

भारतीय मानक

IS 18696 : 2024

Indian Standard

(Superseding IS/ISO 5364 : 2008)

एनेस्थेटिक और श्वसन उपकरण
ओरोफैरिंजल एयरवेज
(ISO 5364 : 2016, संशोधित)

Anaesthetic and Respiratory
Equipment Oropharyngeal
Airways
(ISO 5364 : 2016, MOD)

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NATIONAL FOREWORD

This Indian Standard which is a modified adoption of ISO 5364 : 2016 'Anaesthetic and respiratory equipment — Oropharyngeal airways' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard supersedes IS/ISO 5364 : 2008 'Anaesthetic and respiratory equipment — Oropharyngeal airways' which superseded IS 11807 : 1986 'Oropharyngeal airways-specification (*first revision*)' to align with ISO 5364 : 2008. The ISO standard has been revised in 2016. This standard is a Modified adoption of ISO 5364 : 2016.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 7000 Graphical symbols for use on equipment — Registered symbols	IS 16450 : 2023/ISO 7000 : 2019 Graphical symbols for use on equipment — Registered symbols	Identical
ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices: Part 1 Evaluation and testing within a risk management process	Modified/ Technically Equivalent
ISO 11607-1 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	IS/ISO 11607-1 : 2019 Packaging for terminally sterilized medical devices: Part 1 Requirements for materials sterile barrier systems and packaging systems (<i>first revision</i>)	Identical
ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1 : 2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied: Part 1 General requirements (<i>second revision</i>)	Identical

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Introduction

This International Standard specifies dimensions and other requirements for oropharyngeal airways.

Airway size is designated by length, which is important when selecting an oropharyngeal airway to hold forward the base of the tongue to prevent obstruction of the airway by the soft tissues.

Airway size is indicated by a legible marking and by a colour code, which are important to allow rapid identification and selection in emergencies.

Indian Standard

(ISO 5364 : 2016, MOD)

1 Scope

This International Standard specifies requirements for oropharyngeal airways of plastics materials and/or rubber, including those with a reinforcement insert made of plastics materials and/or metal.

This International Standard is not applicable to metal oropharyngeal airways, nor to requirements concerning flammability of oropharyngeal airways.

Flammability of oropharyngeal airways, for example, if flammable anaesthetics, electrosurgical units, or lasers are used, is a well-recognized hazard. It is addressed by appropriate clinical management, which is outside the scope of this International Standard.

This International Standard is not applicable to supralaryngeal airways without an internal, integral sealing mechanism.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

oropharyngeal airway

device intended to maintain a gas pathway through the oral cavity and pharynx

[SOURCE: ISO 4135:2001, 6.1.1]

3.2

pharyngeal end

that end of an *oropharyngeal airway* (3.1) which is intended to be inserted into a patient's oropharynx

[SOURCE: ISO 4135:2001, 6.1.1.2]

3.3 flanged end

that end of an *oropharyngeal airway* (3.1) which is flanged and is intended to be external to the teeth or gums

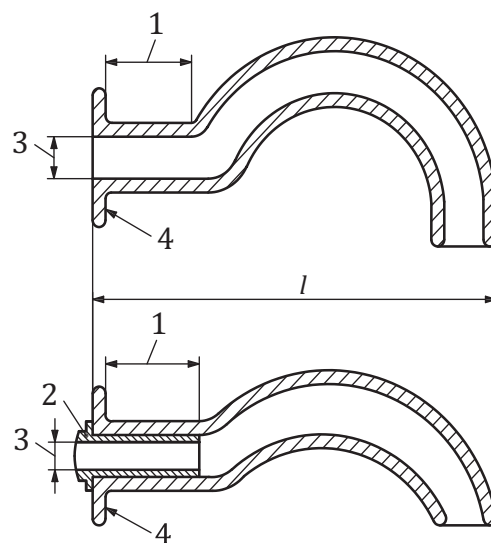
[SOURCE: ISO 4135:2001, 6.1.1.1]

4 Size designation and dimensions

4.1 Size designation

The size of oropharyngeal airways shall be designated by the nominal length (see l , Figure 1) expressed in centimetres, in accordance with Table 1.

NOTE The manufacturer's own size designation may additionally be given, but this is not recommended.



