



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/2023/000072

1. M/s DHWANIT ENTERPRISE, B/203, ABHILASHA RESIDENCY, NEAR NEW INDIA COLONY BUS STAND, NIKOL KATHWADA ROAD, NIKOL, Ahmedabad, Gujarat (India) - 382350 Telephone No.: 9714788844 FAX: 9714788844 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Dhwani Enterprise, Plot No -4, Nakshtra Industrial Hub, Near Amba Hotel, Ahmedabad-Indore Highway, Chandial., Ahmedabad, Gujarat (India) - 382433 Telephone No.: 9924788844 FAX: 9924788844

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:Ophthalmic Drape/Blade Model No.:Keratome Blade (440010) - SS 420 PC Try PC handle ,Eye Drape (FINE - 440058 FINE-440061 FINE-440062) - SMMS Material Ld Pastic drainage pouch Adhesive Tape Incise , Crescent Blade (440015) - SS 420 PC Try PC handle ,Lance Tip Blade (440020) - - SS 420 PC Try PC handle ,Mvr Blade (440029) - SS 420 PC Try PC handle ,Keratome Enlarge Blade (440025) - SS 420 PC Try PC handle ,Eye Pad (440071) - SS 420 PC Try PC handle Intended Use:Ophthalmic drape is intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination Class of medical device:Class B Material of construction:SMMS Material, Ld Pastic, drainage pouch, Adhesive Tape, Incise, SS 420 PC Try, PC handle Dimension(if any):70X70 CM SMS DRAPE - 7X8 CM ADHESIVE AREA - DRAIN BAG 5X7 INCH - 4 PCS EYE HOLDER 80X100 CM SMS DRAPE - 7X8 CM ADHESIVE AREA - DRAIN BAG 5X7 INCH - 4 PCS EYE HOLDER 100X120 CM SMS DRAPE - 7X8 CM ADHESIVE AREA - DRAIN BAG 5X7 INCH - 4 PCS EYE HOLDER SS 420 PC Try, PC handle, Pouch SS 420 PC Try, PC handle, Pouch SS 420 PC Try, PC handle, Pouch SS 420 PC Try, PC handle, Pouch COTTON PAD Shelflife:5 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Fine Wear</p>

2

Generic Name:Orthopedic Drape

Model No.:Hip U Drape (FINE 44143) - SMMS Material LD Pastic Adhesive tape ,Knee O Drape (FINE 44144) - SMMS Material LD Pastic Rubber Adhesive tape ,Arthroscopy Drape(FINE 44146) - SMMS Material LD Pastic Rubber Fluid Collection Pouch Adhesive tape ,Shoulder U Drape (FINE 44147) - SMMS Material LD Pastic Fluid Collection Pouch Adhesive tape ,Lamino Spinal Drape (FINE 44125) - SMMS Material LD Pastic Incise film Adhesive tape ,THR KIT (FINE 441883) - SMMS Material LD Pastic Adhesive tape ,Cling drape (FINE 441584) - Poly plastic , Major Drape (FINE 44121) - SMMS Material LD Pastic Incise film Adhesive tape ,LEG O DRAPE (FINE 441705) - SMMS Material LD Pastic Adhesive tape ,LEG U DRAPE (FINE 447106) - SMMS Material LD Pastic Adhesive tape ,Bilateral Drape (FINE 441708) - SMMS Material LD Pastic Rubber Adhesive tape ,TKR KIT (FINE 441884) - SMMS Material LD Pastic Rubber Adhesive tape

Intended Use:Orthopedic Drape is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial & other contamination

Class of medical device:Class B

Material of construction:SMMS Material, LD Pastic, Adhesive tape, Rubber, pouch, incise film, poly plastic

Dimension(if any):1 hip u drape sms, pe film 240x230 cm, 25 cm round cut, 240x200 cm head sheet, leggins, steripe, knee o drape sms, pe film 240x350cm,aperture 8cm, sms head sheet 160x100cm, leggins sms pe film 160x250 cm, u cut 15x35 cm, head sheet 160x150 cm with leggins, non woven sms pe film,160 cm x 250 cm,with cable holder incise area 15cm x 35 cm with Iodine 1 Knee- O Drape SMS, PE film, 160cm x 300cm 1 hip u drape sms,pe film,200x160 cm (1)surgeon gown - 4 nos. (2)hand towel - 4 nos. (3)plain sheet - 2 nos. (4)medium sheet - 2 nos. (5)long sheet - 2 nos. (6)trolley sheet - 1 nos. (7)cautery bag - 1 nos. (8)mayo trolley cover - 1 nos. (9)knee o drape - 1 nos. (1)surgeon gown - 4 nos. (2)hand towel - 4 nos. (3)plain sheet - 2 nos. (4)medium sheet - 2 nos. (5)long sheet - 2 nos. (6) trolley sheet - 1 nos. (7)cautery bag - 1 nos. (8)mayo trolley cover - 1 nos.(9)hip u drape - 1 nos. Pp Plastic 5 Inch X 10 Mtr

