Plastist kokkupandavad anumad inimvere ja verekomponentide hoidmiseks. Osa 3: Verekotisüsteemid

Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 3826-3:2008 sisaldab Euroopa standardi EN ISO 3826-3:2007 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 3826-3:2008 consists of the English text of the European standard EN ISO 3826-3:2007.
Standard on kinnitatud Eesti Standardikeskuse 28.01.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 28.01.2008 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 12.12.2007.	Date of Availability of the European standard text 12.12.2007.
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 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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 3826-3:2007: E

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.

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 or suppliers of the plastic containers are expected to disclose in confidence to the national control authority, if requested by them, full details of the plastic material(s) and the components of the materials and their methods of manufacture, details of the manufacture of the plastic containers including the chemical names and quantities of any additives, whether incorporated by the manufacturer of the plastic containers or present in the raw material, as well as full details of any additives that have been used.

Plastics collapsible containers for human blood and blood components —

Part 3: Blood bag systems with integrated features

1 Scope

This part of ISO 3826 specifies requirements, including performance requirements, for integrated features on plastic, collapsible, non-vented, sterile containers (blood bag systems). Blood bag systems need not contain all of the integrated features identified in this document.

The integrated features refer to:

— leucocyte filter;

— pre-donation sampling device;

— top-and-bottom bag;

— platelet storage bag;

— needle stick protection device.

In addition to ISO 3826-1, which specifies the requirements of conventional containers, this part of ISO 3826 specifies additional requirements for blood bag systems using multiple units. This part of ISO 3826 does not cover automated blood collection systems.

Unless otherwise specified, all tests specified in this part of ISO 3826 apply to the plastic container as prepared ready for use. Use chemical, physical and biological tests in accordance with ISO 3826-1, where applicable.

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 3826-1:2003, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*