1. Hitex Healthcare has set up manufacturing facilities conforming to international standards at Una, Himachal Pradesh and Gandhidham, Gujarat for production of medical disposables according to standards of ISO with technical collaboration with DINA-HITEX Czech Republic. DINA-HITEX is one of the leading manufacturers of Medical Disposable products in Europe, with established integrated quality system and environmental management according to standards ISO 13485:2003 / ISO 14001:2004. Our products are being used at hospitals in Germany, Austria, Great Britain, Netherlands, Russia, Switzerland, France etc.

2. DINA-HITEX ranks among the most important producers and distributors of medical material in the Czech Republic. It went on the market in 1992 and ever since focuses primarily on the development and production of expendable supplies made of unwoven fabrics. The principal manufacturing program of the company lies in the production of the single-use sterile / non-sterile medical material.

3. The barrier system developed by DINA-HITEX ranges from surgical masks to specialized single-use procedure kits designed for specific customers according to their requirements. Most of our production is custom and for the employment.

4. We manufacture Barrier Systems Sterile Single Use Procedure Kits in India at Gujarat and Himachal Pradesh. Surgical Barrier system enables effective prevention against infection during surgeries. It safely isolates any possible source of infection, especially patient body, Operation Theatre Staff and Equipment simultaneously absorbs body fluids that may be the source of Infection.

5. This Manual has been produced for information of all Hitex Healthcare staff to ensure that they are always updated about products and have in hand information of various raw material used in production.
<table>
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<tr>
<th>Sl.No.</th>
<th>Chapter No.</th>
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**CHAPTER – 1**

**PRODUCTS**

0101. Our surgical Drapes and Gowns conform to EN 13795 which was developed to establish a recognised Pan – European standard of Quality for all single use surgical Drape and Gowns. These standards are:-

(a) Resistance of Microbial Penetration – EN ISO 22612 (Dry and Wet Condition)

(b) Microbial Cleanliness – EN ISO 11737 – 1.

(c) Lining EN ISO – 9073 – 10.

(d) Bursting Strength – EN ISO 13938 – 1 (Dry and Wet Condition)
(e) Tensile Strength – EN ISO 29073 – 3 (Dry and Wet Condition).

These are appended below:

<table>
<thead>
<tr>
<th>Surgical Gown OPTIMUM</th>
<th>Surgical Gown CLASSIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Made from non-woven textile hydrophobic material SIMS that protects against fluid penetration. Gowns are fixed with four ties system.</td>
<td>Made from non-woven textile hydrophobic material SIMS that protects against fluid penetration. Gowns are fixed with four ties system.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surgical Gown PREMIUM</th>
<th>Surgical Gown OPTIMUM With reinforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Made from hydrophobic non-woven material Sontara with enhanced air permeability. Protects from fluid penetration. Gowns are fixed with four ties system.</td>
<td>Gown is reinforced at front side and sleeves with impermeable material that assures perfect protection of surgeon during major surgeries.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ophthalmic Drape</th>
<th>Ophthalmic Drape</th>
</tr>
</thead>
<tbody>
<tr>
<td>With integrated self-adhesive incision foil</td>
<td>With integrated incision foil and one fluid collection pouch with plastic brace</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Knee TEP Set</th>
<th>Knee Drape</th>
</tr>
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<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th>Arthroscopy Set</th>
<th>Vertical Drape</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertical Drape</td>
<td>With incision foil and F/C pouch</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Vertical Drape Large</th>
<th>U-Drapes three-layer DS3</th>
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</table>

<table>
<thead>
<tr>
<th>U-Drapes combined 2SBL + DS2</th>
<th>Hip Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hip TEP Set</td>
<td>Head Surgery Set</td>
</tr>
<tr>
<td>------------</td>
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<tr>
<td><strong>Cardiovascular Drape</strong></td>
<td><strong>Pectoral Surgery Set</strong></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>With incision foil, pouches and tube holder</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>TUR Drape combined</strong></th>
<th><strong>TUR Set</strong></th>
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<table>
<thead>
<tr>
<th><strong>Gynecology Drape</strong></th>
<th><strong>Perineal Set</strong></th>
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<table>
<thead>
<tr>
<th><strong>Gynaecology Set</strong></th>
<th><strong>Rectum Surgery Set</strong></th>
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<table>
<thead>
<tr>
<th><strong>Gynaecology Set for Laparoskopy</strong></th>
<th><strong>Vaginal Drape</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Fenestrated Drape with IF and Pouch</strong></th>
<th><strong>LAVH Set</strong></th>
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<table>
<thead>
<tr>
<th><strong>Caesarotomy Set</strong></th>
<th><strong>Caesarotomy Set without caesarotomy P/C pouch</strong></th>
</tr>
</thead>
</table>
CHAPTER – 2

RAW MATERIAL

0201. Millions of people all over the world acquire HAI (Hospital Acquired Infection) resulting in tens of thousands of fatalities every year. There are many causes for acquiring infections in the hospitals, one of them being during surgery (commonly referred to as SSI – Surgical Site Infection). Nonwoven medical drapes and gowns can help prevent the spread of bacteria and microbes during surgery, thereby reducing the risk of SSI/HAI. Nonwoven medical drapes and gowns offer following:-

(a) A high level hydrostatic head property and thus a high level protection against fluid and particles.

(b) Good air permeability: good air permeability is preserved, which is an important criteria for ethylene oxide sterilization

(c) It delivers a high barrier protection associated with strong mechanical resistance

0202. We use Non Woven Fabric for manufacturing various Surgical Gowns, Drapes Wraps and Sheets. Nonwoven fabric is a fabric like material made from long fibers, bonded together by chemical, mechanical, heat or solvent treatment which is neither woven nor knitted and is flat & porous.

0203. Manufacturing Process of Non Woven Fabric involves following two different methods:-

(a) **Staple Nonwovens** - In this process fiber are:-

(i) Spun, cut to a few centimeters length and put into bales.
Bales are then dispersed on a conveyor belt and the fibers are spread in a uniform web by a wet laid process or by carding.

Rayon used to be a common fiber in nonwovens; which has now been replaced by polyethylene and polypropylene.

Synthetic fiber blends are wet laid along with cellulose for single-use fabrics.

Staple nonwovens are bonded by using either resin or thermally.

Manufacturing Process of Staple Nonwovens

Spun laid nonwovens are:

(i) Made in one continuous process.

(ii) Fibers are spun and then directly dispersed into a web by deflectors.

(iii) This technique leads to faster belt speeds, and cheaper costs.

(iv) The leading technology is the REICOFIL machinery. Polypropylene spun bonds run faster and at lower temperatures than polyethylene spun bonds, mostly due to the difference in melting points.

(v) Spun bond has been combined with melt blown nonwovens, conforming them into a layered product called SMS (Spun-Melt-Spun).

(vi) Melt blown nonwovens have extremely fine fiber diameters but are not strong fabrics. SMS Fabrics, made completely from Polypropylene are water-repellent and fine enough to serve as disposable fabrics.

(vii) Melt blown is often used as filter media, being able to capture very fine particles. Spun laid is bonded by either resin or thermally.
0204. We use Hydrophobic 100% polypropylene non-woven material, three layer structure spunbond-meltblown-spunbond, produced by M/s Ahlstrom, Gujarat the leading manufacturer of the product in India. Attributes/general requirement of medical nonwoven are placed at Appendix A to this Manual.

0205. Properties of SMS:

(a) **High Barrier Property**: It offers a high level hydrostatic head property and thus a high level protection against fluid and particles.

(b) **Good Air Permeability**: Good air permeability is preserved, which is an important criteria for ethylene oxide sterilization.

(c) **Low Shrinkage Rate**: It has a very low shrinkage rate after steam sterilization process.

(d) **Excellent Mechanical Properties**: It has a strong resistance to tears and punctures.

(e) **Good Drapeability**: It offers a cloth-like comfort and feel. It is extremely soft, drapeable and easy to work with.

(f) Nonwovens may be a limited-life, single-use fabric or a very durable fabric. Nonwoven fabrics provide specific functions such as absorbency, liquid repellency, stretch, flame retardancy, washability, cushioning, filtering, bacterial barriers and sterility.

0206. Spunlace Nonwovens: This is the oldest technique for consolidating fibers in a web is mechanical bonding, which entangles the fibers to give strength to the web. Under mechanical bonding, the method is spunlacing (hydro entanglement). Spunlacing uses high-speed jets of water to strike a web so that the fibers knot about one another.

0207. Advantages of Spunlace Nonwovens:

(a) Super absorbency capacity, four times faster than ordinary cotton wipe.

