



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/2020/000107

Endorsement No. 1

1. M/s Medicare Hygiene Limited, Survey No. 1175 (Old-240), Village- Sari, Sarkhej-Bavla Highway, Sanand, Ahmedabad, Gujarat (India) - 382220 Telephone No.: 9376466000 FAX: 79-26934081 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Medicare Hygiene Ltd., survey no 1175(old no 240), Village Sari, Sarkhej-Bavla Highway, Ta. Sanand, Dist. Ahmedabad, Ahmedabad, Gujarat (India) - 382220 Telephone No.: 79 26934081, 9376466000 FAX: 79 26934081

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: Paraffin Gauze Dressing (Std. as per B.P. 1993) Model No.: Medifin / Medica - 10cm thick AND 10cm/30cm/7mtr length Intended Use: The dressing is used as a primary wound contact layer and the paraffin is present to reduce the adherence of the product to the surface of a granulating wound Class of medical device: Class B Material of construction: WHITE SOFT PARAFFIN, COARSE LENO GAUZE CLOTH , PVP PAPER Dimension(if any): various width and length Shelflife: 4 years Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): Medifin, Medica

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c=IN
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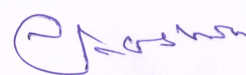
2	Generic Name:Gauze Swab / X-Ray Detectable Gauze Swab (Std. as per B.P. 1993) Model No.:Gauze swab nonsterile - 5 cm x 5 cm - 8/12/16 ply ,Gauze swab nonsterile - 7.5 cm x 7.5 cm - 8/12/16 ply ,Gauze swab nonsterile - 7.5 cm x 6 cm - 8 ply ,Gauze swab nonsterile - 8 cm x 8 cm - 8 ply ,Gauze swab nonsterile - 10 cm x 10 cm - 8/12 ply ,Gauze swab nonsterile - 20 cm x 20 cm - 2 ply ,X ray detectable Gauze swab nonsterile - 5 cm x 5 cm - 12 ply ,X ray detectable Gauze swab nonsterile - 7.5 cm x 7.5 cm - 12 ply ,X ray detectable Gauze swab nonsterile - 10 cm x 10 cm - 8/12 ply ,Gauze swab sterile - 5 cm x 5 cm - 8/12 ply ,Gauze swab sterile - 7.5 cm x 7.5 cm - 8/12/16 ply ,Gauze swab sterile - 10 cm x 10 cm - 8/12 ply ,X ray detectable Gauze swab sterile - 10 cm x 10 cm - 12 ply Intended Use:Gauze swab are used to place over a wound before taping, strapping or bandaging up or can be soaked in antiseptic liquid and used to wipe over wound sites. Gauze swabs are useful can be used for padding, protection, blood spill wound dressing, applying antiseptic and use in surgery to absorb blood & exudates etc. Class of medical device:Class B Material of construction:Absorbent cotton Gauze with/without x ray thread Dimension(if any):various length and width and ply Shelflife:4 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Mediswab, Medica
3	Generic Name:Combine (Operation) Surgical Pad Contains Absorbent Cotton Wool I.P Wrapped In Absorbent Gauze Schfii/Abs Gauze B.P.. Or Non Woven Fabric Model No.:Pad - 10 cm x 10/20/30 cm ,Small pad - 6.25 cm x 6.25 cm ,Small square pad - 25 cm x 22.5 cm ,Medium pad - 12.5 cm x 12.5 cm ,Big pad - 10 cm x 25 cm ,Big square pad - 27.5 cm x 45 cm Intended Use:This is used to protect wounds after initial bleeding control by direct pressure. Do not use it for surgical open wounds Class of medical device:Class B Material of construction:Absorbent Cotton Wool, Absorbent Non Woven Cloth Dimension(if any):various length and width Shelflife:4 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Medica, Medipad
4	Generic Name:Absorbent Cotton Ribbon Gauze (Std. as per B.P. 1993) Model No.:Absorbent Cotton Ribbon Gauze - 1/1.35 /1.5/2.5/5 cm width AND 1/2/5/100 mtr length Intended Use:For wound dressing absorb exudates Used in contaminated exuding wound like cavity wound & fistulas. Class of medical device:Class B Material of construction:Absorbent cotton Gauze , Cotton fabric Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):Mediribon, Medica

