SLOVENSKI STANDARD
SIST EN ISO 3826-1:2013

01-september-2013

Nadomešča:
SIST EN ISO 3826-1:2004

Plastični zložljivi vsebniki za človeško kri in krvne komponente - 1. del: Običajni vsebniki (ISO 3826-1:2013)

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2013)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel (ISO 3826-1:2013)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO 3826-1:2013)

Ta slovenski standard je istoveten z: **EN ISO 3826-1:2013**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 3826-1:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 3826-1

June 2013

ICS 11.040.20

Supersedes EN ISO 3826-1:2003

English Version

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2013)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO 3826-1:2013)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel (ISO 3826-1:2013)

This European Standard was approved by CEN on 22 May 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 3826-1:2013) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection 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 December 2013, and conflicting national standards shall be withdrawn at the latest by December 2013.

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

This document supersedes EN ISO 3826-1:2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 3826-1:2013 has been approved by CEN as EN ISO 3826-1:2013 without any modification.

Annex ZA
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC, Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.2.3, 6.2.8, 6.3, 7.5	7.2	Only the protection to the patients is explicitly addressed. The part of ER 7.2 regarding the packaging is not fully addressed.
5.1 to 5.8, 6.2.5 to 6.2.8, 6.3	7.3	Only the first half sentence of ER 7.3 is addressed.
5.6.3, 6.2.6, 6.2.7, 6.3, 6.4.3, 8.1	7.5 (first and second paragraph)	The part of ER 7.5 relating to phthalates is not explicitly covered.
5.7, 5.8, 6.4.2	7.6	
5.7, 5.8, 6.2.2, 6.4.2	8.1	The part of ER 8.1 relating to easy handling is not addressed.
6.2.2, 7.4, 7.5	8.3	
6.2.2	8.4	
6.2.1	8.5	
5.8, 5.9	9.1	Restrictions indicated on the label or in the instructions for use are not addressed.
5.7, 5.8.1	9.2 (first indent)	
5.6, 5.9, 6.2.7	12.7.1	Only resistance to mechanical stress is addressed.
8.2 to 8.5	13.1	
8.1	13.2	
8.2 to 8.5	13.3	The part of ER 13.3 related to authorized representative is not addressed.
8.2 to 8.5	13.4	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 3826-1

Second edition
2013-06-01

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

Reference number
ISO 3826-1:2013(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 3826-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 3826-1:2003), of which it constitutes a minor revision with the following changes:

— Figure 1 on the schematic representation of plastics containers has been updated;

— Table 1 has been amended to include a plastics container with a nominal capacity of 600 ml;

— subclause 5.6.5 on requirements for sterile connection transfer tubing has been added;

— subclause 5.8.1 on the outlet port(s) has been amended by a specification for placement of the septum and by a Note 2;

— subclauses 5.8.3 and 5.8.4 on further requirements for the outlet port(s) have been added;

— Clause B.5 on a test for sterile connection of tubing has been added;

— Annex C on biological tests has been completely revised and shortened in order to incorporate the linkage to the ISO 10993 series;

— the Bibliography has been updated;

— minor editorial changes have been made throughout the whole document.

ISO 3826 consists of the following parts, under the general title *Plastics collapsible containers for human blood and blood components*:

— *Part 1: Conventional containers*

— *Part 2: Graphical symbols for use on labels and instruction leaflets*

— *Part 3: Blood bag systems with integrated features*

The following parts are under preparation:

— *Part 4: Aphaeresis blood bag systems with integrated features*

Introduction

In some countries, national pharmacopoeias or other government regulations are legally binding and these requirements take precedence over this part of ISO 3826.

The manufacturers of the plastics container, or the suppliers, are expected to disclose in confidence to the national control authority, 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 part of ISO 3826 is considered a basic document for other standards which include technical innovations.

The requirements in this part of ISO 3826 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,

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