(b) Fire retardants can be applied to resist burning, antimicrobial agents to enhance resistance against microorganisms.

(c) No static electricity.

(d) Superior tensile strength, high strength, flexibility, durability, economic and practical.

(e) Environmental protection.

0208. Spunbond Non Woven: Spunbond fabrics are produced by depositing spun filaments onto a collecting belt in a uniform random manner followed by bonding the fibers. Fibers are separated by air jets. Collecting surface is usually perforated to prevent the air stream from...
deflecting and carrying the fibers in an uncontrolled manner. Bonding strength and integrity to the web by applying heated rolls to partially melt the polymer and fuse the fibers together. Polyethylene or ethylene-propylene copolymers are used as low melting bonding sites.

0209. **Advantages:**

(a) Random Fibrous Structure  
(b) High Tear Strength  
(c) High Liquid Retention Capacity  
(d) Low Drapeability  
(e) High Strength-To-Weight Ratios

0210. **Meltblown Non Woven:** Melt blowing (MB) is a process for producing fibrous webs directly from polymers or resins using high-velocity air to attenuate the filaments. The MB process is one of the newer and least developed nonwoven processes. This process is unique because it produces microfibers rather than normal textile fibers.

0211. **Advantages of Meltblown Non Woven:**

(a) Elasticity  
(b) Softness  
(c) Wetability  
(d) Dyeability  
(e) Chemical Resistance

0212. **Protection from Infection and Bacteria:** Nonwoven's SMS medical barrier fabric has a unique multi-layer spunbond and meltblown construction which achieve a high barrier protection and a high level of air permeability; it is an ideal fabric for conversion into different medical and protective products surgical drapes and gowns. The advantage for using nonwovens is protection from the patient's blood, bodily fluids, and these are sterile.

0213. **ANTI STATIC SMS:** The SMS has high resistivity and surface resistance up to $10^{14}$ ohm/cm. It quite easily generates static charge which can cause not only fire but also impact on patient and apparatus. Therefore static property of SMS used by us is improved by:

(a) Damping SMS in Antistatic Agent  
(b) Blending raw material slice with Antistatic Alice  
(c) Spraying antistatic agent on SMS

0214. **Other material used in production:**

(a) Laminates:
(i) **DS2**: Two layer laminated material, bottom layer PE-film 25mu, upper layer viscose 26gsm, total weight 60gsm, absorption 396%, produced by Dina-Hitex in Czech Republic.

(ii) **2SBL**: Two layer laminated material, bottom layer PE-film 25mu, upper layer Spunbond 28gsm, total weight 60gsm, absorption 374%, produced by DINA-HITEX in Czech Republic.

(iii) **FS2**: Two layer laminated material, bottom layer PE-film 25mu, upper layer Spunbond 17gsm, total weight 45gsm, produced by Dina-Hitex Czech Republic.

(iv) **DS3**: Three layer laminated material, bottom layer spunbond 17gsm, middle layer PE-film 25mu, upper layer viscose 26gsm, total weight 78gsm, absorption 417%, produced by Dina-Hitex in Czech Republic.

(b) **Adhesive Tapes**: Adhesive tapes used by us are produced in house by DINA HITEK. These tapes are dermatological certified and do not cause any rashes, irritation and
infection to human skin. These tapes are qualitatively manufactured to last longer than
the procedures. Quality reports of manufacturer in respect of these tapes are placed at
Appendix B to this Manual.

CHAPTER 3
PRODUCTION FACILITIES

0301. We are the only manufacturer of hospital disposables in India who have set up world class
facilities at our factory. These facilities include following:-

(a) **Clean Room:** A clean room is a controlled environment where products are manufactured. It is
a room in which the concentration of airborne particles is controlled to specified limits.
Eliminating sub-micron airborne contamination is a process of control. These contaminants are
generated by people, process, facilities and equipment. They must be continually removed
from the air. The level to which these particles need to be removed depends upon the
standards required. The only way to control contamination is to control the total environment.
Air flow rates and direction, pressurization, temperature, humidity and specialized filtration all
need to be tightly controlled. And the sources of these particles need to controlled or
eliminated to the maximum possible extent. Our Clean Room is planned and manufactured
using strict protocol and methods.

It only takes a quick monitor of the air in a clean room compared to a typical office building to
see the difference. Typical office building air contains from 5,00,000 to 10,00,000 particles (0.5
microns or larger) per cubic foot of air. Our clean room is designed to never allow more than
1,00,000 particles (0.5 microns or larger) per cubic foot of air.
We clean and maintain clean room as per requisite norms to ensure highest standard of
hygiene and maintain positive air pressure inside at all times.

(b) **Heating Ventilation and Air Conditioning (HVAC):** The integrity of the clean room
environment is created by pressure differential compared with the adjacent areas through
heating, ventilation and air-conditioning system. To achieve this we have installed a state of art
HVAC system which ensures:-

(i) Supply of air sufficient volume and cleanliness to support the rating of the room.
(ii) Introduction of air in a manner to prevent stagnant areas where particles could
accumulate.
(iii) Filtering the outside and re-circulated air across high efficiency particulate air (HEPA)
filters.
(iv) Conditioning the air to meet the clean room temperature and humidity requirements

(v) Enough conditioned makeup air to maintain the specified positive pressure

(c) **Dehumidifiers**: To maintain requisite humidity in godown where raw material and finish products are stored, dehumidifiers have been installed.

**CHAPTER 4
STERILISATION**

0401. Sterilisation is a process or act of inactivating or completely destroying all forms of microbial life including viruses. Our products are sterilized through M/s Microtrol Sterilization Services Pvt. Ltd. The following sterilization processes are undertaken by M/s Microtrol Sterilization Services Pvt. Ltd:-

(a) **Ethylene Oxide Sterilisation (EtO)**: This process comprises of pre-packed products being loaded into a specially designed chamber, exposing them to EtO under controlled conditions and unloading them from the steriliser after aeration. This is an effective sterilant at low temperature with excellent penetration properties under controlled conditions. EtO is a gas at ambient temperature since it vapourises at about 10.7°C (51.3 deg F). Being an effective sterilant it destroys all micro-organisms at room temperature. EtO is a tiny molecule in which two carbon and four hydrogen atoms are joined to one oxygen atom in a highly strained epoxy ring. Because of the chemical’s low boiling point (10.7 deg C, ~51.3 deg F) it vapourises and permeates rapidly through packaging and diffuses in medical products. The ability to treat items in sterilant-permeable packaging permits sterility maintenance as long as integrity of the packaging is maintained.

(b) **Gamma rays**: Gama rays are short waves of considerable energy that affects products in following two ways:
   
   (i) Directly causes large molecules (DNA & RNA) to disintegrate into smaller molecules thereby preventing growth of the cell.
   (ii) Causes radiolysis of water producing free radicals that react with chemical groups inactivating them.

0402. Our products are EtO Sterilised as per the Bureau of Indian Standards published guidelines for sterilisation of medical products (IS 10150-1981) indicating EtO as a sterilising agent for medical devices.

0403. We are planning our own sterilisation chamber in house in near future.

CHAPTER – 5
0501. We specialize in individual sets production, with maximum respect for customers' requirements and we offer selected standard items to our customers according to their specific requirements. Each product may be used for a customized set configuration with regards to the: operation technique, organization and equipment of operation theatre, number of operating team. Our products are:-

(a) **Water resistance**: Two and three layer materials, used for drapes production, are laminated with plastic film that works as a perfect barrier against body fluids and microorganism penetration.

(b) **Absorbency**: The drape surface is made from absorbent viscose with high capacity of absorbency 250 ml water/sqm.

(c) **Linting and Dust Proof Material**: The surface is resistant to abrasion; material does not release any fibres.

(d) **Adhesive zones**: Sides of drapes and apertures are lined with adhesive zones, which allow simple effective and safe fixation of the drape to patient body.

(e) **Folding, Packing and Sepsis**: Special folding technique enables that drapes and integrated accessories are applied without any contact with sterile and non-sterile surfaces.

(d) **Simplicity and Functionality**:
- Each part is anatomically shaped
- Materials perfectly adhere to the surface
- All components are ranked into logic sets which include all that is necessary for a surgery preparation
- Always ready to use

0502. **ISO Certification**: We have implemented and documented a Functional Quality Management System in compliance with the requirement of the standard EN ISO 13485:2003 and ISO 9001:2008. Certificates to this effect have been issued to us by Institute for Testing and Certification, Czech Republic. It covers Manufacture and Supplies of Sterile and Non Sterile Protective Surgical Clothing and Hospital Disposable Items.

