



Comprehensive range of Emergency, ICU, OT Care APPERALS, Disposable, Drapes, Kits and CSSD Wraps sheets for every protection towards infection



"YOUR SHIELD AGAINST INFECTION"

www.shaivikinfecon.com

Shaivik Infecon Health Care Pvt. Ltd.

Your Trusted Partner in Non Woven Surgical Disposables

For over five years, **Shaivik Infecon Health Care Pvt. Ltd.** has been a leading manufacturer of high-quality non-woven surgical disposables, catering to the diverse needs of the healthcare industry. Driven by a steadfast commitment to excellence, customer satisfaction, and superior product quality, we have established a reputation as a trusted and reliable partner in delivering innovative, value-driven solutions.

Precision-Engineered Non-Woven Surgical Kits

Non-woven surgical kits are essential medical supplies designed to enhance efficiency and safety in clinical settings. These pre-packaged, sterile kits provide a comprehensive assortment of disposable items, ensuring:

- Infection Control – Single-use components minimize contamination risks.
- Enhanced Efficiency – Ready-to-use kits streamline surgical workflows.
- Uncompromised Hygiene – Safety – Premium non-woven materials ensure optimal patient care.

Each kit includes a selection of non-woven drapes, gowns, and other critical instruments, all meticulously designed to meet the highest standards of hygiene, sterility, and patient safety.

With a reputation built on trust and reliability, **Shaivik Infecon** is your dedicated partner in providing innovative, hygienic, and cost-effective surgical solutions.

Experience the **Shaivik** Advantage – Where Quality Meets Care.



Visionary Leadership Driving Excellence

At **Shaivik Infecon Health Care Pvt. Ltd.**, our success is built upon the vision and expertise of five dedicated directors, each with over a decade of experience in the healthcare sector. More than just leaders, they form a cohesive and dynamic team, united by a shared commitment to innovation, excellence, and customer—centric solutions.

Their collective expertise and strategic leadership drive **Shaivik Infecon** towards continuous growth, ensuring that our operations—from manufacturing and marketing to finance and human resources—function seamlessly and in perfect alignment. This integrated approach allows for agile decision—making, enabling the company to adapt swiftly to industry trends, embrace innovation, and uphold the highest standards of quality and efficiency.

At the core of our organization lies a culture of collaboration and excellence, where each director's specialized knowledge contributes to a broader vision. Their unwavering dedication to delivering superior healthcare solutions reinforces Shaivik Infecon's commitment to being a trusted and valuable partner in the healthcare industry.



Key Strengths and Differentiators:



- **Extensive Product Range:** We offer a comprehensive portfolio of non—woven surgical disposables, including —surgical gowns, drapes, masks, caps, shoe covers, isolation gowns, etc.—, catering to a wide spectrum of medical procedures and applications.



- **Customization Expertise:** Recognizing the unique needs of our clients, we specialize in tailoring our products to specific requirements. Our flexible manufacturing processes allow for size, material, design, and packaging customization.



- **Stringent Quality Control:** We adhere to rigorous quality control standards throughout our manufacturing process, from raw material sourcing to final product inspection. Our facilities are equipped with state—of—the—art technology, and our processes are designed to meet or exceed industry regulations. Specific certifications like **ISO 13485:2016, MDR / MD-5**
Licence no: **MFG/MD/2024/000554.**



- **High—Quality Materials:** We source premium—grade non—woven fabrics that offer optimal performance, comfort, and safety. Our materials are chosen for their barrier properties, breathability, and hypoallergenic qualities.



- **Skilled and Experienced Team:** Our team comprises highly skilled professionals, including Production Managers, Supervisors, and quality control experts, Marketing Team ,who possess extensive experience in the manufacturing of medical disposables.



- **Reliable and Timely Delivery:** We understand the critical importance of timely delivery in the healthcare industry. Our efficient production and logistics systems ensure that orders are completed and delivered on schedule.



- **Competitive Pricing:** We offer competitive pricing without compromising on quality, providing exceptional value to our customers.



- **Customer—Centric Approach:** We prioritize building strong and lasting relationships with our clients. Our dedicated customer support team is readily available to address inquiries, provide technical assistance, and ensure complete satisfaction.



