DRAFT INDIAN STANDARD IN WIDE CIRCULATION

Reference : MHD02(25875) **Date : 18 June 2024**

TECHNICAL COMMITTEE : Orthopaedic Instruments, Implants And Accessories, MHD 02

To,

All concerned

Dear Madam/Sir,

The following document has been prepared by the Orthopaedic Instruments, Implants And Accessories Sectional Committee, MHD 02. Please click here to view the document.

Document Number : MHD 02 (25875) WC
Title of the document : Non-Active Surgical Implants Joint Replacement Implants Specific Requirements for Knee-Joint Replacement Implants First Revision
Document Type : Revision of Indian Standard (IS/ISO 21536 : 2007)

This document has following salient features which may require specific attention for your valuable comments:

1) This document specifies requirements for knee-joint replacement implants. Regarding safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, information supplied by the manufacturer and methods of test.
2) This document applies to both total and partial knee joint replacement implants. It applies to these replacements both with and without the replacement of the patella-femoral joint. It applies to components made of metallic and non-metallic materials.
3) This document applies to a wide variety of knee replacement implants, but for some specific knee replacement implant types, some considerations, not specifically covered in this document, can be applicable.
4) The requirements which are specified in this document are not intended to require the re-design or re-testing of implants which have been legally marketed and for which there is a history of sufficient and safe clinical use. For such implants, compliance with this document can be demonstrated by providing evidence of the implant's sufficient and safe clinical use.

Please examine the document and share your comments regarding further improvement in the document.

Last date for sharing the comments is : 18 July 2024

The comments should be shared in the prescribed template through this portal only; and the comments so received shall be taken up by the Sectional Committee for necessary action. For any other query, please write an email at mhd@bis.gov.in to the undersigned at Bureau of Indian Standard, Manak Bhawan, 9, Bahadur Shah Zafar Marg, New Delhi.

In case no comments are received, we would presume your approval of the documents. However, in case we receive any comments on the document, the same shall be put up to the Sectional Committee for necessary action.

Thanking You,

Yours faithfully,
(UNNIKRISHNAN A R)
Head (Medical Equipment and Hospital Planning Department)
Email: mhd@bis.gov.in

व्यापक परिचालन में मसौदा(दे)

हमारा सन्दर्भ : MHD02(25875) दिनांक : 18-06-2024

तकनीकी समिति : Orthopaedic Instruments, Implants And Accessories Sectional Committee, MHD 02

प्राप्तकर्ता : रूचि रखने वाले सभी निकाय

महोदय/या,

निम्नलिखित मसौदा तैयार किया गया है :

प्रलेख संख्या : MHD 02 (25875) WC
शीर्षक :

कृपया इस/इन मानक(को)/संसोधन(नो) के मसौदे(दो) का अवलोकन करें और अपनी सम्मतियाँ यह बताते हुए भेजें कि यदि ये मानक(को) के संशोधन(नो) के रूप में प्रकाशित हो तो इन पर अमल करने में आपके व्यवसाय अथवा कारोबार में क्या कठिनाइयां आ सकती हैं।

सम्मत्तियाँ भेजने की अंतिम तिथि : 18 July 2024

सम्मतियाँ, यदि कोई हों तो, कृपया यहाँ क्लिक करके ऑनलाइन पोर्टल के माध्यम से ऊपर दी गयी अंतिम तिथि तक दर्ज कराएं।

यह/ये प्रलेख भारतीय मानक ब्यूरो की वेबसाइट www.bis.gov.in पर भी उपलब्ध है/हैं।

धन्यवाद।

भवदीय/भवदिया,

विभाग प्रमुख का नाम : UNNIKRISHNAN A R
(Medical Equipment and Hospital Planning Department)
ई-मेल : mhd@bis.gov.in