0503. **CE Marking**: Efforts are in hand to obtain CE Marking for all our products. The same is expected by middle of this year.

0504. **LAB Reports**: Lab Reports pertaining to various Raw Material used, Tests carried out and sterilization of our products are appended below:-

<table>
<thead>
<tr>
<th>General Requirements/ Attributes Of Medical Nonwovens</th>
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<tbody>
<tr>
<td>Protection</td>
</tr>
<tr>
<td>HH, IPR, Blood test</td>
</tr>
<tr>
<td>Comfort</td>
</tr>
<tr>
<td>Air perm, MVTR, softness</td>
</tr>
<tr>
<td>Mechanical</td>
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<tr>
<td>Bursting, tensile/tear, elongation</td>
</tr>
<tr>
<td>Drapeability</td>
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<tr>
<td>Bending test, hand-o-meter</td>
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<tr>
<td>Aesthetics</td>
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<tr>
<td>Colour, opacity, texture/glairiness, noisiness</td>
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<tr>
<td>Safety</td>
</tr>
<tr>
<td>A/S, biocompatibility, flammability, sterilization</td>
</tr>
</tbody>
</table>

0506 **Alcohol Repellency**

(a) **SCOPE**: This test is designed to measure the resistance of nonwoven fabrics to penetration by an alcohol and/or alcohol/water solutions.
SIGNIFICANCE: This test is used primarily for nonwoven materials that have patient-draping end use in hospital operating rooms. Some liquids used in operating rooms contain alcohol and if spillage occurs it is desirable that it does not penetrate the draping material and “wet” the patient. This test is used to determine if the alcohol repellency of a nonwoven material is satisfactory.

0507. ELECTROSTATIC DECAY (Static Decay)

(a) SCOPE: This method measures the time required to dissipate an induced electrostatic charge on a nonwoven material to 10% of the initial value.

(b) SIGNIFICANCE: It is possible for electrical charges to build up on certain nonwoven materials that are used in hospital operating rooms where flammable gases are present. If sufficient charge builds up on the nonwoven, a spark can be generated when the nonwoven is grounded and the flammable gases can be ignited causing explosions and/or fire. It is desirable that nonwoven materials used in such applications bleed off electrical charges rapidly so that charges of a spark-producing level cannot be accumulated.
Classes of Medical Devices: Medical devices under the regulation have been classified by Medical Device Regulatory Authority of India (MDRA) as per following criteria:

(a) There is complexity and wide variety requiring classification of medical devices so that the level of regulation can be proportional to the level of risk associated with them.

(b) The level of risk inherent in the use of a particular device depends substantially on its intended purpose and is defined by the nature or degree of contact with the human body and the duration of such contact.

(c) The risk classification system may generally consist of four risk classes namely

(i) Class A- devices involving lowest risk levels
(ii) Class B- devices involving low to moderate risks
(iii) Class C- devices involving moderate to high risks
(iv) Class D- devices involving highest risks
0701. **AAMI Standard PB70:2003**

(a) Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities. The main objectives of the standard are:

(b) To help end-users select the types of drapes and gowns most appropriate for a particular task

(c) Assist manufacturers in qualifying, classifying and labeling the barrier performance of their products

(d) These objectives are accomplished through a system of classification based on the products’ liquid barrier performance (in the critical zones)

(e) There are four levels of barrier performance, level 4 being the highest protection available.

0702. **Critical Zones**

AAMI defines the critical zones as those areas where direct contact is likely to occur with

- Body Fluids

- OPIM (other potentially infectious material)

- Critical areas include the material as well as areas of construction, such as seams.

0703. **Surgical Gown and Drape Critical Zones**
0704. AAMI Levels - Test Methods: The AAMI guideline classifies the barrier performance of surgical gowns and drapes through the use of four industry standard tests:

(a) **AATCC 42: Water impact** – measures the resistance of fabrics to penetration of water by spray impact.

(b) **AATCC 127: Hydrostatic Pressure** – measures the resistance of fabrics to the penetration of water under constantly increasing pressure.

(c) **ASTM F1670** - measures the resistance of fabrics to the penetration of synthetic blood under continuous contact.
(d) ASTM F1671- measures the resistance of fabrics to the penetration of blood borne pathogens under continuous contact.
Standards EN 13795 for Gowns

All grades (AR/AS, Antistatic & untreated) pass the standard performance requirements as well as the high performance less critical area for 35 gsm and above

(e) AAMI Level Classifications

<table>
<thead>
<tr>
<th>Level</th>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least Protective</td>
<td>AATCC 42</td>
<td>&lt;4.5 g</td>
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<tr>
<td></td>
<td>Water Impact (WI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>AATCC 42, WI</td>
<td>&lt;1.0 g</td>
</tr>
<tr>
<td></td>
<td>AATCC 127, HH</td>
<td>&gt;20 cm</td>
</tr>
<tr>
<td></td>
<td>AATCC 42, WI</td>
<td>&lt;1.0 g</td>
</tr>
<tr>
<td></td>
<td>AATCC 127, HH</td>
<td>&gt;50 cm</td>
</tr>
<tr>
<td>Most Protective</td>
<td>ASTM F1671, Gowns</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>ASTM F1670, Drapes</td>
<td>Pass</td>
</tr>
</tbody>
</table>

All grades
BARRIER PROTECTION- FREQUENTLY ASKED QUESTIONS

Panel of experts includes:

(DS) – Debra Schotz, Vice President Marketing, Cardinal Health's Convertors Division

(BW) – Brian Wagner, General Manager, Global Surgical, Solutions, Kimberly-Clark Health Care.

(LG) – Lori Gattelfinger, Business Development Leader, DuPont Medical Fabrics.

(DG/CW) – Deborah Gardner, LPN, OPAC, CIC, Technical Service Specialist 3M Health Care and Carol Watson, Market Development Manager 3M’s Health Care Surgical Drapes Division.

Q: What is the No. 1 misconception concerning the use of barrier protection?

(DS) “The No. 1 misconception pertaining to the use of barrier protection is that a repellent material is always impervious. Impervious means that a fabric is impenetrable by fluids and microorganisms. When fluid contacts a repellent material it beads up, giving the appearance that no strikethrough will occur; however, given enough time, fluid and pressure strikethrough may occur.”

(BW) “All barrier protection of surgical gowns and drapes is not created equal, even though they may look similar. Caregivers need to be aware of using the appropriate level of protection for the procedure at hand.”

(LG) “Some clinicians believe that they have to choose between comfort and protection. They assume that products that offer high levels of fluid protection must be hot to be protective. Historically, there was some truth to this as gowns that were comfortable offered less protection. However, with advances in material technology users can get high fluid protection and comfort from one material.”

(DG/CW) “The biggest misconception regarding barrier protection and draping is if you apply drapes in layers they will create a barrier. However, when the drapes become permeated or moist, they must be considered contaminated. Corrective action must be initiated to cover the area in question, or unless the drape has a ‘barrier’ or impervious film layer to prevent strike-through, the drapes must be changed. It is important to remember that when you have fluid and pressure, it always results in strike-through unless you have an impervious layer.”

Q: Can you explain the different fibers used for such products? What are the more effective materials for protection?

(DS) “Disposable surgical drapes and gowns are made from natural or synthetic fibers. Spunlace is a material made of both wood pulp (natural) and polyester (synthetic fibers). Surgical drapes and gowns constructed of spunlace offer a lower level of protection compared to products made entirely of synthetic materials. Additionally, the wood pulp fibers used to create spunlace material may burn at a higher rate than fully synthetic materials. Synthetic fibers such as polypropylene and polyethylene are also commonly used in the construction of surgical drapes and gowns. When variations of synthetic fibers are combined, a higher level of protection can be created. Synthetic fibers also tend to melt away when in contact with a heat source, reducing the potential for a fire hazard.”

(BW) “While there are many unique polymer combinations used to drive different barrier levels in surgical products, the one commonality is that the more uniform the coverage of the barrier layer of material, the better the level of protection will be against strikethrough.”

(LG) “Spunlace fabrics are made with polyester and wood pulp and offer excellent splash resistance and comfort, but lower fluid protection under pressure. Gowns made with spunlace fabrics can be reinforced with fabric or film to provide additional fluid protection. Polypropylene SMS provides higher fluid barrier than spunlace but is less breathable, and can be stiff making it a less comfortable choice. The newest innovation in medical fabrics is made with bi-component technology combining polyester for strength and polyethylene for softness. It offers higher fluid barrier than even PP SMS and is very soft and comfortable. The highest level of protection — AAMI (Association for the Advancement of Medical Instrumentation) level 4 — products must be reinforced with a film to make them totally impervious.”

