



## **DRAFT INDIAN STANDARD IN WIDE CIRCULATION**

**Reference : 25002**

**Date : 28 March 2024**

**TECHNICAL COMMITTEE : Medical and Surgical Cardiology Equipment, MHD 06**

**To,**

**All concerned**

Dear Madam/Sir,

The following document has been prepared by the Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06. Please [click here](#) to view the document.

**Document Number : MHD 06 (25002) WC**

**Title of the document : Implants for surgery Active implantable medical devices Part 4: Implantable infusion pump systems**

**Document Type : New Indian Standard**

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

*1) This document specifies particular requirements for active implantable medical devices intended to deliver a medicinal substance to site-specific locations within the human body, to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2014. The requirements of this document take priority over those of ISO 14708-1. This document is applicable to active implantable medical devices intended to deliver medicinal substances to site-specific locations within the human body. This document is also applicable to some non-implantable parts and accessories of the devices defined in Clause 3. The tests that are specified in this document are type tests intended to be carried out on a sample of a device to show compliance and are not intended to be used for the routine testing of manufactured products.*

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

**Last date for sharing the comments is : 29 April 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](mailto: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](mailto:mhd@bis.gov.in)**



## व्यापक परिचालन में मसौदा(दे)

हमारा सन्दर्भ : 25002

दिनांक : 28-03-2024

**तकनीकी समिति : Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06**

प्राप्तकर्ता : रूचि रखने वाले सभी निकाय

महोदय/या,

निम्नलिखित मसौदा तैयार किया गया है :

प्रलेख संख्या : MHD 06 (25002) WC

शीर्षक :

कृपया इस/इन मानक(को)/संशोधन(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।

**सम्मतियाँ भेजने की अंतिम तिथि : 29 April 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](http://www.bis.gov.in) पर भी उपलब्ध है/हैं।

धन्यवाद।

भवदीय/भवदिया,  
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