IS : 7523 - 1974

Indian Standard

SPECIFICATION FOR RUBBER CATHETER (URINARY)

UDC 615·472·5

INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110001

Price Rs 5·00 *May* 1975

Indian Standard

SPECIFICATION FOR RUBBER CATHETER (URINARY)

Rubber Products Sectional Committee, CDC 6

Chairman	*Representing*
Dr D. Banerjee	Escon Consultants Pvt Ltd, Calcutta
Members	
Shri A. T. Basak	Directorate General of Supplies & Disposals, New Delhi
Shri S. K. Bose	National Test House, Calcutta
Shri A. Ghosh (*Alternate*)	
Shri D. K. Chatterjee	Alkali & Chemical Corporation of India Ltd, Calcutta
Shri S. K. Ray (*Alternate*)	
Shri S. S. Chopra	Export Inspection Council of India, Calcutta
Shri K. M. Bijli (*Alternate*)	
Shri B. H. Dalal	Ministry of Defence (DGI)
Shri M. Kumaran (*Alternate*)	
Shri S. L. Gandhi	Ministry of Defence (R & D)
Shri M. G. Bhargava (*Alternate*)	
Shri G. C. Jain	Hindustan Steel Ltd, Ranchi
Shri O. N. Kohli	Railway Board
Shri Lalit Mohan Jamnadas	Cosmos India Rubber Works Pvt Ltd, Bombay
Shri Pulin L. Kinariwala (*Alternate*)	
Shri S. V. Lathia	Lathia Rubber Manufacturing Co Pvt Ltd, Bombay
Shri D. P. Lathia (*Alternate*)	
Shri S. K. Matthan	Madras Rubber Factory Ltd, Madras
Shri K. J. Abraham (*Alternate*)	
Dr K. N. Modak	All India Rubber Industries Association, Bombay
Shri K. R. Sengupta (*Alternate*)	
Shri S. Mukherjee	Dunlop India Ltd, Calcutta
Shri P. N. S. Myer (*Alternate*)	
Dr C. K. N. Nair	Rubber Board, Kottayam
Shri K. C. Ananth (*Alternate*)	
Shri S. C. Nandy	Bata India Ltd, Calcutta
Shri R. R. Pandit	Bayer (India) Ltd, Bombay
Shri M. M. Patel	Synthetics & Chemicals Ltd, Bombay
Shri K. Rajgopaul	Indian Oil Corporation Ltd, Bombay
Dr N. V. C. Rao	Directorate General of Technical Development, New Delhi
Shri G. R. Inamdar (*Alternate*)	

(*Continued on page* 2)

(*Continued from page* 1)

Members	*Representing*
SHRI B. ROY	National Rubber Manufacturers Ltd, Calcutta
SHRI AMITABHA SEN (*Alternate*)	
SHRI R. C. SYED	Indian Rubber Manufacturers' Research Association, Bombay
SHRI S. K. GHOSH (*Alternate*)	
SHRI D. D. TALWALKAR	All India Automobile & Ancillary Industries Association, Bombay
SHRI K. M. KHALADKAR (*Alternate*)	
DR G. M. SAXENA, Director (Chem)	Director General, ISI (*Ex-officio Member*)

