

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

**सर्जरी के लिए प्रत्यारोपण — प्रत्यारोपण योग्य सामग्रियों और
चिकित्सा उपकरणों पर स्थैतिक और गतिशील संक्षारण परीक्षणों
के लिए परीक्षण समाधान और पर्यावरणीय स्थितियाँ**

Draft Indian Standard

**Implants for Surgery — Test Solutions and
Environmental Conditions for Static and Dynamic
Corrosion Tests on Implantable Materials and Medical
Devices**

ICS 11.040.40

Orthopaedic Instruments, Implants and
Accessories Sectional Committee, MHD 02

Last date for comments: **05 September 2025**

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.

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/ Other Publication</i>	<i>Title</i>
ISO 3696	Water for analytical laboratory use — Specification and test methods

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 16428: 2005 or kindly contact:

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SCOPE

This International Standard specifies standard environmental conditions for the testing of metallic materials intended for implantation, surgical implants, and medical devices. The test conditions described simulate physiological conditions in a simplified manner controlling the test solution, the temperature, the gaseous atmosphere and the proportions of sample size and volume of solution.

These environmental testing conditions can be employed where necessary in combination with various static or dynamic tests where the effect of the physiological environment is to be considered. Typical applications are corrosion fatigue tests and selected fretting and wear tests, as well as general electrochemical tests.

Typical articulating joint simulator tests and aspects particular to the dental field are not considered by this International Standard. Solutions that attempt to replicate the tribological properties of body fluids, such as those used in wear studies, are outside the scope of this International Standard.