

**BUREAU OF INDIAN STANDARDS**

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**भारतीय मानक मसौदा**

**गैर-सक्रिय सर्जिकल प्रत्यारोपण - स्तन प्रत्यारोपण - विशेष  
आवश्यकताएँ**

***Draft Indian Standard***

**Non-Active Surgical Implants — Mammary Implants —  
Particular Requirements**

ICS 11.040.40

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Orthopaedic Instruments, Implants and  
Accessories Sectional Committee, MHD 02

Last date for comments: **20 July 2024**

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**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:

- 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, 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 34-1:2015, Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trousar, angle and crescent test pieces                | IS 3400 (Part 12) : 2022<br>Methods of test for vulcanized rubbers: Part 12 Tear strength-crescent test piece First Revision   | Identical                    |
| ISO 37:2017, Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties   | IS 3400 : 2021 Methods of Test for Vulcanized Rubber Part 1 Tensile Stress-Strain Properties   | Identical                    |
| ISO 4287, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters             | IS 18432 (Part 2) : 2023 Geometrical product specifications (GPS) — Surface texture: Profile: Part 2 Terms, definitions and surface texture parameters   | Modified                     |
| ISO 7619-1, Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)                  | IS 3400 (Part 2/Sec 4) : 2022 Methods of Test for Rubber, Vulcanized or Thermoplastic Part 2 Determination of Hardness Section 4 Indentation Hardness by Durometer Method (Shore Hardness) ( Second Revision ) | Modified                     |
| 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  | Identical                    |
| ISO 10993-5, 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  | Identical                    |
| ISO 10993-18, Biological evaluation of medical devices — Part 18: Chemical characterization of materials   | IS/ISO 10993-18 : 2020 Biological evaluation of medical devices Part 18 Chemical characterization of medical device materials within a risk management process   | Identical                    |
| ISO 11607-1, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems | IS/ISO 11607 : 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems First Revision                                      | Identical                    |
| ISO 14155, Clinical investigation of medical devices for human subjects — Good clinical practice   | IS/ISO 14155 : 2020 Clinical investigation of medical devices for human subjects - Good clinical practice  | Identical                    |

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| ISO 14630:2012, Non-active surgical implants — General requirements | IS 18076 : 2023 Non-active surgical implants General requirements | Identical |
|---|---|-----------|

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

| <i>International Standard/<br/>Other Publication</i> | <i>Title</i>   |
|--|--|
| ASTM D412–16   | Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension                           |
| ASTM D624–00 (2012)                                  | Standard guide for evaluation of thermoplastic polyurethane solids and solutions for biomedical applications |
| ASTM D792–13   | Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement        |
| ASTM D2240–15,                                       | Standard Test Method for Rubber Property — Durometer Hardness  |

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)’.

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**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 14607: 2018 or kindly contact:

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## **SCOPE**

This document specifies particular requirements for mammary implants.

With regard to safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, packaging, sterilization, and information supplied by the manufacturer.