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Indian Standard

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जैव-रक्षात्मक कवरआल — विशिष्टि

(पहला पुनरीक्षण)

Medical Textiles — Bio-Protective Coveralls — Specification

(First Revision)

ICS 11.040.30; 59.080.99

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

This standard was first published in June 2020 as an interim standard. The first revision has been made in the light of experience gained since its publication and to incorporate the following major changes:

a) Title of the standard has been modified. The scope has been modified to cover the requirement of multiple/reusable bio-protective coverall.

b) Terms and definitions, and manufacture clause have been modified.

c) Requirement of resistance to penetration by blood borne pathogens (resistance to viral penetration), breathability (water vapour transmission rate), tensile strength (dry and wet), seam strength (dry and wet), cleanliness – microbial, resistance to dry microbial penetration and biocompatibility have been specified.

d) Four level of performances of coveralls have been specified.

e) Guidelines for reprocessing, storage, handing, transportation, washing, disinfection of multiple use/reusable coveralls has been specified.

f) Packaging and marking clause have been modified.

g) References to Indian Standards have been updated.

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.

The composition of the Committee responsible for the formulation of this standard is given in Annex C.

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 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — BIO-PROTECTIVE COVERALLS — SPECIFICATION

(First Revision)

1 SCOPE

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

1.2 The bio-protective coveralls conforming to this standard may be supplied in sterile as well as unsterile condition, as per the agreement between the buyer and the seller.

1.3 This standard does not address the overall construction and components, or interfaces of garments or other factors during actual use which can affect the overall protection offered by coverall.

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 were 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 indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purpose 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* **3.8**).

3.2 Bio-protective Coverall — Bio-protective 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.

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

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

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

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

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

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

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

3.10 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

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

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

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

3.14 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.

4 MANUFACTURE

4.1 The bio-protective coveralls shall be made from suitable material that is not prohibited for use for the purpose under any applicable law/regulation in force so that the product made out of this meets the requirements specified in this standard.

4.1.1 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.

NOTE — The material used for manufacturing coveralls shall not cause irritation to the user.

4.2 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. In case of elastic waist, it shall be adhered with glue to minimize the potential entry points.

4.3 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.

4.4 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 specified in Table 1. The design of the coverall shall be as per the agreement between the buyer and the seller.

4.5 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.

4.6 The coverall shall be manufactured with light colours only, as it is easy to detect possible contamination on light colours.

NOTE — Coveralls shall not be manufactured with black, dark and culturally unacceptable colours.

4.7 The size of coverall shall be as per agreement between the buyer and the seller. The size shall be designated based on the measurement of height and chest.

5 REQUIREMENTS

5.1 Workmanship and Finish

The bio-protective coveralls shall be clean and free from substances liable to cause tendering during storage. The manufacture and preparation of the coverall shall be conducted under proper hygienic conditions.

5.2 Performance Requirements

The bio-protective coveralls shall conform to the requirements as specified in Table 1.

5.3 The fabric and seam used in the manufacture of shoe cover for coverall shall also conform to the requirements as specified in Table 1.

NOTE — If the fabric used in the manufacture of shoe cover is same as that of coverall then only the seam performance shall be tested as given in Table 1.

5.4 The regulators/user should decide the levels as given in Table 2 to be selected based on anticipated risk from infectious agents, pathogens, microorganism, distance and duration of contact with infectious agents/pathogens/microorganism, barrier protection and performance requirement as given in Table 1.

5.5 The manufacturer shall declare the number of cycles for reusability/multiple use of coveralls based on authentic documentation and validation of the coveralls. The performance requirements of reusable/multiple use products shall meet after every cycle of sterilization/disinfection as given in Table 1. The probable procedures (only for guidance) for reprocessing, storage, handing, transportation, washing, disinfection of multiple use/reusable coveralls has been given in Annex B.

5.6 The shelf life of the bio-protective coverall shall be 2 years minimum. The storage of the coveralls shall be done in a temperature between 2 °C to 30 °C.

6 PACKAGING AND STERILIZATION

6.1 The coverall shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed between the buyer and the seller. Packaging of the product shall be, such as to maintain the integrity of the product.

