

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/2024/000438

1. M/s S.S MEDICAL SYSTEMS (INDIA) PRIVATE LIMITED, MEHRA GAON BHIMTAL NAINITAL UR 263136 INBHIMTAL, Nainital, Uttarakhand (India) - 263136 Telephone No.: 0522 4025395 FAX: 9839022234 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s S. S. Medical Systems (I) Pvt Ltd, 220 Bhopal House, Lalbagh,, Lucknow, Uttar Pradesh (India) - 226001 Telephone No.: 7718022219 FAX: 9022917032

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:Ultrasound Imaging Machine Model No.:DIGI 1100 CD E - High Resolution 15.6 LED Supports JPG BMP FRM image formats and CIN AVI WMV movie format,DIGI 1100 CD PRO - Laptop design Color Doppler with 15.6 inch high resolution medical grade LCD monitor Supports JPG BMP FRM image formats and CIN AVI WMV movie format,DIGI 1100 CD - Laptop design Colour Doppler with 15.6 inch high resolution medical grade LCD monitor Supports JPG BMP FRM image formats and CIN AVI WMV movie format,SSD 6000 CD E - 15 to 19 inch customizeable Monitor size 8 step zoom magnification with PAN facility,SSD 6000 CD PRO - 21.5 inch 1920x1080 high resolution LCD monitor with tilt & swivel facility Supports JPG BMP FRM image formats and CIN AVI movie formats,SSD 6000 CD - 19 inch high resolution LCD monitor with tilt and swivel facility Supports JPG BMP FRM image formats and CIN AVI movie format Intended Use:The device is intended for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Abdominal, Fetal/Obstetric, Gynaecological, Fetal Echo, Musculo- skeletal (conventional), Urology and Paediatric. Class of medical device:Class B Material of construction:PCB, FRP, LCD, Control Board Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SSMED

Place: Lucknow
Date25-Jun-24



(Shashi Mohan Gupta) Drug Licensing and Controlling Authority Uttar Pradesh State Licensing Authority