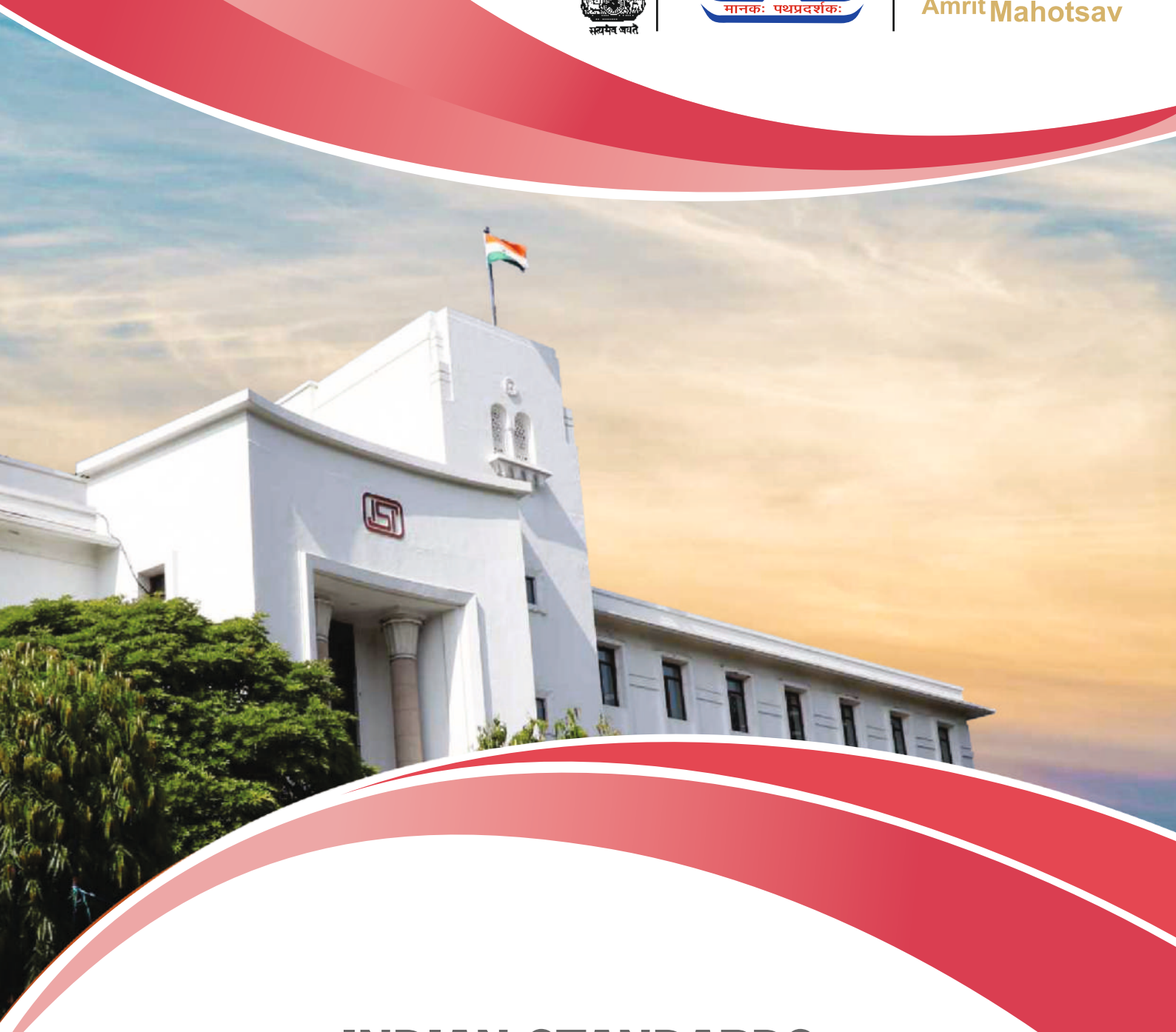
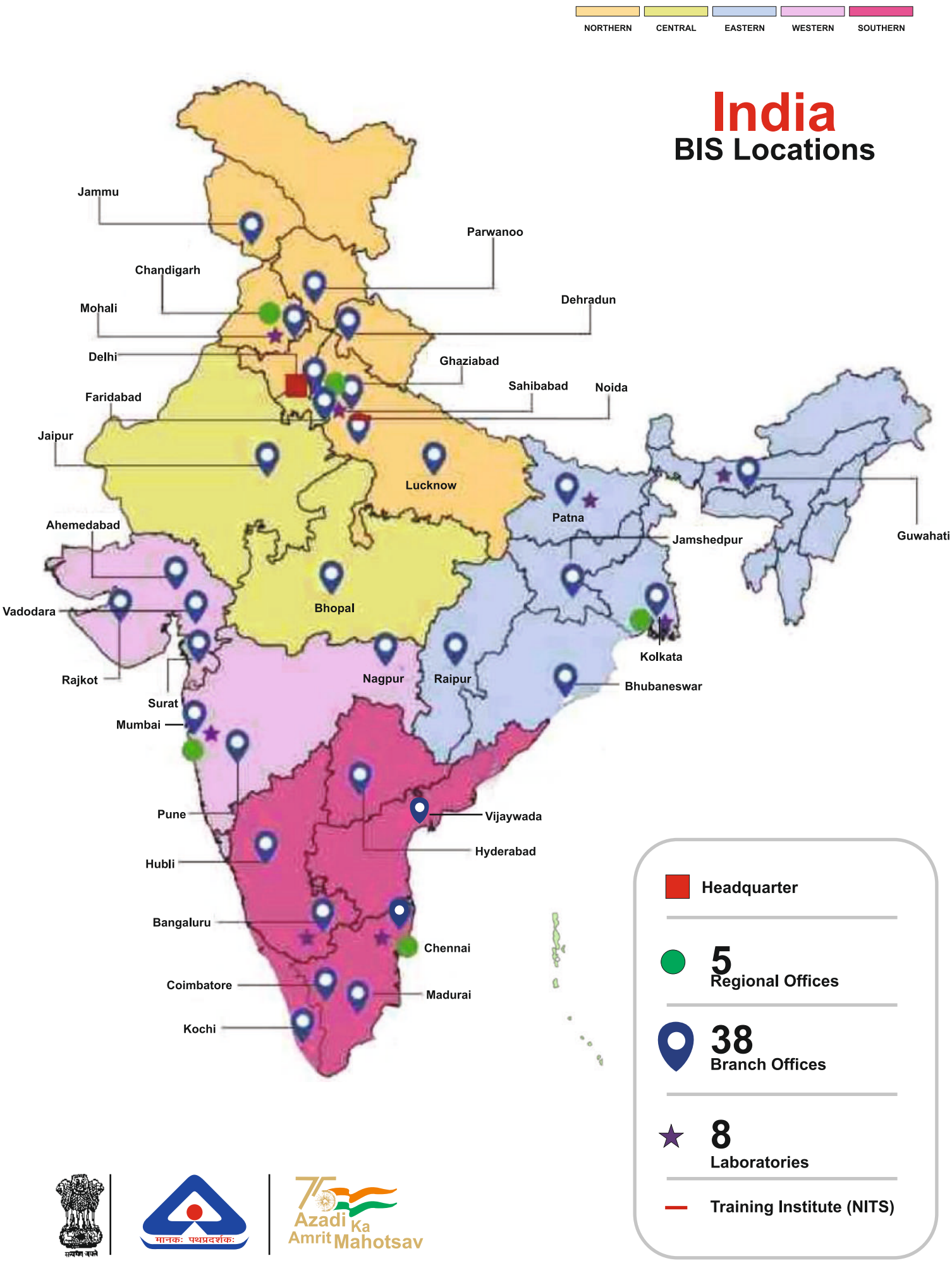


INDIAN STANDARDS ON MEDICAL TEXTILES

BUREAU OF INDIAN STANDARDS
Ministry of Consumer Affairs
Food and Public Distribution
Government of India

भारतीय मानक ब्यूरो
उपभोक्ता मामले, खाद्य और
सार्वजनिक वितरण मंत्रालय
भारत सरकार


NORTHERN
CENTRAL
EASTERN
WESTERN
SOUTHERN
India
BIS Locations
Jammu
Parwanoo
Chandigarh
Mohali
Dehradun
Delhi
Ghaziabad
Sahibabad
Noida
Faridabad
Jaipur
Lucknow
Patna
Guwahati
Jamshedpur
Ahemedabad
Vadodara
Bhopal
Kolkata
Rajkot
Nagpur
Raipur
Bhubaneswar
Surat
Mumbai
Pune
Vijaywada
Hyderabad
Hubli
Bangaluru
Chennai
Coimbatore
Madurai
Kochi
Headquarter
5
Regional Offices
38
Branch Offices
8
Laboratories
Training Institute (NITS)
मानकः पथप्रदर्शकः
Azadi Ka Amrit Mahotsav

ABOUT BIS

Bureau of Indian Standards (BIS), the National Standards Body (NSB) of India was established under the *BIS Act*, 1986 and came into existence on 1 April 1987 assuming the functions of the erstwhile Indian Standards Institution (ISI). The ISI was established on 6 January 1947. *The BIS Act*, 2016 came into force on 12 October 2017 superseding BIS Act 1986. *The BIS Act*, 2016 provides for the establishment of a national standards body for the harmonious development of the activities of standardization, conformity assessment and quality assurance of goods, articles, processes, systems and services and for matters connected therewith or incidental thereto.

BIS through its core activities of standardization and conformity assessment, has been benefiting the national economy by providing safe, reliable and quality goods; minimizing health hazards to consumers; protecting the environment; controlling over proliferation of varieties; promoting exports and imports substitutes, etc. The standardization and conformity assessment schemes of BIS apart from benefitting the consumers and industry also support various public policies especially in areas of product safety, consumer protection, food safety, environment protection, building and infrastructure development, etc.

BIS also represents India in international standards bodies like International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) and participates actively in the international standardization work undertaken by these bodies. BIS presents the national viewpoints on new areas taken up for international standardization and on various draft international standards during the process of development of these standards so that the country's interest is protected and reflected in these standards. This also enables the BIS technical committees to consider adoption of the international standards as Indian Standards, with or without modifications, in order to enable our products and services to integrate with global trade and commerce.

What are Standards?

Standard is a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Importance of Standardization

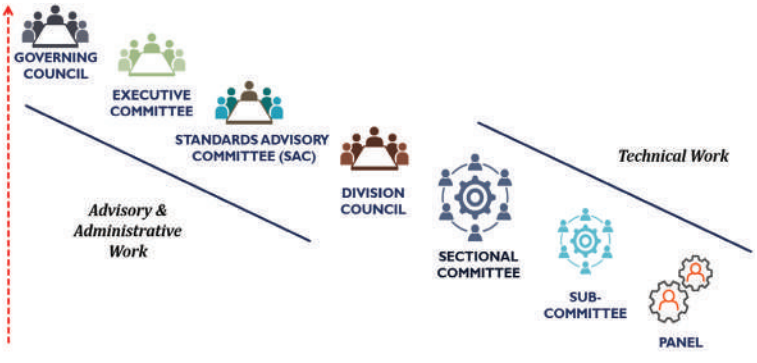
Standardization is the process of developing technical standards through consensus of different parties.This standardization aims to address one or all of compatibility, interchangeability, variety control, safety, environment protection, product protection and fitness for purpose. Standards provide numerable benefits to the technologists, producers, consumers and traders besides defining purpose for each of these entities.

