भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

Draft for comments only Doc No.: TXD 36 (26697)

व्यापक परिचालन मसौदा

वस्त्रादि — चिकित्सीय/सर्जिकल गाउन एवं चिकित्सीय सर्जिकल ड्रैप — विशिष्टि

(IS 17334 का *पहला पुनरीक्षण*)

Wide Circulation Draft

Textiles — Medical/Surgical Gowns and Medical/Surgical Drapes — Specification

(*First Revision* of IS 17334)

ICS 11.140; 59.080.01

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

last date for receipt of comments is 11 Dec 2024

FOREWORD

(Formal clauses will be added later)

Medical/surgical gowns and medical/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 medical/surgical gowns and medical/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. This standard defines testing and reporting performance requirements levels for surgical gowns and surgical drapes manufacturers in order to provide information to end users that can be used in making informed decisions in the selection and purchase of surgical gowns and surgical drapes according to the anticipated exposures.

This standard was originally published in 2019. The present revision has been made in the light of experience gained since its first adoption and to incorporate the following major changes:

i) Amendment has been incorporated in this standard.
ii) Title of the standard has been updated.
iii) The levels given in the standard for surgical gown and surgical drape have been updated.
iv) The requirement of patient gown and isolation gown have been specified.
v) The requirement for blood resistance, particle release, cleanliness– microbial, biocompatibility evaluation (cytotoxicity) have been updated.
vi) The requirement for viral resistance test has been updated for level 4 gown.
vii) The requirement of impact penetration test has been specified for level 2 and level 3 gown and drapes.
viii) The requirement of resistance to dry and wet bacterial penetration test have been updated for level 2 and level 3 gown and drape.
ix) The requirement of breathability test (water vapour transmission rate) has been modified.
x) The general guidelines/recommendations to use different levels of medical/surgical gown and medical/surgical drape have been updated.
xi) References to Indian Standard have been updated.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*).' The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1 SCOPE

1.1 This standard specifies requirements for single use and reusable medical/surgical gowns and medical/surgical drapes intended for medical use.

1.2 This standard is intended to be used primarily by manufacturers of medical/surgical gowns and medical/surgical drapes in qualifying, classifying, packaging, labelling, and sterilization of medical/surgical gowns and medical/surgical drapes, so that healthcare workers can make more informed decisions of selection of right medical/surgical gown and medical/surgical drape in accordance with the protection level and risk involved in the procedure.

1.3 This standard does not include universal procedure packs designed for specific procedures, however, contents of customized procedure packs shall be manufactured in accordance with this standard.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated are valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms shall apply:

3.1 Barrier Properties — Ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne microorganisms at different state (*see* **3.9** and **3.24**).

3.2 Biocompatibility — The ability to be in contact with a living system without producing an adverse effect.

3.3 Blood-borne Pathogen — Infectious microorganisms including virus carried in blood or other body fluids.

3.4 Body Fluids — Any liquid produced (secreted/ excreted) by body.

3.5 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.

3.6 Cleanliness–microbial — Freedom from population of viable microorganism on a product and/ or a package.

3.7 Cleanliness–particulate Matter — Freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact.

3.8 Critical Product Area — Product area with a greater probability to be involved in the transfer of infective agents to or from the wound, for example, front and sleeves of medical/surgical gowns.

3.9 Dry Microbial Penetration — Migration of microorganisms through a barrier material in dry state.

3.10 Infective Agent — Microorganism that has been shown to potentially cause infections.

3.11 Invasive Surgical Procedure — Surgical procedure penetrating skin or mucosa

3.12 Less Critical Product Area — Product area where direct contact with blood, body fluids, and other potentially infectious materials (OPIMs) is less likely to occur.

3.13 Liquid Penetration — Migration of liquid(s) through the material.

3.14 Manufacturer — Means processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use. The term “manufacturer” shall be construed accordingly.

3.15 Microbial Penetration — Migration of microorganisms, from one side of the material through the other.

3.16 Particle Release — Particle release from fiber fragments and other particles during mechanical stress.

3.17 Performance Level — Discrete standard defined to classify products according to the performance requirements of this standard.