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5	Generic Name:Gamjee roll Model No.:Gamjee roll - 10/15/20/25 cm width AND 1/1.75/ 2/2.7/3 mtr length Intended Use:Gamjee Roll are used to place over a wound before taping, strapping or bandaging up or can be soaked in antiseptic liquid and used to wipe over wound sites. Gamjee Roll are useful can be used for padding, protection, blood spill wound dressing, applying antiseptic and use in surgery to absorb blood & exudates etc Class of medical device:Class B Material of construction:Absorbent Fabric (Over Wrap), Cotton wool Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):MEDICA
6	Generic Name:Abdominal Pad . / X-Ray Detectable Abdominal Pad (std. as per B.P. 1993) Model No.:25 cm x 25 cm - 8/12 ply,25 cm x 40 cm - 8 ply,40 cm x 40 cm - 6/8/10/12 ply,30 cm x 30 cm - 6/8/10/12 ply,20 cm x 20 cm - 6/8/12 ply,10 cm x 10 cm - 8 ply,11 cm x 33 cm - 8/12 ply,15 cm x 15 cm - 8/12 ply,17.5 cm x 25 cm - 8/12 ply Intended Use:Abdominal pad used use in abdominal surgery for absorb bleeding & exudates, also used as Padding for pressure points and anywhere high absorbency is needed. Class of medical device:Class B Material of construction:Absorbent cotton gauze with a tape with/without x ray thread Dimension(if any):various length and width and ply Shelflife:4 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):MEDICA, Medimop
7	Generic Name:Absorbent Gauze B.P (Absorbent Gauze Roll) Model No.:Absorbent gauze - 90/100 cm width AND 1/2/3/5/10/50/91/100 mtr length Intended Use:For wound dressing absorb exudates Used in contaminated exuding wound like cavity wound & fistulas. Class of medical device:Class B Material of construction:Absorbent cotton Gauze , Cotton fabric Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Medica
8	Generic Name:Absorbent Gauze USP (Absorbent Gauze Roll) Model No.:Absorbent gauze - 90/100 cm width AND 1/2/3/5/10/50/91/100 mtr length Intended Use:For wound dressing absorb exudates Used in contaminated exuding wound like cavity wound & fistulas.for absorb exudates Class of medical device:Class B Material of construction:Absorbent cotton Gauze , Cotton fabric Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):MEDICA

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9	Generic Name: Absorbent Cotton Wool IP Cotton Ball Model No.: Cotton ball - 0.5/1/500/1000 gm or customised Intended Use: Cotton Wool or Cotton Ball are used to place over a wound before taping, strapping or bandaging up or can be soaked in antiseptic liquid and used to wipe over wound sites. Cotton Wool or Cotton Ball are useful can be used for padding, protection, blood spill wound dressing, applying antiseptic and use in surgery to absorb blood & exudates etc. Class of medical device: Class B Material of construction: Cotton wool Dimension(if any): various weight Shelflife: 4 years Sterile or Non sterile: Both Brand Name(if registered under the Trade Marks Act, 1999): MEDICA
10	Generic Name: Ortho Roll Cast Pading Model No.: Orthoroll cast padding - 7.5/10/15cm width AND 2.7/3 mtr length Intended Use: Extensively used for for protection of bones from elevation or projection, these pads reduces the chances of skin maceration and acts as a cushion between cast and skin. Characteristic: Highly comfortable. Protects bony prominences Class of medical device: Class B Material of construction: Non woven fabric Dimension(if any): various length and width Shelflife: 4 years Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): MEDICA, Medisoft
11	Generic Name: Gauze cloth Sch.FII (T shaped / Triangular) Model No.: Gauze cloth Sch.FII (T shaped / Triangular) - 96 cm x 96 cm x 136 cm, Gauze cloth Sch.FII (T shaped / Triangular) - 50 cm x 48 cm x 90 cm, Gauze cloth Sch.FII (T shaped / Triangular) - 91 cm x 96 cm x 137 cm, Gauze cloth Sch.FII (T shaped / Triangular) - 90 cm x 90 cm x 120 cm, Gauze cloth Sch.FII (T shaped / Triangular) - 90 cm x 90 cm x 131 cm Intended Use: Use Dressing for Wounds and Also In orthopaedic uses Class of medical device: Class B Material of construction: Cotton Bandage Cloth Dimension(if any): various dimension Shelflife: 4 years Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): MEDICA, Mediscope
12	Generic Name: Absorbent Gauze Roll Sch. FII Model No.: ABSORBENT GAUZE ROLL SCH F II / ABSORBENT COTTON GAUZE - 5/6/7.5/8/10/12.5/15cm width AND 3/3.6/4/4.5/5/6 mtr length Intended Use: Use Dressing for Wounds and Also In orthopaedic uses Class of medical device: Class B Material of construction: Cotton Bandage Cloth Dimension(if any): various width and length Shelflife: 4 years Sterile or Non sterile: Both Brand Name(if registered under the Trade Marks Act, 1999): MEDICA



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13	Generic Name:Eye pad (Std. as per B.P. 1993) Model No.:Eye pad - 6 cm x 8 cm Intended Use:This is used to protect wounds after initial bleeding control by direct pressure. Do not use it for surgical open wounds Class of medical device:Class B Material of construction:Absorbent Cotton Wool, Absorbent Non Woven Cloth Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):MEDICA
14	Generic Name:Adhesive Tape (Std. as per U.S.P. 2013) Model No.:Adhesive Tape (std as per USP 2013) - 2.5CM X5MTR,Adhesive Tape (std as per USP 2013) - 5.0CM X5 MTR,Adhesive Tape (std as per USP 2013) - 7.5CM X5 MTR,Adhesive Tape (std as per USP 2013) - 10CM X5 MTR,Adhesive Tape (std as per USP 2013) - 2.5CM X8/9 MTR-12,Adhesive Tape (std as per USP 2013) - 5.0CM X8/9 MTR-6,Adhesive Tape (std as per USP 2013) - 7.5CM X8/9 MTR-4,Adhesive Tape (std as per USP 2013) - 10CM X8/9 MTR-, Adhesive Tape (std as per USP 2013) - Any customised size Intended Use:To secure dressing materials to the skin. .. Adhesive Tape U.S.P. is often used for dressing purposes in case of a wound or cut also. Class of medical device:Class B Material of construction:HOT MELT (RESIN)(ZNO/TRANSPARENT), IODENE POLPLIN CLOTH Dimension(if any):various width and length Shelflife:3 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):MEDICA. Meditape
15	Generic Name:Elastic Adhesive Bandages (Std. as per B.P. 1993)./ Elastic Adhesive bandage (Std. as per B.P 1993)Cannula Fixture Model No.:ELASTIC ADHESIVE BANDAGE - 6/8/10cm width AND 4/6 Mtr Stretched length, ELASTIC ADHESIVE BANDAGE - Any customised size,CANNULA FIXATUR - 05 X 06 Intended Use:Used for maintaining /Holding dressing in its position after operation, fractured of mandible ribs, clade a fingers and chronic ulcers, sprains & joints injuries etc. For External Use Only Class of medical device:Class B Material of construction:P.L.C. 1X Rubber, Zinc Oxide, ZDC, Synthetic resin, Lanolin Anhydrous, N. -Hexane, Crape Cloth Dimension(if any):various width and length Shelflife:3 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):MEDICA, Mediplast, Canfix