Standards can be formulated at various levels ranging from an individual through National (IS) to International level (ISO). Also, depending on the subject in hand, standards can be made on various aspects such as terminology, specification, sampling, testing, code of good practice, systemes and services.

STANDARDIZATION ACTIVITY OF BIS

Standardization Structure

There are 16 Technical Departments formulating standards in various subject areas. Corresponding to these departments, 16 division councils exist. Each division council has several sectional committees working under it. The standards cover important segments of economy and help the industry in upgrading the quality of their goods and services.

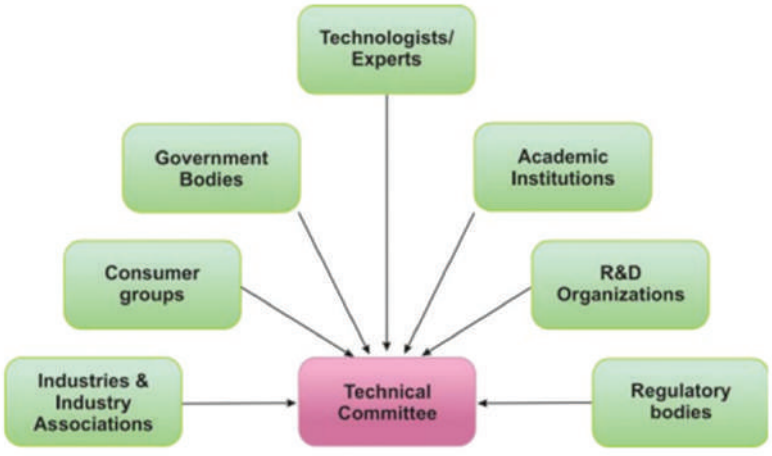


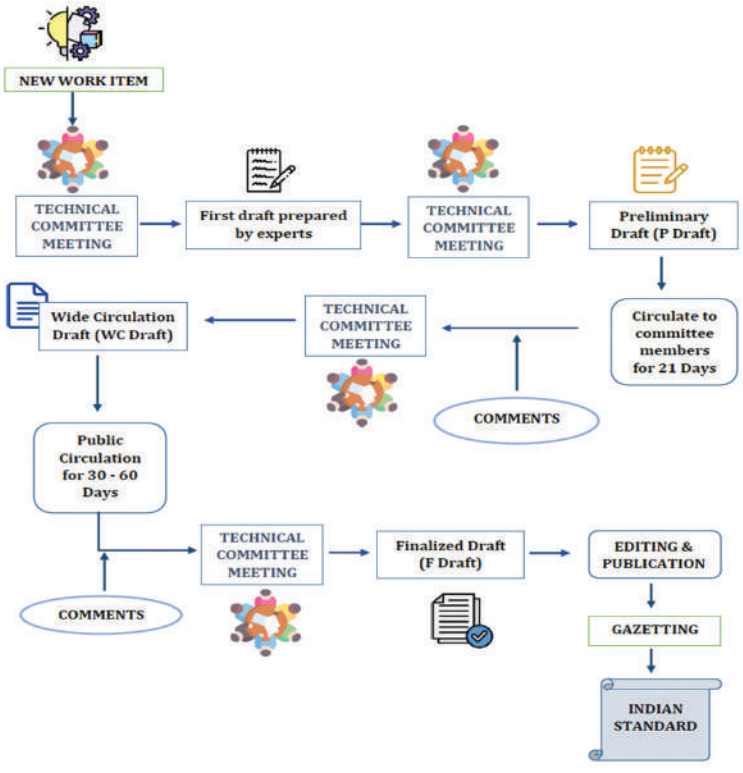
Ayush Division Council (AYDC)	Chemical Division Council (CHDC)	Civil Engineering Division Council (CEDC)	Electro-Technical Division Council (ETDC)
Electronics & Telecommunication Division Council (LITDC)	Food and Agriculture Division Council (FADC)	Mechanical Engineering Division Council (MEDC)	Management and Systems Division Council (MSDC)
Metallurgical Engineering Division Council (MTDC)	Medical Equipment & Hospital Planning Division Council (MHDC)	Petroleum, Coal & Related Products Division Council (PCDC)	Production and General Engineering Division Council (PGDC)
Transport Engineering Division Council (TEDC)	Textile Division Council (TXDC)	Water Resources Division Council (WRDC)	Service Sector Division Council (SSDC)

Standards Formulation Process

The Indian Standards are developed by technical committees that are representative of various stakeholders having interest in the relevant subject of standardization under the scope of such committees through a process of consultation so that views of all are given due consideration and a consensus is evolved in formulating a standard. The stakeholders involved in national standardization can broadly be categorized as industry, consumers/ users, technologists (R&D and scientific institutions, academia, individual subject experts, etc) and government departments/regulators.

The process of standards development of BIS is aligned with accepted international best practices that are based on the core principles of openness, transparency, impartiality and consensus. The process begins with the identification of the standardization needs of the given sector or subject following which the development of the standard is taken up and planned bythe relevant technical committee. Apart from consultation within the technical committees, draft standards are also open for public views/comments.





Standards Development Process Flow

TEXTILES DIVISION COUNCIL

The standardization in the area of textiles including technical textiles is undertaken by Textiles divisional council through a network of 26 sectional committees. The Textiles Division of BIS has published around 1510 standards for textiles, out of which about 600 standards are on the technical textiles and its test methods. The scope of the textiles division council is provided as follows:-

SCOPE: Standardization in the field of textiles and apparel covering natural and man-made fibres and their products, dyestuffs, textile specialty chemicals, textile machinery and technical textiles.

OVERVIEW OF TEXTILES DEPARTMENT (As on 19 September, 2023)

u	Indian Standards published	:	1510			
u	Product standards	:	749	Method of Test	:	534
u	Terminology	:	70	Code of practice	:	66
u	Dimensions, safety &Others	:	91			
u	Standards on Technical Textiles	:	600			
u	Products under certification	:	78			
u	Number of licences granted	:	1054			

The list of the 26 sectional committees are provided as follows :-

i) Physical Methods of Test Sectional Committee, TXD 01

ii) Jute and Jute Products Sectional Committee, TXD 03

iii) Wool, Wool Products and Textile Floor Coverings Sectional Committee, TXD 04

iv) Chemical Methods of Test Sectional Committee, TXD 05

v) Textiles Speciality Chemicals & Dyestuffs Sectional Committee, TXD 07

vi) Handloom and Khadi Sectional Committee, TXD 08

vii) Cordage Sectional Committee, TXD 09

viii) Hosiery Sectional Committee, TXD 10

ix) Textile Materials for Aeronautical and Related Products Sectional Committee,TXD 13

x) Textile Machinery and Accessories Sectional Committee, TXD 14

xi) Textile Materials for Marine/Fishing Purposes Sectional Committee, TXD 18

xii) Made-up Items (Including Ready-made Garments) Sectional Committee, TXD 20

xiii) Textile Materials Made from Polyolefins (Excluding Cordage) Sectional Committee, TXD 23

xiv) Coir and Coir Products Sectional Committee, TXD 25

xv) Silk and Silk Products Sectional Committee, TXD 28

xvi) Geosynthetics Sectional Committee, TXD 30

xvii) Man-Made Fibres, Cotton and their Products Sectional Committee, TXD 31

xviii) Protective Clothing Sectional Committee, TXD 32

xix) Industrial Fabrics Sectional Committee, TXD 33

xx) Technical Textiles for Buildtech Applications Sectional Committee, TXD 34

xxi) Technical Textiles for Agrotech Applications Sectional Committee, TXD 35

xxii) Technical Textiles for Medtech Applications Sectional Committee, TXD 36

xxiii) Technical Textiles for Sportech Applications Sectional Committee, TXD 37

xxiv) Technical Textiles for Mobiltech Applications Sectional Committee, TXD 38

xxv) Technical Textiles for Clothtech Applications including Narrow Fabrics and Braids Sectional Committee, TXD 39

xxvi) High Performance Fibres, Fibrous Structure and Textile Components of Composites, TXD 40

STANDARDIZATION IN THE FIELD OF MEDICAL TEXTILES

- Standardization in the field of Medical Textiles has been undertaken by Technical Textiles for Medtech Application Sectional Committee, TXD 36 under Textiles Division Council at BIS:
- 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 formulated : 75
  - Number of standards under development : 06
  - Product Standards : 63
  - Method of Tests : 12

Standards published by Technical Textiles for Medtech applications Sectional Committee, TXD 36

S.N.	IS No.	TITLE
1	IS 674 : 2023	Medical Textiles - Grey Hospital Flannel Specification (fourth revision)
2	IS 757 : 1971	Specification for handloom cotton lint, absorbent, bleached, non-sterilized (first revision)
3	IS 758 : 1988	Specification for cotton gauze, absorbent, non-sterilized (fourth revision)
4	IS 863 : 1988	Specification for cotton bandage cloth, non-sterilized (second revision)

S.N.	IS No.	TITLE
5	IS 1681 : 1998	Textiles — Hospital blankets, woollen, dyed — Specification (third revision)
6	IS 4605 :2020	Crepe Bandage — Specification (Second Revision)
7	IS 4717 : 2020	Medical Textiles — Zinc Oxide Self-Adhesive Plaster — Specification
		(Second Revision)
8	IS 4738 : 2020	Medical Textiles — Bandage, Plaster of Paris — Specification (Third Revision)
9	IS 4739 : 1986	Specification for zinc oxide elastic self-adhesive bandage (first revision)
10	IS 5405 : 2019	Sanitary napkins — Specification (second revision)
11	IS 6237 : 1971	Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages
12	IS 9751 : 1981	Specification for bandage, suspensory
13	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)
14	IS 11046 : 1984	Specification for towel, operating
15	IS 11163 : 2021	Medical Textiles — First Aid Dressings — Specification (first revision)
16	IS 12839 : 1989	Wool/polyamide blended flannel, hospital, grey - Specification
17	IS 14274 : 1995	Bandage, T - Shaped, calico - Specification
18	IS 14306 : 1995	Bandage, triangular, calico – Specification
19	IS 14316 : 1995	Swabs, small, in bag of 50 - Specification
20	IS 14944 : 2020	Surgical Dressings — Methods of Test (First Revision)
21	IS 16111 : 2013	Elastic bandage
22	IS 16288 : 2014	Medical textiles — Method for evaluation of the bacterial filtration efficiency of surgical face masks
23	IS 16289 : 2014	Medical textiles — Surgical face masks — Specification
24	IS 16290 : 2014	Medical textiles — Knitted viscose primary dressings — Specification
25	IS 16291 : 2014	Medical textiles — Paraffin gauze dressings — Specification
26	IS 16302 : 2020	Medical Textiles — Orthopedic Stockinet — Specification (First Revision)
27	IS 16303 : 2014	Medical textiles — Cast padding for orthopaedic plaster — Specification
28	IS 16466 : 2020	Medical Textiles — Povidone Iodine Ointment Based Knitted Dressing — Specification (First Revision)
29	IS 16467 : 2016	Medical textiles — Graduated medical compression stockings — Specification
30	IS 16468 : 2016	Medical textiles — Absorbent cotton (Sterile and non-sterile) — Specification
31	IS 16469 : 2016	Medical textiles — Open weave bandages — Specification
32	IS 16470 : 2016	Medical textiles — Elastic surgical adhesive tapes — Specification