3.18 Reusable Product — Product intended by the manufacturer to be reprocessed and reused.

3.19 Single-use Product — Product intended by the manufacturer to be used only once.

3.20 Sterile Field — An area created by placing sterile surgical drapes around the patient's surgical site and on the stand that will hold sterile instruments and other items needed during surgery.

3.21 Medical/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.

3.22 Medical/Surgical Drape — A covering for the patient for the prevention of transfer of infective agents, such as microorganisms, body fluids and particulate material. Medical/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.

3.23 Synthetic Blood — Mixture of red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and other body fluids and the colour of blood.

3.24 Wet Microbial Penetration — Migration of microorganisms through a barrier material in wet state.

4 WORKMANSHIP AND FINISH

4.1 A manufacturing and processing specification shall be designed and validated for the product, including visual and hygienic cleanliness. The validation shall include all steps involved in manufacturing and processing.

4.2 The key manufacturing and processing variables shall be identified, monitored and recorded. The type and frequency of routine monitoring shall be documented.

4.3 During manufacturing and processing, the control of decontamination, disinfection procedures and the traceability of sterilization shall be maintained.

'NOTE — The requirements given in 4.1 to 4.3 are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.'

5 GENERAL REQUIREMENTS

5.1 The size of medical/surgical gown and medical/surgical drape shall be as per agreement between the buyer and the seller. The size of gown shall be designated based on the measurement of height and chest. In case of elastic cuff/waist, it should have proper fit and should be adhered with glue to minimize risk of exposure.

5.1.1 Product (s) shall meet all the requirements specified in this standard throughout their useful life. If the manufacturer does not specify critical and/or noncritical area of a product, the product shall meet at least level "1" performance requirements as given in Table 1 and Table 2.

5.2 Manufacturing and Processing Requirements and Documentation

5.2.1 The manufacturer shall establish a formal quality management system including requirements for the product development, design, production, testing, packaging, labeling, distribution and provision of related services as per medical device rules, 2017 for medical/surgical gown and medical/surgical drape. The quality management system shall include a risk management procedure where inputs for product realization shall include the outputs from risk management.

5.2.2 For reusable products, processing and lifecycle control shall be included in the quality management system. The requirements specified in this standard shall be met and documented that the fitness for the intended purpose has been established for each use, both for single-use and reusable medical/surgical gowns and medical/surgical drapes.

5.2.3 Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per IS 18637 Part 1)), sterilization (as per IS/ISO 11135), packaging [as per IS/ISO 11607 (Part 1 and Part 2)], validation [as per IS/ISO 11137 (Part 1 and 2), ISO 11138-t 7] and residual sterility (IS/ISO 10993-7) shall be maintained by the manufacture.

'NOTE — The requirements given are for guidance of the manufacturer. Reference may also be made to the Medical Devices Rules 2017.'

5.3 Barrier Properties

The final performance requirement level shall be based on the performance of the critical zone component. The classification of the product shall indicate the performance of the critical zone component having the lowest barrier performance. The information for principle of critical area for guidance has been given in Annex B.

The performance of seams between and within critical zones shall meet the requirements of this standard. The performance of seams between critical and less critical zones shall meet at least the requirements of the adjacent less critical zone. Non-critical areas of the medical/surgical gowns and medical/surgical drapes can have one level less as compared to the standard earmarked for the medical/surgical gowns and medical/surgical drapes.

The performance requirements of reusable products shall have to be met after declared wash cycle.

6 PERFORMANCE REQUIREMENTS

6.1 The manufacturer shall ensure the maintenance of required performance level after sterilization of the material and testing shall be performed on the finished product. If the product is intended to be used after sterilization, testing shall be carried out on products after sterilization with the exception of microbial cleanliness.

Test specimens shall be taken from different products of the same lot. If multiple tests are to be performed (for example, the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same product.

If the test area of the finished product is too small to perform the test, a representative sample of the same material may be used. The representative sample shall be treated in the same way as the finished product.

