

BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY
(*Not to be reproduced without permission of BIS or used as standard*)

भारतीय मानक मसौदा

**सर्जरी के लिए प्रत्यारोपण - परीक्षण के लिए कृत्रिम संरचनात्मक
हड्डी मॉडल की विशिष्टि और सत्यापन**

Draft Indian Standard

**Implants for surgery — Specification and verification
of synthetic anatomical bone models for testing**

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.

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 22926: 2023 or kindly contact:

Head (MHD)
Bureau of Indian Standards

Doc: MHD02(25943)WC

July 2024

Manak Bhawan

9 Bahadur Shah Zafar Marg

New Delhi 110002

Email: hmhd@bis.gov.in; mhd@bis.gov.in

SCOPE

This document provides requirements and recommendations for specification and verification of synthetic anatomical bone models for use in testing of implants.

The anatomical source of the synthetic model can be digital data from computed tomography (CT) scanning or any other sources such as from cadaveric specimens or statistically determined shape data.

The specifications covered in this document are 3D shape and mechanical characteristics. Other characteristics, such as colour or cosmetic features, are not considered in this document.