- **Hygiene and Sterilization:** Our manufacturing plants are designed to maintain the highest levels of hygiene. Many products are offered as sterile, and we use validated sterilization processes. To uphold these standards, we operate a state—of—the—art clean room facility, adhering strictly to CDSCO norms and Good Manufacturing Practices.



- **R&D :** We are committed to continuous improvement, regularly investing in research and development to enhance our products and processes.



- **Ethical Business Practices:** We operate with the highest ethical standards, ensuring transparency, integrity, and compliance in all our business dealings.

Our Mission:

“To uphold transparency, trust, and loyalty while delivering high quality, efficient products. Driven by customer respect, we strive for excellence and innovation in healthcare solutions”

Our vision:

“To fulfil our social responsibility by delivering high—quality healthcare solutions across all segments, while unwaveringly upholding our core values of integrity, excellence, and innovation.”

OT Care APPERALS

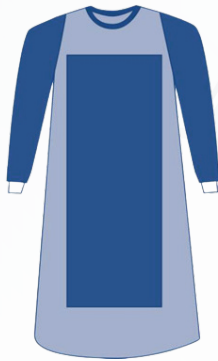
Reinforced Surgeon Gown



- Made of medical grade SMS fabric, which meets AAMI Level 3 standards of barrier protection and prevents blood strike through & fluid contamination.
- Improved barrier protection with reinforced layer in critical zones (Sleeve & Chest areas). Ultrasonically sealed seams prevent strike through
- Breathable, comfort and virtually lint-free.
- Gowns are conveniently folded to attain 100% aseptic technique.
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

SIZES : **S** **M** **L** **XL** **XXL** **XXXL** **X- Long**

Full Reinforced Gown



- Made of medical grade SMS fabric, which meets AAMI Level 3 standards of barrier protection and prevents blood strike through & fluid contamination.
- Improved barrier protection with reinforced absorbent layer in critical zones (Sleeve & Chest areas).
- Ultrasonically sealed seams prevent strike through Breathable, comfort and virtually lint-free.
- Gowns are conveniently folded to attain 100% aseptic technique.
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

SIZES : **S** **M** **L** **XL** **XXL** **XXXL**

Surgeon Gown



- Made of medical grade SMS fabric, which meets AAMI Level 2 standards of barrier protection and prevents blood strike through & fluid contamination.
- Ultrasonically sealed seams prevent strike through
- Advanced technology provides best combination of protection and comfort.
- Breathable, comfort and virtually lint-free.
- Gowns are conveniently folded to attain 100% aseptic technique.
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging
- material that meets ISO 11607-1 and EN 868-5 requirements

SIZES : **S** **M** **L** **XL** **XXL** **XXXL** **X- Long**

Breathable-Viral-Barrier-Gown

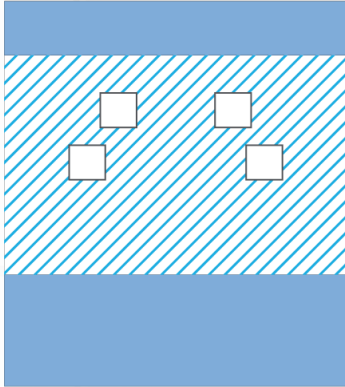


- Made of BVB fabric, which meets AAMI Level 4 standards of barrier protection and prevents blood strike through & fluid contamination.
- Ultrasonically sealed seams prevent strike through
- Suitable for very long-duration surgeries
- Soft, antistatic, breathable, comfort and virtually lint-free.
- Gowns are conveniently folded to attain 100% aseptic technique.
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging
- material that meets ISO 11607-1 and EN 868-5 requirements

SIZES : **L** **XL** **XXL** **X- Long**

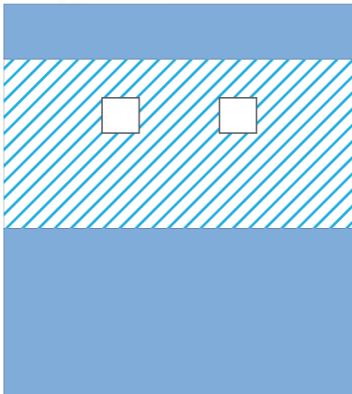
SURGICAL DRAPES

Femoral Radial Drape



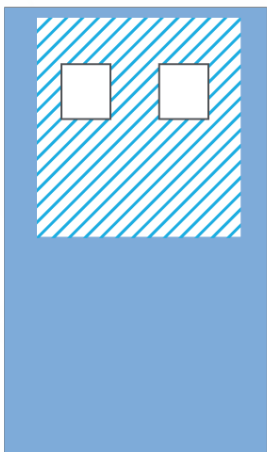
- Large & wide surgical drape to sufficiently cover the patient Femoral Radial drape comes with 4 fenestrations (two for femoral & two for radial with right and left access option)
- All four fenestrations with Incise, which ensure easier accessibility and retain sterility of un-accessed fenestrations
- 70% of drape with absorbent layer, which avoids spillage
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements material that meets ISO 11607-1 and EN 868-5 requirements

