 5 mg/ml 100 ml Vials | Each vial contains: Cetuximab 500 mg in 100 ml (5 mg/ml) Excipients ...q.s. | Solution for infusion, 1 vial of 100 ml | M/s. Merck Healthcare KGaA, Frankfurter Strabe 250 Darmstadt (Germany) - D- 64293 | Imported Products | 12.00 | 30021500 |
| 3 | BAVENCIO | Avelumab 20mg/ml Concentrate For Solution For Infusion. | 200mg/10mL | M/s. Merck Serono S.A., Zone Industrielle de IOuriettaz Aubonne Vaud (Switzerland) - CH-1170 | Imported Products | 12.00 | 22029020 |
| 4 | Tepmetko 225 mg | Tepotinib Hydrochloride Hydrate 250 Mg Equivalent to Tepotinib 225 Mg | 225 Mg/Tables | M/s. Merck Healthcare KGaA, Frankfurter Strabe 250 Darmstadt (Germany) - D- 64293 | Imported Products | 12.00 | 30049099 |

Yours faithfully

| | |
|----------------------------------|---|
| | For Merck Specialities Private Limited |
| | <div>SHARMA Nitesh [M230271]</div> <div>Digitally signed by SHARMA Nitesh [M230271] Date: 2025.05.09 11:07:19 +05'30'</div> |
| Name of the Authorized signatory | Mr. Nitesh Sharma |
| Designation of the signatory | Director, Business Unit Head Market Access / Government Affairs & IB |
| Contact details | 9899002707 |
| Email address | nitesh.sharma@merckgroup.com |

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Date: 2025.06.01
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Merck Specialities Private Limited

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Godrej One, 8th Floor, Pirojshanagar
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Mumbai 400079, India.
Phone +91 22 62109000
Fax +91 22 62109999
www.merck.co.in
CIN: U24100MH2005PTC152680



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|---|---------------------------------|--|---|---|-------------------|-------|----------|
| 5 | GONAL - F 900 IU/1.5 ml | Each pre-filled multidose pen delivers: Follitropin alfa 900 IU/ 1.5 ml(66 mcg/ 1.5 ml). Excipients: Poloxamer 188, sucrose, L-Methionine, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate, m-cresol, O phosphoric acid 85%, sodium hydroxide and water for injections. | 1 multidose pre-filled pen, 20 needles for administration | M/s. Merck Serono S.p.A., Via Delle Magnolie 15 (loc. Frazione Zona Industriale) Bari Modugno (Italy) - 70026 | Imported Products | 12.00 | 30043990 |
| 6 | GONAL - F 450 IU/0.75 ml | Each pre-filled multidose pen delivers: Follitropin alfa 450 IU/ 0.75 ml (33 mcg/0.75 ml). Excipients: Poloxamer 188, sucrose, L-Methionine, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate, m-cresol, O phosphoric acid 85%, sodium hydroxide and water for injections. | 1 multidose pre-filled pen, 12 needles for administration | M/s. Merck Serono S.p.A., Via Delle Magnolie 15 (loc. Frazione Zona Industriale) Bari Modugno (Italy) - 70026 | Imported Products | 12.00 | 30043990 |

Yours faithfully

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|---|---|
| | For Merck Specialities Private Limited SHARMA Nitesh [M230271] |
| Name of the Authorized signatory | Mr. Nitesh Sharma |
| Designation of the signatory | Director, Business Unit Head Market Access / Government Affairs & IB |
| Contact details | 9899002707 |
| Email address | nitesh.sharma@merckgroup.com |

SHOBHA JAGANNATH H

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Merck Specialities Private Limited

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