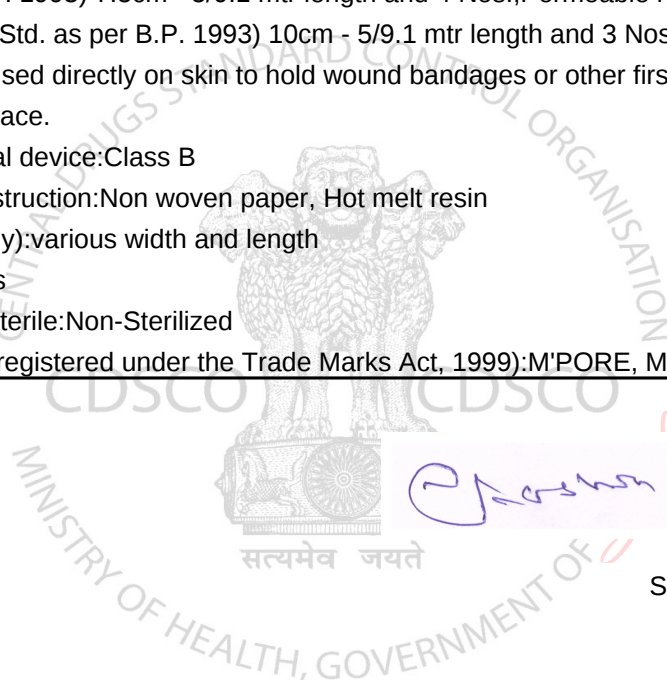
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16	Generic Name:Cotton Crepe Bandage)Std. as per B.P. 1993) Model No.:Cotton Crepe Bandage - 6/8/10/15 cm width AND 4 mtr length,Cotton Crepe Bandage - 15 cm x 4.5 yard Intended Use:Crepe Bandage used for compression bandage for all chronic leg condition varicose veins and there after care as a pressure dressing for burns, for skin graft & whenever elastic support is required for treatment of sprain & similar conditions Class of medical device:Class B Material of construction:Cloth for crepe bandage Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):MEDICA, Medicrepe
17	Generic Name:Cotton Crepe Bandage (White) Model No.:Cotton Crepe Bandage white - 15 cm x 4.5 yard,Cotton Crepe Bandage white - 6/8/10/15 cm width AND 4 mtr length Intended Use:Crepe Bandage used for compression bandage for lighter application Class of medical device:Class B Material of construction:Cloth for crepe bandage Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):MEDICA
18	Generic Name:Stretch Bandage (Synthetic) Model No.:Stretch bandage (synthetic) - 5/7.5/10/15/20 cm width AND 3 mtr stretch length Intended Use:Stretch bandages used for compression bandage for lighter application Class of medical device:Class B Material of construction:Fabric Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):MEDICA, Medistretch
19	Generic Name:Chlorhexidine Gauze Dressing (Std. as per B.P. 1993) Model No.:CHLORHEXIDINE GAUZE DRESSING - 10 cm width AND 10/30/40mm length Intended Use:Intended for use as a wound contact layer for wounds such as: Minor burns and scalds. Lacerations, abrasions and other skin loss wounds. Donor and recipient graft sites. Chlorhexidine Gauze Dressing is containing paraffin & Chlorhexidine Acetate, which prevents the moisture loss from the injured skin, act as barrier between wound & secondary dressing; it helps in stoppage of dehydration of injured skin & wound sites. All kind of skin damages in which humid medium is favourable. Application on burns, , scalds, cuts, Skin loss wounds Class of medical device:Class B Material of construction:WHITE SOFT PARAFFIN, CHLORHEXIDINE ACETATE, COARSE LENO GAUZE CLOTH , PVP PAPER Dimension(if any):various width and length Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):MEDICA. Chlodin

