



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/2024/000145

1. M/s Medister Infection Control Systems Private Limited, G-119, SHAGUN ARCADE, GEN AK VAIDYA MARG NR DINDOSHI BUS DEPOT, GOREGAON EAST. MUMBAI , Mumbai City, Maharashtra (India) - 400097 Telephone No.: 022 28497725 FAX: 022 28497725 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Medister Infection Control Systems Pvt. Ltd., Unit R6-R6A, Qureshi Ind Area, Sagar Industrial Estate, Zilu Parab Road, Chinchoti, Off Kaman Bhiwandi Naka, Naigaon Tal Vasai, Dist Palghar,, Palghar, Maharashtra (India) - 401208 Telephone No.: 022-28495501 28497725 FAX: 022-28495501 28497725

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.

CDSCO ANNEXURE CDSCO

S.No.	Details Of Device(s)
1	<p>Generic Name: Ethylene oxide Gas Sterilizer Model No.: EOSTER-SA (Semi -Automatic) - 25, 35, 43, 56 Ltr, EOSTER-PRO - 25, 35, 43, 56 Ltr, EOSTER-ADV (Advance) - 35, 43, 56, 62, 85 Ltr, EOSTER-FA (Fully Automatic) - 125, 225, 285, 435 Ltr Intended Use: Intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical devices Class of medical device: Class C Material of construction: Stainless Steel and Mild Steel Dimension(if any): Various sizes Shelflife: 5 years Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): MEDISTER</p>
2	<p>Generic Name: Steam Sterilizer Model No.: Horizontal Autoclave - MDS HA SEMI AUTO (135, 75, 113, 245, 432, 648, 810, 972, 1215 L), MDS HA FULLY AUTO (35, 75, 113, 245, 432, 648, 810, 972, 1215 L), Rectangle Horizontal Autoclave - MDS RHA SEMI AUTO (35, 75, 113, 245, 432, 648, 810, 972, 1215 L) MDS RHA FULLY AUTO (35, 75, 113, 245, 432, 648, 810, 972, 1215 L), Vertical Autoclave Models - - Single Drum Manual (20,30), Single Drum with Controller (20,30), Double Drum Manual MDS M (35,75), Double Drum Automatic MDS (35,75), Table Top Class B Autoclave Models - Mediclave Class B3,5,8,17,18,22,48,60 Intended Use: A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical devices by means of pressurized steam. Class of medical device: Class C Material of construction: Stainless Steel (SS 304) Dimension(if any): Various sizes Shelflife: 5 years Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): MEDISTER</p>

Place:

Date 08-Mar-24

Central Licensing Authority

