



सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: **MFG/MD/2023/001015**

Endorsement No. **2**

1. **M/s SEGURO LIFESCIENCES, PLOT 2(i)A EPIP PHASE 1 JHARMAJARI BADDI BADDI, Solan-BBN, Himachal Pradesh (India) - 174205 Telephone No.: 9816015678 FAX: 9816011985** has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s Seguro Lifesciences, PLOT 2(i)A EPIP PHASE 1, JHARMAJARI, BADDI, Solan-BBN, Himachal Pradesh (India) - 173205 Telephone No.: 9816015678 FAX: 9816015678**

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

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): **As per records maintain by the manufacturer**

4. 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	Generic Name : INTRA AORTIC BALLOON CATHETER Model No. : IAB75F25 - Balloon Nominal Volume (cc) 25 ,IAB75F34 - Balloon Nominal Volume (cc) 34 ,IAB75F40 - Balloon Nominal Volume (cc) 40 , - , - , - , - , - , - Intended Use : The Intra-aortic balloon catheter and accessories are used to provide counterpulsation therapy in the aorta, whereby balloon inflation during diastole and deflation during systole increases blood supply to the heart muscle and decreases the work of the left ventricle. Class of medical device : Class C Material of construction : TPU, PEI, Pt,PVC,PE,PC,304 L Stainless steel, ABS, PTFE, HDPE, Pebax, Nylon 12,LLDPE,LDPE Dimension(if any) : Balloon Length 165 ,221, 258 mm $\pm 10\%$, Balloon Diameter 15 mm, Balloon Nominal Volume (cc) 25,34,40 Shelflife : 3 Years Sterile or Non sterile : Sterilized Brand Name(if registered under the Trade Marks Act, 1999) : RUKINTRA

Place:

Date: 17-Mar-26

Central Licensing Authority