20	Generic Name:Rolled bandage SchFII Model No.:Rolled bandage SchFII - width 5/7.5/10/15cm and length 3/3.6/4/4.5/5/6/7/8/9/10 mtr Intended Use:Use Dressing For Wounds and Also In orthopedic uses Class of medical device:Class B Material of construction:Cotton Bandage Cloth / Bandage cloth Dimension(if any):various width and length Shelflife:4 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):MEDICA
21	Generic Name:Permeable nonwoven synthetic adhesive tape (Std. as per B.P. 1993) Model No.:Permeable nonwoven synthetic adhesive tape (Std as per B.P. 1993) 1.25cm - 5/9.1 mtr length and 24 nos.,Permeable nonwoven synthetic adhesive tape (Std. as per B.P. 1993) 2.5cm - 5/9.1 mtr length and 12 nos.,Permeable nonwoven synthetic adhesive tape (Std as per B.P. 1993) 5cm - 5/9.1 mtr length and 6 Nos.,Permeable nonwoven synthetic adhesive tape (Std. as per B.P. 1993) 7.5cm - 5/9.1 mtr length and 4 Nos.,Permeable nonwoven synthetic adhesive tape (Std. as per B.P. 1993) 10cm - 5/9.1 mtr length and 3 Nos. Intended Use:Used directly on skin to hold wound bandages or other first aid or medical appliances in place. Class of medical device:Class B Material of construction:Non woven paper, Hot melt resin Dimension(if any):various width and length Shelflife:3 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):M'PORE, MEDICA

Place: GANDHINAGAR

Date:18-May-20



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State Licensing Authority

Approval of Application(MFG/MD/2025/148724) submitted on Medical Device portal for Retention of Registration Certificate

From cdscoonline-noida@cdac.in <cdscoonline-noida@cdac.in>

Date Tue 11-Mar-25 10:52 AM

To "cdscoonlinemd@gmail.com"@mailsender4.cdac.in <"cdscoonlinemd@gmail.com"@mailsender4.cdac.in>

First Retention of Licence No:-**MFG/MD/2020/000107** of File No:-**MFG/MD/2020/24692**

From

Concered SLA

To- **-MEDICA@MEDICAREHYGIENE.IN**

Sub: First Retention of Licence No: **-MFG/MD/2020/000107** of File No:-**MFG/MD/2020/24692**
regarding
Sir,

This is with reference to your application No:-**MFG/MD/2025/148724** regarding the above subject.After scrutiny, the retention fees w.r.t Licence No:-**MFG/MD/2020/000107** File No:-**MFG/MD/2020/24692** for following product as per MDR-2017 is acknowledged (content for link to be provided by CDSCO) [https://cdscomdonline.gov.in/NewMedDev/ProductDevice?](https://cdscomdonline.gov.in/NewMedDev/ProductDevice?No=Mg==&Id=MTQ4NzI0)
No=Mg==&Id=MTQ4NzI0.

Central Licensing Authority

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"SAVE PAPER - THINK BEFORE YOU PRINT!"



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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/2020/000107

Endorsement No. 4

1. M/s Medicare Hygiene Limited, Survey No. 1175 (Old-240), Village- Sari, Sarkhej-Bavla Highway, Sanand, Ahmedabad, Gujarat (India) - 382220 Telephone No.: 9376466000 FAX: 79-26934081 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Medicare Hygiene Ltd., survey no 1175(old no 240), Village Sari, Sarkhej-Bavla Highway, Ta. Sanand, Dist. Ahmedabad, Ahmedabad, Gujarat (India) - 382220 Telephone No.: 79 26934081, 9376466000 FAX: 79 26934081

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:NON WOVEN ADHESIVE DRESSING Model No.:3501 - 9.2 m length and 5 cm width ,3502 - 9.2 m length and 7.5 cm width ,3503 - 9.2 m length and 10 cm width ,3504 - 9.2 m length and 15 cm width ,3505 - 9.2 m length and 20 cm width Intended Use:Used for wide-area fixation and widely used in place of surgical tapes to secure and retain primary dressings on surgical or wound sites. It is n also used for fixation if iv cannula Class of medical device:Class B Material of construction:NONWOVEN FABRIC COATED WITH ACRYLLIC ADHESIVE , ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width ROLL FORM Shelflife:3 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

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2	Generic Name:NONWOVEN ADHESIVE IV DRESSING Model No.:9956 - 8.5 cm X 10 cm ,9958 - 10 cm X 12cm ,9952 - 6 cm X 7 cm ,9954 - 7 cm X 8.5 cm Intended Use:Used for fixation of IV cannula Class of medical device:Class B Material of construction:NONWOVEN FABRIC COATED WITH ACRYLLIC ADHESIVE , ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width STRIP FORM Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):FIBREX IV
3	Generic Name:TRANSPARENT FILM ADHESIVE DRESSING Model No.:3601 - 10 m length and 5 cm width,3602 - 10 m length and 7.5 cm width,3603 - 10 m length and 10 cm width,3604 - 10 m length and 15 cm width,3605 - 10 m length and 20 cm width Intended Use:Used for Dressing and device securement, pressure ulcer, skin care,, wound care Class of medical device:Class B Material of construction:PU FILM (COATED WITH ACRYLLIC ADHESIVE supported with pet lifter),. ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width ROLL FORM Shelflife:3 years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
4	Generic Name:TRANSPARENT FILM IV DRESSING Model No.:5651 - 6 cm X 7 cm Gamma sterile ,5653 - 7 cm X 8.5 cm Gamma sterile ,5655 - 8.5 cm X 10 cm Gamma sterile ,5657 - 10 cm X 12 cm Gamma sterile ,5652 - 6 cm X 7 cm EO sterile ,5654 - 7 cm X 8.5 cm EO sterile ,5656 - 8.5 cm X 10 cm EO sterile ,5658 - 10 cm X 12 cm EO sterile Intended Use:Used for device securement, AND ACT AS A BARRIER TO PROTECT AGAINST EXTERNAL CONTAMINANTS. Class of medical device:Class B Material of construction:PU FILM (COATED WITH ACRYLLIC ADHESIVE supported with pet lifter),. ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width STRIP FORM Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Clarop IV