Pace Maker Drape

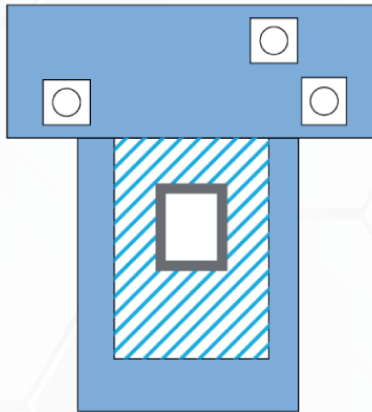


- Large & wide surgical drape to sufficiently cover the patient
- Pacemaker drape comes with two fenestrations
- Both fenestrations with Incise, which ensure easier accessibility and retain sterility of un-accessed fenestration
- 70% of drape with absorbent layer, which avoids spillage
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

Angiography Drape



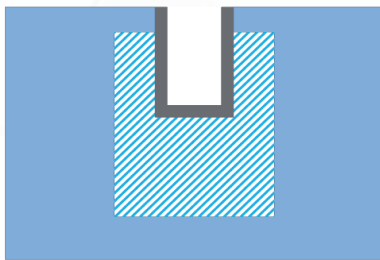
- Large & wide surgical drape to sufficiently cover the patient
- Single CVTS Patient drape saves time compared to techniques that rely on multiple drapes
- Additional absorbent layer around the surgical site to handle excess fluids
- Circular windows provided in screen area of the patient drape for passing tubes and wires of critical instruments
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging
- material that meets ISO 11607-1 and EN 868-5 requirements



CVTC Drape

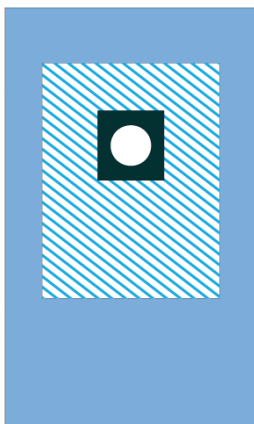
- Large & wide surgical drape to sufficiently cover the patient
- Drape comes with 2 fenestrations
- Advanced technology provides best combination of protection and comfortable draping
- 70% of drape with absorbent layer, which avoids spillage
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

Hip U Drape



- Large & wide surgical drape to sufficiently cover the patient
- Hip U Drape comes with a comfortable U-split
- Additional absorbent layer around the surgical site (U-Split) to handle excess fluids
- Advanced technology provides best combination of protection and comfortable draping
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

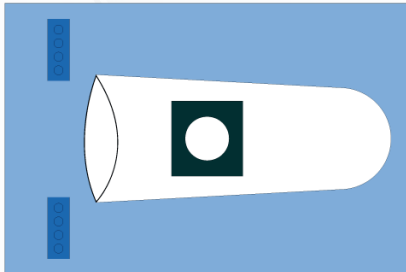
Knee O Drape



- Large & wide surgical drape to sufficiently cover the patient
- Knee- O- Drape comes with a comfortable circular fenestration
- Additional absorbent layer around the surgical site to handle excess fluids
- Advanced technology provides best combination of protection and comfortable draping
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

