



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/2025/000270**

1. **M/s Konkore Packaging Private Limited**, SF 210, Ratna High Street, Nr. Vishwesh Tower, Naranpura Char Rasta, Naranpura Ahmedabad, Ahmedabad, Gujarat (India) - 380013 Telephone No.: 9998083008 FAX: 9998083008 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s Konkore Packaging Private Limited, Shed No.1, Survey No 833/1, Near Bhavini Metal Printers, Kothari Estate, Santej, Kalol, Gandhinagar, Gujarat, 382721, Ahmedabad, Gujarat (India) - 382721 Telephone No.: 9998083008 FAX: 9998083008**
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: Sterilization Wrap Model No.: Sterilization Tyvek Reels - 50MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 55MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 75MM X 70 METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 100MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 150MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 200MM X 70METER , 100METER - ,200METER - , Sterilization Tyvek Reels - 250MM X70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 300MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 350MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 400MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - 450MM X 70METER ,100METER - ,200METER - , Sterilization Tyvek Reels - As per customer required size is available. Intended Use: Sterilization Tyvek Reels is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. Class of medical device: Class B Material of construction: Coated/Uncoated Tyvek, Transparent multi-layer PET/PP copolymer film Dimension(if any): NA Shelflife: Nil Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): Sterilization Tyvek Reels

2	Generic Name: Sterilization Wrap Model No.: Sterilization Tyvek Pouches - 50MM X 100METER ,Sterilization Tyvek Pouches - 55MM X 100METER ,Sterilization Tyvek Pouches - 75MM X 100METER , Sterilization Tyvek Pouches - 100MM X 100METER ,Sterilization Tyvek Pouches - 150MM X 100METER ,Sterilization Tyvek Pouches - 200MM X 100METER ,Sterilization Tyvek Pouches - 250MM X 100METER ,Sterilization Tyvek Pouches - 300MM X 100METER ,Sterilization Tyvek Pouches - 350MM X 100METER ,Sterilization Tyvek Pouches - 400MM X 100METER ,Sterilization Tyvek Pouches - 450MM X 100METER , Sterilization Tyvek Pouches - as per customer required size is available. Intended Use: Sterilization Tyvek Pouch is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. Class of medical device: Class B Material of construction: Coated/Uncoated Tyvek, Transparent multi-layer PET/PP copolymer film Dimension(if any): NA Shelflife: Nil Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): Sterilization Tyvek Pouches
3	Generic Name: Sterilization Wrap Model No.: Sterilization Self-Seal Pouches - 57MM X (100+25)MM ,Sterilization Self-Seal Pouches - 70MM X (230+25)MM ,Sterilization Self-Seal Pouches - 90MM X (135+25)MM ,Sterilization Self-Seal Pouches - 90MM X (230+25)MM ,Sterilization Self-Seal Pouches - 135MM X (250+25)MM ,Sterilization Self-Seal Pouches - 190MM X (330+25)MM ,Sterilization Self-Seal Pouches - 200MM X (290+25)MM ,Sterilization Self-Seal Pouches - 200MM X (330+25)MM ,Sterilization Self-Seal Pouches - 230MM X (365+25)MM ,Sterilization Self-Seal Pouches - 305MM X (400+25)MM ,Sterilization Self-Seal Pouches - 400MM X (505+25)MM ,Sterilization Self-Seal Pouches - 500MM X (600+25)MM Intended Use: Konkore self-seal sterilization pouches are pre-folded and they assure quick and secure closing without a heat sealer. They are especially suited for use in small general practice, dental surgeries and by users who do not want to pay additional costs of sealing devices. Class of medical device: Class B Material of construction: Medical grade paper, transparent CPP/PET multi-layer copolymer film, adhesive strip Dimension(if any): NA Shelflife: Nil Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): Sterilization Self-Seal Pouches
4	Generic Name: Sterilization Process Indicator (Chemical/Physical) Model No.: Steam Indicator Tapes and Strips - 12MM X 50MTR ,Steam Indicator Tapes and Strips - 19MM X 50MTR ,Steam Indicator Tapes and Strips - 25MM X 50MTR ,EO Indicator Tapes and Strips - 12MM X 50MTR ,EO Indicator Tapes and Strips - 19MM X 50MTR ,EO Indicator Tapes and Strips - 25MM X 50MTR ,Plasma Indicator Tapes and Strips - 12MM X 50MTR ,Plasma Indicator Tapes and Strips - 19MM X 50MTR ,Plasma Indicator Tapes and Strips - 25MM X 50MTR ,Steam Indicator Strip with Sticker CLASS 4 - 15MM X 100MM(4") ,Steam Indicator Strip with Sticker CLASS 5 - 20MM X 70MM(3") ,Steam Indicator Strip with Sticker CLASS 6 - 20MM X 107MM(4") ,ETO Indicator Strip with Sticker CLASS 4 - 15MM X 100MM(4") , Bowie Dick Test Pack/Paper - 115MM X 125MM ,Bowie Dick Test Paper - 210MM X 300MM ,Documentation Label 3 Line - Steam ,Documentation Label 3 Line - ETO , Documentation Label 3 Line - Plasma Intended Use: A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process on the medical device. Class of medical device: Class B Material of construction: NA Dimension(if any): NA Shelflife: Nil Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): NA