During manufacture and processing, testing shall be carried out within a formal quality system.

6.2 Medical/surgical gowns and medical/surgical drapes shall conform to the requirements specified when tested according to the method given in Table 1 and Table 2 respectively.

6.3 The general guidelines/recommendations to use different levels of medical/surgical gown and medical/surgical drape for healthcare application and surgeries in hospitals have been given in Table 3.

Table 1 Performance Requirements for Medical/Surgical Gowns

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

Sl No.	**Characteristics**	**Requirement**				**Method of Test,**
		Level 1	Level 2	Level 3	Level 4	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	≤ 4.5	≤ 1.0	≤ 1.0	NA	IS 17375
ii)	Hydrostatic resistance (cmwc) the rate of rising at 60 cmWc/min	NA	≥ 20	≥ 50	NA	IS 391
iii)	Blood resistance, pressure cycle upto 14 kPa, procedure D	NA	NA	NA	Pass	IS 16546
iv)	Viral resistance, pressure cycle upto	NA	NA	NA	Pass	IS 16545

	14 kPa, procedure D					
v)	Particle release [log10 (lint count)] Particle size from 3.0 to 25.0 Microns	≤ 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 cm^2) (for unsterile gown)	≤ 300	≤ 300	≤ 300	≤ 300	IS/ISO 11737-1
ix)	Resistance to microbial penetration — Dry (CFU) *(*see* Note)	NA	≤ 300 (for less critical zones)	≤ 300 (for less critical zones)	NA	IS 16548
x)	Resistance to microbial penetration — Wet (I_B)	NA	≥ 2.8 (for critical zones)	≥ 2.8 (for critical zones))	NA	IS 16549
xi)	Biocompatibility Evaluation Test **(*see* Note)					
	a) Cytotoxicity	non-cytotoxic	non-cytotoxic	non-cytotoxic	non-cytotoxic	IS/ISO 10993 Part 5 IS/ISO 10993 Part 12
	b) Irritation	Non-irritant	Non-irritant	Non-irritant	Non-irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitiz er	Non - sensitiz er	Non - sensitize r	Non - sensitiz er	IS 17932 (Part 6)
xii)	Breathability test (water vapour transmission rate), [g/m^2/day, *Max*]	NA	NA	NA	800	Annex F of IS 16390
NA- Not Applicable						

NOTES –

1) Challenge concentration 108 CFU/g talcum and 30 min vibration time.
2) 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.
3) If agreed by the buyer and seller, the gown used for patient shall confirm level 1 of table 1. In Isolation gowns the critical area is the entire gown including the back and the joints.
4) In case of gown for level 4 when a sample fails in blood resistance test, viral tests shall not be carried out and the sample shall be reported as non- compliance/failure to the standard.

Table 2 Performance Requirements for Medical/Surgical Drapes

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

Sl No.	**Characteristics**	**Requirement**				**Method of Test,**
		Level 1	Level 2	Level 3	Level 4	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	≤ 4.5	≤ 1.0	≤ 1.0	NA	IS 17375
ii)	Hydrostatic resistance (cmwc), the rate of rising at 60 cmWc/min	NA	≥ 20	≥ 50	NA	IS 391
iii)	Blood resistance pressure cycle upto 14 kPa, procedure D	NA	NA	NA	Pass	IS 16546
iv)	Particle release [log10 (lint count)], Particle size from 3.0 to 25.0 Microns	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
v)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)

vi)	Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
vii)	Cleanliness– microbial (CFU/100 cm^2) (for unsterile drape)	≤ 300	≤ 300	≤ 300	≤ 300	IS/ISO 11737-1
viii)	Resistance to microbial penetration — Dry (CFU)	NA	≤ 300 (for less critical zones)	≤ 300 (for less critical zones)	NA	IS 16548
ix)	Resistance to microbial penetration — Wet (I_B)	NA	NA	≥ 2.8 (for critical zones))	NA	IS 16549
x)	Biocompatibility evaluation * (*see* Note)					
	a) Cytotoxicity	non-cytotoxic	non-cytotoxic	non-cytotoxic	non-cytotoxic	IS/ISO 10993 Part 5 IS/ISO 10993 Part 12
	b) Irritation	Non-irritant	Non-irritant	Non-irritant	Non-irritant	IS 17932 (Part 7)
	c) Skin sensitization	Non - sensitizer	Non - sensitizer	Non - sensitizer	Non - sensitizer	IS 17932 (Part 6)

NA- Not Applicable

NOTES –

1) Challenge concentration 108 CFU/g talcum and 30 min vibration time.
2) 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.

