



सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2023/000132

1. M/s Heka Medicals India Pvt Ltd, VILLA NO.9,NOEL IVY CREEK,ANJIKKATH ROAD,KAKKANAD,CSEZ PO, ERNAKULAM, Kerala, India, 682037Ernakulam, Ernakulam, Kerala (India) - 682037 Telephone No.: 4844854010 FAX: 4844854010 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Heka Medicals India Pvt Ltd, First Floor, Room No 85 N, O, Q, U, SH Arcade, Monippally, Kottayam, Kerala (India) - 686636 Telephone No.: 04822242217, 9895731000 FAX: 04822242217

2. Details of medical device(s) [Annexed]

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

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Respiratory Humidifier Model No.:HekaFlo - HM-P-500 Intended Use:The HekaFlo is for the treatment of spontaneously breathing patients who will be benefited by supplying high flow warmed and humidified respiratory gases. Based on the patient interface the flow may be set between 2- 60 L/min. The device is intended to provide the heated and humidified respiratory gases via a breathing circuit and nasal cannula. Class of medical device:Class B Material of construction:ABS Plastics Dimension(if any): Shelflife:nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):HekaFlo</p>

Place:

Date 07-Feb-23

State Licensing Authority