S.N.	IS No.	TITLE
33	IS 16545 : 2016 ISO 16604 : 2004	Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage
34	IS 16546 : 2016 ISO 16603 : 2004	Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood
35	IS 16548 : 2016 ISO 22612 : 2005	Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration
36	IS 16549 : 2020 ISO 22610 : 2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration (first revision)
37	IS 16660 : 2017	Medical textiles — Nonwoven bandage rolls — Specification
38	IS 16668 : 2017	Medical textiles — Salicylic acid adhesive plaster — Specification
39	IS 16669 : 2017	Medical textiles — Elastic adhesive dressing — Specification
40	IS 16670 : 2017	Medical textiles — Absorbent cotton ribbon gauze — Specification
41	IS 16671 : 2020	Medical Textiles — Belladonna Adhesive Plaster — Specification (First Revision)
42	IS 16946 : 2018	Medical textiles — Elasticated tubular bandages — Specification
43	IS 16948 : 2018	Medical textile — Permeable nonwoven surgical adhesive tape — Specification
44	IS 16949 : 2018	Medical textiles — Adhesive extension plaster - Specification
45	IS 16950 : 2018	Medical textiles — X - Ray detectable absorbent cotton gauze —Specification
46	IS 17243 : 2019	Medical textiles — Test methods for compresses for wound management and surgical procedures
47	IS 17333 : Part 1 : 2020	Textiles — Determination of antifungal activity of textile products Part 1 Luminescence method
48	IS 17333 : Part 2 : 2020	Textiles — Determination of antifungal activity of textile products Part 2 Plate count method
49	IS 17334 : 2019	Medical textiles—Surgical gowns and surgical drapes — Specification
50	IS 17347 : 2020	Textiles – Determination of antiviral activity of textile products
51	IS 17348 : 2020	Medical textiles – Adhesive incise drape – Specification
52	IS 17349 : 2020	Medical textiles – Shoe covers – Specification
53	IS 17350 : 2020	Medical textiles – Abdominal binder – Specification
54	IS 17351 : 2020	Medical textiles – Dressing, shell compressed – Specification
55	IS 17352 : 2020	Medical textiles – Foam dressing – Specification
56	IS 17353 : 2020	Medical textiles – Pressure garment – Specification

S.N.	IS No.	TITLE
57	IS 17354 : 2020	Medical textiles – Dental bib/Napkins – Specification
58	IS 17359 : 2020	Medical textiles – Anti-embolic stocking for Post op use upto thigh medium – Specification
59	IS 17423 : 2020	Medical Textiles — Bio-Protective Coveralls — Specification (First Revision)
60	IS 17506 : 2020	Medical Textiles — Hydrocolloid Dressing — Specification
61	IS 17507 : 2020	Medical Textiles —Cellulose Wading — Specification
62	IS 17508 : 2020	Disposable Adult Incontinence Diaper —Specification
63	IS 17509 : 2021	Disposable Baby Diaper —Specification
64	IS 17514 : 2021	Reusable Sanitary Pad/Sanitary Napkin/ Period panties —Specification
65	IS 17528 : 2021	Medical Textiles — Chlorhexidine Gauze Dressing— Specification
66	IS 17628 : 2021	Medical Textiles —Eye Pad —Specification
67	IS 17629 : 2021	Medical Textiles —Caps —Specification
68	IS 17630 : 2021	Medical Textiles— Bedsheet and Pillow Cover — Specification
69	IS 17787 : 2021	Medical Textiles — Nonwoven Wipes — Specification
70	IS 17788 : 2021	Medical Textiles — Nonwoven Fabric for Wipes — Specification
71	IS/ISO 20645:2004 ISO 20645 : 2004	Textile fabrics — Determination of antibacterial activity — Agar diffusing plate test
72	IS/ISO 20743:2021	Textiles — Determination of antibacterial activity of textile products
73	IS 17786 : 2022	Medical Textiles — Underpad — Specification
74	IS 19022: 2023	Medical Textiles — Barrier Face Covering — Specification
75	IS 18266 : 2023	Textiles - Medical Respirator - Specification

UNDER DEVELOPMENT

- Guidelines for reprocessing, of multiple-use healthcare textiles TXD 36 (22466)
- Non-woven gauze swab
- Scrub Suit/Patient Clothing,
- Patient Gown
- Sterilization Wrap
- Surgical Sutures

What is Medical Textiles or Medtech?

The Textile Institute (UK) defines medical textiles as "a general term which describes a textile structure which has been designed and produced for use in any of a variety of medical applications, including implantable applications".

Medical textiles are a major growth area within the scope of technical textiles, which is defined as "textile materials

and products manufactured primarily for their technical performance and functional properties rather than their aesthetic or decoration characteristics".

Medtech 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%.

Global Medical Textiles Market Size is expected to reach around USD 26 billion by 2028 and expected to grow at a CAGR of approx. 4.5 % from 2022-2028 according to a market report.

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

Rising awareness for healthcare practices among the consumers/professional/users

Demand for face masks, PPEs, Surgical gowns, has been increased during pandemic.

India as a popular destination for medical tourism among patients from countries in south and western Asia, Middle East, Africa.

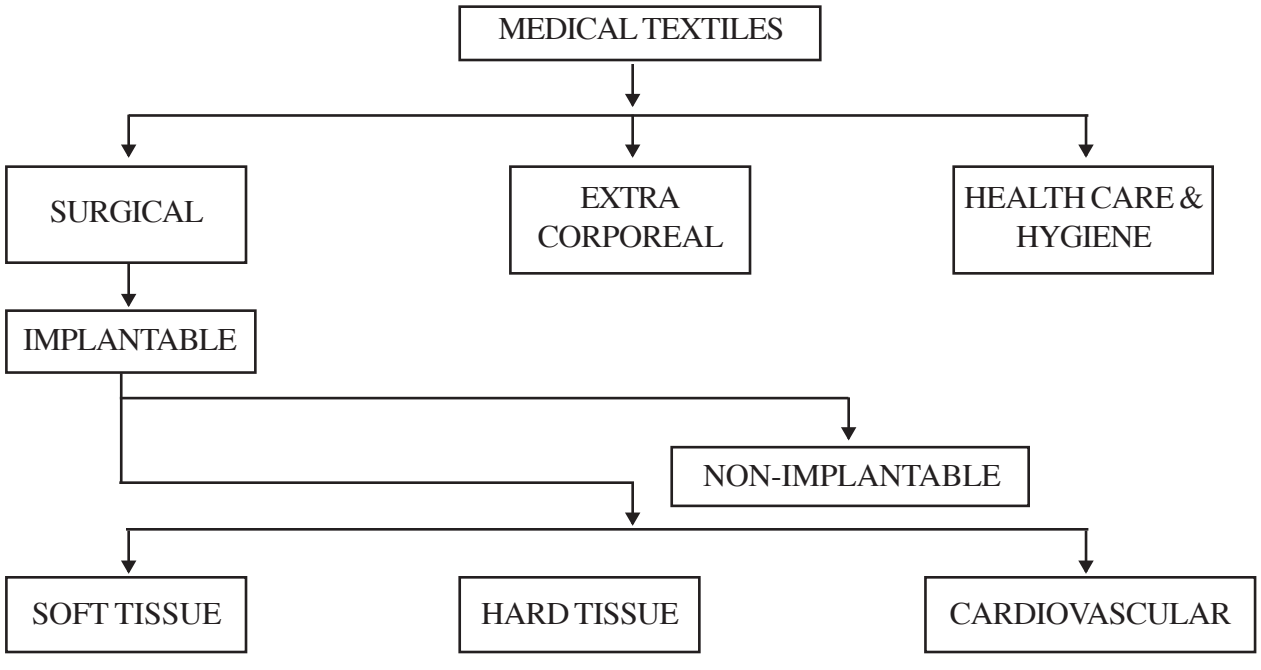
Government initiatives for infrastructure and technological advancements, R & D, skill development through Atmanirbhar Bharat, Production Linked Incentive (PLI) scheme and National Technical Textiles Mission.

Classification of Medical Textiles

Depending upon the usage, they are classified as:

a) Healthcare and Hygiene products
b) Non-implantable materials
c) Implantable materials
d) Extracorporeal devices

Medical textiles can be classified as follows:



Classification of Medical Textiles

1. **Health Care & Hygienic Products:** An important area of medical textile is healthcare and hygiene assurance. These textile materials are used to protect physicians and health workers and to equip wards when treating patients in the hospital and will have non-toxic, non-carcinogenic etc. properties.

   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, doctor and patients.

   Product applications: Surgical masks, PPE Coverall, Surgical Gown and Drape, Disposable Sanitary Pad, Reusable Sanitary Pad/Period Panties, baby diapers, Caps, Wipes etc.

2. **Non-Implantable Materials:** Non - Implantable medical textiles are used for external applications on body that means those are used outside the human body to assist the recovery of wounds are called non-implantable medical textiles. Non-implantable products are typically used to provide protection against infection, to absorb blood and exudates and to promote healing. The term non-implantable is used generally to indicate surface wound treatments of different parts of the human body.

   Product Applications: Absorbent Pads, Bandages, Plasters, swab, Gauze Pads, Lint, Wound Dressing etc.

3. **Implantable Materials:** There is a special type of textile structure that is used for various purposes inside the human body. The use of implantable material can be observed in wound closure or replacement surgery. For example: Satures, Soft tissue implants, Orthopedic implants, cardiovascular implants, etc. are used in textiles.

   Implantable products are biomaterials which are used for wound closure (e.g. suture), replacement surgery (e.g. vascular graft, artificial ligaments etc.) Another important category of implantable products is soft-tissue implants. These are ûexible strong materials commonly used to replace tendons, ligaments and cartilage in both reconstructive and corrective surgery. Suspensors and reinforcing surgical meshes are used in plastic surgery for repairing defects of the abdominal wall.

   Product Applications: Suture, vascular graft, artificial ligaments, heart valves, Artificial Tendon, Artificial Ligament, Artificial Skin, Artificial Bone, Artificial Corneaetc.

4. **Extra Corporal Devices:**

   Extra corporal devices are mechanical organs that are used for blood purification such as apheresis, hemodialysis, hemofiltration, plasma-pheresis or extra corporeal membrane oxygenation. There have been artificial kidney, liver and mechanical lung. The making of these devices requires precise design and manufacture. These products are used to replace various organs inside the body of infected people. These devices must have non-toxic, non-carcinogenic, bio-compatibility properties.

   Product Applications: Artificial Kidney, Artificial Lung, Artificial Liver etc.

STANDARDIZATION IN THE FIELD OF MEDICAL TEXTILES

SURGICAL FACE MASK

IS 16289 : 2014 'MEDICAL TEXTILES — SURGICAL FACE MASKS — SPECIFICATION'

Surgical Face Mask — A medical device covering the mouth, nose and chin providing a barrier to minimize the direct transmission of infective agents between staff and patient.

Medical Professional (Staff and Doctor) involved in treating and caring for patients or individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms and infective agents, can pose significant risks to life and health.

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are, for example noses and mouths of the surgical team. 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. Face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

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.

Design: The surgical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.

The surgical masks have been categorized into three classes based on the barrier performance properties of the surgical face mask materials (fluid resistance, bacterial filtration efficiency, and sub-micron filtration efficiency, splash resistance), i.e., Class 1, Class 2 and Class 3.