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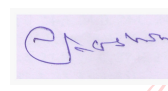
5	Generic Name:TRANSPARENT FILM IV DRESSING FRAME STYLE Model No.:8851 - 6 cm X7 cm Gamma sterile ,8853 - 7cm x8.5cm STRIP FORM Gamma sterile , 8855 - 8.5CM X10 CM STRIP FORM Gamma sterile ,8857 - 10 cm x12cm STRIP FORM Gamma sterile ,8852 - 6 cm X7 cm EO sterile ,8854 - 7cm x8.5cm STRIP FORM EO sterile ,8856 - 8.5 CM X10 CM STRIP FORM EO sterile ,8858 - 10 cm x12cm STRIP FORM EO sterile Intended Use:Used to protect I.V. catheter sites and wounds, to secure devices to the skin and to maintain a moist environment for wound healing. They are breathable, waterproof and act as a barrier to protect against external contaminants , Class of medical device:Class B Material of construction:PU ADHESIVE FILM, ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width STRIP FORM Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):LUCIDFIX FILM IV
6	Generic Name:NON WOVEN ADHESIVE DRESSING WITH NON ADHERENT PAD Model No.:7766 - 10cm x35 cm STRIP FORM EO sterile ,7772 - 6CM X7CM STRIP FORM EO sterile ,7774 - 7cmX8.5cm STRIP FORM EO sterile ,7776 - 8.5cm x10cm STRIP FORM EO sterile ,7782 - 6cm x7cm STRIP FORM (EYE PAD SHAPE) EO sterile ,7781 - 6cm x7cm STRIP FORM(EYE PAD SHAPE) Gamma sterile ,7752 - 5cm x7cm STRIP FORM EO sterile ,7754 - 9CMX12.5CM STRIP FORM EO sterile ,7756 - 9CMX15CM STRIP FORM EO sterile ,7758 - 10cmx10cm STRIP FORM EO sterile ,7760 - 10cm x20cm STRIP FORM EO sterile ,7762 - 10 cm x25 cm STRIP FORM EO sterile ,7764 - 10cm x30 cm STRIP FORM EO sterile Intended Use:To dress post-operative wounds, minor cuts, abrasions, lacerations and puncture sites which aids in the prevention of bacterial contamination, is required. The pad provides a cushion for the wound and absorbs all exudates (e.g., blood, pus).May be used as a secondary dressing over gels, ointments and other primary dressings.it can cut suitable shape for uses for fixation of iv cannual Class of medical device:Class B Material of construction:NONWOVEN ABSORBENT PAD, NONWOVEN ADHESIVE FABRIC , ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width STRIP FORM Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Fibrex, FIBREX IV+PAD, Fibrex eye pad

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Date: 2021.12.14 15:40:02
+05'30'

7	Generic Name:TRANSPARENT DRESSING WITH NON ADHERENT PAD Model No.:5561 - 10cm x25cm STRIP FORM Gamma sterile ,5552 - 5cm x7cm STRIP FORM EO sterile ,5554 - 9CMX12.5 CM STRIP FORM EO sterile ,5556 - 9CMX15CM STRIP FORM EO sterile ,5558 - 10cmx10cm STRIP FORM EO sterile ,5560 - 10cm x20cm STRIP FORM EO sterile ,5562 - 10cm x25cm STRIP FORM EO sterile ,5571 - 6CM X7CM STRIP FORM Gamma Sterile ,5573 - 7cm x8.5cm STRIP FORM Gamma Sterile ,5575 - 8.5CM X10 CM STRIP FORM Gamma Sterile ,5577 - 10 cm x12cm STRIP FORM Gamma Sterile ,5551 - 5cm x7cm STRIP FORM Gamma sterile ,5553 - 9CMX12.5 CM STRIP FORM Gamma sterile ,5555 - 9CMX15CM STRIP FORM Gamma sterile ,5557 - 10cmx10cm STRIP FORM Gamma sterile ,5559 - 10cm x20cm STRIP FORM Gamma sterile ,5572 - 6CM X7CM STRIP FORM EO sterile ,5574 - 7cm x8.5cm STRIP FORM EO Sterile ,5576 - 8.5CM X10 CM STRIP FORM EO Sterile ,5578 - 10 cm x12cm STRIP FORM EO Sterile ,5563 - 10cm x30 cm STRIP FORM Gamma sterile ,5565 - 10cm x35 cm STRIP FORM Gamma sterile ,5564 - 10cm x30 cm STRIP FORM EO sterile ,5566 - 10cm x35 cm STRIP FORM EO sterile Intended Use:Used for partial-thickness wounds with little or no exudate, wounds with necrosis and as both a primary or secondary dressing. Also used to cover IV sites, donor sites, lacerations, abrasions and second-degree burns. Class of medical device:Class B Material of construction:NONWOVEN ABSORBENT PAD, PU ADHESIVE FILM,ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width STRIP FORM Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):CLAROP, CLAROP IV
8	Generic Name:TRANSPARENT FILM IV DRESSING WITH BORDER. Model No.:6651 - 6cm x7 cm STRIP FORM / Similiar 1633IN,6653 - 7cm x8.5cm STRIP FORM / Similiar 1633IN,6655 - 8.5 X10 STRIP FORM / Similiar 1635 IN,6657 - 10X12 STRIP FORM /BUTTERFLY STYLE Intended Use:used to protect I.V. catheter for dressing / holding central lines and long and short term peripheral catheters sites , to secure devices to the skin and to maintain a moist environment for wound healing. Class of medical device:Class B Material of construction:PU ADHESIVE FILM, NON WOVEN ADHESIVE FABRIC,,ONE SIDE SILCON COATED WHITE GLASSIN RELEASE PAPER Dimension(if any):various length and width STRIP FORM Shelflife:3 years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Lucidfix

