

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
सिम्स पैटर्न डबल एंडेड वैजाइनल स्पेक्युलम – विशिष्टि
(IS 6112 का पहला पुनरीक्षण)

Draft Indian Standard

Sim's Pattern Double-ended Vaginal Speculum – Specification
(First Revision of IS 6112)

ICS 11.040.30

Obstetric and Gynaecological Instruments
and Appliances Sectional Committee, MHD 03

Last date for comments: **27 July 2024**

FOREWORD

(Formal clauses will be added later)

This standard was originally published in 1971. The first revision of this standard has been brought out to align the standard with the latest style and format of Indian Standards. This revision incorporates Amendment No.1 issued in 1980. Also, cross-references to Indian Standards 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 same as that of the specified value in this standard.

1 SCOPE

This standard specifies dimensional and other requirements of vaginal speculum, double ended (Sim's pattern).

2 REFERENCES

The standards given below 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 these standards.

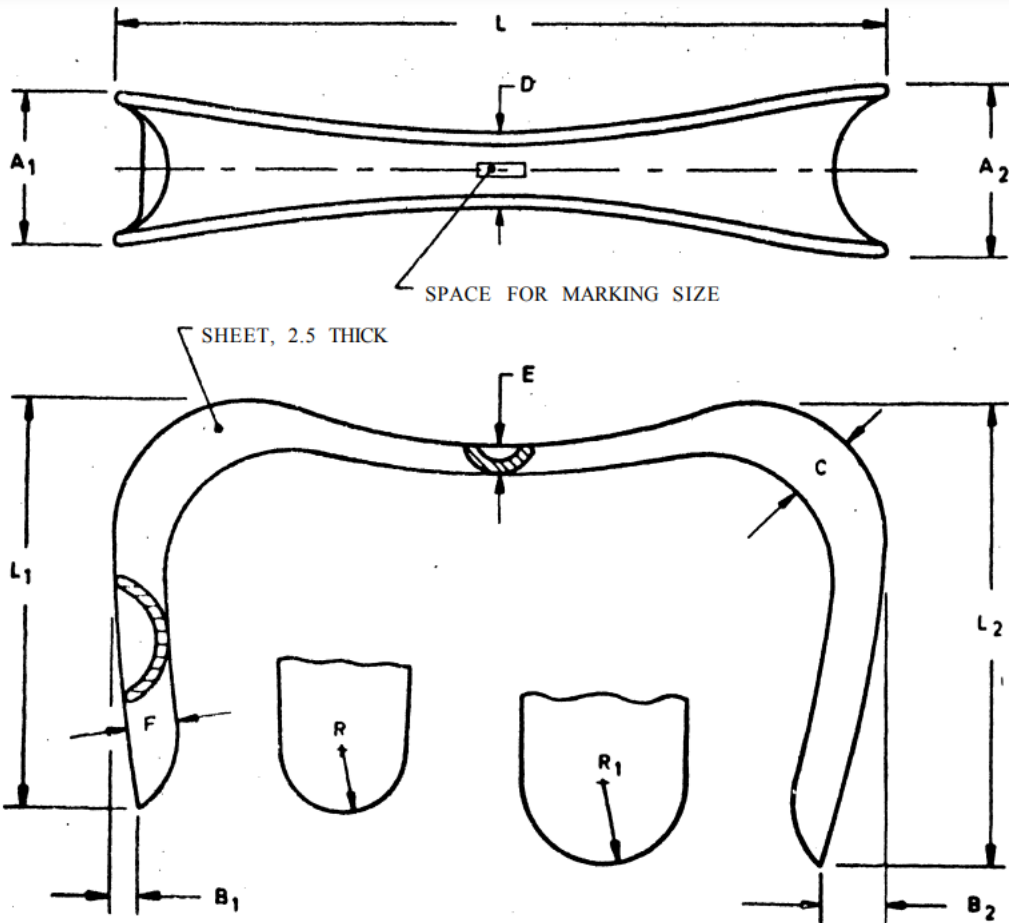
| IS No. | Title |
|------------------------------|---|
| IS 1570 (Part 2/Sec 1): 1979 | Schedules for wrought steels Part 2 Carbon steels (unalloyed steels) Section 1 Wrought products (other than wires) with specified chemical composition and related properties (<i>first revision</i>) |
| IS 1570 (Part 5): 1985 | Schedules for wrought steels Part 5 Stainless and heat-resisting steels (<i>second revision</i>) |
| IS 1068: 1993 | Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium - Specification (<i>third revision</i>) |
| IS 7531: 1990 | Surgical instruments – Corrosion resistance of stainless-steel surgical instruments - Methods of tests (<i>first revision</i>) |

3 MATERIAL

The speculum shall be made of stainless-steel conforming to designation X04Cr19Ni9 or X07Cr18Ni9 of IS 1570 (Part 5), or brass (Min 60 percent copper), or carbon steel of designation 35C4 of IS 1570 (Part 2/Sec 1).

4 SHAPE AND DIMENSIONS

The shape and dimensions shall be as shown in Fig. 1.



| Sizes | L | L_1 | L_2 | A_1 | A_2 | B_1 | B_2 | C | D | E | F | R | R_1 |
|--------|-----|-------|-------|-------|-------|-------|-------|------|------|-----|------|------|-------|
| Small | 130 | 80 | 85 | 26 | 32 | 4.0 | 9.0 | 14.0 | 15.0 | 6.0 | 10.0 | 11.0 | 13.0 |
| Medium | 160 | 85 | 95 | 32 | 36 | 6.0 | 13.0 | 14.0 | 15.0 | 6.0 | 10.0 | 13.0 | 17.0 |
| Large | 175 | 95 | 105 | 36 | 42 | 12.0 | 13.0 | 16.0 | 17.0 | 7.0 | 13.0 | 17.0 | 19.0 |

All dimensions in millimetres.

FIG. 1 SPECULUM, VAGINAL. DOUBLE ENDED (SIM'S PATTERN)

5 WORKMANSHIP AND FINISH

5.1 All surfaces shall be free from burrs, pits, cracks, and other defects.

5.2 All edges shall be smoothly rounded off and shall not be sharp.

5.3 If made of stainless steel the speculum shall be passivated and polished bright. In the case of carbon steel or brass it shall be plated chromium over nickel conforming to Service Condition No. 2 respectively of IS 1068.

6 HEAT TREATMENT

The instrument made of carbon steel shall be hardened and tempered to 380 HV to 420 HV.

7 TESTS

7.1 Grip the blades in a vice and try to straighten the blades by applying a force of 50 N on each blade. The blades shall resist this and show no sign of damage after test.

7.2 Grip the speculum in a vice with its long blade protruding out horizontally. Suspend a load of 150 N from the tip of the blade. Attain this load gradually and allow to act for 2 minutes. After the test the speculum shall show no sign of damage.

7.3 Corrosion Resistance (Applicable Only to Stainless Steel Instruments)

Test the sample in accordance with IS 7531. The sample shall show no sign of corrosion after the test.

8 MARKING

8.1 The product shall be legibly and indelibly marked with the following:

- a) Manufacturer's name, initials or registered trade-mark;
- b) Country of manufacture; and
- c) The words 'Stainless Steel' or the letters 'SS'

8.2 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 there under, and the product(s) may be marked with the Standard Mark.

9 PACKING

The speculum shall be packed as agreed to between the purchaser and supplier.