



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/2023/001033

1. M/s J K IMPEX, GALA NO 6 DEVIDAYAL COMPOUND NEAR PANNA HOUSE LBS MARG BHANDUP WEST MUMBAI BHANDUP WEST, Mumbai City, Maharashtra (India) - 400078 Telephone No.: 9136768148 FAX: 9136768148 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s J K IMPEX, W-407, T.T.C Industrial Area, TETAVALI, SECTOR 8, MIDC, Near Golden Garage, RABALE, Navi Mumbai-400701, Thane, Maharashtra (India) - 400701 Telephone No.: 9136768148 FAX: 9136768148

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	Generic Name: Digital Thermometer Model No.: HM-DT101D - Measurement Range: 32 to 42 degree Celsius and 89.6 to 107.6 degree fahrenheit, Three digit LCD display, Accuracy ± 0.1 degree celsius, HM-DT201D - Measurement Range: 32 to 42 degree Celsius and 89.6 to 107.6 degree fahrenheit, Three digit LCD display, Accuracy ± 0.1 degree celsius, HM-DT301D - Measurement Range: 32 to 42 degree Celsius and 89.6 to 107.6 degree fahrenheit, Three digit LCD display, Accuracy ± 0.1 degree celsius Intended Use: It is device used to record the body temperature. Class of medical device: Class B Material of construction: Temperature sensor probe, Digital display, ON-OFF button, LR 41 button cell, Main Protective plastic body made of ABS Dimension(if any): Shelflife: NIL Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): Housemedic
2	Generic Name: Blood Pressure Monitoring Devices Model No.: HM-BP101 Automatic Blood Pressure Monitor - Pressure measurement range 20 mmHg ~ 280 mmHg, Pulse rate detection range 40-180 pulse per minute, HM-BP201 Automatic Blood Pressure Monitor - Pressure measurement range 20 mmHg ~ 280 mmHg, Pulse rate detection range 40-180 pulse per minute, HM-BP301 Automatic Blood Pressure Monitor - Pressure measurement range 20 mmHg ~ 280 mmHg, Pulse rate detection range 40-180 pulse per minute Intended Use: It is device used to measure the diastolic and systolic blood pressures. Class of medical device: Class B Material of construction: Digital display, Pressure Sensor, Inflatable air bladder cuff, Rubber air tubing, Battery Powered air pump, integrated circuit board, solenoid valve Dimension(if any): Shelflife: NIL Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): Housemedic

3	Generic Name:Blood Lancets Model No.:NIL Intended Use:It is intended for use alone or use with lancing device to draw capillary blood from the finger tip for blood glucose monitoring or for other test requiring one or two drops of blood. Class of medical device:Class B Material of construction:Polyethylene and Stainless steel needle Dimension(if any):21G, 23G, 26G, 28G, 30G, 32G,33G Shelflife:Five Year Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Housemedic
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Place:

Date05-Dec-23

**NARENDRA
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State Licensing Authority