The key performance requirements specified in IS 16289 Surgical Facemask include Bacterial filtration efficiency and Sub-micron particulate filtration efficiency at 0.1 micron for safety, Differential pressure for comfort, splash resistance to protect from blood and body fluids during surgery.

Bacterial Filtration Efficiency (BFE) — The effectiveness of a surgical face mask to filter (prevent passage of) aerosol droplets containing bacteria of a specified particle size of 3.0 µm (micron) ± 0.3 µm. This is expressed as a percentage of a quantity that does not pass through the material.

Differential Pressure/Delta P — It is the pressure drop across a surgical mask under specific conditions of air flow, temperature and humidity. This is an indicator of the breathability of the mask.

A device which measures the pressure differential required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the surgical mask material. The test specimen is placed across the 2.5 cm diameter orifice (total area 4.9 cm^2) and clamped into place so that the tested area of the specimen will be in line and across the flow of air. The pump is started and the flow of air adjusted to 8 litre/ minute.

Sub-micron Particle Filtration Efficiency (PFE) — It is the effectiveness of a material to filter aerosol droplets containing bacteria of a specified particle size range 0.1 µm. This is expressed as a percentage of a quantity that does not pass through the material.

Fluid/Splash Resistance — It is defined as the ability of a facemask's material construction to minimize fluids from traveling through the material and potentially coming into contact with the user of the facemask. Fluid resistance helps reduce potential exposure to blood and body fluids caused from splashes, spray or splatter. Resistance to penetration by synthetic blood is indicated as pass/fail at velocity of 120 mm of Hg. Penetration (visual evidence of synthetic blood on the side opposite impact results in fail at that pressure. Non -penetration results in a pass.

A volume of synthetic blood is disbursed at a specimen mask by a pneumatically controlled valve from a set distance at specified pressure to simulate the impact of blood or other body fluid onto the specimen. The velocity and volume of fluid are set to simulate a given health care scenario 120 mm Hg.

PERFORMANCE REQUIREMENT FOR SURGICAL FACE MASK

Sl.No.	Characteristic	Requirements		
		Class 1	Class 2	Class 3
i)	Bacterial FilteringEfficiency, *Min*	95	98	98
ii)	Differential Pressure, Pa, *Max*	29.4	29.4	49.0
iii)	Splash resistance, mm Hg *Min*	-	-	120
iv)	Sub-micron particulatefiltration Efficiency at 0.1µ, Percent, *Min*	-	-	98

COVERALL

IS 17423 : 2021, Medical Textiles — Bio-Protective Coveralls — Specification (First Revision)

Coveralls are designed to protect the healthcare professional from exposure to virus/bacterial/infective agents. Although coveralls typically provide higher protection because they are designed to cover the whole body, including back and lower legs and sometimes head and feet as well.

By using coverall, it is possible to create a barrier to eliminate or reduce contact and droplet exposure, both known to transmit COVID-19, thus protecting healthcare workers working in close proximity (within 1 meter) of suspect/confirmed COVID-19 cases or their secretions.

Coverall is a type of personal protective equipment (PPE) intended to be worn by healthcare personnel for the purpose of isolating all parts of the body from a potential hazard. The bio-protective coveralls provide protection against various biological agents due to their material sealing arrangements.

This standard specifies the requirements for single use and reusable bio-protective coveralls intended for medical use.

The fabric used for the manufacturing of coverall shall be a single or multi-layered textile structure made of woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted structure with or without coating / lamination engineered to fulfil the functional requirements. The bio-protective coveralls consists of an integrated hood with elastic around face opening. It shall be provided with suitable fastening arrangement which shall be covered with a storm flap provided with suitable self-adhesive sealing arrangement such as a double-sided tape etc.

Coverall shall be joined by sewing, adhesion, thermally/ultrasonically welding or any other suitable technique. The seams shall be sealed with a tape of suitable material of medical grade of minimum 16 mm width or any other sealing arrangement that ensure that the seam shall pass the same tests as the body.

Coverall may also be provided with elastic wrists and ankles for convenience and freedom for movement. It shall also be provided with thumb loop for better and secure fit during overhead work. The seams shall be sealed with a tape of suitable material of medical grade of minimum 16 mm width or any other sealing arrangement. Each coverall shall be provided with a pair of shoe covers with an elastic strip to tighten it with the coverall, so that there is no passage for air through it.

Depending upon the end use the Bio-protective coveralls have been classified into four performance levels (level 1 to level 4)

Requirements	Level 1	Level 2	Level 3	Level 4	Test method
Synthetic blood penetration resistance	up to 1.75 kPa	up to 3.5 kPa	up to 7 kPa	up to 14 kPa	IS 16546/ISO 16603
Resistance to viral penetration	NA	NA	up to 3.5 kPa	up to 7 kPa	IS 16545/ISO 16604
Breathability (water vapour transmission rate), g/m^2/day, *Min*	1200	1200	800	800	Annex F of IS 16390
Tensile strength (dry and wet), N	≥ 20	≥ 20	≥ 40	≥ 40	Non woven IS 15891-3, Woven IS 1969 (Part 1)
Seam strength (dry and wet) (N)	≥ 20	≥ 20	≥ 32	≥ 32	Nonwoven: IS 15891 (Part18), Woven: IS/ISO 13935 (Part1)
Bursting strength (dry & wet) (kPa)	≥ 40	≥40	≥ 40	≥ 40	IS 1966 (Part 1)
Cleanliness–microbial (CFU/100 cm^2)	< 300	< 300	< 300	< 300	ISO 11737 (Part 1)
Resistance to dry microbial penetration ,(log cfu)	NA	NA	< 1	< 1	IS 16548/ISO 22612

Physical Significance of requirements for Bio-protective coveralls

1. Synthetic Blood Penetration Resistance (IS 16546 : 2016 / ISO 16603 : 2004)**:** This test method is required to simulate the actual conditions of blood splash observed by the healthcare personnel, when splashes of blood falls (projectile) onto the surface of coverall.

Workers, primarily those in the health care profession, involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne viruses which cause hepatitis [hepatitis B virus (HBV) and hepatitis C virus (HCV)] and acquired immune deficiency syndrome (AIDS) [human immunodeficiency viruses (HIV)]. Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin contact through the use of protective clothing.

The resistance of a protective clothing material to penetration by blood and body fluids is determined by subjecting the material to synthetic blood as a body fluid simulant for a specified time and pressure sequence and observing if visible penetration of the liquid occurs. In the penetration test apparatus, the clothing material acts as a partition separating the body fluid simulant from the viewing side of the test cell. Any evidence of synthetic blood penetration constitutes failure. Results are reported as "pass/fail"

The synthetic blood shall meet the following requirements:

surface tension: (0,042 ± 0,002) N/m

pH: (7,3 ± 0,1)

viscosity: (2,7 ± 0,3) mPa.s (millipascal second)

conductivity: (12,0 ± 1,2) mS/cm (microSiemen per cm)

Dissolve the carboxymethyl cellulose (CMC) in half the amount of water and mix 60 min on a magnetic stirring plate. Weigh the Tween 20 in a small beaker, add water and mix. Dissolve the sodium chloride, potassium dihydrogen phosphate, disodium hydrogen phosphate, amaranth dye in the solution Dilute the solution with water up to 1000 g.

0 kPa for 5 min, followed by 1,75 kPa for 5 min, followed by 3,5 kPa for 5 min, followed by 7 kPa for 5 min, followed by 14 kPa for 5 min.

Procedure D involves the use of a retaining screen to support extensible or elastomeric materials. When distortion of the test material is suspected of causing failure with Procedure C, Procedure D may be used.

2. Resistance to Viral Penetration (IS 16545 : 2016/ ISO 16604 : 2004): Bacteriophage Phi-X-174 has been used because of its structural properties are quite similar to virus structure. The fabric of the coverall is subject to bacteriophage under certain pressure and performance of the fabric is observed, whether the bacteriophage has passed the fabric or not.

This test method for measuring the resistance of materials used in protective clothing to penetration by blood-borne pathogens. This test method uses a surrogate microbe under conditions of continuous liquid contact. Protective clothing "pass/fail" determinations are based on the detection of viral penetration.

A specimen is subjected to a nutrient broth containing a virus for a specified time and pressure sequence. Visual detection of penetration is supplemented with an assay procedure that will detect viable viruses which penetrate the material even when liquid penetration is not visible. Any evidence of viral penetration for a test specimen constitutes failure. This test method requires a working knowledge of basic microbiological techniques.

The surrogate microbe, Phi-X174 bacteriophage, was selected as the most appropriate model for blood-borne pathogens because of its small size, spherical (icosahedral) morphology, environmental stability, non-human infectivity, high assay sensitivity, rapid assay, and high titre. The Phi-X174 bacteriophage has no envelope and is one of the smallest known viruses (0,027 µm in diameter).

3. Breathability (water vapour transmission rate) (Annex F of IS 16390) : This test method is practiced to simulate the comfort or to determine the wearability of the fabric. The amount of water vapours transmitted over the surface of coverall fabric is detected.

4. Mechanical and physical properties likeTensile strength, Bursting strength and Seam strength in both dry and wet conditions need to be tested in order to ensure the life of the product or to withstand severe loads and pulls during the procedures.

Bursting strength – dry and wet

This test is designed to assess the device's ability to withstand pressure over, for example, a clinician's elbow and to ensure its barrier properties are not prejudiced by mechanical failure. Materials with more than one layer can show several break points when tested for bursting strength, e.g. one corresponding to each layer. In order to address the scope of the requirement it was agreed to evaluate the performance of the material based on the

pressure needed to break or compromise the barrier of the sample.

Tensile strength – dry and wet/Seam Strength

The 'tensile strength' of a material is the maximum stress, generated by pulling or stretching the material that a material can withstand before failing. The test is designed to assess whether the basic strength of the device material is sufficient to ensure its barrier properties are not prejudiced. It is a standard textile material test. Materials with more than one layer can show several break points when tested for tensile strength, e.g. one corresponding to each layer.

5. Cleanliness–microbial: The test for microbial cleanliness is intended to estimate the numbers of viable organisms on the products, before they are sterilized. This is frequently referred to as the 'bioburden', which are used to determine the appropriate sterilization criteria for their products.. In a bioburden (cleanliness) test, the presence of microorganisms is expected, and the test is designed to quantify the amount of microorganisms present. The method/s shall comprise techniques for the following:

a) neutralization of inhibitory substances, if needed;

b) removal of microorganisms, if appropriate;

c) culturing of microorganisms;

d) enumeration of microorganisms

The total no. of colony forming units in CFU/100 cm^2 is determined and shall be less than or equal to 300 CFU/ 100 cm^2.

Resistance to microbial penetration – Dry bacterial penetration (IS 16548)

is a test method that was designed to simulate the penetration of bacteria-carrying skin scales through fabrics. This test provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles. Whilst the relationship between contamination and infection is complex - contamination of the surgical field does not necessarily lead to infection - it is generally agreed that healthcare facilities should consider methods to reduce levels of airborne particles carrying bacteria in operating rooms.

6 Biocompatibility test

- **<u>Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization</u> : The material shall be 'Non-reactive, Non-irritant and Non-sensitizer' respectively.**

Biocompatibility - Quality of being accepted in a specific living environment without adverse or unwanted side effects.