Table 3 General Recommendations for Use of Different Levels of Medical/Surgical Gowns and Medical/Surgical Drapes
(For guidance only)

(*Clause* **6.3**)

Sl No.	**Performance Level**	**Anticipated risk of exposure**	**Examples of Procedures with Anticipated Exposure Risks**
(1)	(2)	(3)	(4)
i)	Level 1	Minimal risk to the patient independent of anesthesia Minimally invasive procedures with little or no body fluid loss Often done in an office setting with the operating room principally for anesthesia and monitoring	Simple excisional biopsies Excision of "lumps and bumps" Ophthalmological procedures Simple ear, nose and throat (ENT) procedures
ii)	Level 2	Minimal to moderately invasive procedure Mild body fluid loss Mild risk to patient independent of anesthesia	Tonsillectomies adenoidectomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery Interventional radiology or catheter lab procedures
iii)	Level 3	Moderate to significantly invasive procedure Moderate body fluid loss Moderate risk to patient independent of anesthesia	Mastectomies Arthroscopic orthopedic procedures Endoscopic urological procedures (for example, transurethral prostate resections) Open gastrointestinal and genito-urinary procedures
iv)	Level 4	Highly invasive procedure High body fluid loss	Any procedure in which the surgeon's hands and arms are in a body cavity Orthopedic procedures without a tourniquet Open cardiovascular or thoracic procedures

		Major/critical risk to patient independent of anesthesia Usual post-operative ICU stay with invasive monitoring	Trauma procedures Caesarean sections

7 MARKING

7.1 Each pack of medical/surgical gown and medical/surgical drape shall be legibly and indelibly marked with following information :-

a) Name of the product;

b) Dimension /size of the product;

c) Manufacturer's name, initials or trade-mark, if any;

d) Month and year of manufacture, batch /lot number;

e) Sterilized or un-sterilized (or) it can be sterile or unsterile;

f) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;

g) An indication that the device has been specified by the manufacturer for single-use only;

h) If the product is multiple use, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where products are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with "the essential principles of safety and performance of medical devices";

j) Performance level; and

k) Any other statutory requirement as required by the law in force or as per Medical Device Rules 2017.

Each product or package, containing medical/surgical gowns, medical/surgical drapes, having a critical area shall be prominently labeled identifying the areas with different performance levels and the performance level of the relevant area(s).

Labelling and marking requirements shall be followed as per Medical Device Rules, 2017.

7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

All the medical/surgical gowns or medical/surgical drapes of the same material and dimensions produced under similar conditions of manufacture and sterilization shall constitute a lot.

8.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

NOTES

1 For level 1, 2, 3 and 4 medical/surgical gowns, the conformance of the performance requirements as given in Table 1 may be accepted at fabric stage (except cleanliness microbial, resistance to blood and resistance to viral) for a product if desired by buyer/ user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

2 Similarly, for level 1, 2, 3 and 4 medical/surgical drapes, the conformance of the performance requirements as given in Table 2 may be accepted at fabric stage (except cleanliness microbial and resistance to blood) for a product if desired by buyer/user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

8.1.2 The number of medical/surgical gowns or medical/surgical drapes to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 2 and 4 of Table 4.

8.1.3 These medical/surgical gowns and medical/surgical drapes shall be selected at random from the lot as per procedure given in IS 4905.

8.2 Number of Tests and Criteria for Conformity.

8.2.1 All the gowns/drapes as per column 2 of Table 4 shall be examined for workmanship and finish (**4.1** to **4.3**).

8.2.1.1 Any gowns/drapes failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 3 of Table 4. Otherwise, the lot shall be rejected.