(DG/CW) “Common drape materials include linen/cotton (reusable drapes), nonwovens, or plastics with adhesive areas. A nonwoven is a fabric produced by bonding or interlocking fibers. The most common
Nonwovens include one layer treated with fluorchemicals for fluid repellency; two or more layers of nonwoven; and two or more layers of which one is made of a plastic. Nonwoven draping products treated with a fluorchemical are repellent. If fluid is applied to a repellent drape, it will run off unless pressure is applied at the fluid site. Two or more layers of a non woven will only ‘slow’ down the penetration of fluids. The best barrier is a drape with a plastic or film layer which creates an impervious barrier.

“Although there are no standards, when draping, the AORN guideline recommendations state, ‘They should provide barriers to microorganisms, particulate matter, and fluids.’ Drape materials should be resistant to penetration by blood and other fluids under normal conditions. But that’s not the only important characteristic of a barrier drape. An impervious drape that is fluid repellent, for example, may be ideal for some applications, but because of its repellency, fluids may bead up and roll off the drape onto the floor or onto the healthcare worker. A drape that is absorbent and impervious is designed to help prevent the risks of both strike-through and roll-off, and eliminates the need for layering while protecting the healthcare worker.”

Q: What aspects should healthcare clinicians be aware of when choosing the correct level of protection?

(DS) “To determine the correct level of protection, a clinician should answer the following four questions:

• What type of procedure is being performed?
• How long will the procedure last?
• How much fluid will be present during the case?
• What is the clinician’s role in the procedure?

“Once these questions are answered the clinician can select the appropriate drape and gown for the procedure. All drapes and gowns are classified with an AAMI level. This AAMI level indicates the level of protection offered by the product on a scale of 1 to 4 based on testing conducted on the critical zones. Level 1 offers minimal protection, while 4 offers the most protection. Typically, AAMI level 4 products are used for long, fluid-intense procedures as they offer impervious protection.”

(BW) “According to AORN Standards, Recommended Practices and Guidelines, there are four critical criteria that should be considered when selecting surgical gowns and drapes:

**Barrier Integrity**
Surgical gowns and drapes should be resistant to penetration by blood and other bodily fluids, which can serve as vehicles for blood viral transmission.

**Linting**
Gowns and drapes should be resistant to tears, cuts, and abrasions and low-linting. Lint can contribute to the transmission of bacteria, or cause foreign-body reactions if particles enter an open wound. Abraded materials can generate lint and distort the original physical properties of the surgical products.

**Flammability**
Gowns and drapes should resist combustion. The OR environment contains the necessary fuel, heat source, and oxygen to cause a potential fire. Choosing materials that resist rapid flame spread will help improve reaction time in the event an OR fire occurs.

**Comfort**
Gowns and drapes should be comfortable and contribute to maintaining the wearer’s desired body temperature. This allows personnel to more readily focus on what is truly important, the procedure at hand.”

(LG) “Clinicians need to evaluate the level of fluid challenge that they are likely to be exposed to in a procedure, and they can then choose the right level of protection. Many cases have very low risk of fluid exposure and an un-reinforced gown provides appropriate comfort and protection. AAMI has developed a Technical Information Report (TIR 11:2005) to provide guidance to clinicians regarding which level of protection is suitable for the major procedure classifications.”

(DG/CW) “The purpose of a drape in infection control is to create a sterile field to eliminate or minimize the passage of microorganisms from non-sterile to sterile areas. Thus it is important to be aware of the amount of absorbency as well as the barrier properties of a drape material. It is also crucial to know the procedure the drape will be used for, and be aware of the amount of fluid generated during that surgical procedure. Accessories should also be chosen based on the procedure (e.g. fluid pouches, equipment drapes, etc.).”

Q: Do you see any common areas of misuse when it comes to barrier products?

(DS) “Barrier products are often misused due to both a lack of product knowledge and cost saving measures by the facility. Some users perceive fully impervious products to be warm and uncomfortable, thus opting to sacrifice protection in pursuit of comfort.”
Q: What message would you most like to convey concerning the “critical zone”?  

(BW) “The most common misuse is under- or over-protection. This can be problematic because caregivers need adequate barrier protection and by not optimizing the level of protection, facilities spend needlessly. By standardizing on fewer and smarter products, facilities can make product selection simpler and save money. “Another area is caregivers employing makeshift solutions to prevent problems they encounter when using barrier protection. For example, caregivers will use self-adhesive sterile tape or adherent incises drapes to prevent slip-down of their gloves during procedures.”

(LG) “We have seen some hospitals that are using all level 4 gowns to provide the ultimate level of protection for their staff, and this is overkill. Hospitals can best meet their staff and patients’ needs by using a mix of protection levels based on their procedure mix. This will be the most cost effective for the hospital and provide the staff with the best combination of comfort and protection. Many hospitals have found that they can standardize with two gowns based on the new options in materials and meet all of their needs for protection.”

(DG/CW) “Not understanding that fluid strikethrough can occur anywhere within the sterile field, not just in the critical zone.”

Q: Can you share some tips on the proper procedure to don a gown? How can you ensure the highest level of protection throughout use of the gown?  

(DS) “The introduction of AAMI PB70:2003 has helped to more clearly define the critical zones of surgical drapes and gowns. AAMI’s definition of critical zones encompasses not only the base fabric but also the construction method of specific areas such as surgical gown sleeve seams.”

(BW) “Know how the products used perform in the critical zones. Clinicians should select a gown whose critical zones have protection levels that are appropriate for the anticipated amount of fluid exposure and the duration of a procedure. In surgical gowns, the critical zone is the front area of the gown from chest to knees and the sleeves from cuff to above the elbow. For the surgical drape critical zone, one should understand how well the reinforcement manages fluids, lints at low levels, and resists rapid flame spread in the event of an OR fire. Most manufacturers define the critical zone of a drape to be the reinforcement area or the immediate area surrounding the fenestration.”

(LG) “One important point is that the level of protection for drapes is defined by the critical zone established by the drape manufacturer. This is commonly the absorbent reinforcement surrounding the fenestration area. This is the area of the drape where fluid barrier is important.”

(DG/CW) “Although the critical zone has been defined as an area approximately 12 inches entirely around the incision area, fluid is very seldom contained to that area. The risk of infection increases when strike-through occurs anywhere within the sterile field — not just in the traditional critical zone. “Sterile surgical drapes protect the patient from infection by preventing microorganisms from making their way into the skin opening created during surgery. Surgical drapes are effective because microorganisms cannot move by themselves and rely on dust, fluids, or contact to move them. If a drape material allows fluid to penetrate, it creates a pathway and mode of transportation for organisms to invade the sterile field. The penetration of a drape, gown, or mask by fluids is known as strike-through. To prevent fluid strike-through anywhere on the drape, many healthcare workers will add layers of fabric. If you use a drape with a barrier material throughout the fabric, it will eliminate the need for layering while giving added protection to your patient.”

Q: Can you share some tips on the proper procedure to place drapes? How can you ensure the highest level of protection throughout use of the drapes?  

(DS) “When donning a surgical gown it is important to ensure that all gown ties are adequately adjusted and that the neck closure provides a secure fit. Clinicians should take the time to ensure that the gown is donned properly so that complications with the gown do not occur during the procedure.”

(BW) “One important tip when donning single-use gowns is to be sure to grab a handful of gown material and pull at the seam when adjusting your surgical gloves. This will ensure the gown does not tear. If your skin feels wet, remove the gown and don a new one.”

(LG) “The highest level of protection can be insured by choosing gowns that are made with fabrics offering good fluid barrier. Users also should evaluate the gown construction and look for gowns that are constructed well with neck closures that stay closed, like Velcro, and with heat-sealed seams. Also seam placement can be important. Seams on the top of the sleeve vs. the bottom offer less risk of a breakdown in barrier in the sleeve.”

Q: Can you share some tips on the proper procedure to place drapes? How can you ensure the highest level of protection throughout use of the drapes?  

(DS) “All disposable surgical drapes provide detailed orientation and donning instructions. In order to ensure the highest level of protection it is recommended that a fully impervious drape be utilized.”

