SLOVENSKI STANDARD

SIST EN ISO 3826-3:2008

01-april-2008

Plastiļ ne vreļ ke za ļ loveġko kri in krvne komponente - 3. del: Sistemi vreļ k za kri z integrirano oznako (ISO 3826-3:2006)

Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features (ISO 3826-3:2006)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 3: Blutbeutelsysteme mit integrierten Merkmalen (ISO 3826-3:2006)

Poches en plastique souple pour le sang et les composants du sang - Partie 3: Systèmes de poches pour le sang avec accessoires intégrés (ISO 3826-3:2006)

Ta slovenski standard je istoveten z: **EN ISO 3826-3:2007**

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11.040.20

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 3826-3

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English Version

Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features (ISO 3826-3:2006)

Poches en plastique souple pour le sang et les composants du sang - Partie 3: Systèmes de poches pour le sang avec accessoires intégrés (ISO 3826-3:2006)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 3: Blutbeutelsysteme mit integrierten Merkmalen (ISO 3826-3:2006)

This European Standard was approved by CEN on 19 November 2007.

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
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Foreword

The text of ISO 3826-3:2006 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 3826-3:2007 by 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 June 2008, and conflicting national standards shall be withdrawn at the latest by June 2008.

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(s), 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 3826-3:2006 has been approved by CEN as a EN ISO 3826-3:2007 without any modification.

Annex ZA
(informative)

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

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission to provide a means of conforming to Essential Requirements of the New Approach 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 normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive and associated EFTA regulations.

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

INTERNATIONAL STANDARD

ISO 3826-3

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2006-09-15

Plastics collapsible containers for human blood and blood components —

Part 3: Blood bag systems with integrated features

Poches en plastique souple pour le sang et les composants du sang —
Partie 3: Systèmes de poches pour le sang avec accessoires intégrés

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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 3826-3 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 3: Blood bag systems with integrated features*

Part 2, which will cover the use of graphical symbols, is currently in preparation.