Table 4 Number of Gown/Drape to be selected
(*Clauses* **8.1.2, 8.2.1, 8.2.1.1, 8.2.2** and **8.2.3)**

Sl No.	Lot Size	Non-destructive Testing		Destructive Testing	
		No. of Gown/Drape to be Selected	Acceptance Number	No. of Gown/Drape to be Selected	Acceptance Number
	N	N	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 50	5	0	2	0
ii)	51 to 150	8	0	3	0
iii)	151 to 280	13	1	3	0
iv)	281 to 500	20	2	3	0
v)	501 to 1 200	32	3	5	0
vi)	1 201 to 3 200	50	5	5	0
vii)	3 201 and above	80	7	5	0

NOTE—The sampling plan given in table 4 is for guidance of manufacturer/user. The other sampling plan may also be followed if agreed between buyer and seller or as per manufacturers quality assurance plans.

8.2.2 Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 4 of Table 4 shall be taken. This sub-sample shall be further tested for the remaining requirements as given in Table 1 and Table 2.

8.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective gowns/drapes found in the sample (as per **8.2.2**) is less than or equal to the acceptance number as given in column 5 of Table 4.

9 EDUCATION

The manufacturer may provide technical information and/or training explaining the performance level classification system and its implications for the end user. Thereafter, the end-user is responsible for making judicious selections of products according to:

a) the performance level of the product, and

b) the anticipated degree of exposure of health care personnel to blood, body fluids, and OPIM during a given procedure or activity.

'NOTE — The requirements given are for guidance of the manufacturer and user.'

9.1 Information on Critical and Less Critical Areas

The manufacturer shall differentiate between the critical and less critical areas of the product, if applicable, and identify the different areas.

10 PACKAGING AND STERILIZATION

For packaging of the products, requirements as per IS/ ISO 11607-1 and 2 shall be followed.

For packaging and sterilization, the Medical Device Rule, 2017 shall be followed.

Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137 -1 and 2, ISO 11138-7 and, IS/ISO 10993-7 standards.

ANNEX A

(*Clause* **2**)

LIST OF REFERRED STANDARDS

IS/Other Publication	*Title*
IS 391: 2020/ISO 811: 2018	Textile fabrics — Determination of resistance to water penetration — Hydrostatic pressure test (second *revision*)
IS 1966 (Part 1): 2022 /ISO 13938-1: 2019	Textiles — Bursting properties of fabrics Part 1 Hydraulic method for determination of bursting strength and bursting distension (*third revision*)
IS 1969 (Part 1): 2018 /ISO 13934-1: 2013	Textiles — Tensile properties of fabrics: Part 1 Determination of maximum force and elongation at maximum force using the strip method (*fourth revision*)
IS 4905: 2015/ISO 24153: 2009	Random sampling and randomization procedures (*first revision*)
IS 15891 (Part 3) : 2024/ ISO 9073-3 : 2023	Nonwovens — Methods of test Part 3 Determination of tensile strength and elongation at break using the strip method (*first revision*)
IS 15891 (Part 10): 2017/ISO 9073-10: 2003	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state
IS 16390: 2015	Agro textiles — Nylon knitted seamless gloves for tobacco harvesters — Specification
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

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
IS 16548: 2016/ISO 22612: 2005	Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration
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*)
IS 17375: 2020/ISO 18695 :2007	Textiles — Determination of resistance to water penetration — Impact penetration test
IS 17932 (Part 6): 2023	Biological evaluation of medical devices Part 6 Tests for skin sensitization
17932 (Part 7): 2024	Biological evaluation of medical devices Part 7 Tests for irritation
IS 18637 (Part 1) : 2024	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
IS 18469 (Part 7): 2023 /ISO 11138-7: 2019	Sterilization of health care products — Biological indicators Part 7 Guidance for the selection use and interpretation of results
IS/ISO 10993-5: 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-12 : 2021	Biological evaluation of medical devices Part 12 Sample preparation and reference materials
IS/ISO 10993-7 : 2018	Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals
IS/ISO 11137-1 : 2006	Sterilization of health care products — Radiation: Part 1 requirements for development, validation and routine control of a sterilization process for medical devices
IS/ISO 11137-2 : 2013	Sterilization of health care products — Radiation: Part 2 establishing the sterilization dose

