



3rd NATIONAL CONCLAVE ON STANDARDS FOR TECHNICAL TEXTILES

PRESENTATION ON MEDICAL TEXTILES

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MEDICAL TEXTILE SECTOR AT A GLANCE

Out of total Indian textile industry, only 13% contributes to technical textiles, and out of this 13%, the share of Meditech, in technical textiles market is in the range of 6-8%.

Meditech is projected to reach Rs. 4281 crore by 2015-16 growing at 9% CAGR and further to Rs. 5142 crore by 2017-18.

The main volume growth driver in Meditech is the Non-implantable segment which includes surgicals & healthcare/hygiene products.

Lack of basic infrastructure in terms of testing facilities, Skilled manpower, Research & Development, Absence of regulatory measures, Lack of standards and awareness among users are hindering the growth rate of Indian Meditech industry.



Classification of Medical Textiles

■ 1.HEALTHCARE AND HYGIENE PRODUCTS

- Healthcare and hygiene textiles materials are mainly used for protection from infections in hospital environment. They are used either in the operation theatre or in the hospital wards for hygiene care safety for the staff and patients.
- e.g. Surgical caps, masks, gowns, drapes and shoe covers, disposable bed sheets, Baby Diapers/Adult Diaper, Sanitary napkins, Under pads, Wipes etc.

■ 2.NON-IMPLANTABLE MEDICAL TEXTILE:

- This is used for external application on the body with or without skin contact. This is used for protection against infection, absorption, and exudation of blood & excess fluids, healing applications etc
- e.g. wound dressing, plaster, bandage, gauge, compression stocking etc.



Classification of Medical Textiles cont....

■ 3. IMPLANTABLE MEDICAL TEXTILE:

- Implantable medical textiles are partly or totally inserted into the human body. These materials are used in effecting repair to the body whether it is wound closure or replacement surgery.
- e.g. suture, Vascular grafts , Artificial Heart Valve, Artificial ligament, Artificial joint etc.

■ 4. EXTRA CORPOREAL

- Extracorporeal mainly deals with artificial organ which are made from specialized textile implants that can function as a part of human body.
- e.g. Artificial kidney, Artificial liver, Artificial valves and Artificial Lungs etc.



STANDARDISATION IN MEDICAL TEXTILES

- **In order to take up the standardization of medical textiles on fast track basis, BIS has constituted a Sectional Committee on Medical Textiles -**
- **TECHNICAL TEXTILES FOR MEDTECH APPLICATION, TXD36**
- **Scope of TXD 36 : To formulate Indian Standards for terminology, testing and specifications for technical textiles for medtech applications such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.**
- **Number of standards published/ Finalized - 48**
- **Number of standards under development -11**



STATUS OF LICENCE GRANTED FOR MEDICAL TEXTILES PRODUCTS

Indian Standard with Title	No. of Licence
IS 4605 : 1981 SPECIFICATION FOR CREPE BANDAGE (First Revision)	4
IS 5405 : 1980 SPECIFICATION FOR SANITARY NAPKINS (First Revision)	7
IS 16111 : 2013 ELASTIC BANDAGE	1
IS 16289 : 2014 MEDICAL TEXTILES — SURGICAL FACE MASKS — SPECIFICATION	2
TOTAL	14



Important Products of Medtech

■ SURGICAL FACE MASK



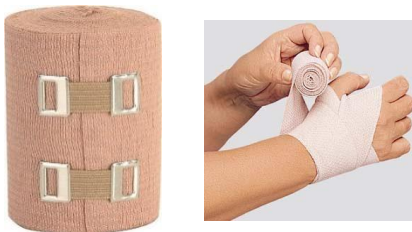
CAST PADDING FOR PLASTER



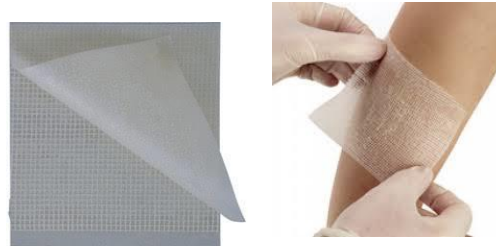
STOCKINETTE



■ ELASTIC BANDAGE



PARAFFIN GAUZE



SURGICAL GOWN



SANITARY NAPKIN





Important standards Formulated on Medtech

- **IS 4605 : 1981 SPECIFICATION FOR CREPE BANDAGE**
- This standard covers requirements pertaining to material, dimension construction (yarn count, warp yarn twist, threads/10cm, gsm) and performance (Stretchability, Recovery, Chemical Neutrality, Breaking load, Scouring loss etc..) of crepe bandage.
- Crepe bandage consists of characteristic fabric of plain weave, in which the warp threads are crepe-twisted for ensuring maximum elasticity.
- Crepe bandage is used for dressing of varicose veins, weak ankles, legs, knees and wrists in case of sprains and other conditions in which light support is required.
- Amendment to above standard is under consideration. (Requirements such as water and ether soluble substances are under consideration)



