Plastist kokkupandavad anumad inimvere ja verekomponentide hoidmiseks. Osa 2: Etikettidel ja infolehtedes kasutatavad graafilised kujutised

Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 3826-2:2008 sisaldab Euroopa standardi EN ISO 3826-2:2008 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 3826-2:2008 consists of the English text of the European standard EN ISO 3826-2:2008.
Standard on kinnitatud Eesti Standardikeskuse 25.09.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 25.09.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.08.2008.	Date of Availability of the European standard text 01.08.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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Võtmesõnad:

EUROPEAN STANDARD

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English Version

Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets (ISO 3826-2:2008)

Poches en plastique souple pour le sang et les composants du sang - Partie 2: Symboles graphiques à utiliser sur les étiquettes et les notices d'utilisation (ISO 3826-2:2008)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 2: Graphische Symbole zur Verwendung auf Etiketten und Beipackzetteln (ISO 3826-2:2008)

This European Standard was approved by CEN on 9 August 2008.

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 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 Management Centre has the same status as the official versions.

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

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

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Ref. No. EN ISO 3826-2:2008: E

Foreword

This document (EN ISO 3826-2:2008) 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 February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.

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

For relationship with EC 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 3826-2:2008 has been approved by CEN as a EN ISO 3826-2:2008 without any modification.

Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This International 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, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices (Medical Device Directive).

Once this International 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 International Standard given in Table ZA.1 confers, within the limits of the scope of this International Standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and EU Directive 93/42/EEC on Medical Devices

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	Clauses 7 to 13	
Annex A	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.

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Introduction

This part of ISO 3826 has been prepared to:

— reduce the need for multiple translations of words into national languages;

— simplify and rationalize the labelling of blood treatment and transfusion devices which are medical devices used in critical situations, thereby reducing risk of misidentification, promoting safety for the patient and reducing the amount of training required by healthcare personnel;

— promote the movement of blood treatment and transfusion devices across national boundaries;

— support the essential requirements of relevant EU Directives.

The meaning of many of these graphical symbols should be self-evident. The meaning of others will become clear with use or when viewed in the context of the device itself. If appropriate, the meaning of symbols should be explained in accompanying literature when provided. Annex A provides examples of how the symbols specified in this part of ISO 3826 can be used. These are illustrative only and do not represent the only ways in which requirements of this part of ISO 3826 can be met.

Plastics collapsible containers for human blood and blood components —

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

1 Scope

This part of ISO 3826 addresses symbols that may be used to convey certain items of information related to medical devices dedicated to blood collection processes and storage. The information may be required on the device itself, as part of the label, or provided with the device. Many countries require that their own language be used to display textual information with medical devices. This raises problems to device manufacturers and users.

The symbols specified in this part of ISO 3826 do not replace current national regulatory requirements.

Manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This results in a major problem of translation, design and logistics when multiple languages are included on a single label or piece of documentation. As other medical devices, blood medical devices, labelled in a number of different languages, can experience confusion and delay in locating the appropriate language. This part of ISO 3826 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined meanings.

This part of ISO 3826 is primarily intended to be used by manufacturers of medical devices dedicated to the blood collection, process storage and distribution, who market identical products in countries having different language requirements for medical device labelling.

This part of ISO 3826 may also be of assistance to different stages of the blood supply chain, e.g.:

— distributors of blood collection devices (manual or automated) or other representatives of manufacturers;

— blood centres and distribution centres to simplify and secure the operating procedures.

The use of these symbols is primarily intended for the medical device rather than the therapeutic product.

This part of ISO 3826 does not specify requirements relating to the size and colour of symbols although the symbols specified have been specially designed so as to be clearly legible when reproduced in the space typically available on the labels of blood treatment and transfusion devices, and also so as to be suitable for on-line printing.

Several of the symbols specified in this part of ISO 3826 may be suitable for application in other areas of medical technology.

2 Normative references

The following referenced documents are indispensable for the application 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 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*