

FORM MD-15

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

Licence to Import Medical Device**Licence No. : IMP/MD/2025/000503**

1. M/s EMERGEX HEALTHCARE, Old No 7 New No 13, Thejas, W Block 5th Main Road Anna Nagar, CHENNAI, Chennai, Tamil Nadu, 600040 , Chennai, Tamil Nadu (India) - 600040 Telephone No.: 87544 17276 FAX: 98840 58375 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 O00 Petr Telegin, Telegin 37D Gagarin Avenue, build.PI, 603009, Nizhny Novgorod, Russia ., Country: Russia Telephone No.: 007 831 2124141 FAX: 007 831 2124141 E-Mail : impex@bplab.com	Actual Manufacturing Site : M/s O00 Petr Telegin, Telegin 37D Gagarin Avenue, build.PI, 603009, Nizhny Novgorod, Russia , Country: Russia Telephone No.: 007 831 2124141 FAX: 007 831 2124141 E-Mail : impex@bplab.com

3. Details of medical device(s):

S.No	Medical Device Details
1	1. Generic Name :Blood Pressure Monitoring Device 2. Brand Name(if registered under the Trade Marks Act, 1999) :BPLab 3. Class of Medical Device :Class B 4. Shelf Life :NIL 5. Sterile/Non-sterile:Non-Sterilized 6. Intended Use :This is a 24 Hour BP Monitoring Device and is intended to be used for Automatic Non Invasive measurement of human's arterial pressure only and not other parameters. 7. Material of Construction: abs plastic, acetal, thermoplastics polyurethane, nylon, polyester, cotton and Electronics. 8. Dimension: 95 x 64 x 28 mm 9. Model No. :Compact 2 - Basic Configuration BP Monitoring only. 10. Accessory/Components :Bags with belts - BP Lab Class A Dimension:NA Material:Nylon Shelflife: Nil Non-Sterilized Intended Use:For carrying support Model No:NA,BP Cuff - BP Lab Class A Dimension:S/M/L/EL/NL Material:polyester cotton Shelflife: NIL Non-Sterilized Intended Use:For measuring BP Model No:NA,Connecting tubing - BP Lab Class A Dimension:NA Material:acetal Shelflife: NIL Non-Sterilized Intended Use:For connecting to the device. Model No:NA,USB Connector - BP Lab Class A Dimension:NA Material:Electronic Shelflife: Nil Non-Sterilized Intended Use:For connecting to the Device Model No:NA,Card reader - BP Lab Class A Dimension:NA Material:Electronics Shelflife: NIL Non-Sterilized Intended Use:To read data Model No:NA, Bluetooth-adapter - BP Lab Class A Dimension:NA Material:Electronics Shelflife: NIL Non-Sterilized Intended Use:For connecting to other devices Model No:NA,Battery charger - BP Lab Class A Dimension:NA Material:Electronics Shelflife: Nil Non-Sterilized Intended Use:For Charging the battery Model No:NA,USB flash driver CD - BP Lab Class A Dimension:NA Material:Electronics Shelflife: NIL Non-Sterilized Intended Use:For Software Model No:NA

4. The authorised agent M/s EMERGEX HEALTHCARE, Old No 7 New No 13, Thejas, W Block 5th Main Road Anna Nagar, CHENNAI, Chennai, Tamil Nadu, 600040 , Chennai, Tamil Nadu (India) - 600040 Telephone No.: 87544 17276 FAX: 98840 58375 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