Secretary

SHRI SATISH CHANDER
Deputy Director (Chem), ISI

Medical Rubber Goods Subcommittee, CDC 6 : 7

Convener	
SHRI B. H. DALAL	Ministry of Defence (DGI)
Members	
MAJ L. K. BANERJEE	Directorate General of Armed Forces Medical Services, Ministry of Defence
LT-COL B. R. BHATTACHARYA (*Alternate*)	
SHRI A. BOSE	Bengal Waterproof Works (1940) Ltd, Calcutta
SHRI R. S. ROY (*Alternate*)	
SHRI S. K BOSE	National Test House, Calcutta
SHRI S. P. MULLICK (*Alternate*)	
SHRI G. C. CHAKRAVARTI	Ministry of Defence (DGI)
SHRI P. C. KAPUR	Directorate General of Health Services (Ministry of Health & Family Planning), New Delhi
DR K. V. KULKARNI	Haffkine Institute, Bombay
SHRI R. S. KARBHARI (*Alternate*)	
SHRI S. V. LATHIA	Lathia Rubber Manufacturing Co Pvt Ltd, Bombay
SHRI D. P. LATHIA (*Alternate*)	
SHRI MANUBHAI M. PATEL	Rubberex Industries Pvt Ltd, Bombay
SHRI K. C. SHAH (*Alternate*)	
SHRI M. M. PATEL	Synthetics & Chemicals Ltd, Bombay
SHRI N. M REGE (*Alternate*)	
SHRI M. N. PATHAK	Associated Rubber Industries Ltd, Bhavnagar
SHRI V. D. PENDSE	Swastik Rubber Products Ltd, Poona
SHRI K. D. DIGHE (*Alternate*)	
SHRI P. S. RAMACHANDRAN	Directorate General of Health Services (Ministry of Health & Family Planning), New Delhi
DR G. P. SENGUPTA (*Alternate*)	
DR N. V. C. RAO	Directorate General of Technical Development, New Delhi
SHRI G. R. INAMDAR (*Alternate*)	
SHRI B. ROY	National Rubber Manufacturers Ltd, Calcutta
SHRI AMITABHA SEN (*Alternate*)	
SHRI B. L. SEN	Indian Oxygen Ltd, Calcutta
SHRI A. K. MOITRA (*Alternate*)	

Indian Standard

SPECIFICATION FOR RUBBER CATHETER (URINARY)

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 10 March 1974, after the draft finalized by the Rubber Products Sectional Committee had been approved by the Chemical Division Council.

0.2 Since catheters are put inside the body, it is essential that utmost care is taken in the selection of materials for rubber compounding used for making catheters. The rubber used should be free from all harmful contaminants. Besides, the catheter should be of such shape and finish so as not to cause any irritation. This Standard has been formulated to guide the manufacturers to produce catheters of proper quality.

0.3 In the preparation of this standard, considerable assistance has been derived from Specification No. IND/MED/TC/2500 ' Rubber catheters ', issued by Ministry to produce catheters of Defence, India.

0.4 This standard contains clauses **2.1.5**, **4.1** and **4.2** which call for agreement between the purchaser and the supplier.

0.5 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*. 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 prescribes the requirements and methods of test for rubber catheters (urinary) with eye and funnel end.

2. REQUIREMENTS

2.1 General

2.1.1 The rubber catheters (urinary) shall be made of natural or synthetic rubber or combination of both, compounded and vulcanized to meet all the requirements of this specification.

*Rules for rounding off numerical values (*revised*).

2.1.2 The catheters shall not contain any reclaimed rubber or vulcanized waste.

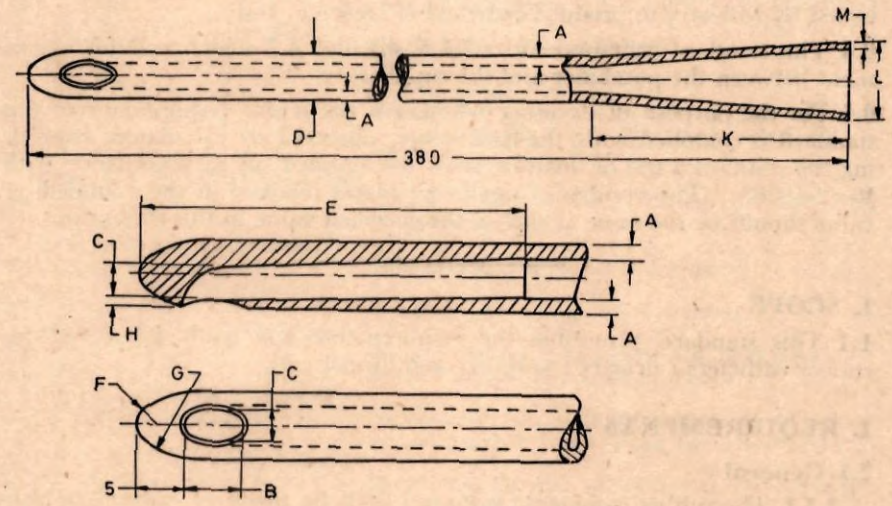
2.1.3 The catheters shall be homogeneous in composition, shall be adequately vulcanized, evenly and smoothly finished and shall be free from pinholes, pits, cracks, crevices, grooves and other defects. The distal end of the eye shall have smooth finish and shall be entirely free from projections, grit and embedded particles.