6.2 For packaging of the products, requirements as per IS/ISO 11607-1 and 2; and Medical Device Rule, 2017 shall be followed.

6.3 For 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, IS/ISO 10993-7 and ISO 17665-1 standards.

7 MARKING

7.1 Each pack of the coverall 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 trademark, if any;
d) Month and year of manufacture, batch/lot number;
e) No. of coveralls in a package;
f) Sterilized or un-sterilized;
g) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;
h) An indication that the product has been specified by the manufacturer for single-use only;
j) Declared life cycle/maximum wash cycle, if the product is multiple/reusable;

Table 1 Requirements for Bio-protective Coveralls

(*Clauses* 4.4, 5.2, 5.3, 5.4, 5.5 *and* 7.1)

Sl No.	Characteristics	Requirements				Method of test, Ref to
		Level 1	Level 2	Level 3	Level 4	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Resistance to penetration by blood and body fluids (synthetic blood penetration resistance), procedure d (*see* note 1)	Pass (for pressure cycle up to 1.75 kPa)	Pass (for pressure cycle up to 3.5 kPa)	Pass (for pressure cycle up to 7 kPa)	Pass (for pressure cycle up to 14 kPa)	IS 16546
ii)	Resistance to penetration by blood borne pathognes (resistance to viral penetration), procedure d (*see* note 1)	–	–	Pass (for pressure cycle up to 3.5 kPa)	Pass (for pressure cycle up to 7 kPa)	IS 16545
iii)	Breathability (water vapour transmission rate), g/m^2/day, *Max*	1200	1200	800	800	Annex F of IS 16390
iv)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 40	≥ 40	Nonwoven: IS 15891 (Part 3), Woven : 1969 (Part 1)
v)	Seam strength (dry and wet) (N) (*see* note 2)	≥ 20	≥ 20	≥ 32	≥ 32	Nonwoven: IS 15891 (Part18), Woven: IS/ISO 13935 (Part 1)
vi)	Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
vii)	Cleanliness-microbial (CFU/100 cm^2)	< 300	< 300	< 300	< 300	ISO 11737 (Part 1)
viii)	Resistance to dry microbial penetration ,(log cfu) (At challenge concentration 10^8 CFU/g talcum and 30 min vibration time)	–	–	< 1	< 1	IS 16548
ix)	Biocompatibility evaluation (*see* Note 3)					
	Cytotoxicity	None	None	None	None	IS/ISO 10993-5
	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

NOTES

1 The tests of synthetic blood penetration resistance and resistance to viral penetration shall also be carried out on samples, covering the seam, in order to test the seam performance. Take at least 2 specimens from critical/cross or double seam curvatures.

2 For determination of seam strength, the seam shall be in the centre of the test sample. The seam strength shall be tested in sample as received with tape.

3 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 the product.

k) 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 including compliance to all the requirements of this specification and Table 1 at every point of use and methodology of certification before every use ";

m) Performance level;

n) Shelf life and storage condition; and

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

Table 2 Use of Different Levels of Bio Protective Coverall

(*Clause* 5.4)

Sl No.	Performance Level	Anticipated Exposure of Risks
(1)	(2)	(3)
i)	Level 1	Low
ii)	Level 2	Medium
iii)	Level 3	High
iv)	Level 4	Very high

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 product(s) may be marked with the Standard Mark.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

The quantity of the coveralls of same material and performance level delivered to the buyer against one dispatch note shall constitute a lot.

8.2 The conformity of the lot to the various requirements specified in the standard shall be determined on the basis of tests carried out on the sample selected from the lot.

8.3 Unless otherwise agreed, the number of pieces selected at random for inspection shall be in accordance with Table 3.

8.3.1 For selection of samples at random from the lot, procedure given in IS 4905 may be followed.

8.4 Number of Samples and Criteria for Conformity

It shall be as follows:

Sl No.	*Characteristics*	*Number of Samples*	*Criteria for Conformity*
(1)	(2)	(3)	(4)
i)	Manufacture, workmanship and finish	According to column 3 of Table 3	Number of non-conforming pieces shall not exceed the corresponding number given in column 4 of Table 3
ii)	**5.3, 5.5** and all other requirements as specified in Table 1	According to column 5 of Table 3	Number of non-conforming pieces shall not exceed the corresponding number given in column 6 of Table 3

