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# Medical devices — Transfusion set and blood bag compatibility test method

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# National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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# Medical devices — Transfusion set and blood bag compatibility test method

*Dispositifs médicaux — Méthode d'essai de compatibilité entre les appareils de transfusion et les poches de sang*

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

The connection between a blood bag (as specified in ISO 3826-1, ISO 3826-3 and ISO 3826-4) and a transfusion set (ISO 1135-4 and ISO 1135-5) is provided by the bag port and transfusion set closure piercing device referred to in this document by the abbreviation 'spike'. The spike is a rigid structure with tightly defined dimensions whereas the blood bag port is of flexible material in order to accommodate the spike. Transfusion sets are compatible with a range of commercially available blood bags and vice versa. It is vitally important in setting up a blood transfusion that the force required to insert the spike into the port is not excessive. This can lead to difficulties in piercing the port septum, damage to the blood bag, leakage of its contents and injuries to bedside staff.

**TECHNICAL SPECIFICATION** **ISO/TS 23128:2019**

# Medical devices — Transfusion set and blood bag compatibility test method

## 1 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.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1135-4, *Transfusion equipment for medical use — Part 4: 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*

ISO 3826-1, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 3826-3, *Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features*

ISO 3826-4, *Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features*

## 3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

## 4 Materials and equipment

The following materials and equipment shall be used for the test set-up.

— Transfusion set spike in conformance with ISO 1135-4 or ISO 1135-5.