

SLOVENSKI STANDARD
SIST EN ISO 3826-2:2008

01-november-2008

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

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 2: Graphische
Symbole zur Verwendung auf Etiketten und Beipackzetteln (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-
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Ta slovenski standard je istoveten z: EN ISO 3826-2:2008

ICS:

01.080.20	Ölæã } ãã à [á æá [•^à } [] !^ { [Graphical symbols for use on specific equipment
11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 3826-2:2008

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 3826-2

August 2008

ICS 01.080.20; 11.040.20

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/GENELEC 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.

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

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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.

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Endorsement notice

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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	

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

INTERNATIONAL STANDARD

ISO
3826-2

First edition
2008-08-01

Plastics collapsible containers for human blood and blood components —

Part 2:

Graphical symbols for use on labels and instruction leaflets

iTeh STANDARD PREVIEW
Poches en plastique souple pour le sang et les composants du sang —
Partie 2: Symboles graphiques à utiliser sur les étiquettes et les notices
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Reference number
ISO 3826-2:2008(E)

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ISO 3826-2:2008(E)

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 3826-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

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*

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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.

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