5	Generic Name:Sterilization Wrap Model No.:Medical Crepe Paper Wrapping Sheet (60gsm) - 30 CM X 30 CM (11") , Medical Crepe Paper Wrapping Sheet (60gsm) - 40 CM X 40 CM (16") ,Medical Crepe Paper Wrapping Sheet (60gsm) - 45 CM X 45 CM (18") ,Medical Crepe Paper Wrapping Sheet (60gsm) - 50 CM X 50 CM (20") ,Medical Crepe Paper Wrapping Sheet (60gsm) - 60 CM X 60 CM (24") ,Medical Crepe Paper Wrapping Sheet (60gsm) - 75 CM X 75 CM (30") ,Medical Crepe Paper Wrapping Sheet (60gsm) - 90 CM X 90 CM (35") ,Medical Crepe Paper Wrapping Sheet (60gsm) - 100 CM X 100 CM (40") ,Medical Crepe Paper Wrapping Sheet (60gsm) - 120 CM X 120 CM (47") , Medical Crepe Paper Wrapping Sheet (60gsm) - 150 CM X 150 CM (60") Intended Use:Medical Crepe Paper Wrapping Sheet (60gsm) is a suitable and particular packaging solution for lighter instruments and sets. Also, it can be used for inner and outer wrapping. Crepe is suitable for Steam sterilization, Ethylene Oxide sterilization, Gamma Ray sterilization and Irradiation sterilization or Formaldehyde sterilization in low temperatures and is a reliable solution for preventing cross-contamination with bacteria. Class of medical device:Class B Material of construction:Crepe Paper Dimension(if any):NA Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Medical Crepe Paper Wrapping Sheet (60gsm)
6	Generic Name:Sterilization Wrap Model No.:Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 30 CM X 30 CM (11") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 40 CM X 40 CM (16") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 45 CM X 45 CM (18") ,Wrapping material non-woven SMS Fabric ((43gsm) (35gsm) - 50 CM X 50 CM (20") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 60 CM X 60 CM (24") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 75 CM X 75 CM (30") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 90 CM X 90 CM (35") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 100 CM X 100 CM (40") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 120 CM X 120 CM (47") ,Wrapping material non-woven SMS Fabric (43gsm) (35gsm) - 150 CM X 150 CM (60") Intended Use:Medical Non-Woven SMS Fabric Wrapping Sheet (43gsm), (35gsm) (SMS, SMMS and SMMMS) wraps that are single or double-wrapped are suitable for steam, ethylene oxide, hydrogen peroxide, plasma and irradiation sterilization methods. They can be used either as inner or outer wrapping for medical devices. Class of medical device:Class B Material of construction:SMS, SMMS and SMMMS non-woven fabric Dimension(if any):NA Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Medical Non-Woven SMS Fabric Wrapping Sheet (43gsm), (35gsm)
7	Generic Name:Sterilization Wrap Model No.:Sterilization Gusseted Reels - 75 MM X 100 METERS ,Sterilization Gusseted Reels - 150 MM X 100 METERS ,Sterilization Gusseted Reels - 200 MM X 100 METERS ,Sterilization Gusseted Reels - 250 MM X 100 METERS ,Sterilization Gusseted Reels - 300 MM X 100 METERS ,Sterilization Gusseted Reels - 350 MM X 100 METERS ,Sterilization Gusseted Reels - 400 MM X 100 METERS Intended Use:Konkore Sterilization Gusseted Reels are a universal packing solution for sterilization applications. They ensure reliable and effective protection of the medical equipment against contamination with bacteria from the time of sterilization until the use of the sterile medical equipment. Class of medical device:Class B Material of construction:Medical Grade Paper, Transparent CPP/Polyster Multi-layer Lamination Film Dimension(if any):NA Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Sterilization Gusseted Reels

