

**BUREAU OF INDIAN STANDARDS**

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**भारतीय मानक मसौदा**  
**सर्जरी के लिए प्रत्यारोपण — दो-भाग एडिशन-क्योर सिलिकॉन**  
**इलास्टोमर्स**

***Draft Indian Standard***

**Implants for Surgery — Two-part Addition-cure  
Silicone Elastomers**

ICS 11.040.40

Orthopaedic Instruments, Implants and  
Accessories Sectional Committee, MHD 02

Last date for comments: **22 August 2024**

**NATIONAL FOREWORD**

(*Adoption clause will be added later*)

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

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- 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 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 34-1:1994, Rubber, vulcanized or thermoplastic —	IS 3400 (Part 12) : 2022 Methods of test for vulcanized	Modified

**Doc: MHD02(25944)WC**  
**July 2024**

determination of tear strength — part 1: trouser, angle and crescent test pieces	rubbers: Part 12 tear strength-crescent test piece first revision	
ISO 48:1994, Rubber, vulcanized or thermoplastic — determination of hardness (hardness between 10 IRHD and 100 IRHD)	IS 3400 (Part 2) : 2023 Methods of test for rubber, vulcanized or thermoplastic Part 2 determination of hardness section 2 hardness between 10 irhd and 100 irhd ( fifth revision )	Modified
ISO 527-2:1993, Plastics — determination of tensile properties — Part 2: test conditions for moulding and extrusion plastics	IS 13360 (Part 5/Sec 2) : 2017 Plastics - methods of testing: Part 5 mechanical properties section 2 determination of tensile properties - test conditions for moulding and extrusion plastics (first revision)	Modified
ISO 3417:1991, Rubber — measurement of vulcanization characteristics with the oscillating disc curemeter	IS 11720 (Part 2) : 2013 ISO 3417 :2008 Methods of test for synthetic rubber: Part 2 measurement of vulcanization characteristics with the oscillating disc curemeter (second revision)	Modified
ISO 6502:1999, Rubber — guide to the use of curemeters	IS 16848 : 2018 Rubber - guide to the use of curemeters	Modified
ISO 10993-1:1997, Biological evaluation of medical devices — Part 1: evaluation and testing	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices Part 1: evaluation and testing within a risk management process (ISO 10993-1 : 2018, MOD)	Modified
ISO 10993-5:1999, Biological evaluation of medical devices — Part 5: tests for in vitro cytotoxicity	IS/ISO 10993-5 : 2009 Biological evaluation of medical devices Part 5 tests for in vitro cytotoxicity	Modified

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)'.

**Note:** The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 14949 : 2001 or kindly contact:

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## **SCOPE**

This International Standard specifies the characteristics of, and corresponding test methods for, the two-part addition-cure high consistency or liquid silicone elastomer for use in the manufacture (partially or totally) of surgical implants.