(BW) “Drapes should be applied in a smooth, controlled fashion and handled as little as possible during the draping procedure. Follow the manufacturer’s instructions; use the body stamp and arrows to properly place the drape. Don’t move a drape once it is in place. Make sure the prep solution is dry...
before draping. Use proper disposal methods. "Though drapes will resist punctures, avoid placing shape objects and electrical instruments on the drapes. Make sure lines and cables don’t pull on the drape. If the drape has pouches, make sure they are open before starting the procedure. Use a drape that has low linting and doesn’t abrade."

(LG) “The highest level of protection throughout the use of the drape can also be insured through selecting materials that provide excellent fluid barrier and strength as well as fabrics that drape well and stay in place.”

(DG/CW) “Standardized symbols are placed on drapes for direction. Always make sure you begin with the drape in the correct direction. The center of the final fold is commonly lined up with the center of the incision area. Once a drape is placed it should not be moved around. Drape adhesion is very important to prevent drape migration. If a material does not contain a laminated plastic layer, it is important to create a barrier level, (ideally with a plastic drape) prior to placing your final drapes.”

Q: Can you explain the testing these products endure to be cleared as safe for its purposes?

(DS) “As all surgical drapes and gowns are class I medical devices, Cardinal Health must submit and obtain 510(k) approval from the FDA (Food and Drug Administration) prior to making the product available for commercial use. Biocompatibility is one of the main tests required within the 510(k) submission and is conducted on all surgical drapes and gowns. This test ensures that the products do not cause adverse reactions when in contact with living tissue.”

(BW) “Our goal at Kimberly-Clark is to closely align our product specifications with that of AORN Standards, Recommended Practices, and Guidelines. Depending of the type of surgical gown for barrier protection, we use:

- Spray Impact AATCC 42, which stimulates the resistance to liquid penetration by water spray impact
- HydroHead Test AATCC 127, which measures the resistance to the penetration of water under static pressure
- Kimberly-Clark Blood-Strikethrough Test Method
- ASTM 1670 (for drapes only), which measures resistance of materials used in protective clothing to penetration by synthetic blood and ambient pressure
- ASTM 1671 (for gowns only), which measures resistance of materials used in protective clothing to bloodborne pathogens using viral penetration and ambient pressure
- Gelbo Lint Test which determines the relative number of lint particles released from a fabric
- Martindale Abrasion Test ASTM D4966, which compares the abrasion resistance of fabric

For linting, we use:

- NFPA 702-1980, the most stringent measure ignition rate and flame spread

For comfort, we use:

- A 'cup crush' test which measures the drapeability of a fabric
- Air permeability measures air flow through a fabric
- Moisture apour transmission rates which identifies the ability of a fabric to transmit moisture

Gown design is a consideration; gowns with raglan sleeve design offer a wider range of motion as opposed to those with set-in-sleeves.”

(LG) “DuPont Medical Fabrics go through extensive testing measuring their fluid barrier to determine their performance vs. the AAMI standards that have been established. In addition to fluid barrier, DuPont Medical Fabrics are evaluated for strength characteristics, alcohol repellency, MVTR (moisture apour transmission rate), surface stability, and flammability using the CPSC (16 CFR part 1610). Medline evaluates all of the gowns and drapes made with DuPont Medical Fabrics to meet rigorous quality standards to meet their customers’ needs.”

(DG/CW) “Standards only apply to these materials when they are converted into drapes, gowns, or masks intended for sale. The FDA regulates these products as Class 1 sterile medical devices, per Rule 1 for non-invasive devices, meeting all standards for basic safety and efficacy. Every surgical drape on the market has met these basic standards to gain approval for sale. Drape manufacturers also receive guidance from industrial associations such as the Association of the Non Woven Fabric Industry (INDA) and AAMI. The purpose of these industrial associations is to create standardized terms and test methods, which will protect the interests of the industry at large, and member companies specifically. Standards and test methods developed under these organizations are voluntary and enforced by the member manufacturers. These guidance tests include absorbency, level of barrier, linting, etc.”
WHY USE HITEX HEALTHCARE PRODUCTS? HOW IS IT SUPERIOR TO OTHER PRODUCTS IN THE MARKET?

1. **SMS**: The quality of the product will depend on the quality of raw material used. We import SMS from world leaders … Ahlstrom. There are various types of SMS material available with Ahlstrom or any other international standard manufacturer:
   (a) **Grade 2 (CHEAPEST)**: Defective or rejected material. No certification issued by manufacturer. You may be surprised; many companies in India buy ONLY Grade 2 and make disposables which is currently available in Indian market.
   (b) **Untreated (COSTLY THAN GRADE 2)**: This is the premium product but UNTREATED. Many companies in India buy this quality.
   (c) **Treated (COSTLY THAN UNTREATED)**: This is the most expensive product which is Anti Static and has been treated at plant. **WE BUY THIS QUALITY FOR OUR GOWNS/DRAPES.**

2. **Other Raw Material**: Other raw material like 2 and 3 layer laminates, adhesive tapes etc are imported from Dina Hitex. Dina Hitex manufactures these materials at their factory in Europe. No other company in India uses such high quality raw material. You can demonstrate absorbency by sprinkling water on the fabric in swatches.

3. **Certificates**: Each and every material used in our product is backed by certificates from authorized laboratory / manufacturer. Not many companies in Indian market can provide such certification. This is very important and can help Hospitals in fighting legal battles.

4. **FACTORY**: We are the only one in this country which manufactures non woven disposables in international standard CLEAN ROOM. Inside Clean Room the temp, pressure, humidity etc is maintained as per laid down regulations. In addition air changes take place on regular intervals. Further, we are the only one in India which uses AUTOMATIC MACHINES for manufacturing various drapes. Rest everyone does it manually.

5. **Technical Knowhow**: We have technical collaboration with Dina Hitex which is a leading player for more than two decades in this field. The drapes have been developed through regular feedback from leading hospitals. On other hand, our competitors are manufacturing with "Hit & Trial" method, without any technical expertise.

6. **Training**: Team from Europe keep visiting our factories for imparting training on production, usage etc on regular intervals. We also will conduct CME at regular intervals where we will train the OT staff on how to use the drape, how to prepare the patient for any procedure etc.

7. **Sterilisation**: Sterilisation is a very critical step in production of sterile disposables. We get our products sterilized through Microtrol, a trusted and certified source in India.

**ABOVE ALL, HOSPITALS BUY DISPOSABLES TO ENSURE THAT NO INFECTION TAKES PLACE DURING OPERATION. IN CASE YOU BUY A PRODUCT WHICH LOOKS SIMILAR, BUT DOES NOT PROVIDE BARRIER CONTROL AND HENCE IS INEFFECTIVE IN RULING OUT INFECTION….. THE PURPOSE GETS DEFEATED. YOU MIGHT HAVE SAVED SOME MONEY BUT AT WHAT COST? IT IS SIMILAR TO BUYING A HELMET WHICH SAVES YOU FROM GETTING FINED BY POLICE; HOWEVER, IT IS NOT STRONG ENOUGH TO SAVE YOUR HEAD FROM INJURY DUE TO ACCIDENT! HENCE, LET US USE A PRODUCT WHICH MEETS THE PURPOSE FOR WHICH WE HAVE SPENT MONEY IN BUYING THE PRODUCT!!**

**Advantages of disposable drapes/procedure packs**

**For the patient**
- receives only the original
- Impermeable film keeps the patient perfectly dry
- Thermally isolates, prevents the patient from getting cold and after the operation the patient is clean and dry.

**For nurse and personnel**
- Draping is light and handy
- Preparation is easy
- Always well packed and labelled
- Gowns have cuffs and covered back
- No pitchfork system
- Draping is done by 2, rarely 1 person
• Easy to handle after completion of operation
• Uncomplicated work for nurse & mainly a high quality care of the patient.
Description of products – the main advantages
• Dustless
• Strength
• Bodied
• Perfectly isolates the wounds due self adhesive edges
• High absorbency, liquid doesn't drain on the floor of the hall
• Impermeability to microorganisms, fluids and blood
• After the operation the used material is packed in bags with bio-waste & heads for incineration
• No additional staff handling of biologically contaminated material in the laundry room or central sterilization
• No need for decontamination of infectious linen
• Their use facilitates the easy disposal after the operation& prevents contamination of operating theatres
• Longer shelf life
• There are no costs associated with maintenance
• Sets are customized
• Storage advantages of single use sets - minimum storage space is required
• All material is produced in a biologically non-contaminated environment, supplied sterile by the manufacturer.