Key

- 1 buccal portion
- 2 reinforcement insert, if provided
- 3 position for measuring minimum inside dimension (see Table 1)
- 4 flanged end

NOTE For l , see 4.1 and 4.2.1.

Figure 1 — Dimensions for size designation of oropharyngeal airways

Table 1 — Size designation of oropharyngeal airways — Dimensions and tolerances

Designated size (nominal length)	Length and tolerance	Minimum inside dimension
cm	mm	mm
3	30 ± 2,5	2,5
3,5	35 ± 2,5	3,0
4	40 ± 2,5	3,0
4,5	45 ± 2,5	3,0
5	50 ± 2,5	3,5
5,5	55 ± 2,5	3,5
6	60 ± 2,5	4,0
6,5	65 ± 2,5	4,0
7	70 ^{+5,0} _{-2,5}	4,0
8	80 ± 5,0	4,5
9	90 ± 5,0	4,5
10	100 ± 5,0	5,0
11	110 ± 5,0	5,5
12	120 ± 5,0	5,5

4.2 Dimensions

4.2.1 The length (see *l*, [Figure 1](#)) shall be in accordance with [Table 1](#).

4.2.2 The minimum inside dimension at any point along the length of the airway shall be not less than that specified in [Table 1](#).

NOTE This dimension is relevant to the ability to pass other devices, e.g. a suction catheter, through the airway.

5 Materials

Oropharyngeal airways, in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1.

6 Design

Edges and corners intended to come into contact with the patients tissues shall have a minimum radius of curvature of 0,5 mm.

7 Performance requirements

7.1 Resistance to collapse of the buccal portion

When tested in accordance with [Annex B](#), the minimum inside dimension of the buccal portion of the airway shall be not less than 75 % of that given in [Table 1](#) for the size of the airway being tested.

7.2 Patency of lumen

When tested in accordance with [Annex C](#), the patency of the oropharyngeal airway lumen shall be maintained.

8 Sterility assurance

Oropharyngeal airways supplied and marked "STERILE" shall satisfy the requirements of EN 556-1:2001, 4.1.

9 Packaging of oropharyngeal airways supplied sterile

9.1 Each oropharyngeal airway supplied and marked "STERILE" shall be contained in an individual pack.

9.2 The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material in accordance with ISO 11607-1.

9.3 The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

9.4 The designated size of the airway shall be apparent on visual examination of the intact unit container.

9.5 Individual packs shall be contained within a shelf or multi-unit pack.

10 Marking

10.1 General

Marking of oropharyngeal airways, of unit packs and of shelf or multi-unit packs and information to be supplied by the manufacturer should comply with EN 1041.

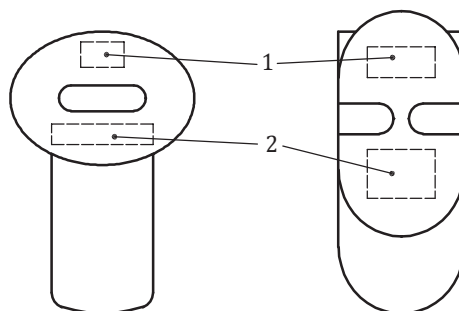
10.2 Use of symbols

The requirements of [10.4](#) and [10.5](#) may be met by use of appropriate symbols as given in ISO 7000 or ISO 15223-1.

10.3 Marking of oropharyngeal airways

10.3.1 The flanged end of the oropharyngeal airway shall be marked with the following:

- a) the designated size (nominal length, in centimetres) in accordance with [4.1](#) (see [Figure 2](#));
- b) the name and/or trademark of the manufacturer and/or supplier (see [Figure 2](#));
- c) an indication of the presence of natural rubber (latex), if present in the device.



Key

- 1 designated size
2 name and/or trademark of manufacturer or supplier

NOTE The designs shown in [Figures 1](#) and [2](#) are intended to illustrate common types of oropharyngeal airway for the purpose of size designation and marking, but are for example only.

Figure 2 — Typical marking locations on flanged end of oropharyngeal airways

10.3.2 *Markings in accordance with a) and b) shall be clearly legible from the flanged end when viewed at a distance of $500 \text{ mm} \pm 10 \text{ mm}$ at an illuminance of $215 \text{ lx} \pm 15 \text{ lx}$ using normal vision (corrected, if necessary).

Check compliance by visual inspection.