Important standards Formulated on Medtech

- **IS 5405 :1980 SPECIFICATION FOR SANITARY NAPKINS**
- This standard covers the requirements for sanitary napkins for external use.
- **This standard specifies the following requirements-**
- **MATERIALS-** Absorbent Filler, Covering
- **SIZES –** Regular, Large, Extra Large or as agreed between purchaser and supplier
- **REQUIREMENTS-** Absorbency and Ability to withstand pressure after absorption , Disposability, pH Value
- The above standard is under revision. (Additional requirement such as Hygiene Testing i.e. bioburden and total absence of common skin and uterine pathogen, Skin Irritation test, adhesive strength requirement for front and back covering under consideration.)



Important standards Formulated on Medtech

■ IS 16111 : 2013 ELASTIC BANDAGE

- This standard covers the dimensions and other requirement (weight, stretch length and extensibility, regain etc.) for elastic bandages.
- Elastic bandages can be classified as follows based on type of yarn with their method of manufacturer:
 - A — woven cellulosic yarn bandage, B — knitted cellulosic yarn bandage, C — woven non-cellulosic yarn bandage, D — knitted non-cellulosic yarn bandage, E — combination of both cellulosic yarn/noncellulosic yarns woven knitted, F — combination of both cellulosic yarn/noncellulosic yarns knitted
- An elastic bandage is one continuous strip without joints, of woven/knitted material stretches along its intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopaedic purposes.



Important standards Formulated on Medtech

- **IS 16289:2014 Medical Textiles — Surgical Face Masks — Specification**
- **This standard specifies the performance requirements and test methods of surgical face masks intended to limit the transmission of infective agents from staff to patients and (in certain situations) vice-versa during surgical procedures in operating theatres and other healthcare services such as patient care, with similar requirements. This standard is not applicable to masks intended exclusively for the personal protection of staff.**
- **Classes :** Class 1, Class 2 and Class 3 based on performance requirement such as Bacterial filtration efficiency, Differential Pressure, Splash Resistance, Sub micron particulate filtration efficiency.
- **The main intended use of surgical masks is to protect the patients from infective agents from the noses and mouths of the staff and, in certain situations, additionally to protect the wearer against splashes of potentially contaminated liquids. The protection of the healthcare professional, as well as the patient, has, therefore more recently become an issue of infection control and is becoming more complex and this standard addresses all the issues.**



Important standards Formulated on Medtech

- **IS 16302:2014 MEDICAL TEXTILES – ORTHOPAEDIC STOCKINET – SPECIFICATION**
- This standard specifies performance requirements for orthopaedic stockinet intended for medical use.
- **Orthopaedic Stockinet** is a grey knitted tubular cotton sleeve in continuous length, wound in roll form and packed in a sealed polybag.
- Orthopedic Stockinette provide a barrier material between the sensitive skin and the harsh plaster, protective wrap during surgery.
- Covers performance requirements such as weight per square metre, stretchability and regain %, breaking strength, Elongation in machine and cross direction) and orthopedic appliances.



Important standards Formulated on Medtech

- **IS 16468 : 2016 Medical Textiles- Absorbent cotton (sterile and non-sterile) – Specification**
- This standard specifies performance requirements for absorbent cotton (sterile and non-sterile) intended for medical use.
- **Absorbent Cotton** – It is composed of fibres of average length not less than 10 mm, cleaned, purified, bleached and carefully carded. It offers appreciable resistance when pulled.
- **Performance requirements such as**
- foreign fibers, neps, fluorescence, loss on drying,
- absorbency (including sinking time and water holding capacity)
- pH of aqueous extract, extractable coloring matter,
- water soluble substance, surface active substances,
- sterility (Only for sterile cotton)



Important standards Formulated on Medtech

- **IS 16660 : 2017 Medical Textiles — Nonwoven bandage rolls — Specification**
- This standard specifies the requirement of nonwoven bandage rolls intended for medical use.
- The nonwoven bandage rolls shall consist of rolled absorbent nonwoven fabric
- **covers the performance requirements such as**
- weight per square meter,
- Absorption (Including sinking time and water holding capacity)
- tensile strength (Dry and wet),
- water and ether soluble substance,
- Acidity / Alkalinity, Cytotoxicity
- Fluorescence etc.



