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Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2019)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/20

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English Version

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2019)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO 3826-1:2019)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel (ISO 3826-1:2019)

This European Standard was approved by CEN on 25 August 2019.

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European foreword

This document (EN ISO 3826-1:2019) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 3826-1:2019 has been approved by CEN as EN ISO 3826-1:2019 without any modification.

INTERNATIONAL STANDARD

ISO 3826-1

Third edition
2019-09

Plastics collapsible containers for human blood and blood components —

Part 1: Conventional containers

Poches en plastique souple pour le sang et les composants du sang — Partie 1: Poches conventionnelles

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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

This third edition cancels and replaces the second edition (ISO 3826-1:2013), which has been technically revised.

The main changes compared to the previous edition are as follows:

— in Clause 3 'Terms and definitions' four new entries have been added;

— in Clause 4, the designation example has been removed;

— Clause 5 'Design' has been revised, especially regarding the pilot samples, collection and transfer tube(s), blood-taking needle and outlet port(s);

— the physical requirements in 6.2 have been slightly amended;

— Clause 8 'Labelling' has been reviewed and amended with barcoding information;

— the normative references in Clause 2 and the Bibliography have been updated.

A list of all parts in the ISO 3826 series can be found on the ISO website.

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 manufacturers, or the suppliers, of plastics containers are expected to disclose in confidence to control authorities, if requested by them, full details of the plastics material(s) and the components of the materials and their methods of manufacture, details of manufacture of the plastics containers, including the chemical names and quantities of any additives, whether incorporated by the manufacturer of the plastics containers or present in the raw material, as well as full details of any additives that have been used.

Universal leucocyte depletion is mandatory in various countries. This document is considered as a basic for other standards which include technical innovations.

The requirements in this document are intended to

a) ensure that the quality of blood and blood components is maintained as high as necessary,

b) make possible efficient and safe collection, identification, storage, separation, and transfusion of the contents, with special attention to reducing or minimizing the risks resulting from

   — contamination, in particular, microbiological contamination,

   — air embolism,

   — errors in identification of plastics containers and any representative samples of contents,

   — interaction between the plastics container and its contents,

c) ensure functional compatibility when used in combination with transfusion sets as specified in ISO 1135-4 or ISO 1135-5,

d) provide a package with appropriate resistance to breakage and deterioration.

INTERNATIONAL STANDARD **ISO 3826-1:2019(E)**

Plastics collapsible containers for human blood and blood components —

Part 1: Conventional containers

1 Scope

This document specifies requirements, including performance requirements, for plastics collapsible, non-vented, sterile containers (known as plastics containers) complete with collecting tube outlet port(s), integral needle, and with optional transfer tube(s), for the collection, storage, processing, transport, separation, and administration of blood and blood components. The plastics containers can contain anticoagulant and/or preservative solutions, depending on the application envisaged.

This document is also applicable to multiple units of plastics containers, e.g. to double, triple, quadruple, or multiple units.

Unless otherwise specified, all tests specified in this document apply to the plastics container as prepared ready for use.

This document is not applicable to plastics containers with an integrated filter.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