Digitally signed by Dr.
H.G.KOSHIA
DN: cn=Dr. H.G.KOSHIA,
o=Food and Drugs Control
Administration,
ou=Commissioner,
email=comfdca@gujarat.gov.i
n, c=IN
Date: 2021.12.14 15:39:51
+05'30'

9	Generic Name:LAP SPONGE WITH X-RAY DETECTABLE THREAD (CONTAINS ABSORBENT COTTON GAUZE STD AS PER B.P.1993/EN 14079) Model No.:52-E13-12 - 25cmX25cmX8plyX5 Nos EO Sterile ,28-017-06 - 17.5 cmX35cmX6plyX5 Nos ,28-013-16 - 30cmX30cmX6plyX5 Nos ,28-013-17 - 30cmX30cmX8plyX5 Nos ,52-E17-13 - 25cmX25cmX8plyX10Nos EO Sterile ,52-E17-14 - 25cmX40cmX8plyX5Nos EO Sterile ,52-E17-15 - 25cmX40cmX12plyX1Nos EO Sterile ,52-E17-16 - 30cmX30cmX6plyX5 Nos EO Sterile ,52-E17-17 - 30cmX30cmX8plyX5 Nos EO Sterile ,52-E17-18 - 30cmX30cmX8plyX10 Nos EO Sterile ,52-E17-19 - 30cmX30cmX12plyX5 Nos EO Sterile ,52-E17-20 - 30cmX30cmX12plyX10 Nos EO Sterile ,52-E17-21 - 37cmX45cmX6plyX5 Nos EO Sterile ,52-E17-22 - 37cmX45cmX8plyX5 Nos EO Sterile ,52-E17-32 - 30cmX30cmX8plyX1Nos EO Sterile ,52-E17-33 - 30cmX30cmX10plyX1 Nos EO Sterile ,52-E17-34 - 30cmX30cmX12plyX1 Nos EO Sterile ,52-E17-35 - 40cmX40cmX8plyX1 Nos EO Sterile ,52-E20-01 - 15cmX15cmX12plyX5 Nos EO Sterile ,52-E20-02 - 25cmX25cmX8plyX1 Nos EO Sterile ,52-E20-03 - 11cmX33cmX8plyX10 Nos EO Sterile ,52-G17-01 - 25cmX25cmX6plyX1 Nos Gamma Sterile ,52-G17-02 - 25cmX25cmX8plyX1 Nos Gamma Sterile ,52-G17-03 - 40cmX40cmX6plyX1 Nos Gamma Sterile ,52-G17-04 - 25cmX40cmX8plyX1 Nos Gamma Sterile ,52-G20-01 - 25cmX25cmX6plyX1 Nos Gamma Sterile ,52-G20-02 - 25cmX25cmX8plyX1 Nos Gamma Sterile ,52-G20-03 - 25cmX40cmX8plyX1 Nos Gamma Sterile ,52-E13-33 - 30cmX30cmX10plyX1 Nos EO Sterile , 52-E17-23 - 37cmX45cmX12plyX5 Nos EO Sterile ,52-E17-24 - 40cmX40cmX6plyX5 Nos EO Sterile ,52-E17-25 - 40cmX40cmX8plyX5 Nos EO Sterile ,52-E17-26 - 40cmX40cmX12plyX5 Nos EO Sterile ,52-E17-27 - 45cmX45cmX6plyX5 Nos EO Sterile ,52-E17-28 - 45cmX45cmX8plyX5 Nos EO Sterile ,52-E17-29 - 45cmX45cmX12plyX5 Nos EO Sterile ,52-E17-31 - 25cmX40cmX8plyX1 Nos EO Sterile ,52-E13-13 - 25cmX25cmX8plyX10 Nos EO Sterile ,52-E13-14 - 25cmX40cmX8plyX5 Nos EO Sterile ,52-E13-15 - 25cmX40cmX12plyX1Nos EO Sterile ,52-E13-16 - 30cmX30cmX6plyX5 Nos EO Sterile ,52-E13-17 - 30cmX30cmX8plyX5 Nos EO Sterile ,52-E13-18 - 30cmX30cmX8plyX10 Nos EO Sterile ,52-E13-19 - 30cmX30cmX12plyX5 Nos EO Sterile ,52-E13-20 - 30cmX30cmX12plyX10 Nos EO Sterile ,52-E13-21 - 37cmX45cmX6plyX5 Nos EO Sterile ,52-E13-22 - 37cmX45cmX8plyX5 Nos EO Sterile ,52-E17-30 - 25cmX25cmX12plyX1 Nos EO Sterile ,28-017-19 - 30cmX30cmX12plyX5 Nos ,28-017-20 - 30cmX30cmX12plyX10 Nos ,28-017-21 - 37cmX45cmX6plyX5 Nos ,28-017-22 - 37cmX45cmX8plyX5 Nos ,28-017-23 - 37cmX45cmX12plyX5 Nos ,28-017-24 - 40cmX40cmX6plyX5 Nos ,28-017-25 - 40cmX40cm8plyX5 Nos ,28-017-26 - 40cmX40cmX12plyX5 Nos ,28-013-03 - 11cmX33cmX12plyX10 Nos ,28-013-04 - 15cmX15cmX8plyX5 Nos ,28-013-05 - 15cmX15cmX12plyX5 Nos ,28-013-06 - 17.5cmX35cmX6plyX5 Nos ,28-013-07 - 17.5 cmX35cmX8plyX5 Nos ,28-013-08 - 17.5cmX35cmX12plyX5 Nos ,28-013-09 - 20cmX20cmX8plyX10 Nos ,28-013-10 - 20cmX20cmX12plyX5 Nos ,28-013-11 - 25cmX25cmX8plyX1 Nos ,28-013-15 - 25cmX40cmX12plyX1 Nos ,28-017-07 - 17.5 cmX35cmX8plyX5 Nos ,28-017-08 - 17.5cmX35cmX12plyX5 Nos ,28-017-09 - 20cmX20cmX8plyX10 Nos ,52-E17-05 - 15cmX15cmX12plyX5 Nos EO Sterile ,52-E17-06 - 17.5cmX35cmX6plyX5 