SLOVENSKI STANDARD
SIST EN ISO 3826-1:2004

01-februar-2004

Plastiļ ni zloģljivi vsebniki za ļ loveģko kri in krvne komponente ï 1. del: Obiļ ajni vsebniki (ISO 3826-1:2003)

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2003)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel (ISO 3826-1:2003)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO 3826-1:2003)

Ta slovenski standard je istoveten z: **EN ISO 3826-1:2003**

ICS:

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

SIST EN ISO 3826-1:2004 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 3826-1

November 2003

ICS 11.040.20

English version

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2003)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO 3826-1:2003)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel (ISO 3826-1:2003)

This European Standard was approved by CEN on 14 November 2003.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

CORRECTED 2003-12-17

Foreword

This document (EN ISO 3826-1:2003) 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 BSI.

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 May 2004, and conflicting national standards shall be withdrawn at the latest by May 2004.

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(s), see informative Annex ZB, 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 3826-1:2003 has been approved by CEN as EN ISO 3826-1:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93 /42 / EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission to provide a means of conforming to Essential Requirements of the New Approach Directive (European Directive 93 / 42 / EEC)

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 ZB 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 ZB — Correspondence between this European Standard and Directive (European Directive 93 / 42 / EEC)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6	Clauses 1 to 6	
6.1	Clauses 7 to 13	Clause 7.1 For formulation of the plastic material reference is given to National Pharmacopeia. No reference is given to the flammability of the device.
6.2	Clauses 7 to 13	
6.3	Clauses 7 to 13	
6.4	Clauses 7 to 13	
7	Clauses 7 to 13	
8	Clauses 7 to 13	

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

First edition
2003-11-15

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 3826-1:2003(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 equipment for medical and pharmaceutical use*.

This first edition of ISO 3826-1, together with other parts of ISO 3826 under preparation, cancels and replaces ISO 3826:1993.

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

— *Part 1: Conventional containers*

The following part is under preparation:

— *Part 2: Graphical symbols*

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 future standards which include technical innovations, e.g. integrated leucocyte filters.

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 appropriate resistance to breakage and deterioration in a package of minimal mass and volume.