These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion. These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

Many products have chemical additives for the purposes of

- To Improve barrier property/stain resistance

- Leach Out

The raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use. The biocompatibility of the material shall be detected by evaluating cytotoxicity,

irritation and skin sensitization test as per IS/ISO 10993 (Part 5) and IS/ISO 10993 (Part 10) respectively. For cytotoxicity, the material shall show reactivity as "None" when tested as per IS/ISO 10995 (Part 5). Similarly, the material shall be "Non-irritant and Non-sensitizer" when tested as per IS/ISO 10993 (Part 10).

Confirm the biocompatibility of raw material at designed stage. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing

BIOCOMPATIBILITY EVALUATION TESTS

ISO 10993-5 : 2009, Biological evaluation of medical devices

- In vitro cytotoxicity (i.e. testing to be done within the glass tubes)

3 categories of tests

i) Extract test;

ii) Direct contact; and

iii) Indirect contact test

Principle :

Preparation of cultured cells

↓

Exposed to

↓

Samples or their extracts

↓

Measurement of cytotoxicity is undertaken:

a) assessments of cell damage by morphological means;
b) measurements of cell damage;
c) measurements of cell growth;
d) measurements of specific aspects of cellular metabolism.

Assessment based on the above measurement to be taken is to be decided.

- Incubation of cultured cells → in contact with a device/extract
- Extraction : 24 ± 2 h @ 37 ± 1 °C
- Direct contact test
- Preparation of controls

a) Positive control

b) Negative control

c) Blank : To check inherent toxicity, if any of the apparatus.

- Cell lines - from living cells tissues
- To check (at regular intervals)

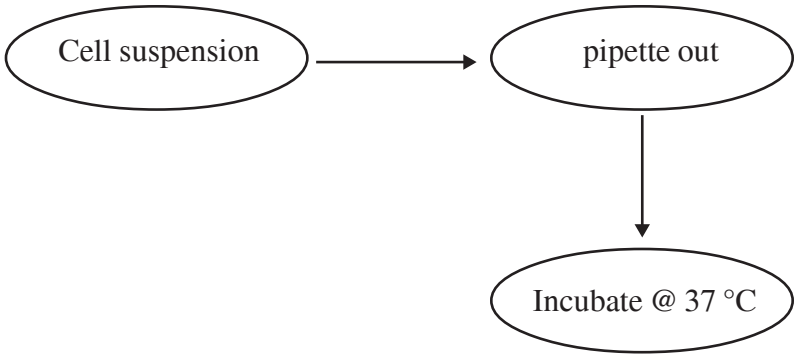
a) morphology

b) doubling time

c) modal chromosome no.

Cell stock culture

PROCEDURE:

- 

- Place test samples at centre of culture vessels
- Replicate the same procedure for negative and positive controls as well
- Incubate the vessels for 24 h
- Assessment to be done and do the grading as given below:

a) 0 – No detectable zone

b) 1 – some malformed/ degenerated cells under specimen

c) 2 – mild

d) 3 – moderate

c) 4 – severe

BIOCOMPATIBILITY EVALUATION TESTS

ISO 10993-10 : 2016, Biological evaluation of medical devices – Tests for irritation and skin sensitization

- In vivo testing
- In vitro testing for dermal exposure and in vivo testing for irritation and skin sensitization
- Allergen used : hypersensitive substance
- Positive control – Pig sensitization assay

In vitro irritation test ⟶ with rat skin

- Assay formation/extract formation
- Apply on rat skin/tissues

In vivo irritation test ⟶ Rabbit is the preferred animal

- Take 3 rabbits
- Liquid extract to be taken on a gauge
- Apply these liquid gauges on both sides on the rabbit
- Wait for 24 h and check for skin irritation
- Grading is done accordingly as given below:

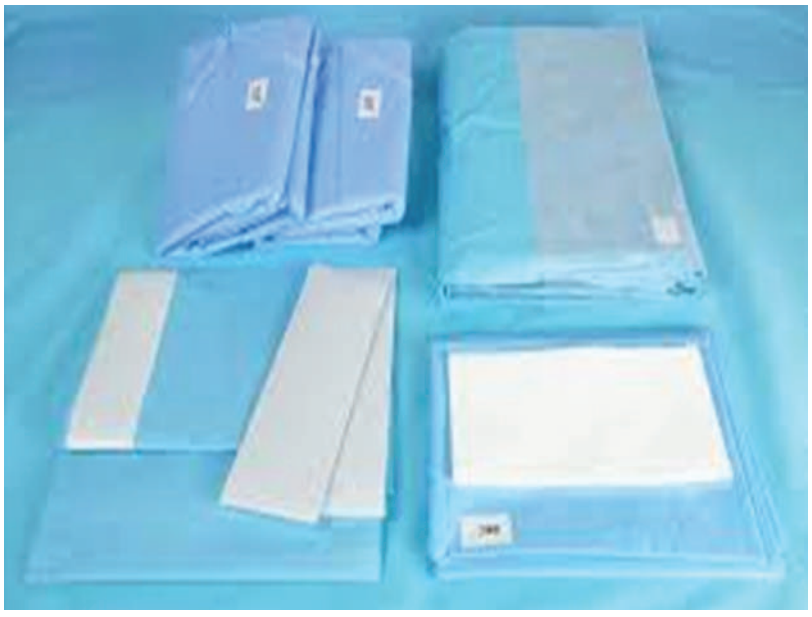
  Grade - 0, 1, 2, 3 and 4

SKIN SENSITIZATION TEST

- Liquid assay – 0.5 % w/v carboxyl methyl cellulose
- Healthy female mice is the test animal
- Measure the level of radioactivity in the lymph node cells in counts/minutes (cpm/mouse)
- To disintegrate per minute (dpm)
- Determine SI (Sensitization Index) = cpm/dpm

Value of SI less than equal to (de 3.0) is passing criteria

SURGICAL DRAPE/ GOWN



IS 17334 : 2019 SURGICAL GOWNS AND SURGICAL DRAPES

Surgical Gown — Protective clothing that is intended to be worn by healthcare workers during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate matter.

Surgical Drape — A covering for the patient for the prevention of transfer of infective agents, such as microorganisms, body fluids and particulate material. "Surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings".

Surgical drapes, including the intended use as a sterile field, and surgical gowns are used to minimize the spread of infective agents to and from patients' operating wounds, thereby helping to prevent postoperative wound infections.

Surgical gowns and surgical drapes are intended to be used to minimize the transmission of infective agents between patients and clinical staff during the surgical and other invasive procedures. This standard addresses the performance of surgical gowns and surgical drapes designed to protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other healthcare procedures.

Depending upon the various end uses, surgical gowns and surgical drapes have been categorized into four levels (Level 0, Level 1, Level 2 and Level 3). The final performance requirement level shall be based on the performance of the critical zone component. The information for principle of critical area has been specified in the standard.

The following important performance requirements have been covered in this standard for surgical gowns and drapes:

- **Impact penetration** (g)
- **Hydrostatic resistance** (cmwc)
- **Blood resistance** and **viral resistance**
- **Particle release**
- **Tensile strength** and **bursting strength** (dry and wet)

- **Resistance to microbial penetration** – dry and wet
- **Biocompatibility** evaluation (cytotoxicity and irritation sensitization)

To ensure the **comfort**, requirement for **moisture vapour transmission rate** has also been specified for **level 3 gowns**

Table 1 Performance Requirements for Surgical Gowns

(*Clauses* 5.1, 6.2, 8.1.1, 8.2.2 *and* 9.1)

Sl No.	Characteristics	Requirement				Method of Test, Ref to
		Level 0	Level 1	Level 2	Level 3	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	< 4.5	NA	NA	NA	ISO 18695
ii)	Hydrostatic resistance (cmwc)	NA	≥ 20	≥ 50	NA	ISO 811
iii)	Blood resistance	NA	NA	NA	Pass	IS 16546
iv)	Viral resistance	—	—	—	Pass	IS 16545
v)	Particle release [log10 (lint count)]	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
vi)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
vii)	Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
viii)	Cleanliness–microbial (CFU/100 cm²)	≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
ix)	Resistance to microbial penetration — Dry (CFU)	NA	≤ 300	≤ 300 (for less critical zones)	NA	IS 16548
x)	Resistance to microbial penetration — Wet (I_p)	NA	NA	6.0 (for critical zones)	—	IS 16549
xi)	*Biocompatibility Evaluation — Cytotoxicity	None	None	None	None	IS/ISO 10993-5
	*Biocompatibility Evaluation — Irritation and skin sensitization	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	IS/ISO 10993-10
xii)	Moisture vapour transmission rate (*Max.*) (optional)	NA	NA	NA	40 m² Pa/W	ISO 11092

*Remarks : Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

Particle release IS 15891 (Part 10)

This method is designed to measure the release of particles from the product. Particle release is a concern during surgery as foreign body contamination can cause an increased frequency of post-operative complications such as keloids, wound dehiscence, incisional hernias, chronic abscesses, intestinal obstruction and, in some circumstances, even death. Fibres from gowns and drapes which have been deposited in wounds have been shown to cause post-operative granulomas . Blood clots around fibres can cause emboli, obstructing vital blood vessels. Fibres can also reduce the ability of tissue to resist infection, due to impaired function of the blood and tissue macrophage systems.

Resistance to liquid penetration/ hydrostatic head test

This test is a standard test used for textiles, which measures how high a column of water has to be before it penetrates through the material under test. It is generally accepted to be a measure of the water-resistant properties of a material. It is relevant to surgical fabrics as it is related to the ability of the fabric to prevent splashes of fluid and droplets penetrating the fabric under mechanical pressure.

Bursting strength – dry and wet

This test is designed to assess the device's ability to withstand pressure over, for example, a clinician's elbow and to ensure its barrier properties are not prejudiced by mechanical failure. Materials with more than one layer can show several break points when tested for bursting strength, e.g. one corresponding to each layer. In order to address the scope of the requirement it was agreed to evaluate the performance of the material based on the pressure needed to break or compromise the barrier of the sample.

Tensile strength – dry and wet

The 'tensile strength' of a material is the maximum stress, generated by pulling or stretching the material that a material can withstand before failing. The test is designed to assess whether the basic strength of the device material is sufficient to ensure its barrier properties are not prejudiced. It is a standard textile material test. Materials with more than one layer can show several break points when tested for tensile strength, e.g. one corresponding to each layer.

Resistance to microbial penetration – Dry bacterial penetration (IS 16548)

is a test method that was designed to simulate the penetration of bacteria-carrying skin scales through fabrics. This test provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles. Whilst the relationship between contamination and infection is complex - contamination of the surgical field does not necessarily lead to infection - it is generally agreed that healthcare facilities should consider methods to reduce levels of airborne particles carrying bacteria in operating rooms.

Resistance to microbial penetration – wet (IS 16549)

This test determines the resistance of a material to the penetration of bacteria from a dry surface through a material by the combined effect of friction, pressure and wetting [34]. The pressure is intended to mimic the type of pressure exerted by a surgeon's elbow during a procedure [35] and was developed specifically to measure the penetration by bacteria through operation materials of reusable or single-use material. The method has been difficult to standardize, and multiple inter-laboratory comparisons have taken place where it has been difficult to demonstrate consistent results between laboratories. The method went into immediate revision after initial publication.

SANITARY NAPKIN

IS 5405 : 2019, SANITARY NAPKINS

Sanitary napkin is an absorbent material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage.