Description Cotton draping
• Does not have a long life
• Laundry
• Ironing
• Sterilization
• Repairs
• Time taking process of folding involving nurses
• Time-limited sterility
• Increasing energy costs
• For regular supply it is necessary to have a warehouse clean clothes, warehouse for sterile containers, space for laundry & repairs, space for empty containers waiting for clothes from the laundry room
• Increased dust – operation theatres are areas where the number of dust particles and microorganisms in the air are pre defined . Dust particles manifest their infectious, toxic and allergenic effects.
• Structure of the woven material offers only a minor obstacle to the fluid, which rapidly penetrates the entire layer
• Almost after 50 washes the linen tends to loose its strength by 40% which leads to the fraying and tearing of fibre resulting in loose webbing thus high dustiness.
Characteristics of three-layer material:
- The first layer is based on viscose fibre – provides absorbency
- A second layer of polyethylene film – impermeable layer which provides a barrier
- The third layer of polypropylene ensures comfort for the patient, pleasant, retains heat and absorbs sweat

Comparison of the various stages of handling of single and multiple used woven material

**Disposable masks**
- Production at the factory
- Central sterilization, storage
- Operating room
- Disposal of contaminated material in the incinerator

**Woven material**
- Laundry – disinfectant, water, energy, manpower, handling laundry, counting, sorting
- Central Sterilization – manpower, computation, visual inspection, folding, packaging (packaging material and foil), sterilization including water and energy
- Operation theatre – counting, large area for storage, handling after use in protective bags for contaminated material
- Transport to the laundry

**Conclusion**

*In some hospitals the way of draping has not changed since J. Lister in 1891 formulated the principles of a bacterial barrier during surgery.*

*The basic functionality of the operating cover is to create a barrier between the outside surface of the body and its own operating field – cotton fulfills this function only hypothetically.*

*Essential prerequisite for successful surgery is sterility and asepsis.*

*The option to use disposable devices now a days has become a need to ensure aseptic, quiet and fast operations.*

*Everyone must compare the cost of using textile draping, the risk of infection and resulting in reoperations of expensive implants, use of antibiotics and finally the prestige and reputation of the hospitals, clinics & doctors in public.*

*Aim is to try & eliminate all risk factors threatening sterility and thus achieve a strict aseptic environment.*

*Advantages of disposable draping were verified in many workplaces in many operations and it is clear that from the point of view of functionality provides secure protection for both patients and the operating team.*

*Usage of disposable operational kits is another step towards ecological approaches in health and reflects the modern trend in patient care.*
CHAPTER – 10
USEFUL WEBSITES

http://www.inda.org/
http://www.aami.org/
http://www.edana.org
http://www.cardinal.com
http://www.medline.com/
http://www.dst.gov.in
http://www.ita.doc.gov

CHAPTER - 11
TERMS AND ABBREVIATIONS USED

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Terms</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>WHO</td>
<td>World Health organisation.</td>
</tr>
<tr>
<td>2</td>
<td>GSM</td>
<td>Gram Per Square meter</td>
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CHAPTER – 12

CONTACT DETAILS

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<thead>
<tr>
<th>Sl.No</th>
<th>Name</th>
<th>Designation</th>
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<tr>
<td>(a)</td>
<td>Cdr Manoj Kumar (Retd)</td>
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<td>+919969040124</td>
<td><a href="mailto:ceo@hitexhealthcare.com">ceo@hitexhealthcare.com</a></td>
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<tr>
<td>(b)</td>
<td>CP Singh</td>
<td>Sr. Manager</td>
<td>+918469707221</td>
<td><a href="mailto:cp.singh@hitexhealthcare.com">cp.singh@hitexhealthcare.com</a></td>
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CHAPTER 13

FREQUENTLY ASKED QUESTIONS
FAQ’s before you start.....

1301. When do I start making the calls?
You have been provided with the training manual. Once you have grabbed thorough knowledge from the manual, once you have understand the fabrics, once you are familiar with terminologies like GSM, SMS, AAMI, EN 13795 etc then you are ready to go to the field. All the sales tools should be with you before making any call. (Visiting cards, Swatches / fabric sample, brochure, Laptop, presentations, video's etc.)

(b) You should be also ready for demonstrations of our products.

1302. Who are my target customers?

(a) All the Hospitals where surgeries have been performed are our customers. This includes Corporate hospitals such as Apollo, Fortis, Government Hospitals, Defence hospital etc.
(b) We can also target small nursing homes where small operations procedures have been performed. This includes clinics of Ophthalmic surgeons, ENT surgeons, Small nursing homes etc.

1303. How to make a cold call? or how to present Hitex Products?

(a) Introduce Hitex with a small brief. Mention your presence in Europe and more than 20 years experience. Show the Swatch / Fabric sample and explain the use of each fabric. If prospects taking interest in the fabric please go deep into it. Depending upon prospects subject such as Ortho, Cardio, Gynae we have to move on and show our miniature drapes and should explain the features of our products. Create interest in his (prospects) mind and keep on talking about safety in the OT (Explain Anti Static feature) Low cost (for e.g. compare with Linen Gown used with plastic apron v/s Reinforced gown) Explain hidden costs such as CSSD and laundry cost (explain water, power and manpower costs) Explain our price of the drape / pack and get prima facial approval before we give sample. (How to quote is mentioned ahead)
(b) Successful discussions should lead us or we have to take the discussions towards demonstration of actual product inside the OT.
(c) Ask for demonstration date. Before committing the date make sure that you are equipped with sample and prepare for demonstration. Try and be inside the OT. If you don’t allow inside the OT then explain our drape to OT in-charge, Sisters, brothers, Assistance Surgeons before drape. Please do not forget to mention the contents of the products. Many a time due to confusion they will not use all the contents of the pack and will not get complete satisfaction.
(d) Wait outside of the OT till the procedure is complete or come back when the procedure is about to complete. We have to show our self to the surgeon and must get the feed back immediately otherwise 90% of time our efforts will be in vain.

1304. How do I quote my products?

(a) There are many factors involved before we quote. But basically our hoe work should be ready. This means we should have the knowledge about the current products being used by the prospect, we should be aware of our competition and most important we should give perfect solution to the prospect as we do have many options to play around with the price.

(b) We have a price list which is Ex Factory. This means all the prices mentioned in the price list are ex Una and additional charges are applicable. Generally following rule is applicable but it is not a thumb rule!

<table>
<thead>
<tr>
<th>Description</th>
<th>Price</th>
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<tbody>
<tr>
<td>Ex factory cost</td>
<td>Rs. 100</td>
</tr>
<tr>
<td>Add 2% CST</td>
<td>Rs. 002</td>
</tr>
<tr>
<td>Add 5% freight</td>
<td>Rs. 005</td>
</tr>
<tr>
<td>Add local LBT if applicable</td>
<td>Rs. 005</td>
</tr>
<tr>
<td>Landing cost</td>
<td>Rs. 112</td>
</tr>
<tr>
<td>Add distributor margin 20% (you may add 30-35% and give discount in negotiations)</td>
<td>Rs. 022</td>
</tr>
<tr>
<td>Hospital Cost</td>
<td>Rs. 134</td>
</tr>
<tr>
<td>MRP (Normally double than ex factory)</td>
<td>Rs. 200</td>
</tr>
</tbody>
</table>
This way hospital also make 30-40% margin and acceptance is easy in certain markets. In certain markets hospital requires less MRP and wish to give more benefit to the customer.

1305. **Which are my quick moving products or how can I quickly contribute to the company?**

(a) We have a huge range of accessories and you can focus on the same as prices are very aggressive in this segment and these products are required no demonstration, can be sold at purchase department level and need no approval of higher authorities.

(b) It is recommended that one should start promoting drape with ophthalmic surgeons for a week’s time. Turnaround time with ophthalmologist is quick in comparison with other surgeons and this should give us enough motivation and confidence to move ahead and promote bigger drapes.

(c) Pick the segment where you are most confident, such as Orthopaedic, Cardiac etc and focus on the same segment. This will help you in servicing the account better and sampling problems can be resolved quickly.