10.3.3 *Oropharyngeal airways shall be colour coded by size in accordance with [Table 2](#).

10.3.4 Colour code shall be visible from the flanged end.

Table 2 — Oropharyngeal airway colour code

Designated size	Colour
3	Lilac
3,5	Light green
4	Pink
4,5	Cream
5	Blue
5,5	Grey
6	Black
6,5	Brown
7	White
8	Green
9	Yellow
10	Red
11	Orange
12	Purple

10.4 Marking of unit packs

The marking of individual packs or a package insert shall include the following:

- a) the word “STERILE”, if appropriate (it is recommended that the method of sterilization be given);

- b) for oropharyngeal airways not intended for re-use, the words “single use” or equivalent;
- c) an indication of the presence of natural rubber (latex), if present in the device.

10.5 Marking of shelf or multi-unit packs

The marking of shelf or multi-unit packs shall include the following:

- a) a description of contents;
- b) the designated size in accordance with [4.1](#);
- c) the name and/or trademark and address of the manufacturer and/or supplier;
- d) the batch number;
- e) the word “STERILE”, if appropriate (it is recommended that the method of sterilization be given);
- f) for oropharyngeal airways not intended for re-use, the words “single use” or equivalent.

It is strongly recommended that the “use by” date be given.

11 Information to be supplied by the manufacturer

11.1 Unless the oropharyngeal airway is intended and marked as being for single use, the manufacturer shall recommend methods of cleaning and disinfection or sterilization.

11.2 The manufacturer shall indicate the presence of natural rubber (latex), if present in the device.

Annex A (informative)

Rationale

General

This Annex provides a concise rationale for the important requirements of this International Standard and is intended for use by those who are familiar with the subject of this International Standard, but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this International Standard necessitated by those developments.

The subclauses in this Annex have been numbered to correspond to the subclauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

[10.3.2](#)

This legibility requirement is adapted from EN 980:2008, 4.2.5.

[10.3.3](#)

The subcommittee agreed that a unique colour for each designated size was important for patient safety. The subcommittee was aware that existing colour codes vary by manufacturer, making rapid identification and selection of the proper size for the patient very difficult and confusing. Current manufacturers were surveyed and the following chart of various colour codes in use in 2013 was developed. The colours mandated in this standard were then selected by determining those most commonly used by manufacturers with an aim to reduce the burden of change by the manufacturers and to reduce confusion by the users who have become accustomed to the current colour designations.

[Tables A.1](#) and [A.2](#) compare size colour code identified in the survey of 13 airway manufacturers to the size colour code selected for this International Standard.

Table A.1 — Size colour code identified in a survey of 13 airway manufacturers

		SIZE													
		3	3.5	4	4.5	5	5.5	6	6.5	7	8	9	10	11	12
Airway Manufacturers	A	Pink		Orange		Blue		Violet			Green	Yellow	Red	Light Blue	
	B		White			Blue		Black		White	Green	Orange	Red		
	C			Pink		Blue		Black		White	Green	Yellow	Red	Orange	
	D			Purple			Blue	Black		White	Green	Orange	Red	Yellow	
	E			Pink		Blue		Black		White	Green	Yellow	Red	Orange	
	F	Clear		Pink		Blue		Black		White	Green	Yellow	Red		Purple
	G			Pink		Blue		Black		White	Green	Yellow	Red	Orange	
	H	Clear		Pink		Blue		Black		White	Green	Yellow	Red		Purple
	I					Blue		Black		White	Green	Yellow	Red		
	J					Blue		Black		White	Green	Yellow	Red		
	K	Clear		Pink		Blue		Black		White	Green	Yellow	Red		Purple
	L			Blue		Black		Clear		Green	Orange	Pink	Red	Yellow	
	M		Pink			Blue	Grey		White	Yellow	Green	Orange	Red		Purple

Table A.2 — Size colour code selected for this International Standard

SIZE														
3	3.5	4	4.5	5	5.5	6	6.5	7	8	9	10	11	12	
Lilac	Light Green	Pink	Cream	Blue	Grey	Black	Brown	White	Green	Yellow	Red	Orange	Purple	

Annex B (normative)

Test method for resistance to collapse of the buccal portion

B.1 Principle

The resistance of the buccal portion to collapse is tested by measuring the minimum inside dimension during compression.