2.1.4 The rubber compound used for catheters shall be reasonably free from substances known to have deleterious action on rubber. The composition shall be free from irritants and have no known injurious effect on persons with whom it may come in contact. It shall not react with body fluids.

2.1.5 The catheters (urinary) shall be red in colour unless otherwise agreed to between the purchaser and the supplier.

2.2 Dimensions

2.2.1 The catheters (urinary) shall be manufactured in accordance with h dimensions given in Table 1, read with Fig. 1.



All dimensions in millimetres.

FIG. 1 CATHETER WITH EYE AND FUNNEL END

TABLE 1 DIMENSIONS OF CATHETERS (URINARY)

(*Clause* 2.2.1)

(All dimensions in millimetres.)

Sl No.	Size No.										
	*D**	*A*	*B*	*C*	*E*	*F*	*G*	*H*	*K*	*L*	*M*
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
i)	2·5	0·5	3·6	1·3	15	0·5	3·5	0·4	30	4	0·3
ii)	4	0·85	4·8	2·0	24	1·0	6	0·7	35	8	0·6
iii)	5	1·0	5·2	2·5	30	1·3	7	0·8	36	9	0·7
iv)	5·5	1·25	5·6	2·75	33	1·5	8	0·9	37	10	0·8
v)	6	1·35	6·5	3·0	36	1·7	9	0·95	38	11	0·9
vi)	7	1·5	8·5	3·5	42	2·0	10	1·0	40	12	1·0

*The tolerance on this dimension shall be ± 0·3 mm.

2.3 Physical Requirements — The physical requirements of rubber used for catheters shall conform to the requirements given in Table 2.

TABLE 2 PHYSICAL REQUIREMENTS OF RUBBER USED FOR CATHETERS

Sl No.	Characteristic	Value Before Ageing	Maximum Change From the Original Value After Accelerated Ageing at 70 ± 1°C for 168 Hours in Air Oven
(1)	(2)	(3)	(4)
i)	Tensile strength, MN/m^2 (kgf/cm^2), *Min*	10 0 (approx 100)	$^{+10}_{-25}$ } percent
ii)	Elongation at break, percent, *Min*	400	$^{+0}_{-25}$ } percent
iii)	Percent elongation under a tensile stress of 2 800 kN/m^2 (approx 28 kgf/cm^2) of original area of cross section of test piece	Between 100 and 250	—
iv)	Tension set (at 200 percent elongation), percent, *Max*	10	—
v)	*p*H of water extract	7 ± 0·5	—
vi)	Extractable colour	No colour or precipitate shall be formed but faint turbidity (to the extent of slight translucence) may be permitted	—

2.4 The catheters shall be free from harmful contaminations of heavy metals, arsenic, copper and manganese.

2.4.1 The concentration of each of the metallic impurities in **2.4** shall not exceed 5 ppm in the sterile pyrogen-free isotonic saline solution prescribed in **4.4.1**.

2.5 Resistance to Ageing Under Tension — Tubing cut from the catheter when subjected to accelerated ageing under tension as prescribed in **4.5** shall not show any signs of cracking or other evidence of failure of the stretched part.

2.6 Hydraulic Test — The catheters shall withstand the internal hydraulic pressure of 70 kN/m² (approx 0·7 kgf/cm²) above atmospheric pressure without leakage.

3. PRESERVATION, MARKING AND PACKING

3.1 Preservation — Before packing, each catheter shall be thoroughly dusted with french chalk powder (*see* IS : 380-1967*).

3.2 Packing — Ten catheters of one size treated with preservatives shall be laid straight enclosed in a bag made of unpigmented polyethylene film of thickness not less than 0·04 mm and the bag sealed. The polyethylene bag shall be kept inside a folding cardboard carton of suitable size.

