

इंटरनेट

मानक

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“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS/ISO 10555-3 (1996): Sterile, Single-Use Intravascular Catheters, Part 3: Central Venous Catheters [MHD 16: Surgical Dressings and Disposable Products]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”



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जीवाणु रहित, एक बार प्रयोग में आने वाले इंद्रावस्कुलर कैथेटर्स  
भाग ३ केन्द्रीय वीनस कैथेटर्स

*Indian Standard*  
**STERILE, SINGLE-USE INTRAVASCULAR CATHETERS**  
PART 3 CENTRAL VENOUS CATHETERS

ICS 11.040.20

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**BUREAU OF INDIAN STANDARDS**  
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NEW DELHI 110002

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Price Group 4

## NATIONAL FOREWORD

This Indian Standard (Part 3) which is identical with ISO 10555-3 :1996'Sterile, single-use intravascular catheters — Part 3: Central venous catheters' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Surgical Disposables and Dressings Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Intravascular central venous catheter single or multilumen, designed for introduction into or withdrawn of liquids from the central venous system and/or for pressure or other measurement

Other parts of this standard are as follows:

- Part 1 General requirements
- Part 2 Angiographic catheters
- Part 4 Balloon dilatation catheters
- Part 5 Over-needle peripheral catheters

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'.
- b) Comma (,) has been used as a decimal marker in the International Standard 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 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 594-1 :1986 Conical fittings with a 6 percent (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	IS 3234 (Part 1): 1986 Conical fittings with a 6 percent (Luer) taper for syringes, needles and certain other medical equipment Part 1 General requirements {second revision}	Identical
IS010555-1 :1995 Sterile, single-use intravascular catheters — Part 1: General requirements	IS/ISO 10555-1 : 1995 Sterile, single-use intravascular catheter: Part 1 General requirements	do

The standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

Technical Corrigendum 1 to the above International Standard has been given at the end of this standard.

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}'<sup>1</sup>. 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*  
**STERILE, SINGLE-USE INTRAVASCULAR CATHETERS**  
**PART 3 CENTRAL VENOUS CATHETERS**

## 1 Scope

This part of ISO 10555 specifies requirements for central venous catheters supplied in the sterile condition, and intended for single use.

NOTE 1 Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

## 3 Definitions

For the purposes of this part of ISO 10555, the definitions given in ISO 10555-1 and the following definition apply.

**3.1 central venous catheter:** Intravascular catheter, single- or multilumen, designed for introduction into, or withdrawal of liquids from, the central venous system and/or for pressure or other measurements.

NOTE 2 The catheter may have a fixation system which is part of the device.

## 4 Requirements

### 4.1 General

Catheters shall comply with ISO 10555-1, except for the force at break (see ISO 10555-1:1995, subclause 4.5), for which the requirements of subclause 4.7 of this part of ISO 10555 shall apply.

### 4.2 Radio-detectability

The catheter shall be radio-detectable.

NOTE 3 At the time of publication of this part of ISO 10555, there is no acceptable, validated test method to determine radio-detectability. An approved test method for producing a value of radio-detectability will be established. Until that time, a manufacturer may label his product "radio-opaque" provided he can support this claim by demonstrating that he has an appropriate method for showing radio-opacity.

### 4.3 Tip configuration

In order to minimize trauma to vessels during use, the tip of the distal end should be smooth, rounded, tapered or similarly finished.

### 4.4 Distance markings

If the catheter is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks shall not exceed 5 cm.

NOTE 4 It is recommended that the distance marks be 1 cm apart on that portion of the catheter likely to be of importance to the user in positioning the catheter and monitoring catheter migration.

#### 4.5 Lumen markings

For multilumen catheters, identification of each lumen shall be apparent to the user.

#### 4.6 Flowrate

When tested in accordance with annex A, the flowrate for each lumen shall be between 80 % and 125 % of that stated by the manufacturer for catheters of nominal outside diameter less than 1,0 mm or between 90 % and 115 % of that stated by the manufacturer for catheters of nominal outside diameter 1,0 mm or greater.

#### 4.7 Force at break

**4.7.1** For catheters having a tip of softer durometer material or of different construction to the shaft and not exceeding 20 mm in length, the minimum force at break of the tip shall be as given in table 1 when tested in accordance with the method given in annex B of ISO 10555-1:1995.

The minimum force at break of all other parts of such catheters shall comply with ISO 10555-1:1995, subclause 4.5.

**4.7.2** The minimum force at break of all parts of catheters other than those to which 4.7.1 applies shall comply with ISO 10555-1:1995, sub-clause 4.5.

**Table 1 — Minimum force at break of soft tips of length not exceeding 20 mm**

Smallest outside diameter of catheter body mm	Minimum force at break N
> 0,550 and < 0,75	3
> 0,75 and < 1,85	4
> 1,85	5

#### 4.8 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also contain the following:

- a) if the catheter is provided with distance markings, a description of the marking system;
- b) flowrate for each lumen;
- c) maximum guidewire diameter, where applicable;
- d) if applicable, a warning against attempting to withdraw the catheter back through the needle.