8	Generic Name:Sterilization Wrap Model No.:Sterilization Flat Reels - 50 MM X 200 METERS ,Sterilization Flat Reels - 75 MM X 200 METERS ,Sterilization Flat Reels - 100 MM X 200 METERS ,Sterilization Flat Reels - 150 MM X 200 METERS ,Sterilization Flat Reels - 200 MM X 200 METERS ,Sterilization Flat Reels - 250 MM X 200 METERS ,Sterilization Flat Reels - 300 MM X 200 METERS ,Sterilization Flat Reels - 350 MM X 200 METERS ,Sterilization Flat Reels - 400 MM X 200 METERS ,Sterilization Flat Reels - 450 MM X 200 METERS ,Sterilization Flat Reels - 500 MM X 200 METERS ,Sterilization Flat Reels - 600 MM X 200 METERS Intended Use:Konkore Sterilization Flat Reels are a universal packing solution for sterilization applications. They ensure reliable and effective protection of the medical equipment against contamination with bacteria from the time of sterilization until the use of the sterile medical equipment. Class of medical device:Class B Material of construction:Medical Grade Paper, Transparent CPP/Polyster Multi-layer Lamination Film Dimension(if any):NA Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Sterilization Flat Reels
9	Generic Name:Sterilization Wrap Model No.:Sterilization Gusseted Pouches - 75 MM X 50 MM X 100 MM ,Sterilization Gusseted Pouches - 100 MM X 50 MM X 150 MM ,Sterilization Gusseted Pouches - 125 MM X 60 MM X 200 MM ,Sterilization Gusseted Pouches - 150MM X 80 MM X 250 MM ,Sterilization Gusseted Pouches - 150 MM X 80 MM X 300 MM ,Sterilization Gusseted Pouches - 200 MM X 100 MM X 300 MM ,Sterilization Gusseted Pouches - 250 MM X 100 MM X 300 MM ,Sterilization Gusseted Pouches - as per customer size is available Intended Use:Konkore Sterilization Gusseted Pouches are a universal packing solution for sterilization applications. They ensure reliable and effective protection of the medical equipment against contamination with bacteria from the time of sterilization until the use of the sterile medical equipment. Class of medical device:Class B Material of construction:Medical Grade Paper, Transparent CPP/Polyster Multi-layer Lamination Film Dimension(if any):NA Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Sterilization Gusseted Pouches
10	Generic Name:Sterilization Wrap Model No.:Sterilization Flat Pouches - 50 MM X 170 METER ,Sterilization Flat Pouches - 100 MM X 250 METER ,Sterilization Flat Pouches - 75 MM X 225 METER ,Sterilization Flat Pouches - 150 MM X 230 METER ,Sterilization Flat Pouches - 200 MM X 250 METER ,Sterilization Flat Pouches - 250 MM X 300 METER ,Sterilization Flat Pouches - 250 MM X 350 METER ,Sterilization Flat Pouches - 300 MM X 330 METER ,Sterilization Flat Pouches - 350 MM X 450 METER ,Sterilization Flat Pouches - 400 MM X 600 METER ,Sterilization Flat Pouches - as per customer size is available Intended Use:Konkore Sterilization Flat Pouches are a universal packing solution for sterilization applications. They ensure reliable and effective protection of the medical equipment against contamination with bacteria from the time of sterilization until the use of the sterile medical equipment. Class of medical device:Class B Material of construction:Medical Grade Paper, Transparent CPP/Polyster Multi-layer Lamination Film Dimension(if any):NA Shelflife:Nil Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Sterilization Flat Pouches