Table 3 Sample Size and Permissible Number of Non-Conforming Coveralls

(*Clauses* 8.3 *and* 8.4)

Sl No.	Lot Size	Sample Size	Permissible Number of Non-Conforming Coveralls	Sub Sample Size	Permissible Number of Non-Conforming Coveralls for Sub Sample
(1)	(2)	(3)	(4)	(5)	(6)
(i)	Up to 50	5	0	3	0
(ii)	51 to 150	8	1	5	0
(iii)	151 to 280	13	1	8	0
(iv)	281 to 500	20	2	8	0
(v)	501 to 1200	32	3	13	0
(vi)	1201 to 3200	50	5	13	0
(vii)	3201 to 10000	80	7	20	1
(viii)	10001 to 35000	125	10	20	1
(ix)	35001 to 150000	200	14	32	1
(x)	150001 to 500000	315	21	32	1
(xi)	500001 and above	500	21	50	2

ANNEX A

(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
1966 (Part 1) : 2009/ ISO 13938-1 : 1999	Textiles — Bursting properties of fabrics — Determination of bursting strength and bursting distension: Part 1 Hydraulic method (*second revision*)
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*)
4905 : 2015/ ISO 24153 : 2009	Random sampling and randomization procedures (*first revision*)
15891 (Part 3) : 2011/ISO 9073-3 : 1989	Textiles — Test methods for nonwovens: Part 3 Determination of tensile strength and elongation
15891(Part 18) : 2017/ISO 9073-18 : 2007	Textiles — Test methods for nonwovens: Part 18 Determination of breaking strength and elongation of nonwoven materials using the grab tensile test
16390 : 2015	Agro textiles — Nylon knitted seamless gloves for tobacco harvesters — Specification
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
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/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
IS/ISO 10993-7 : 2008	Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals
IS/ISO 10993-10 : 2010	Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization
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 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 11607-1 : 2006	Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems
IS/ISO 11607-2 : 2006	Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes
IS/ISO 13935-1 : 2014	Textiles — Seam tensile properties of fabrics and made-up textile articles: Part 1 Determination of maximum force to seam rupture using the strip method (*first revision*)

IS No.	*Title*	*IS No.*	*Title*
ISO 11138-7 : 2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results	ISO 14698-1 : 2003	Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods
ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	ISO 17665-1 : 2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 14644-1 : 2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration		

ANNEX B

(*Clause* 5.5)

GUIDELINES FOR REPROCESSING AND DISINFECTION OF BIO-PROTECTIVE COVERALLS (ONLY FOR GUIDANCE)

a) This document is only for guidance, the onus of selection of the applicable process/procedure, claims and its validation are solely the responsibility of the manufacturer/industry/supplier suiting to their respective product for reprocessing (storage, handing, transportation, washing, disinfection) of multiple use/reusable coveralls.

b) The manufacturer shall decide the suitable and effective reprocessing and disinfection method depending upon type of raw material, manufacturing process, design, anticipated risk, type of coating etc.

c) The manufacturer shall establish, document, implement and maintain a formal quality management system, which includes risk management and maintain its effectiveness. This quality management system shall include requirements throughout product realization, including development, design, manufacture, testing, packaging, labelling, distribution, processing and life-cycle control.

d) Microbiological monitoring (as per ISO 14698-1) and air monitoring of clean room (as per ISO 14644-1) shall be maintained by the manufacture.

e) The 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 shall be provided by the manufacturer.

f) The manufacturer shall follow all the applicable statutory guidelines including the medical device rules, the essential principles of safety and performance of medical devices or other rules published from time to time for coveralls.

g) For reprocessing and disinfection the seller is required to select and recommend a suitable method/technology for their product. one of the following methods or their combinations as suggested by the seller (complete and detailed protocol for reprocessing ,disinfection and quality control has to be prepared by seller/designer) based on the scientific experimentations, specific to their product and agreed by the buyer may be used:

1) Washing with detergent;
2) Sodium hypochlorite and/or soap solution;
3) Ultraviolet (UV) irradiation;
4) Gamma and electron beam irradiation;
5) Ethylene oxide sterilization;
6) Vapourised hydrogen peroxide or hydrogen peroxide gas plasma sterilization; and
7) Steam (autoclaving).

