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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/2026/000530

1. M/s SUREHEAL HEALTHCARE, PLOT NO 15, FIRST FLOOR, H.NO. 5159/1, OPP. ASTHA HEIGHT, SILVASSA ROAD, DUNGRA, NEAR PRIMARY SCHOOL Vapi, Valsad, Gujarat (India) - 396195 Telephone No.: 8866338858 FAX: 8866338858 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s SUREHEAL HEALTHCARE, PLOT NO. 15, FIRST FLOOR, H.NO. 5159/1, OPP. ASTHA HEIGHT, SILVASSA ROAD, DUNGRA, NR PRIMARY SCHOOL, VAPI, Valsad, Gujarat (India) - 396195 Telephone No.: 07383933344 FAX: 07383933344
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 : Roller bandage Intended Use : Roller bandage can be used in wound care for cleaning or covering the wound or bandaging the wound area or plastic packaging. Class of medical device : Class A Material of construction : Cotton, Gauze fabric Dimension(if any) : 5 CM X 2.5 MTR, 7.5 CM X 4 MTR, 10 CM X4 MTR, 15 CM X4 MTR Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
2	Generic Name : Gamjee roll/Pad Intended Use : Gamjee pad/roll can be used in wound care for covering the wound, applying medicine over the wound or bandaging the wound area. Class of medical device : Class A Material of construction : Absorbent Cotton Wool, Absorbent Gauze, Non Woven Fabric Dimension(if any) : 10 cm X 2, 3 Meter , 15 cm X 2, 3 Meter Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal

3	Generic Name : Absorbent cotton/Cotton balls/Rolls/Pads/Zigzag Cotton Intended Use : Product is basically absorbent cotton. Useful in absorbency and other wound cleaning process etc Class of medical device : Class A Material of construction : Purified, bleached and carded natural cotton fibers Dimension(if any) : 20gm, 50 gm, 100gm, 200gm, 400gm, 500gm Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
4	Generic Name : Absorbent Gauze cloth Intended Use : Gauze can be used for Cleaning ,Packing , Scrubbing , Covering and Securing in a variety of wounds. Closely woven gauze is best for extra strength or greater Protection while open or loose weave is better for absorbency or drainage Class of medical device : Class A Material of construction : Fabric Dimension(if any) : 45 cm, 60 cm, 90 cm , 100 cm, 120 cm with any Length Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
5	Generic Name : Abdominal Sponge (ABSORBENT GAUZE WITH COTTON PAD WITH X-RAY DETECTABLE THREAD) Intended Use : IT IS USED MEDICAL WOUND DRESSINGS AND SURGICAL WOUND DRESSINGS. IT IS USED FOR CLINICAL AND HOSPITAL PURPOSE. Class of medical device : Class A Material of construction : Fabric, X ray Thread Dimension(if any) : 25 cm X 25cm, 25 cm X 40cm, 30 cm X 30 cm, 40 cm X 40 cm, 45 cm X 45 cm with any ply Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
6	Generic Name : TRACHEOSTOMY GAUZE Intended Use : A Tracheostomy Gauze is used in surgery and medicine for cleaning wounds, applying medication, or taking specimens. Class of medical device : Class A Material of construction : Cotton, Gauze fabric Dimension(if any) : as per specification Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
7	Generic Name : Ward Gauze / Theatre Gauze Intended Use : Ward Gauze is used in surgery and medicine for cleaning wounds, applying medication, or taking specimens Class of medical device : Class A Material of construction : Cotton, Gauze fabric Dimension(if any) : Pre-cut T, Standard Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal

8	Generic Name : X-RAY DETECTABLE COTTON BALLS, Gauze Balls / Pledgets/ Peanuts Intended Use : A prosthetic and orthotic accessory, intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Class of medical device : Class A Material of construction : Cotton, Gauze fabric, X Ray detectable Thread, Non Woven Fabric Dimension(if any) : As per specification Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
9	Generic Name : Surgical Face Mask Intended Use : A disposable surgical facemask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates during a public health medical emergency Class of medical device : Class A Material of construction : SMS Non-woven Polypropylene Dimension(if any) : 3 Ply, 5 Ply Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
10	Generic Name : Eye pad Intended Use : Eye dressing pad with gauze layers on both sides is used for postoperative eye care or injuries to the external eye. The eye dressing pad is open at the sides making it very absorbent. Class of medical device : Class A Material of construction : Cotton, Gauze fabric, Non woven Dimension(if any) : 6 cm X 8 cm , any size Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
11	Generic Name : PLASTER OF PARIS BANDAGE Intended Use : Plaster is widely used as a support for broken bones; a bandage impregnated with plaster is moistened and then wrapped around the damaged limb, setting into a close-fitting yet easily removed tube, known as an orthopedic cast. Also used in preparation for radiotherapy when fabricating individualized immobilization shells for patients. Plaster bandages are used to construct an impression of a patient's head and neck, and liquid plaster is used to fill the impression and produce a plaster bust. Class of medical device : Class A Material of construction : Cotton gauze / bleached cotton leno fabric Dimension(if any) : 5 cm, 7.5 cm, 10cm, 15 cm, 20 cm and any length Shelflife : 3 years Sterile or Non sterile : Non-Sterilized Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
12	Generic Name : Combine Dressing pad Intended Use : Combine dressing Pad is used for protecting surgical injuries or wound. Class of medical device : Class A Material of construction : Cotton, Gauze fabric, Non woven Dimension(if any) : 10 cm X 10cm , 10 cm X 20cm, 10 cm X 12 cm and any size Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal

13	Generic Name : Gauze Swab Intended Use : Gauze swabs can be used in wound care for cleaning the wound, applying medicine over the wound, covering the wound or bandaging the wound area. Class of medical device : Class A Material of construction : Cotton Gauze fabric, Non woven Dimension(if any) : 5 cm × 5 cm in 8-ply, 12-ply and 16-ply; 7.5 cm × 7.5 cm in 8-ply, 12-ply and 16-ply; and 10 cm × 10 cm in 8-ply, 12-ply and 16-ply. Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
14	Generic Name : Gauze Ribbon Intended Use : Appropriate use of gauze. Gauze can be used for cleansing, packing, scrubbing, covering, and securing in a variety of wounds. Closely woven gauze is best for extra strength or greater protection, while open or loose weave is better for absorbency or drainage Class of medical device : Class A Material of construction : Gauze fabric and X ray detectable thread Dimension(if any) : 1.25 cm, 2.5 cm, 5 cm any length Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
15	Generic Name : Ortho roll cast Padding Intended Use : A prosthetic and orthotic accessory, intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Class of medical device : Class A Material of construction : Cotton, Viscos Dimension(if any) : 5 cm, 7.5 cm, 10cm, 15 cm, 20 cm and any length Shelflife : 4 years Sterile or Non sterile : Both Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
16	Generic Name : Nitrile Examination Gloves Powder free Intended Use : Gloves made of synthetic materials, and used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery. Class of medical device : Class A Material of construction : synthetic nitrile butadiene rubber (NBR), compounded with suitable accelerators, stabilizers, pigments, fillers and surface-treatment agents. Dimension(if any) : Small, Medium, Large, X-Large, XX-Large Shelflife : 3 years Sterile or Non sterile : Non-Sterilized Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal
17	Generic Name : PPE Gown (Surgical Gown) Intended Use : Used to protect the doctor /staff & prevent any contamination from patient to doctor or vice versa. They are used to prevent strike through of blood & other fluids. Class of medical device : Class A Material of construction : SMS, Non Woven Dimension(if any) : Small, Medium, Large, X-Large, XX-Large Shelflife : 4 years Sterile or Non sterile : Sterilized Model No. : NIL 15. Accessory: NIL Brand Name(if registered under the Trade Marks Act, 1999) : SureHeal



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