

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

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*भारतीय मानक मसौदा*

**स्वास्थ्य देखभाल उत्पादों का विसंक्रमण — विकिरण — चयनित  
विसंक्रमण खुराक की पुष्टि: वी डी मैक्स एस डी विधि**

*Draft Indian Standard*

**Sterilization of Health Care Products — Radiation —  
Substantiation of Selected Sterilization Dose: Method VDmaxSD**

ICS 11.080.01

Hospital Equipment and Surgical Disposable  
Products Sectional Committee, MHD 12

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

**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 this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 11137-1:2006, Sterilization of health care products — Radiation — Part 1: Requirements for	IS/ISO 11137-1 : 2006, Sterilization of Health Care Products — Radiation Part 1 Requirements for	Identical

development, validation and routine control of a sterilization process for medical devices	Development, Validation and Routine Control of a Sterilization Process for Medical Devices	
ISO 11737-1:2018, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	IS/ISO 11737-1 : 2018, Sterilization of Health Care Products — Microbiological Methods Part 1 Determination of a Population of Microorganisms on Products	Identical
ISO 11737-2, Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	IS/ISO 11737-2 : 2019, Sterilization of Health Care Products — Microbiological Methods Part 2 Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process	Identical

## Scope

This document describes a method for substantiating a selected sterilization dose that achieves a sterility assurance level radiation sterilization of health care products. This document also specifies a method of sterilization dose audit used to demonstrate the continued effectiveness of the substantiated sterilization dose.

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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 13004:2022 or kindly contact:

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