B.2 Apparatus

B.2.1 Means of conditioning the oropharyngeal airway at (34 ± 2) °C and carrying out the test under the same conditions.

B.2.2 Means of applying a force of either (100 ± 10) N or (200 ± 20) N, as appropriate.

B.2.3 Means of measuring the minimum inside dimension of the buccal portion during compression, with an accuracy of $\pm 0,10$ mm.

B.3 Test procedure

B.3.1 Condition the oropharyngeal airway at (34 ± 2) °C for 1 h and carry out the test under the same conditions.

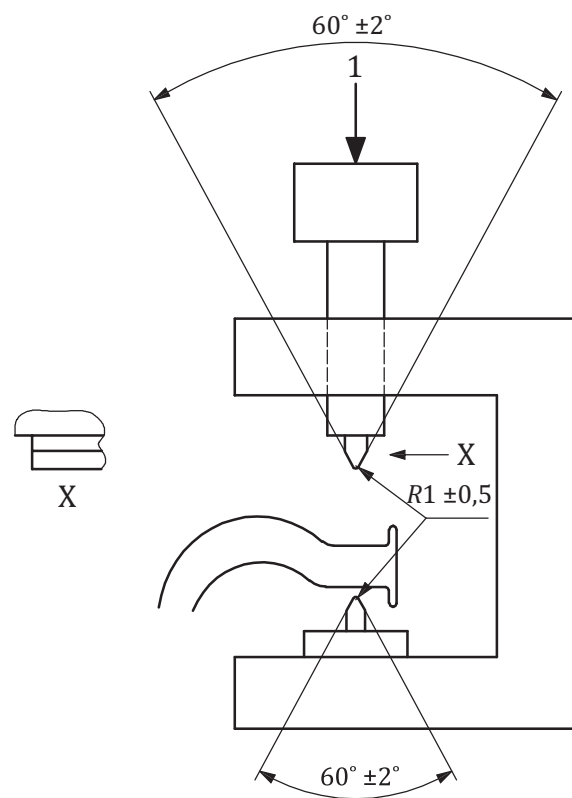
B.3.2 Compress the middle of the buccal portion (see [Figure 1](#)) of the oropharyngeal airway using blocks with a $(60 \pm 2)^\circ$ included angle and radius of curvature of $(1,0 \pm 0,5)$ mm to the mating surfaces and a width at least as great as that of the buccal portion of the airway being tested (see [Figure B.1](#)).

B.3.3 For oropharyngeal airways of designated size 5,5 or smaller, apply a force of (100 ± 10) N and maintain that force for 3 min while measuring the minimum dimension.

B.3.4 For oropharyngeal airways of designated size 6,0 or larger, apply a force of (200 ± 20) N and maintain that force for 3 min while measuring the minimum dimension.

B.4 Expression of result

Express the minimum inside dimension of the buccal portion during compression as a percentage of that value specified in [Table 1](#) for the size of airway being tested.

**Key**

- 1 compressive force applied as in [B.3.3](#) or [B.3.4](#)
- X width of blocks as great as buccal portion of airway being tested
- R block tip radius of curvature of $(1 \pm 0,5)$ mm

Figure B.1 — Apparatus for testing resistance to collapse of the buccal portion

Annex C (normative)

Test method for patency of lumen

C.1 Principle

The patency of the oropharyngeal airway lumen is tested by clamping the buccal portion, applying a force to the pharyngeal end, and passing a steel ball through the lumen of the oropharyngeal airway.

C.2 Apparatus

C.2.1 Means of conditioning the oropharyngeal airway at (34 ± 2) °C and carrying out the test under the same conditions.

C.2.2 Clamp, for suspending the oropharyngeal airway.

C.2.3 Means of applying a force of $(5,0 \pm 0,5)$ N.

C.2.4 Steel ball, of diameter 75 % of the minimum inside dimension of the oropharyngeal airway (see [Table 1](#)).