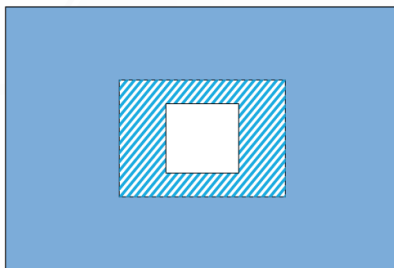


Shoulder Arthroscopy Drape



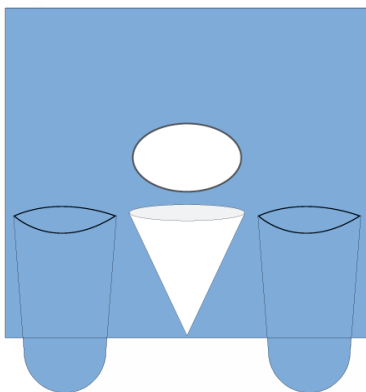
- Large & wide surgical drape to sufficiently cover the patient
- Shoulder Arthroscopy drape comes with comfortable circular fenestration and with a wide collection pouch and suction port
- Advanced technology provides best combination of protection and comfortable draping
- Best suitable for shoulder arthroscopy, Shoulder replacement, SLAP repair procedures
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

Lamino Spinal Drape

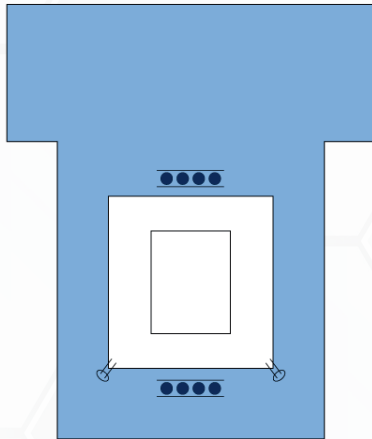


- Large & wide surgical drape to sufficiently cover the patient
- Lamino Spinal drapes comes with sufficient fenestration with incise, which ensure easier accessibility and
- retain sterility of un-accessed fenestration
- Additional absorbent layer around the surgical site to handle excess fluids
- Advanced technology provides best combination of protection and comfortable draping
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements

Normal Delivery Drape

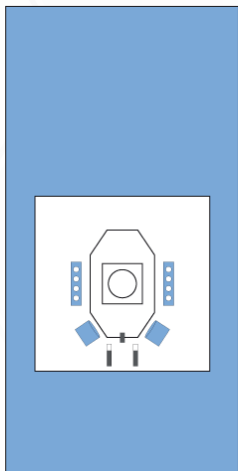


- Large & wide surgical drape to sufficiently cover the patient
- Normal delivery drape comes with a wide collection of pouch and suction port
- Sufficient fenestration with adhesive
- Drape comes with attached leggings
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements



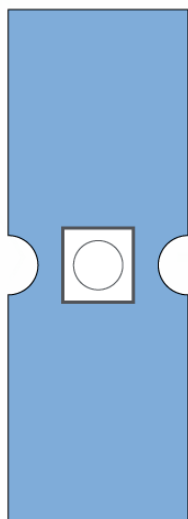
Cesarane Drape

- Large & wide surgical drape to sufficiently cover the patient
- Caesarean drape comes with a wide collection pouch and suction port
- Sufficient fenestration with incise, which ensures easier accessibility and retains sterile of un-accessed
- fenestrations
- Advanced technology provides best combination of protection and comfortable draping
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements



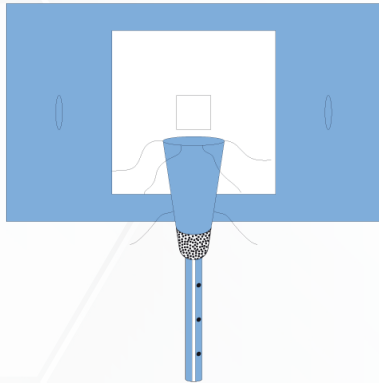
Craniotomy Drape

- Large & wide craniotomy drape to sufficiently cover the patient
- Craniotomy drape comes with a wide collection of pouch and suction port
- Drape comes with sufficient fenestration with incise, which ensure easier accessibility and retain sterility of un-
- accessed fenestration
- Optimal folding for aseptic application
- Cautery bag comes with 3 distinct compartments
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements



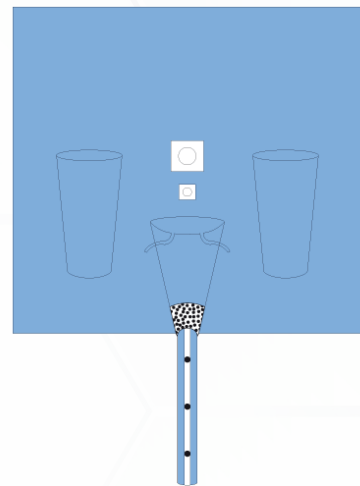
Perinal Drapes

- Large & wide surgical drape to sufficiently cover the patient
- Perineal drape comes with sufficient fenestration with adhesive.
- Advanced technology provides best combination of protection and comfortable draping
- Suitable for IVF, D&C, MTP
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements



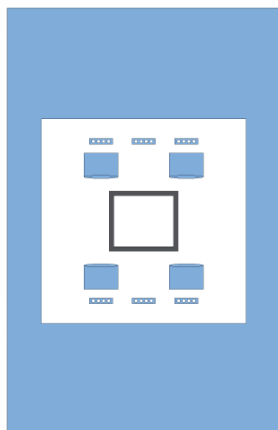
PCNL Drape

- Large & wide surgical drape to sufficiently cover the patient
- PCNL drape comes with wide collection pouch
- Advanced technology provides best combination of protection and comfortable draping
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements



TURP Drape

- Large & wide surgical drape to sufficiently cover the patient
- TURP drape comes with wide collection pouch
- Drape comes with attached leggings
- Advanced technology provides best combination of protection and comfortable draping
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements



Laparoscopy Drape

- Large & wide surgical drape to sufficiently cover the patient
- Drape comes with sufficient fenestration area with adhesive
- Around fenestration provide four cautery pouches and 6 tube holders, which ensure easier accessibility
- Advanced technology provides best combination of protection and comfortable draping
- Optimal folding for aseptic application
- EO sterilized as per internationally acknowledged ISO 11135 standards, using medical grade packaging material that meets ISO 11607-1 and EN 868-5 requirements



SURGICAL KITS

Angiogram Drape Kit

- An **Angiogram Drape Kit** is a sterile, single-use surgical drape set designed to maintain an aseptic field and manage fluids effectively during angiography, catheterization, and interventional radiology procedures. These drapes provide optimal coverage and protection for both the patient and the surgical team. This kit Includes Surgical Gowns And Drape Sheets
- **Impermeable & Lint-Free Material** – Prevents fluid penetration and maintains sterility.
- **Strong Adhesion** – Ensures the drape stays in place throughout the procedure.
- **Fluid Management System** – Helps control blood, saline, and contrast media spillage.
- **Customizable Options** – Available in different sizes and configurations for femoral, radial, or brachial access procedures.

Craniotomy Drape Kit

- A Craniotomy Drape Kit is a sterile, single-use drape set designed for neurosurgical procedures involving the skull. It ensures a sterile surgical field, effective fluid control, and optimal patient coverage during craniotomies. This kit Includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, lint-free, and fluid-resistant material to maintain sterility.
- Secure adhesion around the incision site to prevent bacterial contamination.
- Integrated fluid management system to handle irrigation and blood loss.
- Customizable sizes and configurations for various cranial procedures.

CABG (Coronary Artery Bypass Grafting) Drape Kit

- A CABG Drape Kit is a sterile, single-use drape set designed specifically for coronary artery bypass grafting (CABG) surgeries. It ensures a sterile surgical field, effective fluid management, and optimal patient coverage during open-heart procedures. This kit Includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, lint-free, and fluid-resistant material to maintain a sterile field.
- Strong adhesive edges to prevent bacterial contamination and maintain a secure fit.
- Integrated fluid control system to manage blood and irrigation fluids effectively.
- Available in various sizes and configurations to meet specific surgical requirements.

ENT (Ear, Nose, and Throat) Drape Kit

- An ENT Drape Kit is a sterile, single-use surgical drape set designed to provide a sterile field, fluid control, and optimal patient coverage during ear, nose, and throat surgeries. These drapes help reduce the risk of infection and enhance surgical efficiency. This kit includes Surgical Gowns And Drape Sheets
- Impermeable, lint-free, and fluid-resistant material to maintain sterility.
- Strong adhesive edges for secure placement and minimal contamination risk.
- Lightweight and breathable fabric for patient comfort.
- Available in different sizes and configurations for various ENT procedures (e.g., tonsillectomy, sinus surgery, tympanoplasty).