NOTE 5 Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.

## Annex A (normative)

### Determination of flowrate through the catheter

#### A.1 Principle

Water is allowed to flow through the catheter and the amount of flow is measured either volumetrically or gravimetrically.

#### A.2 Reagent

Distilled or deionized water.

#### A.3 Apparatus

**A.3.1** Constant-level tank, fitted with a delivery tube and a male 6 % (Luer) taper fitting complying with ISO 594-1, capable, when no test catheter is attached, of providing a flowrate of  $(525 \pm 25)$  ml/min, and having a hydrostatic head height of  $(1\ 000 \pm 5)$  mm.

An example of a suitable apparatus is shown in figure A.1.

**A.3.2** Equipment for collecting and determining the mass or volume of the catheter efflux to an accuracy of  $\pm 1$  %,

**A.3.3** **Timer**, for measuring collection time.

#### A.4 Test procedure

**A.4.1** Supply the constant-level tank (A.3.1) with water at  $(22 \pm 2)$  °C. Fit the catheter to be tested to the male 6 % (Luer) taper fitting.

**A.4.2** Start the water flowing through the catheter. Collect the efflux for a measured period of time (not less than 30 s) in a suitable vessel and determine its volume by means of a measuring cylinder or by weighing, assuming that the density of water equals 1 000 kg/m<sup>3</sup>.

**A.4.3** Perform three determinations on each catheter lumen.

#### A.5 Expression of results

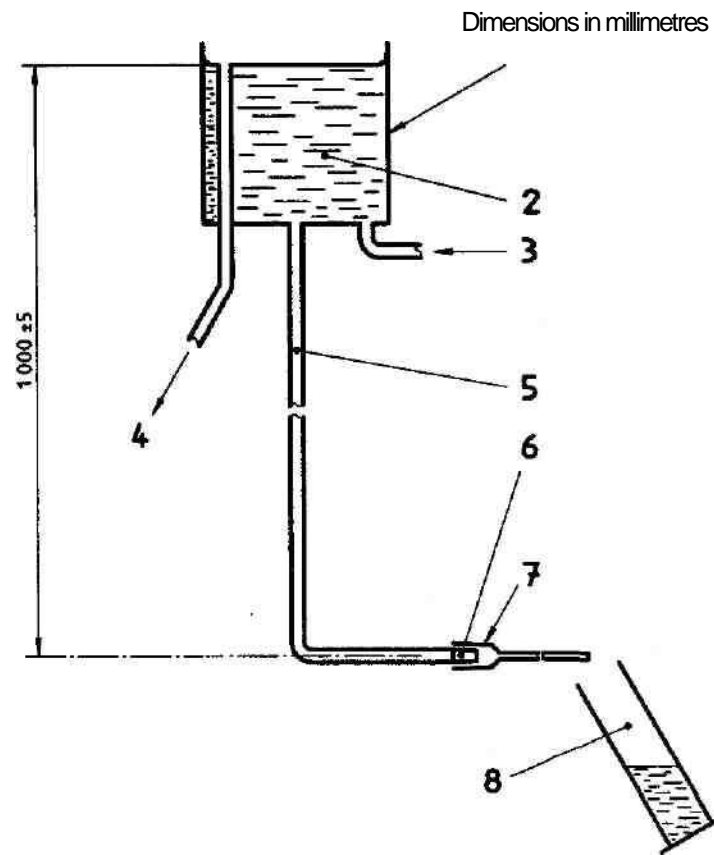
Calculate the arithmetic average of the three determinations and express it as water flowrate through the catheter, in millilitres per minute. Round the calculated average water flowrate to the nearest whole number of millilitres.

#### A.6 Test report

The test report shall include the following information:

- a) identity of the catheter;
- b) average flowrate, expressed in millilitres per minute, for each lumen.





**Key**

- 1 Constant-level tank
- 2 Distilled or deionized water
- 3 Inlet
- 4 Overflow
- 5 Delivery tube
- 6 Male 6% (Luer) taper fitting
- 7 Catheter under test
- 8 Collecting/measuring vessel

**Figure A.1 — Example of apparatus for determination of flowrate of water through catheter**

**Annex B**  
(informative)

**Bibliography**

- [1] ISO 11070:—<sup>1)</sup> *Sterils, single-use intravascular catheter introducers.*

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<sup>1)</sup> To be published.

TECHNICAL CORRIGENDUM 1

Technical Corrigendum 1 to International Standard ISO 10555-3:1996 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

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**4.2 Radio-detectability**

Delete the entire Note 3 given in this subclause.

**4.4 Distance markings**

Renumber Note 4 given in this subclause to become Note 3.

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**4.8 Information to be supplied by the manufacturer**

Renumber Note 5 given in this subclause to become Note 4.

**NATIONAL ANNEX A**  
{*National Foreword*}

**A-1 BIS CERTIFICATION MARKING**

**A-1.1** The product may also be marked with the Standard Mark.

**A-1.1.1** The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

## 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 alongwith 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'.

This Indian Standard has been developed from Doc No.: MHR 16 (0053).

#### Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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