3.2.1 Any packing other than the above may also be employed if agreed to between the purchaser and the supplier.

3.3 Marking — Each catheter shall be legibly and indelibly marked with the manufacturer's name or recognised trade-mark, if any, and the year of manufacture together with the size number.

3.3.1 The package shall also be marked legibly and indelibly with the name and trade-mark of the manufacturer, lot and serial number of the package, size and number of the catheters, month and year of manufacture, and gross mass of the package in kg.

3.3.2 The catheter may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

*Specification for french chalk, technical (*first revision*).

4. TEST METHODS

4.1 Unless otherwise agreed to between the purchaser and the supplier, all tests shall be carried out within 3 months of the date of receipt of the material by the purchaser.

4.2 Test Pieces — It is not possible to carry out conveniently some of the tests on the catheter itself. In such cases tests shall be carried out on press cured slabs made from the same mix and vulcanized as closely as possible to the same degree as to the catheter. The number of slabs to be provided with the lot shall be as agreed to between the purchaser and the supplier.

4.3 Physical Properties

4.3.1 *Tensile Strength and Elongation at Break* — Carry out the test on dumb-bell test pieces cut out of press cured slabs in accordance with the method prescribed in IS : 3400 (Part I)-1965*.

4.3.2 *Accelerated Ageing* — Subject dumb-bell test pieces to aging at 70 ± 1°C for 168 hours in an air-oven or a cell oven in accordance with the method prescribed in IS : 3400 (Part IV)-1965† and test it according to **4.3.1**.

4.3.3 *Elongation Under a Fixed Tensile Stress* — This test shall be carried out as indicated in **4.3.1** on the catheter tubing itself and the percentage elongation is measured when a tensile stress of 2 800 kN/m² (approx 28 kgf/cm²) of the original area of cross section of test piece has been applied.

4.3.4 *Tension Set* — This test shall be carried out on the catheter tubing in accordance with IS : 3400 (Part XIII)-1972‡.

4.3.5 *pH of Water Extract* — This test shall be carried out in accordance with Appendix A.

4.3.6 *Extractable Colour* — Carry out this test in accordance with Appendix B.

4.4 Test for Metallic Contaminations in the Catheter

4.4.1 *Preparation of Test Solution* — Pass 40 ml portions of sterile pyrogen-free isotonic saline solution containing 9 g of sodium chloride per litre at room temperature through the catheter at a flow rate of approximately 10 ml per minute and collect the effluent. Make up the solution to 250 ml.

4.4.2 *Test for Arsenic* — Carry out the test for arsenic as prescribed in IS : 2088-1962§ with 10 ml of the solution, using for comparison 0·005 mg of arsenic trioxide (As_2O_3).

*Methods of test for vulcanized rubbers: Part I Tensile stress-strain properties.
†Methods of test for vulcanized rubbers: Part IV Accelerated ageing.
‡Methods of test for vulcanized rubbers: Part XIII Tension set.
§Modified Gutzeit method of test for arsenic.

4.4.3 *Test for Copper and Manganese* — Carry out test for copper and manganese as prescribed in NR : 4 and NR : 5 of IS : 3660 (Part I)-1972* respectively with test solutions prepared according to **4.4.1**.

4.4.4 *Test for Heavy Metal* — Heavy metal contamination shall be tested in accordance with the method given in Appendix C.

4.5 Resistance to Ageing Under Tension — Cut end of a piece of tubing of the catheter shall be fitted over a glass tube of external diameter 40 to 50 percent greater than the internal diameter of the rubber tubing and the hole subjected to accelerated ageing for 168 hours at 70 ± 1°C as prescribed in **4.3.2**.