Shelflife:5 Years

Sterile or Non sterile:Sterilized

Brand Name(if registered under the Trade Marks Act, 1999):Fine Wear

3	<p>Generic Name:Cardiac drape</p> <p>Model No.:CATHLAB DRAPE KITS (FINE - 441687) - SMMS Material Ld Pastic Adhesive Tape Incise ,CABG CARDIAC PACK (FINE - 44258) - SMMS Material Ld Pastic Adhesive Tape Incise , ANGIO DRAPE (FINE - 441717) - SMMS Material Ld Pastic Adhesive Tape Incise , ANGIOGRAPHY DRAPE KIT (FINE - 441688) - SMMS Material Ld Pastic Adhesive Tape Incise , CATHLAB DRAPE (FINE - 441723) - SMMS Material Ld Pastic Adhesive Tape Incise</p> <p>Intended Use:Cardiac surgical drape is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination</p> <p>Class of medical device:Class B</p> <p>Material of construction:SMMS material, LD Plastic, Adhesive Tape, incise</p> <p>Dimension(if any):1 Angioplasty Drape Sms Fabric Of 45 Gsm With High Absorbent Reinforcement With Femoral Fenestrations 160 X 350 Cm, (1)Surgeon gown-2 Pcs (2)Hand Towel-4 Nos,(3)Main Trolley Drape Reinforced-1 Nos (4)Shoe Cover-1 Pair, (5)Femoral &amp; Radial Drape-1 Nos, (6)Ply Mask &amp; Surgeon Cap-1 Nos, (7)Wrap-1 Nos., 1 cathlab drape sms with absorbent reinforcement 160x300 cm, hole size 10x12 cm, (1)Surgeon Gown-2 Nos, (2)Hand Towel-4Nos, (3)Main Trolley Drape-1 No, (4) Basin Stand Sheet-1 No, (5)Femoral Sheet-1 No, (6)Radial Sheet-1 No., (1)Long drape-1pc (2)Groin drape-1pc (3)Paper drape-1pc (4)Triangle drape-2pcs (5)Side absorbent drape-2pcs (6)Abdominal absorbent drape (7)Screen sheet absorbent drape-1pc (8)Main trolley drape-1pc (9)Leg trolley drape- 1pc (10)Rolling sheet-1pc (11)Basin stand sheet-1pc (12)Mayo trolley sheet-1pc (13)Cautry bag-3pcs</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Fine Wear</p>
4	<p>Generic Name:Craniotomy Drape</p> <p>Model No.:NIL</p> <p>Intended Use:Craniotomy Drape is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination</p> <p>Class of medical device:Class B</p> <p>Material of construction:SMMS material, LD Plastic, Adhesive Tape, incise</p> <p>Dimension(if any):Craniotomy Drape Size 160 X 320 Cm, Circular Adhesive Area With Drainage Pouch</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Fine Wear</p>