C.3 Test procedure

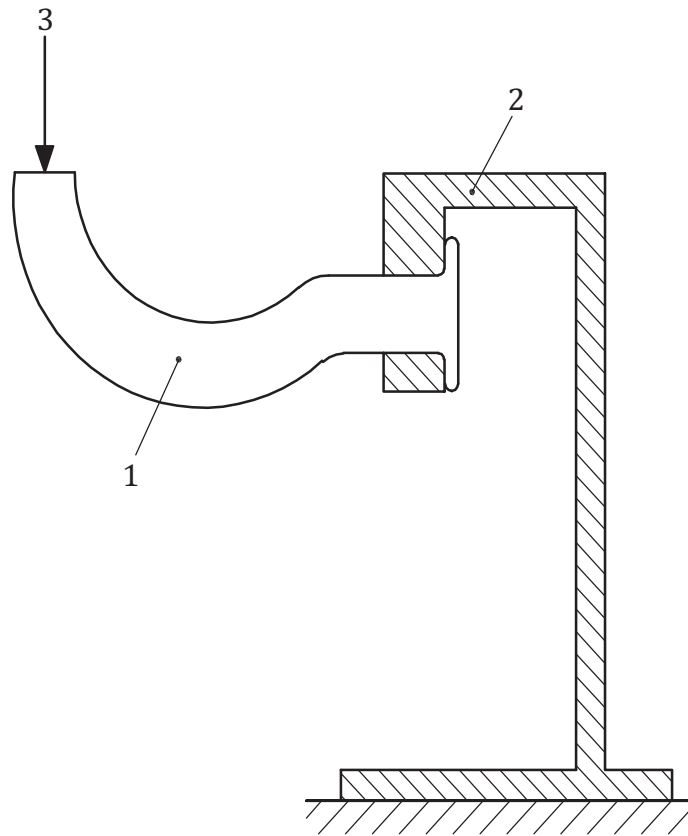
C.3.1 Condition the oropharyngeal airway at (34 ± 2) °C for 1 h and carry out the test under the same conditions.

C.3.2 Clamp the buccal portion of the oropharyngeal airway so that it does not move and apply a force of $(5,0 \pm 0,5)$ N to the pharyngeal end, maintaining this force for not less than 1 min (see [Figure C.1](#)).

C.3.3 Pass a steel ball ([C.2.4](#)) through the lumen while the force is being applied.

C.4 Expression of results

Record whether or not the steel ball passes freely through the tube.



Key

- 1 test piece (oropharyngeal airway)
- 2 clamp
- 3 force applied as in [C.3.2](#)

Figure C.1 — Apparatus for testing patency of lumen

Annex D (informative)

Guidance on materials and design

Materials and design should be such as to minimize the risk of dental trauma in use.

Unless intended and marked for single use, oropharyngeal airways and any marking materials used on oropharyngeal airways should be resistant to deterioration by methods of cleaning, disinfection and sterilization recommended by the manufacturer.

The recommended method or methods of sterilization should not produce changes in the materials which will compromise the biological safety of the oropharyngeal airway (see [Clause 5](#)).

Oropharyngeal airways and any marking materials used on oropharyngeal airways under normal conditions of use should be resistant to deterioration by clinically used concentrations of anaesthetic vapours and gases and commonly used water-soluble lubricants and topical anaesthetics.

Where an insert is used, it should be permanently attached and of a suitable corrosion-resistant type or finished with a durable corrosion-resistant finish.

Oropharyngeal airways should have smooth inner and outer surfaces.

Bibliography

- [1] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*
- [2] ISO 11712, *Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors*
- [3] ISO/TR 11991, *Guidance on airway management during laser surgery of upper airway*
- [4] EN 980, *Graphical symbols for use in the labelling of medical devices*

NATIONAL ANNEX A

[*\(National Foreword\)*](#)

A-1 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.

(Continued from second cover)

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
EN 1041 Information supplied by the manufacturer with medical devices	IS/ISO 20417 : 2021 Medical devices Information to be supplied by the manufacturer	Modified/ Technically Equivalent

The Committee has reviewed the provisions of the following International Standard referred in this draft standard proposed to be adopted and has decided that it is acceptable for use in conjunction with this standard:

<i>International Standard/Other Publication</i>	<i>Title</i>
EN 556-1 : 2001	Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices

This standard is a modified/Technically Equivalent adoption, as some of the cross references mentioned in the second column are not identical with the referred international standard in the corresponding row of the first column in the first table above.

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 shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'

This standard also makes a reference to the BIS Certification Marking of the product, details of which are given in [National Annex A](#).

Bureau of Indian Standards

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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 website- www.bis.gov.in or www.standardsbis.in.

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