This standard covers the requirements for disposable (non-reusable) sanitary napkins for external use. All types of sanitary napkins basically consist of three major components:

a) cover or the top sheet;

The cover/top sheet is the material which comes under contact with skin during use. The cover of sanitary napkin shall be of good quality cotton, rayon knitted sleeve or gauze, non-woven fabric or any other materials with sufficient porosity to permit the assembled pad to meet the absorbency requirements.

b) absorbent core, and

An absorbent core forming the middle layer(s) shall consist of filler materials, such as cellulose pulp, cellulose wadding, tissue, cotton, wood pulp, other absorbent and super absorbent materials or combination of these materials, etc. It shall be free from lumps, oil spots, dirt or foreign material.

c) the barrier or bottom sheet.

The barrier shall be made of suitable leak proof material so that it meets the requirement.

SIZE

Sizes of sanitary napkins shall be variable depending on the absorbent capacity, purchaser's needs and wing features. The recommended sizes are classified as follows:

Regular d" 210 Min 55

Large 211 to 240

Extra-large 241 to 280

XXL ≥ 281.

PERFORMANCE REQUIREMENT OF SANITARY PAD

❖ ***pH*** **: 5.5 – 8.0 (Test method IS 1390 : 2019 ISO 3071 : 2005)**

The pH-value of an aqueous extract of a textile is measured electrometrically at room temperature by means of a glass electrode.

Take from the laboratory sample three test samples of (2,00 ± 0,05) g. Place each test sample and 100 ml of extracting solution [either water or potassium chloride solution into a stoppered flask .Agitate the flask for a short period by hand to ensure that the textile material is properly wetted out, then shake it mechanically for 2 h ± 5 min.

Calibrate the pH-meter and record the reading.

❖ **Ability to withstand pressure after absorption : No leakage after absorption of 30 ml coloured distilled water.**

Add 0.01 g colour of Bromocresol Purple (Grade – Chemical analytical grade or equivalent) in 1 000 ml of distilled water and stir evenly to get uniform coloured solution.

Lay the sanitary napkin on a flat level transparent surface, so that underside of sanitary napkin can be observed. Drip at the rate of 5 ml per minute, 30 ml of coloured distilled water maintained at temperature of 27°C ± 2°C on to the centre of the napkin from a height of 1-2 mm. After the napkin has absorbed full amount of coloured distilled water, keep a standard weight of 1 kg for 1 min on the portion where coloured distilled water was absorbed. Observe the bottom and sides of sanitary napkin for any leak through. Test sample passes if liquid does not leak through and fails if liquid leak through.

❖ **Bacterial and Fungal Bioburden : Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm**

A sample of 5 gm cut from the centre portion of the napkin shall be checked for its absorbency in eluent such as 0.85 percent sodium chloride or equivalent medium till it reaches saturation limit.

Plate count agar (PCA) for bacterial bioburden and sabouraud chloramphenicol agar (SCA) for fungal bioburden. Incubate PCA plates at 30-35°C for 24 h and count colonies. Continue incubation upto 72 h, re-examine the plates after 48 h and 72 h, and report the results that have not resulted in overgrowth. Similarly incubate SCA plates at 20-25°C for 3 days and count the fungi. Re-examine after incubation for 5 and 7 days. Report the results from incubation time that does not result in over growth.

❖ **Test for Common Skin Pathogen — Staphylococcus Aureus : Shall be absent when tested as per IS IS 5887 (Part 2)**

❖ **Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization : The material shall be 'Non-reactive, Non-irritant and Non-sensitizer' respectively.**

Biocompatibility - Quality of being accepted in a specific living environment without adverse or unwanted side effects.

Part 5 These methods specify the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion. These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

Many products have chemical additives for the purposes of

- Extra absorbency (super absorbent polymers etc.)
- Fragrances and deodorizing agents
- Bleaching and coloring agents
- Anti-wicking additives

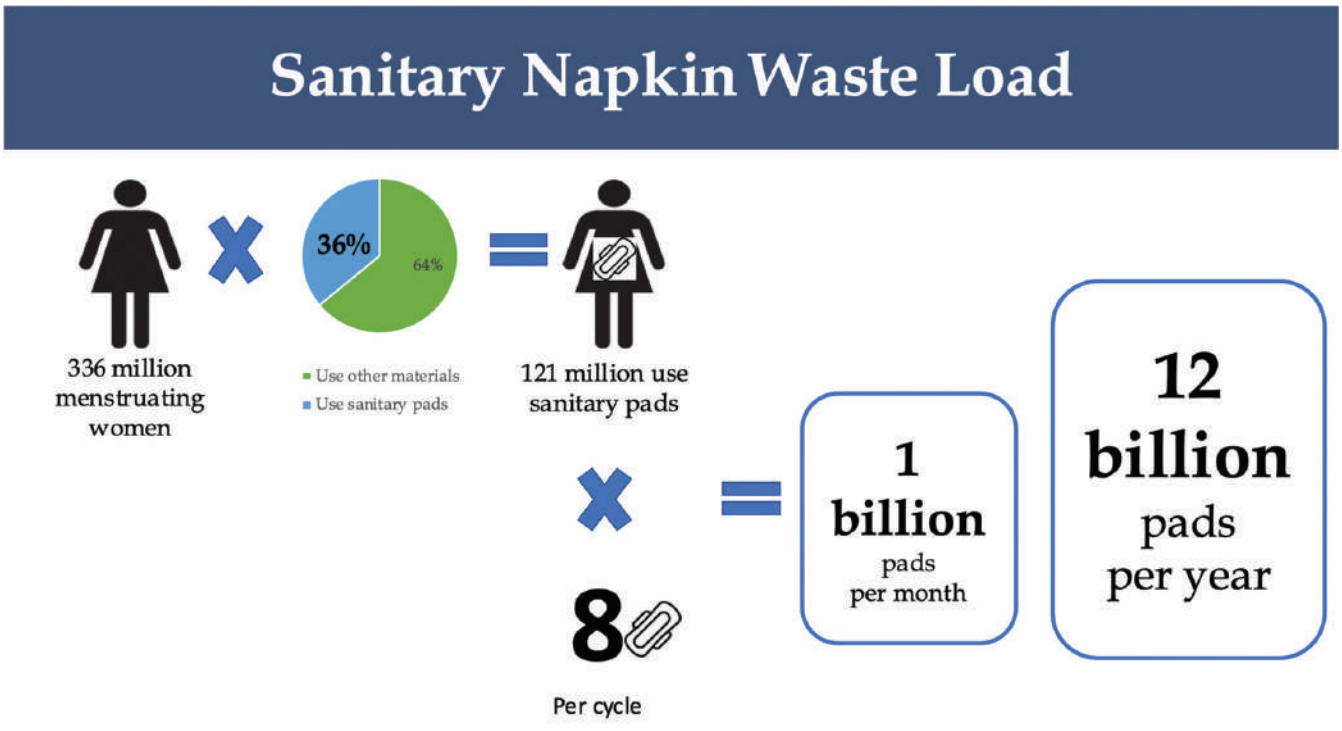
The raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use. The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 (Part 5) and IS/ISO 10993 (Part 10) respectively. For cytotoxicity, the material shall show reactivity as "None" when tested as per IS/ISO 10995 (Part 5). Similarly, the material shall be "Non-irritant and Non-sensitizer" when tested as per IS/ISO 10993 (Part 10).

❖ **Optional requirement for Biodegradability and Compostability (IS 17088)**

The manufacturer who are claiming their product as biodegradable or compostable shall perform the above testing for the final product. The product shall be biodegradable or compostable when tested as per IS/ ISO 17088.

A plastic product is considered to have demonstrated satisfactory disintegration/compositing if, after 84 days in a controlled composting test, no more than 10 % of its original dry mass remains after sieving through a 2,0 mm sieve.

A plastic product is considered to have demonstrated satisfactory disintegration if, after 84 days in a controlled composting test, no more than 10 % of its original dry mass remains after sieving through a 2,0 mm sieve.



❖ **GOOD MANUFACTURING PRACTICE GUIDELINES FOR HYGIENE REQUIREMENT HAVE BEEN SPECIFIED IN THE STANDARD.**

Location should be free from objectionable odours, smoke, dust and other contaminants. b) Separate areas shall be demarcated for storing raw materials, production and final product storage. c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination. d) Toilet and hand-washing station shall be provisioned away from storage/ production area. e) Provision of 70 percent isopropyl alcohol (IPA) solution for hand sanitization inside the production facility. f) Appropriate lighting and proper ventilation of the facility shall be ensured. g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt. h) Regular pest control measures shall be put in place. j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned. k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. shall be displayed. m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants. n) Hand hygiene shall be practised during manufacturing. p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/ disinfection of the equipment.

THROUGH AMENDMENT 1 IN IS 5405, BIOCOMPATIBILITY EVALUATION — CYTOTOXICITY, IRRITATION AND SKIN SENSITIZATION IS MADE (OPTIONAL)

REUSABLE SANITARY NAPKIN

IS 17514 : 2021, REUSABLE SANITARY PAD/ SANITARY NAPKIN / PERIOD PANTIES

Reusable sanitary pad/sanitary napkin/period panties are hygiene products that are worn by menstruators (children and adults) to absorb blood and other fluids during menstrual periods.

This standard covers the requirements for reusable (multiple use) sanitary pad/sanitary napkin/period panties for external use.

The raw material/fabric used for manufacturing the product shall meet the following requirements (initially and after declared cycle washes).

3.1 Cover/Top Sheet The cover/top sheet is the material which comes under contact with skin during use. The material used for the top layer/cover shall be safe, soft to the touch and should not shed any fibers when rubbed dry or wet. The cover of reusable sanitary pad/sanitary napkin/period panties shall be of good quality cotton, polyester, polyester/cotton blended fabric, viscose, polyester/viscose blended fabric, rayon knitted sleeve or gauze, non-woven fabric, or any other suitable materials as agreed mutually between the buyer and seller.

3.2 Absorbent Core An absorbent core forming the middle layer(s) shall consist of filler materials, such as cotton, viscose, polyester, micro terry, viscose/polyester, cellulose pulp, cellulose wadding, tissue, nonwoven materials, a combination of these materials or any other suitable absorbent materials as agreed mutually between the buyer and seller. The absorbent materials must be free from lumps, oil spots, dirt or foreign material. The absorbent material shall not form lumps with the effect of sudden pressure.

3.3 Bottom Layer The bottom layer of reusable sanitary pad/sanitary napkin/period panties shall be made of suitable material(s) that prevents the leakage when used.

FASTENING MECHANISM

If the style/design of the reusable sanitary pad/sanitary napkin/period panties requires a fastening mechanism, there shall be a suitable device for fastening the reusable sanitary pad/sanitary napkin/period panties for secure use for example, buttons, clasps, elastic, string, velcro or any other suitable material.The material used for the fastening mechanisms shall not cause harm to skin and shall not be abrasive when the product is used. The fastening mechanism shall be durable and free from rusting until the life cycle of the product as declared by the manufacturer.