5	<p>Generic Name:General Drape</p> <p>Model No.:ISOLATION GOWN (FINE - 441892) - NON WOVEN DISPOSABLE ,PP GOWN 40 GSM (FINE - 441919) - NON WOVEN DISPOSABLE ,PP GOWN 25 GSM (FINE - 441906) - NON WOVEN DISPOSABLE ,SURGERY SUPPORT KIT (FINE - 441904) - SMMS Material Ld Pastic Adhesive Tape ,PLAIN SHEET SMALL SIZE 120X150CM (FINE - 44128) - LD Pastic ,PLAIN SHEET SIZE 120X210CM (FINE - 44129) - LD Pastic ,POLY APRON (FINE - 441187) - LD Pastic ,CAMARA COVER (FINE - 441184) - LD Pastic ,C-ARM COVER (FINE - 441189) - LD Pastic , REINFORCE GOWN (FINE - 441686) - SMMS MATERIAL ,45 GSM SMS SURGEON GOWN (FINE - 440099) - SMMS MATERIAL ,LAPROSCOPY DRAPE (FINE - 441696) - SMMS Material Ld Pastic Adhesive Tape Incise ,HIV KIT (FINE - 44150) - SMMS Material Ld Pastic Adhesive Tape Incise Pouch</p> <p>Intended Use:A surgical drape &amp; drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination</p> <p>Class of medical device:Class B</p> <p>Material of construction:SMMS material, LD Plastic, Adhesive Tape, incise</p> <p>Dimension(if any):Laparoscopy drape 160 cm x 275 cm, adhesive area 30x40 cm, fixed with super strong tape, PP Plain Gown-1, Cap-1, Mask-1, Plastic Gloves-1 Pair, Plastic Shoe Cover Pair,Goggles-1, Surgical Gown Polypropylene - 3pcs, Hole Sheet - 1pcs, Trolley Cover 1pcs, Drape Towel -6pcs, Face Mask - 3pcs, Surgeons Cap - 3pcs, Shoe Cover - 3pair, Plain Sheet Small , Size 120x150cm, Plain Sheet , Size 120x210cm , 100 X 140 CM FRONT TYING FACILITY., 15 CM X 2.5 MTR LD, SIZE 80X70CM LD PLASTIC , 45+40 GSM SMMS FABRIC,SURGEON GOWN 45 GSM SMS WITH HAND TOWEL, SURGEON GOWN 45 GSM SMS WITH HAND TOWEL, POLYPROPYLENE GOWN 25 GSM, PP GOWN, 60 GSM</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Fine Wear</p>
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6	<p>Generic Name:Gynec and Casarean drape</p> <p>Model No.:CAESAREAN DRAPE (FINE - 441769) - SMMS Material Ld Pastic Adhesive Tape Incise ,IVF KIT (FINE - 441928) - Smms Material Ld Pastic Adhesive Tape ,FULL GYNAC DRAPE (FINE - 44141) - SMMS Material LD Pastic Adhesive Tape ,CAESARIAN DRAPE KIT (FINE - 441712) - SMMS Material Ld Pastic Adhesive Tape Incise ,DELIVERY KIT (FINE - 441707) - SMMS Material Ld Pastic Adhesive Tape ,L.S.C.S. KIT (FINE - 441700) - SMMS Material Ld Pastic Adhesive Tape ,MTP DRAPE KIT (FINE - 441710) - SMMS Material Ld Pastic Adhesive Tape Incise ,MATERNITY DRAPE SHEET (FINE - 441736) - Smms Material Ld Pastic Adhesive Tape Pouch</p> <p>Intended Use:Gynec and Casarean drape are disposable surgical drape which is intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination.</p> <p>Class of medical device:Class B</p> <p>Material of construction:SMMS material, LD Plastic, Adhesive Tape, incise</p> <p>Dimension(if any):160x250 cm cesarean drape,incise area 15x35 cm with collar &amp; drainage funnel, 240x350 cm,Aperture 20x13 cm, Adhesive Area 24x17 cm, (1)Caesarian Drape with funnel=1pc (2) Surgical gown=1pc (3)Hand towel=1pc (4)surgical gown Eco=2 pcs (5)Plain Sheet=1 pcs (6)Wrap=1 pc, (1)face mask=1 nos (2)Shoe Cover=1 pair (3)Surgeon Cap=1 nos(4) Sterile Gloves=1 pair (5)Bouffant Cap=1 nos (6)Waste Carry Bag=1 nos (7)Gown=1 nos (8)Prep Razor=1nos (9)Power Pad=1nos (10) Apron=1nos (11)Cord Clamp=2 nos (12)Bed Sheet=1 nos, (1)Surgeon's Gown=3pcs (2)Absorbent Hand Towel=3pcs (3)Central Hole Sheet=3pcs (4) Large Sheet=2pcs (5)Medium Sheet=4pcs (6)Apron Large=2pcs (7)Cauty Bag With Strip=1pc (8)Baby Towel=1pc (9)Cord Clamp=1pc (10)Trolley Sheet=1pc (11)Top Wrap Cover Sheet=1pc, (1)Drape 80x125 cm,Hole 15x15 cm Leggings-1 Pair (2) Surgical Gown-1 Pc,(3)Plain Sheet 140x150 cm=1 pc (4)Half Gown=1 pc (5)Wrap=1 pc, maternity drape sheet with absorbent pad &amp; collection pouch, drape 80x125cm, hole 15x15cm, leggings-1 pair, plain sheet 140x150 - 1 pcs.</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Fine Wear</p>
7	<p>Generic Name:Urology drape</p> <p>Model No.:PCNL Drape (FINE - 441693) - SMMS Material Ld Pastic Adhesive Tape Incise ,TURP Drape (FINE - 441694) - SMMS Material LD Pastic Adhesive Tape Pouch ,Laproscopy Drape (FINE - 441696) - SMMS Material LD Pastic Incise Adhesive Tape ,Laparoscopy Kit ( FINE - 441798) - SMMS Material LD Pastic Incise Adhesive Tape</p> <p>Intended Use:Urology Drape is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination</p> <p>Class of medical device:Class B</p> <p>Material of construction:SMMS Material, LD Pastic, Incise, Adhesive Tape</p> <p>Dimension(if any):1 pcnl drape 160 x 250 cm , incise area 20cm x 25cm with funnel turp drape sms, 160cm x 180cm with leggings and drainage funnel laparoscopy drape 160 cm x 275 cm, adhesive area 30x40 cm, fixed with super strong tape (1) surgeon gowns - 4pcs (2)ot cap - 4pcs (3)ot mask - 4pcs (4)camera cover - 1pc (5)trolley cover - 3 pcs (6)patient drape - 1pc</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Fine Wear</p>

