



## DRAFT INDIAN STANDARD IN WIDE CIRCULATION

Reference : 25205

Date : 09 April 2024

**TECHNICAL COMMITTEE : Anaesthetic, Resuscitation And Allied Equipment, MHD 11**

To,

**All concerned**

Dear Madam/Sir,

The following document has been prepared by the Anaesthetic, Resuscitation And Allied Equipment Sectional Committee, MHD 11. Please [click here](#) to view the document.

**Document Number : MHD 11 (25205) WC**

**Title of the document : Biocompatibility evaluation of breathing gas pathways in healthcare applications  
Part 1: Evaluation and testing within a risk management process**

**Document Type : New Indian Standard**

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

*1) This Indian Standard represents the application of the best-known science, in order to improve patient safety, by addressing the risk of potentially hazardous substances being conveyed to the patient by the gas stream. This Indian Standard is intended to cover the biological evaluation of gas pathways of medical devices within a risk management process, as part of the overall medical device evaluation and development. This approach combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests.*

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

**Last date for sharing the comments is : 09 May 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 : 25205

दिनांक : 09-04-2024

**तकनीकी समिति : Anaesthetic, Resuscitation And Allied Equipment Sectional Committee, MHD 11**

**प्राप्तकर्ता : रूचि रखने वाले सभी निकाय**

महोदय/या,

**निम्नलिखित मसौदा तैयार किया गया है :**

**प्रलेख संख्या : MHD 11 (25205) 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 : 09 May 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,**  
**विभाग प्रमुख का नाम : UNNIKRISHNAN A R**  
**(Medical Equipment and Hospital Planning Department)**  
**ई-मेल : mhd@bis.gov.in**