SLOVENSKI STANDARD
oSIST prEN ISO 3826-1:2010

01-december-2010

Plastični zložljivi vsebniki za človeško kri in krvne komponente - 1. del: Običajni vsebniki (ISO/DIS 3826-1:2010)

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO/DIS 3826-1:2010)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO/DIS 3826-1:2010)

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

ICS:

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 3826-1

October 2010

ICS 11.040.20

Will supersede EN ISO 3826-1:2003

English Version

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO/DIS 3826-1:2010)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO/DIS 3826-1:2010)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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

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Foreword

This document (prEN ISO 3826-1:2010) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 3826-1:2003.

Endorsement notice

The text of ISO/DIS 3826-1:2010 has been approved by CEN as a prEN ISO 3826-1:2010 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 3826-1

ISO/TC **76** Secretariat: **DIN**

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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

[Revision of first edition (ISO 3826-1:2003)]

ICS 11.040.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition, which has been technically revised. Especially the following changes have been made:

- 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;
- a new clause 5.6.5 on requirements for sterile connection transfer tubing has been added;
- 5.7 on the blood-taking needle has been widely aligned with the relevant paragraph in ISO 1135-3;
- 5.8 on the outlet port(s) has been updated regarding a good compatibility with closure piercing-devices in accordance with ISO 1135-4;
- a new 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 through 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*

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.