



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/2023/000867

1. M/s Vandana Surgicals, BH-14, EAST SHALIMAR BAGHSHALIMAR BAGH, North West Delhi, Delhi (India) - 110088 Telephone No.: 9999049518 FAX: 9999049518 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Vandana Surgicals, M 155, Sector-3, Bawana Industrial Area, North West Delhi, Delhi (India) - 110039 Telephone No.: 7827819335 FAX: 9999049518

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:General-purpose manually-operated operation table Model No.:Ventek 1000 - NIL ,Ventek 1000+ - NIL ,Ventek 2001 - NIL ,Ventek 2001+ - NIL Intended Use:A completely mobile surgical table (general-purpose) that has been improved to make it usable for almost all parts of the body that require surgery. Manual or hydraulic operation Class of medical device:Class A Material of construction:SS304, SS302, Actuators, Hydraulic Pumps, Gas Springs, Mild Steel, Aluminum, Polycarbonate Polymer Dimension(if any):NA Shelflife:nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Ventek</p>

2	<p>Generic Name:Powered General Purpose Operation Table</p> <p>Model No.:Amaze 3001 - NIL ,Amaze 4001 - NIL ,Amaze 4001+ - NIL ,Amaze 5001 - NIL , Amaze 5001+ - NIL ,Amaze 6001 - NIL ,Amaze 6001+ - NIL ,Amaze 7001 - NIL ,Amaze 7001+ - NIL ,Amaze Series Ortho Attachments - NIL ,Amaze Neuro Attachments - NIL ,Dura Series - NII ,Ultima Series - Nil</p> <p>Intended Use:A completely mobile surgical table (general-purpose) that has been improved to make it useable for almost all parts of the body that require surgery. Electrically line or battery operated.</p> <p>Class of medical device:Class A</p> <p>Material of construction:SS304, SS302, Actuators, Battery, Gas Springs, Mild Steel, Aluminum, Polycarbonate Polymer</p> <p>Dimension(if any):NA</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Ventek</p>
3	<p>Generic Name:Surgical Light System</p> <p>Model No.:Laminar 54 +54 - NIL ,Laminar 54 Ceiling - NIL ,Laminar 54 Mobile - NIL ,Solitaire 48 Camera Light - NIL ,Solitaire 48 Advanced Twin - NIL ,Solitaire 48 Advanced Ceiling - NIL , Solitaire 48 Advanced Mobile - NIL ,Solitaire 48 Classic Twin - NIL ,Solitaire 48 Classic Ceiling - NIL ,Solitaire 48 Classic Mobile - NIL ,Venus 6 - NIL ,Venus 6+6 - NIL ,Venus 5 - NIL ,Venus 5+5 - NIL ,Venus 4 - NIL ,Venus 4+4 - NIL ,Venus 3 - NIL ,Venus 3+3 - NIL ,Star 105 - NIL ,Star 105+105 - NIL ,Star 84 - NIL ,Star 84+84 - NIL ,Star 63 - NIL ,Star 63+63 - NIL ,Miraz 5 - NIL , Miraz 5+5 - NIL ,Miraz 4 - NIL ,Miraz 4+4 - NIL ,Miraz 3 - NIL ,Miraz 3+3 - NIL ,Solitaire 60 - NIL ,Solitaire 60+60 - NIL ,ClearVision 6 - NIL ,ClearVision 6+6 - NIL ,ClearVision 5 - NIL , ClearVision 5+5 - NIL ,ClearVision 4 - NIL ,ClearVision 4+4 - NIL ,ClearVision 3 - NIL , ClearVision 3+3 - NIL ,Apex 6+6 - NIL ,Apex 6 - NIL ,Apex 5+5 - NIL ,Apex 5 - NIL ,Apex 4+4 - NIL ,Apex 4 - NIL ,Apex 3+3 - NIL ,Apex 3 - NIL</p> <p>Intended Use:An illuminator device intended to providing optimal light and colour rendering to aid in performing surgery</p> <p>Class of medical device:Class A सत्यमेव जयते</p> <p>Material of construction:SS302, SS304, Mild Steel, Aluminium, Polycarbonate Polymer, Nylon Polymer, ABS Ploymer, LED, Optic Lenses, PCB, Silicone Vellow, Digital Controllers</p> <p>Dimension(if any):NA</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Ventek</p>
4	<p>Generic Name:Medical Examination Light, AC powered or battery</p> <p>Model No.:Solar 42 - NIL ,Solar 42 + 42 - NIL ,Solar 42 Mobile - NIL ,Venus 1 Examination Light - NIL ,Star 21 Examination Light - NIL ,Magna Examination Light - NIL ,Pluto Spot Light - NIL</p> <p>Intended Use:Intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.</p> <p>Class of medical device:Class A</p> <p>Material of construction:SS302, SS304, Mild Steel, Aluminium, Polycarbonate Polymer, Nylon Polymer, ABS Ploymer, LED, Optic Lenses, PCB, Silicone Vellow, Digital Controllers</p> <p>Dimension(if any):NA</p> <p>Shelflife:NIL</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Ventek</p>

Place:

Date 26-Sep-23

State Licensing Authority