1306. **Whom to promote which product?**

<table>
<thead>
<tr>
<th>Segment</th>
<th>Products</th>
</tr>
</thead>
</table>
| All Hospitals / nursing homes etc | Surgical Gown  
                                 | Reinforced Gown  
                                 | Body apron  
                                 | Half Gown  
                                 | Leggings  
                                 | Plain Sheet  
                                 | Plain or fenestrated drapes  
                                 | Universal pack  
                                 | Bed roll  
                                 | Mayo cover  
                                 | All pouches and device covers  |
| Orthopaedic              | Knee Drape and pack  
                                 | Hip Drape and pack  
                                 | Extremity drape  
                                 | Universal set  
                                 | Arthroscopy drape  
                                 | Arthroscopy pouch  
                                 | U drape  |
| Neurology                | Head drape  
                                 | Craniotomy drape  
                                 | Spine drape  |
| Cardiovascular /Cath lab | Angiography drape / set  
                                 | By pass set  
                                 | Valves set  
                                 | Cardiovascular drape  
                                 | C –Arm covers  |
| Urology and Gynaecology  | TUR Drape / set  
                                 | Gynaecology drape  
                                 | Rectum surgery  
                                 | Vaginal drape  
                                 | Fenestrated drape with IF and pouch  
                                 | Caesareotomy set  |

1306. **Who are my competitors?**

(a) North – Kimberly Clerk, 3M, Mölnlycke, Surgiwear, Prime wear, Surgine, Romsons, Safetec, Dispoline, Dispocraft, Amarllys, Medi Blue etc.
There are many local manufacturers as well who cater from 3 – 4 hospitals and restrict themselves to a state only.

Our core competition as far as quality is concern with K-C and 3M.

**Who should be our distributor?**

(a) One who is selling disposable products to the hospitals
(b) Dealing in surgical products
(c) Implants dealers
(d) Financially sound dealers
(e) We can also look at those who are working on their own or free lancers.
(f) But before appointing him as official dealer discuss the same with your immediate manager.

**Do we have a distributor policy?**

(a) Yes we do have and will be shared with you. This policy / agreement is mandatory without that we will not raise the invoice
(b) Payments terms should be not more than 30 days and advance security cheques (3 nos. undated, signed and raised on Hitex Healthcare should kept in the company custody)

**What is the delivery time for our products to the distributor?**

(a) If the products are readily available then we can dispatch it immediately from Una factory.
(b) Maximum 14 days should be lead time for dispatch. However some time it may required some ore time as few things are not in our control such as holidays. Sterilization, transport etc.

**How do I send the PO?**

(a) We have a format for the PO. We need to fill all the necessary information in that. We have to take the stamp and signature from the distributor or Distributor should raise the PO in our format.
(b) This PO should be mailed to:

   (i) Factory – s.bisht@hitexhealthcare.com
   (ii) Immediate manager
   (iii) General Manager (Sales) – sumedh@hitexhealthcare.com
   (iv) CEO – ceo@hitexhealthcare.com
   (v) Mr. Rakesh Bhardwaj - rks.hitexhealthcare@gmail.com
   (vi) Mr. S.K. Sharma – s.sharma@hitexhealthcare.com

**How do I collect the payment?**

(a) Upon due date we should collect the fresh cheque from the party and should be deposited in the company account. Same to be intimated to Mr. Rakesh Bhardwaj marking cc to concerned persons to whom you have sent the PO.
(b) Payment should match the invoice amount

**How to write daily reports and whom to send it?**

(a) Daily report should be sent every day. If it is not possible to send at night then we should send it first thing in the morning. The daily report should be brief and to the point and as per the format.
(b) You have to send the report to your immediate manager and cc to:-

   (i) CEO = ceo@hitexhealthcare.com
   (ii) GM- Sales = sumedh@hitexhealthcare.com
   (iii) Dina – Hitex =S.singh@dina-hitex.com

   (iv) Head office = dipali.hitex@gmail.com

**What is monthly report?**

Monthly report is the synopsis for the past month. It should be sent to only CEO and GM sales in a format shared with you.

**How should I send the mails?**

(a) You have been given laptops. Configure your account in MS Outlook.
(b) Signature should be common as you can copy paste our logo from mails received from Cdr. Manoj Kumar also follow the same way of signature style.
APPENDIX “A”

AHLSTROM

Provisional Technical Datasheet
Surgical Gown and Scrub Fabric
Grade B/G13S035

Characteristics:
Light basis weight blue or green SMS, treated with antistatic, designed for various medical uses. Can be sterilized by steam, ethylene oxide and gas plasma.

<table>
<thead>
<tr>
<th>Application</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple applications including gowns, scrubs and protective apparels</td>
<td>Comfort due to its soft and light basis weight and cleanliness (virtually lint free)</td>
</tr>
</tbody>
</table>

### Physical properties AAMI-PB70

<table>
<thead>
<tr>
<th>Property</th>
<th>Method</th>
<th>Units</th>
<th>Typical Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basis weight</td>
<td>ASTM D 3776</td>
<td>g/m²</td>
<td>35</td>
</tr>
<tr>
<td>Grab Tensile MD</td>
<td>ASTM D 5034</td>
<td>g</td>
<td>10000</td>
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<tr>
<td>Grab Tensile CD</td>
<td>ASTM D 5034</td>
<td>g</td>
<td>7500</td>
</tr>
<tr>
<td>Grab Elongation MD</td>
<td>ASTM D 5034</td>
<td>%</td>
<td>50</td>
</tr>
<tr>
<td>Grab Elongation CD</td>
<td>ASTM D 5034</td>
<td>%</td>
<td>85</td>
</tr>
<tr>
<td>Trapezoid Tear MD</td>
<td>ASTM D 5733-95</td>
<td>g</td>
<td>2500</td>
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<tr>
<td>Trapezoid Tear CD</td>
<td>ASTM D 5733-95</td>
<td>g</td>
<td>3000</td>
</tr>
<tr>
<td>Hydrohead</td>
<td>ISO 811</td>
<td>cm</td>
<td>45</td>
</tr>
<tr>
<td>Alcohol Repellency (IPA)</td>
<td>ISO 40.1</td>
<td>rating</td>
<td>n/a</td>
</tr>
<tr>
<td>Static Decay (+/-)</td>
<td>EDANA 40.2</td>
<td>sec</td>
<td>0.01/0.01</td>
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</table>

### Physical properties EN-13795

<table>
<thead>
<tr>
<th>Property</th>
<th>Method</th>
<th>Units</th>
<th>Typical Values</th>
</tr>
</thead>
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<tr>
<td>Basis weight</td>
<td>ASTM D 3776</td>
<td>g/m²</td>
<td>35</td>
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<td>log¹⁰ (cfu)</td>
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<tr>
<td>Res. Microbial penetration - Wet</td>
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<td>BI</td>
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<tr>
<td>Cleanliness – microbial</td>
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<tr>
<td>Cleanliness – particulate</td>
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<td>PM</td>
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<tr>
<td>Linting</td>
<td>ISO 9073-10 - 2003</td>
<td>log¹⁰ (lint count)</td>
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<td>Resistance to liquid / Hydrohead</td>
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<td>Cm H2O</td>
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<td>Bursting Strength – Dry</td>
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<td>kPa</td>
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<td>Tensile Dry – CD</td>
<td>EN 29073-3 1992</td>
<td>N</td>
<td>40</td>
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<td>Tensile Wet – MD</td>
<td>EN 29073-3 1992</td>
<td>N</td>
<td>60</td>
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<td>Tensile Wet – CD</td>
<td>EN 29073-3 1992</td>
<td>N</td>
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### Other properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Method</th>
<th>Units</th>
<th>Typical Values</th>
</tr>
</thead>
</table>
AHLSTROM
Provisional Technical Datasheet
Surgical Drape and Gown Fabric
Grade B/G13S050

Characteristics:
Blue or green SMS, treated with antistatic, designed for various medical uses. Can be sterilized by steam, ethylene oxide and gas plasma.

Applications:
Multiple applications including drapes, gowns and protective apparel.

Benefits:
It is a cost effective, soft, lightweight, good abrasion and low lint PP based fabric.

Physical properties AAMI-PB70

<table>
<thead>
<tr>
<th>Property</th>
<th>Method</th>
<th>Units</th>
<th>Typical Values</th>
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<td>Basis weight</td>
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<td>ASTM D 5034</td>
<td>%</td>
<td>65</td>
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Physical properties EN-13795

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<td>Res. Microbial penetration - Wet</td>
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<td>log¹⁰⁰ (lint count)</td>
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<td>N</td>
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<td>EN 29073-3 1992</td>
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<td>50</td>
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Other properties

<table>
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<tr>
<td>Alcohol Repellency (IPA)</td>
<td></td>
<td>rating</td>
<td>N/A</td>
</tr>
<tr>
<td>Surface Resistivity</td>
<td>WSP 40.1</td>
<td>Ohm</td>
<td>10⁻¹⁰</td>
</tr>
</tbody>
</table>
Characteristics:

Light basis weight blue or green SMS, untreated, designed for various medical uses. Can be sterilized by steam, ethylene oxide and gas plasma.

Applications:

Multiple applications including drapes, gowns and apparel.