General Ortho Pack

- A General Ortho Pack is a sterile, single-use surgical pack designed for various orthopedic procedures, including joint surgeries, fracture fixations, and soft tissue repairs. It ensures a sterile surgical field, effective fluid management, and comprehensive patient coverage to enhance efficiency and infection control. This kit includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, fluid-resistant material to maintain a sterile surgical environment.
- Strong adhesion and reinforced edges to prevent drape movement.
- Designed for various orthopedic procedures (e.g., trauma, joint replacement, arthroscopy).
- Available in multiple sizes and configurations to meet different surgical needs.

General Surgery Pack

- A General Surgery Pack is a sterile, single-use surgical drape and accessory set designed for various open and laparoscopic procedures. It provides optimal patient coverage, fluid management, and infection control to maintain a sterile surgical environment. This kit includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, lint-free, and fluid-resistant material to maintain sterility.
- Strong adhesive borders to ensure secure placement and prevent bacterial contamination.
- Designed for a wide range of general surgical procedures, including laparotomy, hernia repair, appendectomy, and colorectal surgeries.
- Available in various sizes and configurations to suit different surgical needs.

Kidney Donor Pack

- A Kidney Donor Pack is a sterile, single-use surgical pack designed for live or cadaveric kidney donation procedures. It ensures a sterile operating field, efficient fluid management, and optimal coverage for both open and laparoscopic nephrectomy (kidney removal) surgeries. This kit includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, fluid-resistant, and lint-free material to maintain sterility.
- Strong adhesive borders for a secure fit and to prevent bacterial contamination.
- Designed for both open and laparoscopic nephrectomy procedures.
- Available in different sizes and configurations to accommodate surgical preferences.

Lamino Spinal Drape Kit

- A Lamino Spinal Drape Kit is a sterile, single-use drape set specifically designed for laminectomy, spinal decompression, and other spinal surgeries. It ensures a sterile surgical field, fluid management, and optimal patient coverage, reducing the risk of contamination and improving surgical efficiency. This kit includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, lint-free, and fluid-resistant material to maintain a sterile environment.
- Strong adhesive borders to prevent shifting and contamination.
- Designed for lumbar, thoracic, and cervical spinal procedures.
- Available in multiple sizes and configurations to suit various surgical requirements.

Liver Transplant Drape Kit

- A Liver Transplant Drape Kit is a sterile, single-use drape set designed to provide comprehensive patient coverage, fluid management, and infection control during hepatectomy and liver transplant procedures. It ensures a sterile surgical field while accommodating the complexity of the procedure. This kit includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, lint-free, and highly absorbent material to maintain sterility.
- Reinforced zones in high-exposure areas for extra fluid control.
- Designed for both donor and recipient procedures in liver transplantation.
- Available in multiple sizes and configurations to accommodate different surgical approaches.

Neurosurgery Drape Kit

- A Neurosurgery Drape Kit is a sterile, single-use surgical drape set designed for cranial and spinal neurosurgical procedures. It provides optimal patient coverage, fluid management, and infection control, ensuring a sterile surgical environment. This kit Includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, lint-free, and fluid-resistant material to maintain a sterile field.
- Strong adhesive borders to ensure a secure fit and minimize bacterial contamination.
- Designed for cranial, spinal, and other neurosurgical procedures.
- Available in multiple sizes and configurations to suit various surgical needs.

Total Knee Replacement (TKR) Surgery Drape Kit

- A Total Knee Replacement (TKR) Surgery Drape Kit is a sterile, single-use drape set designed to provide maximum patient coverage, infection control, and fluid management during knee arthroplasty procedures. It ensures a sterile surgical field while facilitating easy access to the knee joint.
- Impermeable, lint-free, and fluid-resistant material for a sterile environment.
- Strong adhesive borders to ensure drape stability and prevent bacterial contamination.
- Designed for easy positioning and maximum patient coverage.
- Available in different sizes and configurations for various surgical preferences.

Total Hip Replacement (THR) Surgery Drape Kit

- A Total Hip Replacement (THR) Surgery Drape Kit is a sterile, single-use drape set designed to provide maximum patient coverage, fluid management, and infection control during hip arthroplasty procedures. It ensures a sterile surgical field while allowing precise access to the hip joint. This kit Includes Reinforced Surgical Gowns and Drape Sheets
- Impermeable, lint-free, and fluid-resistant material for a sterile environment.
- Strong adhesive borders to ensure drape stability and prevent bacterial contamination.
- Designed for easy positioning and maximum patient coverage.
- Available in different sizes and configurations for various surgical preferences.

