

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

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भारतीय मानक मसौदा  
स्वास्थ्य देखभाल उत्पादों का विसंक्रमण — सूक्ष्मजैविकीय विधियाँ  
भाग 3 बैक्टीरियल एंडोटॉक्सिन परीक्षण

*Draft Indian Standard*

**Sterilization of Health Care Products — Microbiological Methods**  
**Part 3 Bacterial Endotoxin Testing**

ICS 07.100.10; 11.080.01

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Hospital Equipment and Surgical Disposable  
Products Sectional Committee, MHD 12

Last date for comments: **07 June 2024**

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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 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.

In reporting the result of a test or analysis made in accordance with this standard, is to be rounded off, it shall be done in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'.

## Scope

This document specifies general criteria to be applied in the determination of bacterial endotoxins on or in health care products, components or raw materials using bacterial endotoxins test (BET) methods, using amebocyte lysate reagents.

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The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard.  
For details, please refer to ISO 11737-3:2023 or kindly contact:

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