IS/ISO 11135 : 2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
IS/ISO 11607-1: 2019	Packaging for terminally sterilized medical devices Part 1 Requirements for materials, sterile barrier systems and packaging systems (*first revision*)
IS/ISO 11607-2: 2019	Packaging for terminally sterilized medical devices Part 2 Validation requirements for forming, sealing and assembly processes (*first revision*)
IS/ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 14698-1: 2003	Cleanrooms and associated controlled environments — Bio contamination control — Part 1: General principles and methods

ANNEX B
(*Clause* **5.3**)

B-1 PRINCIPLES OF THE CRITICAL ZONE

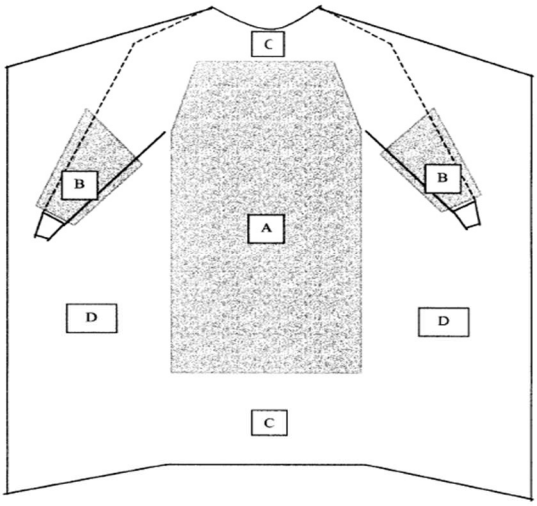
The critical zone can be described as an area approximately 12 inches around the fenestration of a drape where it is thought that reinforcement is needed to resist the penetration and strike through of fluids. Additionally, the critical zone (see Fig. 1) on medical/surgical gown encompasses the front area from mid-chest to waist and the sleeves to 2 inches above the elbows.

However, there are two important factors as related to the critical zone. Fluid is often not always contained in the proximity of the critical zone. For example, during an arthroscopic procedure a large amount of fluid can be used during the procedure and is not contained within the critical zone of the arthroscopic drape.

Specialty drapes, such as extremity drapes, may have a reinforced critical zone (*see* Fig. 2). However, due to the amount of fluids that may be encountered and/or manipulation of the body parts the surgical team should consider draping reinforcement of the areas outside of the critical zone. For example, during a hip arthroplasty, the leg is placed through several maneuvers to initially dislocate the joint, facilitate bone excision and placement of the prostheses, put the joint back into place, and further maneuvers to test the prostheses prior to closing the surgical wound. This calls for draping reinforcement of the entire leg and foot in order to prevent an SSI.

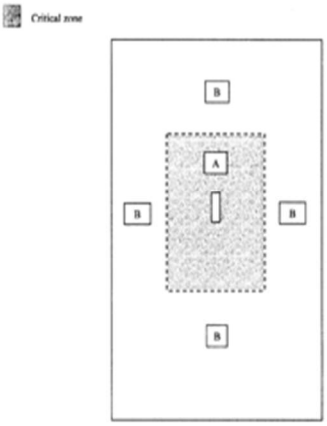
In this situation, it may be considered that the critical zone should be further expanded outside of the manufacturers region of reinforcement around the fenestration, thus further suggesting that the critical zone is a fluctuating zone that dependent on the procedure to be performed.

The final performance requirement level of the product shall be based on the performance of the critical zone component.



A and B - Critical zone
C and D - Less critical zone

FIG. 1 MEDICAL/SURGICAL GOWN



A - Critical zone
B - Less critical zone

FIG. 2 MEDICAL/SURGICAL DRAPE