Table 1 Colourfastness and Dimensional Stability Requirement of Raw Material/Fabric

(*Clauses* 8 *and* 11.2.4)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Colour fastness to rubbing		IS/ISO 105-X12
	a) Dry	4 or better	
	b) Wet	3 or better	
ii)	Colour fastness to perspiration (acidic and alkaline)		
	a) Colour change	4 or better	IS/ISO 105-E04
	b) Staining	4 or better	
iii)	Colour fastness to washing		
	a) Colour change	4 or better	IS/ISO 105-C06
	b) Staining	4 or better	
iv)	Dimensional stability to washing, percentage, *Max*		Annex C of IS 16394
	Length and width	± 5	

PERFORMANCE REQUIREMENT OF REUSABLE SANITARY PAD/ SANITARY NAPKIN / PERIOD PANTIES

- *p*H : 5.5 – 8.0
- Ability to withstand pressure after absorption : No leakage after absorption of 10 ml coloured distilled water.
- Bacterial and Fungal Bioburden : Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm
- Test for Common Skin Pathogen — Staphylococcus Aureus : Shall be absent
- Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization : The material shall be 'Non-reactive, Non-irritant and Non-sensitizer' respectively.
- Anti-bacterial value (before and after declared wash cycles : Shall be greater than or equal to 2 when tested

by the absorption method prescribed in IS/ISO 20743

- ❖ test methods to determine the antibacterial activity of all antibacterial textile products including nonwovens.

  absorption method (an evaluation method in which the test bacterial suspension is inoculated directly onto specimens);

- ❖ Good manufacturing practice guidelines for hygiene requirement have been specified in the standard.

THROUGH AMENDMENT 1 IN IS 17514, BIOCOMPATIBILITY EVALUATION — CYTOTOXICITY, IRRITATION AND SKIN SENSITIZATION IS MADE OPTIONAL)'

BABY DIAPER

IS 17509 : 2021, DISPOSABLE BABY DIAPER — SPECIFICATION

Baby diapers are personal hygiene products that allows the baby to defecate or urinate without the use of a toilet, by absorbing or containing waste products to prevent soiling of outer clothing or the external environment.

This standard covers the requirements for disposable (non-reusable) baby diaper for external use. This standard also covers the types and sizes and requirement for fastening and securing mechanism of the baby diaper. On the basis of the weight of infant and/or toddler the baby diapers are classified into new born, small, medium, large, extra-large.

New Born 2 – 5 kg

Small 3 – 8 kg

Medium 6 – 11 kg

Large 9 – 11 kg

X Large 13 + kg

The weight of baby diaper may vary between different types as per the agreement between the buyer and the seller

Minimum Absorption Capacity	Size	Number of Gushes	Requirement
	New Born	3	3 x 20 ml
	Small	3	3 x 35 ml
	Medium	3	3 x 50 ml
	Large	3	3 x 60 ml
	X Large	3	3 x 70 ml
Rate of absorption per gush (s), Max	All sizes	-	60
Rewet under load, (g), Max	All sizes	-	5

FASTENING AND SECURING MECHANISM

- Baby diaper shall have a suitable device (e.g. mechanical or adhesive) to ensure a good fit of the diaper at the waist and around the legs. The material used shall be safe under normal conditions of use and shall not provide a physical hazard.
- There shall be a device e.g. elastic band or elastic threads on both sides of the absorbentcore that are suitably stretched and fixed between top sheet and back sheet or fixed on topsheet or back sheet to keep the diaper fit on the user's waist and legs and prevent leakage of liquid.
- The adhesive used shall keep the diaper component together and shall not allow shifting of absorbent core or top sheet. The adhesive material used shall not be harmful to the skin of the baby.

PERFORMANCE REQUIREMENTS

❖ ***p*H Value -** 5.5 to 8.0 when tested by the method given in IS 1390.

❖ **Rate of Absorption, Rewet under Load and Minimum Absorption Capacity**

This method measures the rate of absorption of fixed quantity of a test solution under constant load and pressure. The time taken by the specimen to absorb completely 0.9 percent saline solution of a specified amount is the measure of the rate of absorption of the test specimen. The shorter the time taken by the specimen to absorb the solution, the better is rate of absorption.

Take at least 3 diapers randomly selected sample. Mark the loading point in the middle of the absorbent core. Measure the length and width of the absorbent core.

Place diaper with top sheet facing up on the tray with the front of the diaper facing away from the operator, the front of the diaper normally has smaller ears, the back of the diaper normally has the larger elastic ears and fastening tapes.

Place the acquisition plate on the diaper, ensure the plate is centered and the cylinder opening is placed over the marked loading point, the diaper should be gently stretched to remove any wrinkles in the diaper. Take care not to tear the diaper when positioning the acquisition plate to remove the wrinkles.

Gently place the provided weight on the acquisition plate.

Fill the measuring cylinder with the respective amount of saline solution depending on the diaper size.

Use the small pipette to make fine adjustments of the volume to bring it to the required amount ± 1 ml.

Set stop watch to 5 min. Start the stop watch and gently pour the saline solution onto the diaper. Record the time taken in seconds by the stop watch to absorb saline solution per gush specified in Table 2 by the diaper as the absorption rate.

If gush is absorbed after 5 min, that is, no more liquid in the cylinder and no liquid on the surface outside the cuffs of the product, then proceed to next step.

Leave the diaper without any disturbance for 5 min.

Repeat step another 2 times on same diaper.

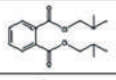
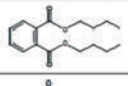
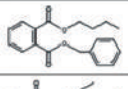
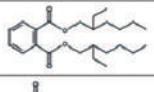
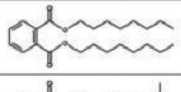
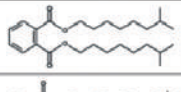
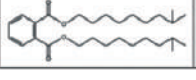
- **Hygiene Testing Requirement**
- Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/g and *Staphylococcus aureus* shall be absent.
- **Phthalate Test** - The amount of phthalate present in baby diaper shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6).

Phthalates are used as plasticizers (softening agents) in the manufacture of soft vinyl [also known as polyvinyl chloride (PVC)], which in turn is used in toys and childcare articles. Phthalates do not bind to the soft vinyl, but are present as mobile components of the vinyl. However, the mere presence of phthalates in soft vinyl does not in itself equate to a health risk. It is the amount of phthalates that leach out of soft vinyl and are absorbed into the body that can be harmful. Although exposure to phthalates in soft vinyl through dermal contact or inhalation is negligible, phthalates may leach out of soft vinyl during periods of sustained mouthing action (sucking and chewing, but not licking) and enter the body through the saliva. Once in the body, some phthalates have the potential to cause adverse effects on reproduction system and development of child.

The test specimen is extracted through a Soxhlet extractor, solvent extractor or ultrasonic bath with dichloromethane. Phthalate esters in the extract are determined qualitatively and quantitatively by gas chromatography-mass spectrometry (GC-MS).

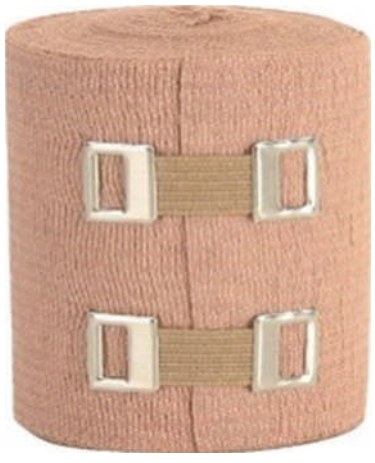
IS 9873 (Part 6) is method for the determination of di-iso-butyl phthalate (DIBP), di-n-butyl phthalate (DBP), benzylbutyl phthalate (BBP), bis-(2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DNOP), di-iso-nonylphthalate (DINP) and di-iso-decyl phthalate (DIDP) in toys and children's products.

Table A.1 — Phthalate esters

No.	Phthalate esters (initialism)	CAS No.	Structure formula[a]	Molecular formula
1	Di-*iso*-butyl phthalate (DIBP)	84-69-5		$C_{16}H_{22}O_4$
2	Di-*n*-butyl phthalate (DBP)	84-74-2		$C_{16}H_{22}O_4$
3	Benzyl butyl phthalate (BBP)	85-68-7		$C_{19}H_{20}O_4$
4	*Bis*-(2-ethylhexyl) phthalate (DEHP)	117-81-7		$C_{24}H_{38}O_4$
5	Di-*n*-octyl phthalate (DNOP)	117-84-0		$C_{24}H_{38}O_4$
6	Di-*iso*-nonyl phthalate (DINP)	28553-12-0[b] 68515-48-0[c]		$C_{26}H_{42}O_4$
7	Di-*iso*-decyl phthalate (DIDP)	26761-40-0[d] 68515-49-1[e]		$C_{28}H_{46}O_4$

- **Biocompatibility Evaluation —** Cytotoxicity, Irritation and Skin Sensitization
- The material shall be 'Non-reactive, Non-irritant and Non-sensitizer' respectively
- **Biodegradability and Compostability (Optional)** - The product shall be biodegradable or compostable when tested as per IS/ISO 17088.
- **Anti-Bacterial Activity Value (Optional) –** Baby diaper shall have antibacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

CREPE BANDAGE



IS 4605 : 2020, CREPE BANDAGE — SPECIFICATION (SECOND REVISION)

Crepe bandage consists of characteristic fabric of plain weave or needle loom 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.

This standard covers requirements pertaining to material, construction and performance of crepe bandage.

PERFORMANCE REQUIREMENTS

- Material - Cotton or mixture of rayon and cotton shall be used in the manufacture of crepe bandage.
- Threads per Stated Length - Ends: Not less than 170 per dm.
- Picks: Not less than 78 per dm, determined on the fully stretched bandage.
- Weight per Unit Area - The weight of the bandage in fully stretched conditions shall be not less than 160 g/m^2.
- Elasticity - The regain length shall not be more than 80 percent of the fully stretched length
- pH value - 6 to 8.5
- Breaking Load - minimum 150 N (15 kgf) on a test specimen of 20 cm test length and not greater than 5 cm in width
- The water-soluble and ether soluble substances shall not be more than 1 percent respectively.

CAPS

IS 17629: 2021, MEDICAL TEXTILES — CAPS — SPECIFICATION

Caps are worn as personnel protective clothing for head covering by surgeon, operating room staff and other healthcare professional. Caps are helpful to prevent contamination of the operating field, patient and materials from microorganisms/particulates that originate in the personnel's hair or scalps.

This standard specifies the requirements for caps intended to be worn by surgeon, operating room staff and other healthcare professional during the surgical and other invasive procedures to prevent contamination of the operating field, patient and materials from transfer of hair, microorganisms, particulates etc. They can be single use or re-useable. These caps are also known by other nomenclature, such as operation theatre cap, surgeon cap, surgeon hood, head cover, bouffant cap, nurse cap etc.

PERFORMANCE REQUIREMENT OF CAP

Sl No.	Characteristics	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Cleanliness – Microbial (CFU/100 cm^2)	≤ 300	ISO 11737-1
ii)	Tensile strength (Dry and wet) (N)	≥ 20	Nonwoven, IS 15891 (Part 3), Woven, IS 1969 (Part 1)
iii)	Bursting strength (Dry and wet) (kPa)	≥ 40	IS 1966 (Part 1)
iv)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
v)	Resistance to microbial penetration — Dry (CFU)	≤ 300	IS 16548
vi)	Moisture vapour transmission rate (*Max.*) (*optional*) (*see note*)	40 m^2 Pa/W	IS 17376

NOTE — Moisture vapour transmission is the ability of water vapour to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable. This test is recommended to be performed for caps that are being used in high risk surgeries with prolonged duration where the doctors/healthcare personnel are subjected to heat stress due to which they may feel uncomfortable.

