COMPENDIUM OF INDIAN STANDARDS ON

Medical Textiles for Menstrual and Personnel Hygiene Products

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INTRODUCTION

Menstrual and personal hygiene products play a vital role in promoting reproductive and overall health by preventing infections and ensuring cleanliness, especially during menstruation and in cases of incontinence/personnel hygiene. Access to safe, reliable hygiene solutions also supports social equity, reduces stigma, and enhances public health outcomes, particularly for women, adolescents, the elderly, and persons with disabilities.

This compendium provides the list of product standards and test methods, outlines the scope of the standard, variety/size covered in the standard for menstrual and personnel hygiene product; and serve as an informative tool for industries/stakeholders, regulators, public health authorities, and consumers for better decision-making and product awareness. The standardization in the field of menstrual and personnel hygiene application is undertaken by Technical Textiles for Medtech Application Sectional Committee, TXD 36 under Textiles Division Council.

1) LIST OF PRODUCT STANDARDS COVERED IN COMPENDIUM FOR MENSTRUAL AND PERSONNEL HYGIENE PRODUCTS

i) IS 5405 : 2025 Disposable Sanitary Napkin/Panty Liner/Maternity Pad/Period Panty — Specification (*third revision*)

This standard covers the requirements for disposable (non-reusable) sanitary napkin/ pantyliner/maternity pad/period panty for external use. On the basis on the size, the sanitary napkin has been classified in 4 types – Regular, Large, Extra-large, XXL and Panty liner has been classified in 3 types – Small, Regular, Large.

ii) IS 17514 : 2025 Reusable Sanitary Pad/Sanitary Napkin/Period Panties — Specification (*first revision*)

This standard covers the requirements for reusable (multiple-use) sanitary pad/sanitary napkin/period panties for external use. On the basis on the size, the sanitary napkin has been classified in 4 types – Small, Regular, Large, Extra-large.

iii) IS 17509 : 2021 Disposable Baby Diaper — Specification

This standard covers the requirements for disposable (non-reusable) baby diaper for external use. On the basis on the weight, the baby diaper is classified into 8 category - Premature baby, New born, Small, Medium, Large, X large, XX large and XXX large.

iv) IS 17787 : 2021 Medical Textiles — Nonwoven Wipes — Specification

This standard covers minimum performance requirements for single use nonwoven dry or wet wipes used for baby care and personal hygiene (baby, adult, facial, skin etc) excluding wipes impregnated with alcohol or claiming germicidal properties.

v) 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).

vi) IS 17508 : 2020 Disposable Adult Incontinence Diaper — Specification

This standard covers the requirements and test methods for disposable (non-reusable) adult incontinence diapers for external use. On the basis of dimension, the adult diaper is classified into four sizes - small, medium, large, extra-large.

vii) IS 17786 : 2022 Medical Textiles — Underpad — Specification

This standard specifies the requirement of underpads (single use or re-useable) used as top cover for bed, mattress or furniture to prevent soiling by bedridden patient suffering from incontinence

or any other condition resulting in leakage of body fluids. Underpad may also be used in operation theatres as spreadsheet or bedcover to prevent leakage of body fluids. On the basis of dimension, the underpad are classified into four sizes - small, medium, large, extra-large.

2) LIST OF TEST METHOD STANDARD FOR MENSTRUAL AND PERSONNEL HYGIENE PRODUCTS

i) IS 1390: 2022/ISO 3071 : 2020, Textiles — Determination of pH of aqueous extract (*third revision*)

This standard specifies a method for determining the pH of the aqueous extract of textiles. The method is applicable to textiles in any form (e.g. fibres, yarns, fabrics). The pH-value of an aqueous extract of a textile is measured electrometrically at room temperature by means of glass electrode.

ii) IS 4905 : 2015/ISO 24153 : 2009 Random sampling and randomization procedures (*first revision*)

This standard defines procedures for random sampling and randomization. This standard is applicable whenever a regulation, contract, or other standard requires random sampling or randomization to be used.

iii) IS 5887 (Part 2) : 1976, Methods for detection of bacteria responsible for food poisoning: Part 2 Isolation, identification and enumeration of Staphylococcus aureus and faecal Streptococci (*first revision*)

This standard (Part 2) prescribes method for isolation, identification and enumeration of staphylococcus aureus and faecal streptococci in foods.

iv) IS 9873 (Part 6) : 2021/ISO 8124- 6 : 2018, Safety of toys: Part 6 Determination of certain phthalate esters in toys and children's products (first revision)

This standard specifies a method for the determination of di-iso-butyl phthalate (DIBP), di-n-butyl phthalate (DBP), benzyl-butyl phthalate (BBP), bis-(2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DNOP), di-iso-nonyl phthalate (DINP) and di-iso-decyl phthalate (DIDP) in toys. This document applies to toys made of plastics, textiles, coatings and liquids.

v) IS 17932(Part 6) : 2023, Biological evaluation of medical devices: Tests for skin sensitization

This standard specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to induce skin sensitization. This document includes: —

details of in vivo skin sensitization test procedures; — key factors for the interpretation of the results.

vi) **IS 17932 (Part 7) : 2024, Biological evaluation of medical devices: Tests for irritation**

This standard specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation. This standard includes: — pre-test considerations for irritation, including in silico and in vitro methods for dermal exposure; — details of in vitro and in vivo irritation test procedures

vii) **IS/ISO 10993-5 : 2009, Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity**

This standard describes test methods to assess the in vitro cytotoxicity of medical devices. 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.

viii) **IS/ISO 10993-12 : 2021, Biological evaluation of medical devices Part 12 Sample preparation and reference materials**