OUR CERTIFICATIONS

"Highly Certified Products on International Standards"

ISO13485:2016, MDR / MD-5 License no: MFG/MD/2024/000554.
Certified Company All Kinds of OT Care Disposables, Drapes, Wraps, Kits
& Personal Protective Equipment's

CERTIFICATE

CERTIFICATE No. MTIC/MD/1097

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

SHAIVIK INFECON HEALTHCARE PRIVATE LIMITED

Ground Floor & 1st Floor, H No.5-9-262/P-2/1, Prashanth Nagar,
Kukatpally, Hyderabad 500 072, India.

IS IN COMPLIANCE WITH THE REQUIREMENTS OF STANDARD

ISO 13485:2016

THIS CERTIFICATE IS VALID FOR THE FOLLOWING ACTIVITIES

**Design, Manufacture & Supply of Sterile and Non -Sterile
Personal Protective Wear, Surgical Drapes, Gowns, Kits and
CSSD Wraps.**

Permissible Exclusion: Cls 7.5.3 -Installation Activities, Cls 7.5.4 Servicing Activities, Cls 7.5.9.2 Particular Requirements for
Implantable Medical Devices.

AUDIT REPORT No. MTIC/MED/0306

First issue date 29-10-2023 Revision date: 00 Expiry date 28-10-2026

The validity of this certificate is subject to periodical audits and the complete re-assessment of the system every three years. For any further question with regard to
this certificate please contact www.mtic-group.in

Place : Bengaluru

Head of Certification

MTIC INTERCERT Certification Body

MTIC InterCerti India Private Limited
No. 122/1, 3rd Main Road, Margosa Road, Malleswaram, Bengaluru - 560 003, Karnataka, India
www.mtic-group.in india@mtic-group.in

CERTIFICATE • CERTIFICATO • ZERTIFIKAT • SERTIFIKA • CERTIFICADO • گواهینامه • ΠΙΣΤΟΠΟΙΗΣΗ

DCA DRUGS CONTROL ADMINISTRATION
Government of Telangana

Post Approval

File No: MD/PostAppr/2024/25225 Date: 10-Jan-2025

To
M/s SHAIVIK INFECON HEALTHCARE PRIVATE LIMITED, SY NO-376/A.P-65, Rajeev Gandhi Nagar, Kukatpally, Hyderabad, Telangana, India, 500072 HYDERABAD, Hyderabad, Telangana (India) - 500072
Telephone No: 9490186678 FAX: 9490186678
Email: vijay.sakunala0037@gmail.com

Sub: Post approval change in Manufacturing License No: MFG/MD/2024/000554 dated: 02/08/2024

Sir,
This is with reference to your application number MD/PostAppr/2024/25225 dated: 10/01/2025 regarding the above subject.

The Change in Manufacturing License Form MD-5 No: MFG/MD/2024/000554 as mentioned below is approved with subject to the same condition of license.

Change Description	In Place of	To be Read as
Change of Address of the domestic manufacturer or its manufacturing site	Sy No - 376/A, P-65, Rajeev Gandhi Nagar, Kukatpally, Hyderabad Telangana, - 500072, 9490186678, India, Telephone No - 9490186678, Fax 9490186678, E-mail : 9490186678, India, Telephone No: 9490186678, Fax : 9490186678, E-mail :	SHAIVIK INFECON HEALTHCARE PRIVATE LIMITED, Ground Floor and 1st Floor, H No. 5-9-262 P-2/1, Prashanth Nagar, Kukatpally, Hyderabad, Medchal Malkajgiri, Hyderabad Telangana, 500072, India, Telephone No: 9490186678, Fax : 9490186678, E-mail :

Yours faithfully,
G. RAMDHAN, M.Pharm
JOINT DIRECTOR (En)
Licensing & Controlling Authority
DRUGS CONTROL ADMINISTRATION
Government of Telangana
Hyderabad

Page 1 of 1

DCA DRUGS CONTROL ADMINISTRATION
Government of Telangana

File No: MFG/MD/2023/71276, Date: 02-08-2024.

To
M/s SHAIVIK INFECON HEALTHCARE PRIVATE LIMITED,
SY NO-376/A.P-65, Rajeev Gandhi Nagar, Kukatpally,
Hyderabad, Telangana, India.