WIPES

IS 17788 : 2021, MEDICAL TEXTILES — NONWOVEN FABRIC FOR WIPES — SPECIFICATION

This standard specifies minimum performance requirements for non-woven fabric for single use dry or wet wipes for baby care and personal hygiene (baby, adult, facial, skin etc).

The key performance requirements specified in the standards are fibre identification, GSM, Absorption, ph, Dry and wet breaking strength.

IS 17787 : 2021, MEDICAL TEXTILES — NONWOVEN WIPES — SPECIFICATION

This standard specifies minimum performance requirements for single use nonwoven dry or wet wipes used for baby care and personal hygiene (baby, adult, facial, skin etc).

The key performance requirements specified in the standards are length and width, ph, seal leakage test, Total viable count, microbiological requirements, antibacterial activity.

UNDERPAD

IS 17786 : 2022, Medical Textiles — Underpad — Specification

Underpad — Flat pad with absorbent filler and waterproof backing, designed to absorb bodily fluids resulting from incontinence, surgical procedure or other reason and to prevent soiling of bedding, furniture and medical equipment.

Table 1 Dimensions of Underpad (mm) (For reference only)

(*Clause* 5)

Size	Underpad Length (mm)	Underpad Width (mm)	Absorbent core Length (mm)	Absorbent Core Width (mm)
Small	400 ± 10	600 ± 10	340 ± 10	550 ± 10
Medium	600 ± 10	600 ± 10	510 ± 10	550 ± 10
Large	900 ± 10	600 ± 10	770 ± 10	550 ± 10
X Large	1 500 ± 20	600 ± 10	1280 ± 30	550 ± 10

Table 2 Requirement of Underpad

(*Clause* 8.2)

Sl No.	Characteristics	Size	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)	(5)
i)	Minimum absorption capacity (*ml*)	Small	150	ISO 11948-1
		Medium	200	
		Large	300	
		X Large	400	
ii)	Absorption Time, *s/ml, Max*	All sizes	6	Annex B
iii)	Retention Capacity #, *Min*	All sizes	7.5 times of initial weight	Annex C
# Sinking time - 10 s (maximum) and retention time – 30 s (minimum).				

IS 19022: 2023, Medical Textiles — Barrier Face Covering — Specification

A barrier face covering is a non-medical mask, also called fabric mask, community mask or face covering, is neither a medical device nor personal protective equipment. The common uses of barrier face covering are as follows:

- a) General population in public setting such as shops, shared workplaces, schools, worship places, restaurants, gyms, etc or in enclosed settings such as public transportation; and
- b) For households, in indoor settings, when there is a visitor who is not a member of the household.

Barrier face covering are intended to be used to minimize the transmission of aerosol mediated disease transmission among general public. This standard has been formulated to address the performance of barrier face covering designed to protect others from exposure to wearer's respiratory droplets, saliva, sputum or respiratory secretions when talking, sneezing, coughing and breathing heavily.

Table 2 Performance Requirements for Barrier Face Covering
(*Clauses* 8 *and* 9.1)

Sl No.	Characteristic	Requirement	Method of Tests
(1)	(2)	(3)	(4)
i)	Differential pressure, Pa/cm^2	≤ 60	Annex B
ii)	Particulate filtration efficiency (at 3.0 µm), percent	≥ 70	Annex C
iii)	Tie and attachment strength, N, *Min* (apply axial tensile force for 10 s)	The sample shall not break before Single use - 10 Multiple use -50	IS 1969 (Part 2)

❖ **IS 18266 : 2023, TEXTILES — MEDICAL RESPIRATOR — SPECIFICATION**

Workers, primarily those in the health care profession, involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health.

A medical respirator is a respiratory protective device designed to achieve a very close facial fit and covers at least the nose, mouth and may cover the chin. A respirator is worn by healthcare personnel (HCP) to reduce the wearer's risk of inhaling hazardous airborne particles such as dusts, fumes, vapors, infectious agents and aerosol/ fluids (for example splashes, sprays) for use in healthcare settings.

Table 1 Performance Requirements for Medical Respirator
(*Clause* 5.1)

Sl No.	Characteristic	Requirements		Method of Test, Ref to
		IN95	IN99	
(1)	(2)	(3)	(4)	(5)
i)	Breathing resistance Pa, *Max*			IS 17274 (Part 2)
	(Method 1: Static breathing resistance)			
	a) Inhalation (@30 lpm)	70	100	
	b) Inhalation (@95 lpm)	240	300	
	c) Exhalation (@160 lpm)	300	300	
ii)	Splash resistance, mmHg, *Min*	Pass at 120	Pass at 160	Annex B
iii)	Penetration of filter, percent, *Max*	5	1	IS 17274 (Part 3)
	Sodium chloride test method (Full exposure particle penetration test)			
iv)	Inward leakage, percent, *Max* (*see* Note 1)	11	5	IS 17274 (Part 1)
v)	CO_2 content, percent, *Max*	1	1	IS 17274 (Part 9)
vi)	Cleanliness-microbial (CFU/g)	< 30	< 30	ISO 11737 (Part 1)
vi)	Flammability (resistance to flame, single burner, dynamic test) as received, (optional) (*see* Note 2),	Pass	Pass	IS 17274 (Part 10)
vii)	Biocompatibility Evaluation (optional) (*see* Note 2)			
	a) Cytotoxicity	None	None	IS/ISO 10993-5
	b) Irritation and skin sensitization	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	IS/ISO 10993-10 and ISO 10993-23

This standard specifies the performance requirements and test methods of medical respirator intended to be worn by operating room personnel/staff during surgical procedures and other healthcare services such as patient care, with similar requirements. It specifies the important requirement like Breathing resistance, Splash resistance, Penetration of filter, Inward leakage, CO2 content, Cleanliness-microbial, Flammability, Biocompatibility Evaluation (Cytotoxicity, Irritation and skin Sensitization) etc.

IMPORTANT WORK AT INTERNATIONAL LEVEL

a) **ISO/TC 338 Menstrual Product**

ISO TC 338 on Menstrual product is newly established committee. There are 3 working groups (adhoc, working group, task group) in ISO TC/338 and in all the groups BIS (India) has leadership role and nominated experts from India.

- ❖ Smt. Tanya Mahajan, The Pad Project (NGO), India (Convenor) - Adhoc group to define terminology
- ❖ Shri S. Sivakumar, (Head, Medical Textiles), SITRA, Coimbatore (Convenor) - Working Group for General requirements
- ❖ Dr. E. Santhini, SITRA, Coimbatore, (Convenor), Task group for the development of ISO/TC 338 Strategic Business Plan

b) **New work item proposal for Guidelines for Reprocessing of Multiple-Use Healthcare Textilesunder consideration in ISO/TC 304 Healthcare Organization Management**

This document provides the general guidelines for re-processing of multiple-use healthcare textiles under hospital laundry whether in-house or outsourced laundry services. The re-processing guidelines are applicable to hospital laundry in the following areas: i) Hospitals – private, public and any extended healthcare facilities ii) Clinics iii) Dental Services iv) Nursing homes v) Mental health institutions vi) General healthcare centres etc.

c) Experts from India nominated in ISO/NP 20384, Surgical clothing and drapes — Requirements and test methods

This document gives information on the characteristics and performance requirements for surgical drapes, surgical gowns, and equipment covers used as medical devices for the purpose to create a sterile field, that are labelled with barrier performance claims and intended to minimize the transmission of infective agents between patients and clinical staff in health care facilities (e.g., single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment). This standard specifies the following concerning the manufacturing and processing of the products specified above: - test methods for evaluating the characteristics as identified in this document, - performance requirements for these products, - information to be supplied to users and third parties, for instance proper verifier authorities

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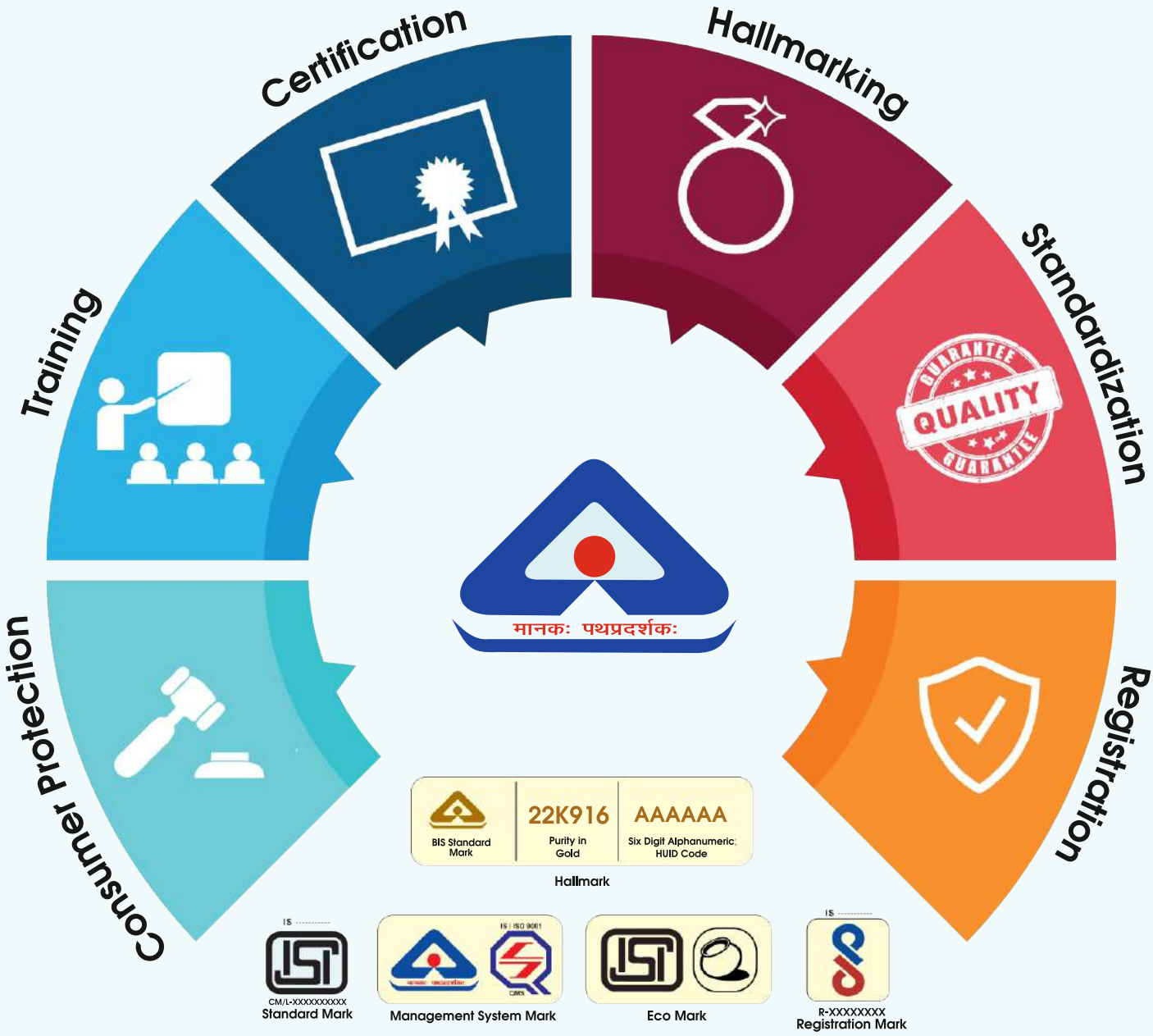

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