Nos EO Sterile ,52-E17-07 - 17.5cmX35cmX8plyX5 Nos EO Sterile ,52-E17-08 - 17.5cmX35cmX12plyX5 Nos EO Sterile ,52-E17-09 - 20cmX20cmX8plyX10 Nos EO Sterile ,52-E17-10 - 20cmX20cmX12plyX5Nos EO Sterile ,52-E17-01 - 10cmX10cmX8plyX10 Nos. EO Sterile ,52-E17-02 - 11cmX33cmX8plyX10 Nos EO Sterile ,52-E17-03 - 11cmX33cmX12plyX10 Nos EO Sterile ,52-E17-04 - 15cmX15cmX8plyX5 Nos EO Sterile ,52-E17-11 - 25cmX25cmX8plyX1Nos EO Sterile ,52-E17-12 - 25cmX25cmX8plyX51Nos EO Sterile , 28-017-10 - 20cmX20cmX12plyX5 Nos ,28-017-11 - 25cmX25cmX8plyX1 Nos ,28-017-12 - 25cmX25cmX8plyX5 Nos ,28-017-13 - 25cmX25cmX8plyX10 Nos ,28-017-14 - 25cmX40cmX8plyX5 Nos ,28-017-15 - 25cmX40cmX12plyX1 Nos ,28-017-16 -
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30cmX30cmX6plyX5 Nos ,28-017-17 - 30cmX30cmX8plyX5 Nos ,28-017-18 -
30cmX30cmX8plyX10 Nos ,28-013-13 - 25cmX25cmX8plyX10 Nos ,28-013-24 -
40cmX40cmX6plyX5 Nos ,28-013-25 - 40cmX40cmX8plyX5 Nos ,28-013-26 -
40cmX40cmX12plyX5 Nos ,28-013-27 - 45cmX45cmX6plyX5 Nos ,28-013-28 -
45cmX45cmX8plyX5 Nos ,52-E13-23 - 37cmX45cmX12plyX5 Nos EO Sterile ,52-E13-24 -
40cmX40cmX6plyX5 Nos EO Sterile ,52-E13-25 - 40cmX40cmX8plyX5 Nos EO Sterile ,52-E13-26 - 40cmX40cmX12plyX5 Nos EO Sterile ,52-E13-27 - 45cmX45cmX6plyX5 Nos EO Sterile ,52-E13-28 - 45cmX45cmX8plyX5 Nos EO Sterile ,52-E13-29 - 45cmX45cmX12plyX5 Nos EO Sterile ,52-E13-30 - 25cmX25cmX12plyX1 Nos EO Sterile ,52-E13-31 - 25cmX40cmX8plyX1 Nos EO Sterile ,52-E13-32 - 30cmX30cmX8plyX1 Nos EO Sterile ,52-E13-34 - 30cmX30cmX12plyX1 Nos EO Sterile ,52-E13-35 - 19cmX45cmX6plyX5 Nos EO Sterile ,52-E13-01 - 10cmX10cmX8plyX10 Nos. EO Sterile ,52-E13-02 - 11cmX33cmX8plyX10 Nos. EO Sterile ,52-E13-03 - 11cmX33cmX12plyX10 Nos. EO Sterile ,52-E13-04 - 15cmX15cmX8plyX5 Nos. EO Sterile ,52-E13-05 - 15cmX15cmX12plyX5 Nos. EO Sterile ,52-E13-06 - 17.5cmX35cmX6plyX5 Nos. EO Sterile ,52-E13-07 - 17.5cmX35cmX8plyX5 Nos. EO Sterile ,52-E13-08 - 17.5cmX35cmX12plyX5 Nos. EO Sterile ,52-E13-09 - 20cmX20cmX8plyX10 Nos. EO Sterile ,52-E13-10 - 20cmX20cmX8plyX5 Nos. EO Sterile ,52-E13-11 - 25cmX25cmX8plyX1 Nos. EO Sterile ,28-017-27 - 45cmX45cmX6plyX5 Nos ,28-017-28 - 45cmX45cmX8plyX5 Nos ,28-017-29 - 45cmX45cmX12plyX5 Nos ,28-017-30 - 30cmX30cmX6plyX10 Nos ,28-017-31 - 22.5cmX22.5cmX8plyX5 Nos ,28-017-32 - 25cmX25cmX12plyX10Nos ,28-017-33 - 11cmX33cmX8plyX5 Nos ,28-017-34 - 11cmX33cmX12plyX5 Nos ,28-017-35 - 17.5cmX25cmX8plyX5 Nos ,28-020-01 - 15cmX15cmX12plyX5 Nos ,28-020-02 - 25cmX25cmX8plyX1 Nos ,28-020-03 - 11cmX33cmX8plyX10 Nos ,28-020-04 - 25cmX25cmX12plyX10 Nos ,28-020-05 - 11cmX33cmX12plyX10 Nos ,28-020-06 - 25cmX25cmX12plyX5 Nos ,28-020-07 - 11cmX33cmX12plyX5 Nos ,28-017-01 - 10cmX10cmX8plyX10 Nos ,28-017-02 - 11cmX33cmX8plyX10 Nos ,28-017-03 - 11cmX33cmX12plyX10 Nos ,28-017-04 - 15cmX15cmX8plyX5 Nos ,28-017-05 - 15cmX15cmX12plyX5 Nos ,28-013-18 - 30cmX30cmX8plyX10 Nos ,28-013-19 - 30cmX30cmX12plyX5 Nos ,28-013-20 - 30cmX30cmX12plyX10 Nos ,28-013-21 - 37cmX45cmX6plyX5 Nos ,28-013-22 - 37cmX45cmX8plyX5 Nos ,28-013-23 - 37cmX45cmX12plyX5 Nos ,28-013-14 - 25cmX40cmX8plyX5 Nos ,28-013-12 - 25cmX25cmX8plyX5 Nos ,28-013-30 - 30cmX30cmX6plyX10 Nos ,28-013-31 - 22.5cmX22.5cmX8plyX5 Nos ,28-013-32 - 19cmX45cmX6plyX5 Nos ,28-013-01 - 10cmX10cmX8plyX10 Nos. ,28-013-02 - 11cmX33cmX8plyX10 Nos

