

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

**गैर-सक्रिय सर्जिकल प्रत्यारोपण — अस्थिसंश्लेषण के लिए
प्रत्यारोपण — विशेष आवश्यकताएं**

Draft Indian Standard

**Non-active Surgical Implants — Implants for
Osteosynthesis — Particular Requirements**

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.

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 14630:2008, Non-active surgical implants — General requirements	IS 18076:2023/ISO 14630: 2012, Non-active surgical implants - General requirements	Identical

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

Doc: MHD02 (28422) WC
August 2025

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 14602: 2010 or kindly contact:

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SCOPE

This International Standard specifies particular requirements for non-active surgical implants for osteosynthesis, hereafter referred to as implants.

In addition to ISO 14630, this International Standard gives particular requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.