h) The manufacturer shall maintain the data for the adequacy of the disinfection method, testing of performance requirement after each cycle, usage life estimation/maximum cycle, validation of the disinfection process and certification. This technical and validated data shall be provided to the user or regulator as and when required.

j) The manufacturer shall check the performance requirement of coveralls randomly after each cycle and validate the process for conformity of the product. The technical data shall be maintained by the manufacturers for each cycle in such cases.

k) All the coveralls of the same material, dimensions, produced under similar conditions of manufacture and disinfection shall constitute a lot.

m) At least 5 percent random sample of the lot to be tested after final cycle declared for all the test specified in the standard including parameter as mentioned in Table 1.

n) The manufacturer shall do self-assessment for no. of cycles for multiple/reuse and declare 50 percent as the maximum cycle for multiple/reuse.

p) The user may check coveralls randomly from a lot for conformity of the quality of the product.

q) The manufacturer shall provide technical information and/or training explaining reprocessing process, disinfection method and its implications for the end-user.

r) The user shall follow all the instruction and guidelines provided by the manufacturer however the final responsibility for product compliance shall lie with the manufacturer.

s) The user shall assess capacity for onsite decontamination and storage of treated coveralls. For offsite decontamination, healthcare facilities may need to plan for transport of hazardous materials.

ANNEX C

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

Organization	*Representative(s)*
The South India Textile Research Association, Coimbatore	Dr Prakash Vasudevan (***Chairman***)
3 M India Limited, New Delhi	Shri Kulveen Singh Bali Shrimati Prabha Hegde (*Alternate*)
Association of Indian Medical Devices (AiMeD), New Delhi	Dr G. D. Agarwal Shri Jitendra Sachchade (*Alternate*)
All Indian Institute of Medical Sciences, New Delhi	Dr Vijaydeep Siddharth Dr Anoop Daga (*Alternate*)
Business Coordination House, New Delhi	Shri Sameer Gupta Shrimati Ritika Gupta (*Alternate*)
Cologenesis Healthcare Pvt Ltd, Salem	Shri R. Krishnakumar Shri K. Ramprasad (*Alternate*)
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DGQA (Ministry of Defence), New Delhi	Shri Senthil Kumar Shri Arnab Das (*Alternate*)
Director General of Health Services, New Delhi	Dr Inder Prakash Dr Sunny Swarnkar (*Alternate*)
M/s Dispoline India Private Limited, Bengaluru	Shri Sumit Marwah.
Dr Sabharwals Manufacturing Labs Pvt Ltd, Panchkula	Shri Manish Sabharwal Shri Dhruv Sabharwal (*Alternate*)
Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr Sanjiiv Rehlan Ms Tulsi (*Alternate*)
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Livinguard Technologies Pvt Ltd, Mumbai	Ms Shivani Swami Dr Shefali Mishra (*Alternate*)

Organization	*Representative(s)*
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Medline Healthcare Industries Pvt Ltd, Pune	Mr Anthony Dcosta Shri Dhaval Ghuge (*Alternate*)
National Physical Laboratory, New Delhi	Dr Sanjay Yadav Dr Shankar G. Aggarwal (*Alternate*)
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Office of the Textile Commissioner, Mumbai	Shri Sivakumar S. Shri Narrotam Kumar (*Alternate*)
PGIMER, Chandigarh	Dr Pankaj Arora
Procter and Gamble Co, Mumbai	Shri Prashant Jadhav Shri Sivakumar (*Alternate*)
Surgicotfab Textile Pvt Ltd, Ahmedabad	Shri Paresh Patel
Textiles Committee, Mumbai	Shri Kartikeyan Dhanda Ms Shilpi Chauhan (*Alternate*)
The Bombay Textile Research Association, Mumbai	Shrimati Aruna Apte
The South India Textile Research Association, Coimbatore	Dr E. Santhini Shri Veera Subramaniam (*Alternate*)
The Synthetics and Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur Shrimati S. S. Dongre (*Alternate*)
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Member Secretary

Shri Dharmbeer
Scientist 'C' (TXD), BIS

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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