Benefits:

Economic, reasonable protection and strength. for light basis weight, virtually lint free

### Physical properties AAMI-PB70

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<td>7500</td>
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<td>cm</td>
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<td>rating</td>
<td>n/a</td>
</tr>
<tr>
<td>Static Decay (+/-)</td>
<td>EDANA 40.2</td>
<td>sec</td>
<td>n/a</td>
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### Physical properties EN-13795

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<tr>
<td>Res. Microbial penetration – Dry</td>
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<td>log₁₀ (cfu)</td>
<td>*</td>
</tr>
<tr>
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<td>ISO 22610</td>
<td>BI</td>
<td>*</td>
</tr>
<tr>
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<td>EN 1174-2 – 1996</td>
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<td>ISO 9073-10 - 2003</td>
<td>IPM</td>
<td>*</td>
</tr>
<tr>
<td>Linting</td>
<td>ISO 9073-10 - 2003</td>
<td>log₁₀ (lint count)</td>
<td>*</td>
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<tr>
<td>Resistance to liquid / Hydrohead</td>
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<tr>
<td>Bursting Strength – Wet</td>
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<td>kPa</td>
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<td>Tensile Dry – MD</td>
<td>EN 29073-3 1992</td>
<td>N</td>
<td>90</td>
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<tr>
<td>Tensile Dry – CD</td>
<td>EN 29073-3 1992</td>
<td>N</td>
<td>404</td>
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<tr>
<td>Tensile Wet – MD</td>
<td>EN 29073-3 1992</td>
<td>N</td>
<td>90</td>
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<tr>
<td>Tensile Wet – CD</td>
<td>EN 29073-3 1992</td>
<td>N</td>
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### Other properties

<table>
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<tr>
<th>Property</th>
<th>Method</th>
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<tbody>
<tr>
<td>Alcohol Repellency (IPA)</td>
<td>IST 40.1</td>
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<tr>
<td>Surface Resistivity</td>
<td>WSP 40.1</td>
<td>Ohm</td>
<td>n/a</td>
</tr>
</tbody>
</table>
Test Report No. 3/09/88 - 90

Sponsor: DIN - HITEK spol. s r.o.
Address: Zdánská 987, 686 01 Bučovice, Czech Republic
Reference No.: CLČ 551-4337/09

Identification:
TM 3/09/88: Two-layer laminated material DS2
TM 3/09/89: Two-layer laminated material DS3
TM 3/09/90: Two-layer laminated material 2SBL

Laboratory Tests
SOP 1/3 Tests for in vitro cytotoxicity (ISO 10993-5:1999 Biological evaluation of medical devices – Part 5, Articles 1, 2, 3, 4, 5, 6, 7, 8.1, 8.2, 8.3, 8.5, 9, 10)
SOP 2/3 Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2003 Biological evaluation of medical devices – Part 10, Articles 1, 2, 3, 4, 5, 6.2, 6.3, 6.4, 7.1, 7.2, 7.3, 7.4, 8, Annex A, B.1, B.2, B.3, C, ZB)
SOP 4/3 Determination of free and hydrolyzed formaldehyde - water extraction method (CSN EN ISO 14184 -1, part 1)
SOP 5/3 Determination of pH (CSN 68 1504, CSN 68 1507, CSN 68 1512, CSN 68 1513, CSN ISO 11 609, CSN ISO 4045, CSN EN ISO 3071)

Expertise reception date: 9.12.2009
Final report date: 25.1.2010
Number of pages: 19


Technical manager: Dagmar Jirová, M.D., Ph.D.

The test results refer only to the objectives of the study and this test report does not substitute for any other document or certification of the product. Without written approval of the testing laboratory this report should not be reproduced in other form than as a whole.

3/09/88 - 90 – 1/19

Sanicare HM 8626
Summary
Sanicare HM 8626 (SAP 107458) was tested under occlusive epicutaneous application according to a use related situation. Under this test conditions Sanicare HM 8626 was very good skin compatible. The claim “dermatologically tested” is supported.
ASS 0403344-5 Sanicare HM 8626

This evaluation refers exclusively to the product Sanicare HM 8626 (SAP 107458) in the quality as specified and provided by Henkel KGaA. The test product is a hotmelt adhesive intended for medical applications.

Single 24h Patch Test
The product was tested by closed epicutaneous application (back, healthy skin, according to COLIPA guideline 1996) (1). Therefore, 20 volunteers were treated with the test substance over a of 24 hours period. The application was performed using large Finn chambers to create occlusive conditions for a higher penetration of the test substance. From a sheet having a 1 mm thickness the test substance was cut into discs which fit into the size of the Finn chamber. This occlusive test method describes conditions compared to the intended use of the test substance. As a positive standard 0,5% Sodium Dodecylsulfate (SDS) in an aqueous dilution was used which is known for its skin irritation potential. Aqua demin. served as a negative standard.
The observed reactions on the skin was monitored and documented 6, 24, 48, and 72 hours after removal of the plasters according to the scale of Frosch (2).
The positive standard caused slight, medium, and strong reactions (erythema, edema, scaling) in 19 out of 20 volunteers. The negative standard Aqua demin. induced no reaction within all volunteers. The test result thus has to be accepted as valid.
The test product Sanicare HM 8626 (SAP 107458) caused slight erythema in one of 20 volunteers

Dermatological Evaluation
The occlusive epicutaneous application referred to a use related situation for this specific test product. Under this test conditions single slight skin reactions were observed. The reaction profile of the test product Sanicare HM 8626 (SAP 107458) was comparable to Aqua demin. Sanicare HM 8626 (SAP 107458) can be assessed as very good skin compatible.

The claim “dermatologically tested” is supported.

Düsseldorf, 16.09.2004

Dr. Joachim Kremer

References:
2. P.J. Frosch, A.M. Kligman; J Am Acad Dermatol 1, 1979, 35-41
3. Henkel KGaA (2004); unpublished data, Report No: R 040076
Test Report No. 13/07/022

Sponsor: DINA-HITEX s.r.o.
Address: Žáňská 987, 685 01 Bučovice, Czech Republic
Expertise No.: 070336

Test Material

Identification: TM 022: Double-side adhesive tape

Laboratory Tests

SOP 2/13 Tests for in vitro cytotoxicity, test on extract (or test by direct contact).
   (ISO 10993–5: 1999 Biological evaluation of medical devices – Part 5, Articles 1, 2, 3, 4, 5, 6, 7, 8.1, 8.2, 8.3, 8.5, 9, 10)
SOP 3/13 Tests for irritation and sensitization using laboratory animals (ISO 10993–10:
   Biological evaluation of medical devices – Part 10, Articles 0, 1, 2, 3, 4, 5.1, 5.2, 5.3, 5.4, 6, Annex A, B, C) - modified as test on volunteers.

Expertise reception date: 6.3.2007
Final report date: 10.5.2007
Number of pages: 9

Technical manager: Dagmar Jirová, M.D., Ph.D.

The test results refer only to the objectives of the study and this test report does not substitute for certification of the product. Without written approval of the testing laboratory this report should not be reproduced in other form than as a whole.
HM 2200

Description
HM 2200 is a light colored, low viscosity and economical hot melt pressure sensitive adhesive for general purpose pressure sensitive applications with balanced tack and peel characteristics. It exhibits good adhesion to different substrates.

Suggested Uses
Permanent Labels & Tapes

Physical Properties

1) Softening Point 85 ± 3 °C
   Ring and Ball (Herzog-ASTM E 28)

2) Thermoset Viscosity, mPa s 12000 ± 1500 @ 150°C
   (Brookfield – ASTM D 3236)

Adhesive Properties
Coat weight 22g/m²
Values evaluated with 23 micron PET film and SS substrate
1) 180° Peel Adhesion 2.3 Kg/in
   (PSTC 101)

2) Loop Tack 2.7 Kg/in²
   (FINAT 9)

3) Shear > 100 Hours
   (PSTC 7, 23°C, 1 Kg weight)

Suggested Running
Temperature 150 – 170°C

Storage
Can be stored minimum 1 year in a clean dry place, in its original package at an average temperature of 25°C or below.

Safety and Handling

➢ Clean-up Procedure: Mineral oil or paraffin wax, not to exceed flash point as stated in the MSDS, followed by a thorough purge with the adhesive itself.

➢ Material Safety Data Sheet should be consulted for proper handling before use.

➢ Wear Safety gloves when handling molten adhesive to minimize the risk of burns.

➢ Keep containers covered to minimize contamination

➢ HM 2200 compositionally complies with FDA 175.105.