4.6 Hydraulic Test — Carry out this test in accordance with **11** of IS : 443-1963†.

APPENDIX A
(*Clause* 4.3.5)

DETERMINATION OF *p*H OF WATER EXTRACT

A-1. PROCEDURE

A-1.1 Cut 5 catheters into 2 mm pieces. Autoclave the pieces for 5 minutes at a pressure of 40 to 50 kN/m² (approx 0·4 to 0·5 kgf/cm²) with 200 ml of water. Discard the first extract and repeat the process with another 500 ml of water for 40 minutes. Decant the extract, cool and determine the *p*H with a *p*H meter

APPENDIX B
(*Clause* 4.3.6)

TEST FOR EXTRACTABLE COLOUR

B-1. PROCEDURE

B-1.1 Cut 5 catheters into 10 mm pieces and mix them. Weigh about 20 g of these pieces. Autoclave them with 100 ml of water under a steam pressure of 100 to 135 kN/m² (approx 1 to 135 kgf/cm²) at a temperature of 120 to 125°C for 30 minutes. Cool and examine the extracted solution.

*Methods of test for natural rubber: Part I (*first revision*).
†Methods of sampling and test for hoses (*revised*).

APPENDIX C

(*Clause* 4.4.4)

TEST FOR HEAVY METALS

C-0. OUTLINE OF THE METHOD

C-0.1 The solution is prepared as in **4.4.1** and tested with aqueous hydrogen sulphide solution. The resultant brown colour, if any, is matched with that produced with a standard lead solution.

C-1. APPARATUS

C-1.1 Nessler Cylinders — 100 ml capacity (*see* IS : 4161-1967*).

C-2. REAGENTS

C-2.1 Citric Acid

C-2.2 Concentrated Nitric Acid — *See* IS : 264-1968†.

C-2.3 Bromophenol Blue Indicator — Dissolve 0·1 g of bromophenol blue in 100 ml of rectified spirit (conforming to IS : 323-1959‡).

C-2.4 Copper Sulphate

C-2.5 Hydrogen Sulphide Gas — from Kipp's apparatus.

C-2.6 Dilute Nitric Acid — approximately 1 percent.

C-2.7 Ammonium Hydroxide — Dilute 1 volume of liquor ammonia (r. d. 0·92) with 10 volumes of water.

C-2.8 Thymol Blue Indicator — Dissolve 0·1 g of thymol blue in 100 ml of rectified spirit (conforming to IS : 323-1959‡).

C-2.9 Potassium Cyanide Solution — 10 percent (m/v).

C-2.10 Hydrogen Sulphide Solution — freshly prepared saturated solution.

C-2.11 Standard Lead Solution — Dissolve 0·800 g of lead nitrate in water and make up the solution to exactly 1 000 ml. Pipette out 10 ml of the solution and dilute it again with water to 1 000 ml. One millilitre of the final solution contains 0·500 mg of lead (Pb). The solution shall be freshly prepared.

*Specification for Nessler cylinder.
†Specification for nitric acid (*first revision*).
‡Specification for rectified spirit (*revised*).

C-3. PROCEDURE

C-3.1 Prepare a solution as in **4.4.1** but make up the volume to 100 ml. Transfer the solution to a beaker. Add 5 g of citric acid and adjust *p*H from 3·0 to 3·4 by adding ammonium hydroxide to give a yellow purple colour with bromophenol blue indicator. Add about 5 g of copper sulphate to act as co-precipitant. Precipitate sulphides by passing hydrogen sulphide until solution is saturated. Dissolve the sulphides, without previous washing, with 5 ml of hot dilute nitric acid, drawing solution through filter into the original flask; wash with hot water, and collect the washing along with the solution in nitric acid. Boil to remove sulphuretted hydrogen. Concentrate the content to about 75 ml. Add 3 to 4 g of concentrated nitric acid previously dissolved in water, make ammoniacal to bring *p*H between 8·5 and 10 (bluish-green to blue towards drop of thymol blue indicator) and add 5 ml of potassium cyanide solution. Transfer to a Nessler cylinder, add 10 ml of hydrogen sulphide solution, dilute to the mark and shake. Carry out a control test using 1 ml of standard lead solution and the same quantities of other reagents as used in test with the material.

C-3.2 The test solution shall be taken as not having exceeded the limit prescribed if the intensity of colour produced in the test with the material is not greater than that produced in the control test.