

**BUREAU OF INDIAN STANDARDS**

**DRAFT FOR COMMENTS ONLY**

*(Not to be reproduced without permission of BIS or used as an Indian Standard)*

भारतीय मानक मसौदा  
**चिकित्सा उपकरण - ट्रांसफ्यूजन सेट और ब्लड बैग कम्पेटिबिलिटी  
परीक्षण विधि**

*Draft Indian Standard*

**Medical Devices — Transfusion Set and Blood Bag Compatibility  
Test Method**

ICS 11.040.20

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 1135-4, Transfusion equipment for medical use — Part 4	IS/ISO 1135-4 : 2015, Transfusion Equipment for Medical Use Part 4	Identical

Transfusion sets for single use, gravity feed	Transfusion Sets for Single use, Gravity Feed	
ISO 1135-5, Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus	IS 18474 (Part 5) : 2023/ISO 1135-5 : 2015, Transfusion Equipment for Medical Use Part 5 Transfusion Sets for Single Use with Pressure Infusion Apparatus	Identical
ISO 3826-1, Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers	IS/ISO 3826-1 : 2019, Plastics Collapsible Containers for Human Blood and Blood Components Part 1 Conventional Containers ( <i>First Revision</i> )	Identical
ISO 3826-3, Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features	IS/ISO 3826-3 : 2006, Plastics Collapsible Containers for Human Blood and Blood Components Part 3 Blood Bag Systems with Integrated Features	Identical
ISO 3826-4, Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features	IS/ISO 3826-4 : 2015, Plastics Collapsible Containers for Human Blood and Blood Components Part 4 Aphaeresis Blood Bag Systems with Integrated Features	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*)’.

## Scope

This document details suitable equipment, a test method, acceptance criteria and advisable limits to help to ensure that there is compatibility (by measuring the insertion force) between a transfusion set closure piercing device (referred to in this document by the abbreviation 'spike') and a blood bag outlet port.

The test procedure in its entirety is complex and beyond the scope of each of the relevant transfusion set and blood bag standards. This document was therefore developed to support the implementation of the existing standards for blood bags and transfusion sets.

The procedure described in this document can be used by manufacturers of blood bags to test the compatibility with transfusion set spikes available on the market or by manufacturers of the transfusion set spikes to test the compatibility with blood bags available on the market.

---

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/TS 23128:2019 or kindly contact:

Head  
Medical Equipment and Hospital Planning Department  
Bureau of Indian Standards  
9 Bahadur Shah Zafar Marg  
New Delhi-110002  
Email: [mhd@bis.gov.in](mailto:mhd@bis.gov.in)  
[hmhd@bis.gov.in](mailto:hmhd@bis.gov.in)