This standard specifies requirements and gives guidance on the procedures in the preparation of samples and the selection of reference materials for medical device testing primarily in biological test systems primarily in accordance with one or more parts of the ISO 10993 series. Specifically, this document addresses — test sample selection; selection of representative portions from a medical device; test sample preparation; experimental controls; selection of, and requirements for, reference materials; preparation of extracts.

ix) **IS/ISO 11737-1 : 2018 Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products**

This standard specifies requirements and provides guidance on the enumeration and microbial characterization of the population of viable microorganisms on or in a health care product, component, raw material or package.

x) **IS/ISO 17088 : 2021, Compostable plastics — Specification (second revision)**

This standard specifies procedures and requirements for plastics, and products made from plastics, that are suitable for recovery through organic recycling a) disintegration during composting; b) ultimate aerobic biodegradation; c) no adverse effects of compost on terrestrial organisms; d) control of constituents. These four aspects are suitable to assess the effects on the industrial composting process. This document is intended to be used as the basis for systems of labelling and claims for compostable plastics materials and products.

xi) **IS/ISO 20743 : 2021, Textiles — Determination of antibacterial activity of textile**

products (*first revision*)

This document specifies quantitative test methods to determine the antibacterial activity of all antibacterial textile products including nonwovens. This document covers three inoculation methods for the determination of antibacterial activity: a) absorption method (an evaluation method in which the test bacterial suspension is inoculated directly onto specimens); b) transfer method (an evaluation method in which test bacteria are placed on an agar plate and transferred onto specimens); c) printing method (an evaluation method in which test bacteria are placed on a filter and printed onto specimens).

xi) **IS 16394 : 2015 Textiles — Woven shirting made of cotton, man-made fibres/filaments and their blend — Specification**

This standard specifies the requirements for woven shirting's made of cotton, man- made fibers/filaments and their blends. The Annex C of IS 16394 has been referred for determination of dimensional stability to washing for reusable cloth pad.

xi) **IS/ISO 105-C06 : 2010, Textiles — Tests for colour fastness: Part C06 Colour fastness to domestic and commercial laundering (*first revision*)**

This standard specifies methods intended for determining the resistance of the colour of textiles of all kinds and in all forms to domestic or commercial laundering procedures used for normal household articles using a reference detergent.

xii) **IS/ISO 105-E04 : 2013, Textiles — Tests for colour fastness: Part E04 Colour fastness to perspiration (*first revision*)**

This standard specifies a method for determining the resistance of the colour of textiles of all kinds and in all forms to the action of human perspiration.

xiii) **IS/ISO 105-X12 : 2016, Textiles — Tests for colour fastness: Part X12 Colour fastness to rubbing (*first revision*)**

This standard specifies a method for determining the resistance of the colour of textiles of all kinds, including textile floor coverings and other pile fabrics, to rubbing off and staining other materials. The method is applicable to textiles made from all kinds of fibres in the form of yarn or fabric, including textile floor coverings, whether dyed or printed. Two tests may be made, one with a dry rubbing cloth and one with a wet rubbing cloth.

xiv) **IS 6359: 2023 Method for conditioning of textiles (*first revision*)**

This standard prescribes a procedure for conditioning of all textile materials. Most of the textiles being hygroscopic in nature, the relative humidity and temperature of the atmosphere affect their physical and mechanical properties appreciably. In order that reliable comparisons was to be

made among different materials and products and among different laboratories, it is necessary to standardize the humidity and temperature conditions and the procedure by which the textile material may be brought to the moisture equilibrium before testing.

xv) IS 14648 : 2011, Microbiological examination of cosmetics and cosmetic raw materials — Methods of test (*second revision*)

This standard prescribes methods for determination of microbial content of cosmetics and cosmetic raw materials. This standard lays down widely applicable methods but does not restrict the use of other validated methods. Microbial limits for finished cosmetic products and guideline for the neutralizers to be used with different preservatives are also covered in the standard.

xvi) IS 667 : 1981 Methods for identification of textile fibres (*first revision*)

This standard prescribes methods of tests for identification of textile fibres (natural, man-made and regenerated fibre by microscopic, chemical dissolution, burning behaviours etc.

xvii) IS 15891 (Part 1) : 2024/ ISO 9073-1: 2023, Nonwovens — Methods of Test Part 1 Determination of Mass Per Unit Area (*first revision*)

This standard specifies a method for the determination of the mass per unit area of nonwoven fabrics. A precisely measured area of the nonwoven is weighed and the mass is divided by this area, leading to the measurement of the mass per unit area.

xviii) IS 15891 (Part 6) : 2012/ ISO 9073-6 : 2000, Textiles — Test methods for nonwovens: Part 6 Absorption

This standard describes methods for the evaluation of some aspects of the behaviour of nonwoven fabrics in the presence of liquids. In particular: the liquid absorbency time; the liquid absorptive capacity; the liquid wicking rate (capillarity).

xix) **IS 15891 (Part 18) : 2024 ISO 9073-18 : 2023, Nonwovens — Methods of Test Part 18 Determination of Tensile Strength and Elongation at Break Using the Grab Tensile Test (*first revision*)**

This standard specifies a test method for the determination of the breaking force of nonwovens using a grab method in conditioned or wet state. This standard specifies methods using constant rate of specimen extension (CRE) tensile testers. Constant rate of loading(CRL)

xx) ISO 11948-1 : 1996, Urine-absorbing aids — Part 1: Whole-product testing

This standard specifies a method for determining the absorption capacity of the absorbent core of body-worn urine-absorbing aids.