



भारतीय मानक ब्यूरो

(उपभोक्ता मामले, खाद्य एवं सार्वजनिक वितरण मंत्रालय, भारत सरकार)

BUREAU OF INDIAN STANDARDS

(Ministry of Consumer Affairs, Food & Public Distribution, Govt. of India)

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DRAFT INDIAN STANDARD IN WIDE CIRCULATION

Reference : 25390

Date : 29 July 2024

TECHNICAL COMMITTEE : Anesthetic, Resuscitation and Allied Equipment, MHD 11

To,

All concerned

Dear Madam/Sir,

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

Document Number : MHD 11 (25390) WC

Title of the document : Biocompatibility evaluation of breathing gas pathways in healthcare applications

Part 4: Tests for leachables in condensate

Document Type : New Indian Standard

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

1) **SCOPE** - This Indian standard specifies tests for substances leached by liquid water condensing in gas pathways of a medical device, its parts or accessories, which are intended to provide respiratory care or supply substances via the respiratory tract to a patient in all environments. The chemical characterization methods described in this document apply to chemical substances that could leach from the medical device, its parts or accessories into the condensate. This document establishes verifiable acceptance criteria for these tests. The identity and quantity of each chemical released is intended for toxicological risk assessment as described in ISO 18562-1:2024.

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

Last date for sharing the comments is : 28 August 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 : 25390

दिनांक : 29-07-2024

तकनीकी समिति : Anesthetic, 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 (25390) 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 : 28 August 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।

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