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BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

इन विट्रो डायग्नोस्टिक चिकित्सा उपकरण - रक्त के अलावा मनुष्यों से नमूनों के संग्रह के लिए एकल-उपयोग कंटेनर

Draft Indian Standard

In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

[ICS 11.100.10]

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

Last date for comments: 19 **October 2023**

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 terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) 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 places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IS/ISO 15223-1 : 2016, Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision)	Identical

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)'.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 6717:2021 or kindly contact:

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Scope

This document specifies requirements and test methods for specialized single-use evacuated and non-evacuated containers, intended by their manufacturers, for the primary containment and preservation of specimens, other than blood specimens, derived from the human body, for the purposes of in vitro diagnostic examination. It is not intended to cover specimen containers for forensic investigations.
Examples of such specimens include, but are not limited to, cerebral spinal fluid (CSF), faeces, infected bodily fluids, saliva, ejaculate, sputum, urine, tissue samples.
Specimens and types of devices specifically excluded are specialized containers for cryo-preservation, samples for nucleic acid testing and swabs.

NOTE Requirements and test methods for evacuated and non-evacuated single-use human venous blood specimen collection containers are specified in ISO 6710.

This document does not specify requirements for auxiliary devices used in conjunction with specimen containers.