Important standards Formulated on Medtech

- **IS 16291 : 2014 Medical Textiles - Paraffin Gauze Dressings – Specification**
- This standard specifies the requirements of paraffin gauze dressings intended for medical use
- **Paraffin Gauze Dressings** — It consists of fabric of leno weave with two picks in each shed in which warp and weft threads are of cotton, or viscose, or of combined cotton and viscose rayon which has been impregnated with white paraffin or with yellow soft paraffin.
- Paraffin Gauze is suitable for use in the first aid management of minor burns & wounds.
- **Covers the performance requirements such as**
- Construction
- Weight per Square Metre
- Ether soluble substances (Light, Normal Heavy Loading)
- Sterility



Important standards Formulated on Medtech

- **IS 16670 : 2017 Medical Textiles - Absorbent cotton ribbon gauze -Specification**
- This standard specifies performance requirement for absorbent cotton ribbon gauze intended for medical use
- **Absorbent Cotton Ribbon Gauze-** It is a woven cloth supplied in continuous ribbons of various widths with fast selvages made from cotton threads that are purified, bleached and made absorbent before or after weaving.
- Use for the primary dressing of dirty, infected and deep wounds.
- **Covers the performance requirements such as,**
- Fibre identification, Construction, GSM
- moisture content, pH,
- absorbency, water soluble substances %, residual starch
- sulphated ash %, surface active substances,
- extractable colouring matter etc



Important standards Formulated on Medtech

- **IS 16671 : 2017 Medical Textiles - Belladonna adhesive plaster- Specification**
- This standard specifies performance requirement for belladonna adhesive plaster intended for medical use.
- **Belladonna Adhesive Plaster** – It consists of fabric of plain weave in which the warp and weft threads are of cotton, or viscose or combination of cotton and viscose yarn, which has been spread evenly with an adhesive mass containing about 0.25 percent of alkaloids of belladonna calculated as hyoscyamine.
- Provides temporary relief from aches and pains by producing heat.
- **Covers the performance requirements such as**
- Fibre identification, Construction, GSM
- Adhesiveness, width
- Breaking Strength
- Perforation
- Identification of belladonna



Important standards Formulated on Medtech

- **IS 16303 : 2014 Medical Textiles - Cast padding for orthopedic plaster- Specification**
- This standard specifies performance requirements for cast padding for orthopaedic plaster intended.
- **Cast Padding for Orthopaedic Plaster** — It is white non-woven absorbent fabric made from cotton/ viscose/polyester staple fibres or their blends, clean and reasonably free from foreign matter. It is undyed and has no chemical binder.
- Cast Padding is used in providing cushion (liner) under the Synthetic Cast or Plaster.
- Absorbs Sweat and Exudate, add comfort to accidental portion
- **Covers the performance requirements such as**
- GSM
- Breaking Strength (Machine and cross section)
- Absorbency
- Water Soluble substance
- Extractable coloring matter



Other Important standards Formulated on Medtech

- IS 16669 : 2017 Medical Textiles - Elastic adhesive dressing- Specification
- IS 16668 : 2017 Medical Textiles - Salicylic acid adhesive plaster - Specification
- IS 16466 : 2016 Medical Textiles - Povidone Iodine Ointment based Knitted Dressing - Specification
- IS 16467 : 2016 Medical Textiles - Graduated medical compression stockings- Specification
- IS 16469 : 2016 Medical Textiles - Open weave bandages- Specification
- IS 16470 : 2016 Medical Textiles - Elastic surgical adhesive tapes- Specification
- IS 16290 : 2014 Medical Textiles - Knitted Viscose Primary Dressings – Specification
- IS 14316 : 1995 Swabs Small In Bag Of 50



Other Important standards Formulated on Medtech

- IS 14306 : 1995 Bandage Triangular Calico
- IS 14274 : 1995 Bandage t Shaped Calico
- IS 12839 : 1989 Wool polyamide Blended Flannel Hospital Grey
- IS 11163 : 1985 First-aid Dressings
- IS 10829 : 1993 X-Ray Detectable Gauze Swabs and Laparotomy Sponges
- IS 4738:1998 Bandage – Plaster of Paris
- IS 4739:1986 Zinc oxide elastic self-adhesive bandage
- IS 4717:1980 Zinc oxide self adhesive plaster
- IS 863 : 1988 Handloom Cotton Bandage Cloth Non-Sterilized
- IS 758 : 1988 Handloom Cotton Gauze Absorbent Non-Sterilized
- IS 674 : 1987 Flannel Hospital Grey



Important standards under development on Medtech

- **Under Finalization Stage**
- X-ray detectable absorbent cotton gauze
- Adhesive extension plaster
- Permeable Nonwoven Surgical Adhesive Tape
- Elastic crepe bandage
- **WC Stage**
- Surgical Drapes
- Surgical Gowns
- Medical Textiles - Nonwoven gauze swab with X-ray and without X-ray detectable thread (Sterile and non-sterile) – Specification
- **NWIP-**
- Baby/adult diapers/Underpad
- Chlorhexidine Gauze dressings
- Polyurethane foam dressing



Thank You