Sub: Drug Control Administration - Licence in Form MD-5 for Class -B Device - Forwarded - Regarding.

Ref: Your application vide Medical Devices portal dated: 31-03-2023

With reference to your application cited, I herewith forward your licence in Form MD-5 bearing License No. MFG/MD/2024/000554, dated: 02-08-2024 to manufacture for sale or for class B devices.

You are hereby permitted to manufacture the device mentioned in the Form MD5 enclosed, as per the provisions of Medical Devices Rules 2017.

The manufacturing and testing activity shall be undertaken under direction and supervision of competent technical staff only as per Rule 22 of Medical Devices Rules 2017.

You are directed to comply with the requirements of the Quality Management System as specified under the Fifth Schedule and you are also directed to comply with the Conditions for Manufacturing Licence as per Rule 26 of Medical Devices Rules 2017.

In case of change in constitution you shall inform the State Licensing Authority within forty five days and shall make an application under sub-rule (1) of rule 20 as the case may be, for grant of licence within a period of one hundred eighty days from the date of such change in constitution and the existing licence shall be deemed to be valid till such time, a fresh licence is issued.

Yours faithfully,
G. RAMDHAN, M.Pharm
JOINT DIRECTOR & LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE

DCA DRUGS CONTROL ADMINISTRATION
Government of Telangana

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

License Number: MFG/MD/2024/000554

1. M/s SHAIVIK INFECON HEALTHCARE PRIVATE LIMITED, SY NO-376/A.P-65, Rajeev Gandhi Nagar, Kukatpally, Hyderabad, Telangana, India, 500072 HYDERABAD, Hyderabad, Telangana (India) - 500072 Telephone No.: 9490186678 FAX: 9490186678 has been licensed to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Shaivik Infecon Healthcare Private Limited, Sy No - 376/A, P-65, Rajeev Gandhi Nagar, Kukatpally, Hyderabad, Telangana (India) - 500072 Telephone No.: 9490186678 FAX: 9490186678

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: Surgical gown (Sterile) Model No.: NIL Intended Use: A sterile garment made of natural and/or synthetic materials intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. Class of medical device: Class B Material of construction: Non woven Fabric Dimension (if any): Small, Medium, Large, XL and XXL Shelf life: 3 years Sterile or Non sterile: Sterilized Brand Name (if registered under the Trade Marks Act, 1999): NIL
2	Generic Name: Isolation Gown (Sterile) Model No.: NIL Intended Use: A sterile garment made of natural and/or synthetic materials intended to be worn by healthcare providers or visitors to isolate themselves from patients to protect the themselves from a contagious agent which has infected the patient. Class of medical device: Class B Material of construction: Non woven Fabric Dimension (if any): Small, Medium, Large, XL and XXL Shelf life: 3 years Sterile or Non sterile: Sterilized Brand Name (if registered under the Trade Marks Act, 1999): NIL

Yours faithfully,
G. RAMDHAN, M.Pharm
JOINT DIRECTOR (En)
Licensing & Controlling Authority
DRUGS CONTROL ADMINISTRATION
Government of Telangana
Hyderabad

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3. Generic Name: Surgical Drape & Drape Accessories
Model No.: NIL
Intended Use: A surgical drape & 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 & other contamination.
Class of medical device: Class B
Material of construction: Non woven Fabric
Dimension (if any): Small, Medium, Large, XL and XXL
Shelf life: 3 years
Sterile or Non sterile: Sterilized
Brand Name (if registered under the Trade Marks Act, 1999): NIL

4. Generic Name: Personal Protective Equipment
Model No.: NIL
Intended Use: PPE kit used to acts as a barrier between infectious materials such as viral and bacterial contaminants and skin, mouth, nose, or eyes. It refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.
Class of medical device: Class B
Material of construction: Non woven Fabric
Dimension (if any): Small, Medium, Large, XL and XXL
Shelf life: 3 years
Sterile or Non sterile: Sterilized
Brand Name (if registered under the Trade Marks Act, 1999): NIL

Place: Hyderabad, Telangana State
Date: 02-Aug-24

Yours faithfully,
G. RAMDHAN, M.Pharm
JOINT DIRECTOR (En)
Licensing & Controlling Authority
DRUGS CONTROL ADMINISTRATION
Government of Telangana
Hyderabad

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