Intended Use:LAP SPONGE WITH X-RAY DETECTABLE THREAD used use in abdominal surgery for absorb bleeding & exudates, also used as Padding for pressure points and anywhere high absorbency is needed.

Class of medical device:Class B

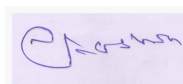
Material of construction:LAP SPONGE WITH X-RAY DETECTABLE THREAD consists of Absorbent cotton gauze, folded into rectangles or squares, in such a manner that no cut edges are exposed, & stitched around the open side. A tape extending not less than 10cm from the pad stitched into one corner. The pad incorporates an –X-Ray detectable thread.

Dimension(if any):various length, width and ply

Shelflife:4 years

Sterile or Non sterile:Both

Brand Name(if registered under the Trade Marks Act, 1999):medica as a trade name



Place: GANDHINAGAR

Date: 14-Dec-21

Digitally signed by Dr. H.G.KOSHIA
DN: cn=Dr. H.G.KOSHIA, o=Food and
Drugs Control Administration,
ou=Commissioner,
email=comfdca@gujarat.gov.in, c=IN
Date: 2021.12.14 15:39:16 +05'30'

State Licensing Authority



Approval of Application(MFG/MD/2025/148777) submitted on Medical Device portal for Retention of Registration Certificate

From cdscoonline-noida@cdac.in <cdscoonline-noida@cdac.in>

Date Tue 11-Mar-25 10:53 AM

To "cdscoonlinemd@gmail.com"@mailsender4.cdac.in <"cdscoonlinemd@gmail.com"@mailsender4.cdac.in>

First Retention of Licence No:-**MFG/MD/2020/000107** of File No:-**MFG/MD/2021/51329**

From

Concered SLA

To- **-MEDICA@MEDICAREHYGIENE.IN**

Sub: First Retention of Licence No: **-MFG/MD/2020/000107** of File No:-**MFG/MD/2021/51329**
regarding
Sir,

This is with reference to your application No:-**MFG/MD/2025/148777** regarding the above subject.After scrutiny, the retention fees w.r.t Licence No:-**MFG/MD/2020/000107** File No:-**MFG/MD/2021/51329** for following product as per MDR-2017 is acknowledged (content for link to be provided by CDSCO) [https://cdscomdonline.gov.in/NewMedDev/ProductDevice?](https://cdscomdonline.gov.in/NewMedDev/ProductDevice?No=Mg==&Id=MTQ4Nzc3)
No=Mg==&Id=MTQ4Nzc3.

Central Licensing Authority

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