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Kollaberbara plastbehållare för humant blod och blodkomponenter –
Del 3: System för blodpåsar med integrerade komponenter (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)

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Europastandarden EN ISO 3826-3:2007 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 3826-3:2007.

The European Standard EN ISO 3826-3:2007 has the status of a Swedish Standard. This document contains the official English version of EN ISO 3826-3:2007.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

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.

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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.

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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of an identical text or by endorsement, at the latest by June 2008, and conflicting national standards shall be withdrawn at the latest by June 2008.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.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3826-1 and the following apply.

3.1
leucocyte filter
LCF
filter used to reduce the content of leucocytes in blood or blood components

3.2
pre-donation sampling device
PDS
device integrated in the donor line of blood bag systems and designed to separate the first volume of donated blood

NOTE The pre-donation sampling device is integrated in the donor line through a Y-piece, such that blood may only flow into the pre-donation sampling device or into the blood bag.

3.3
top-and-bottom bag
TBB
bag containing top-and-bottom inlets and outlets

NOTE The top-and-bottom bag is part of a multiple bag system and is designed to allow centrifugation of anticoagulated whole blood. After centrifugation the plasma is separated through the top and red cell concentrate through the bottom outlet of the bag.

3.4
platelet storage bag
PSB
bag suitable for appropriate storage of a therapeutic dose of platelet concentrates, obtained from a single donation or a pool of donations

NOTE The platelet storage bag can stand alone or be part of a blood bag system.

3.5
needle stick protection device
NPD
device integrated in the donor line of blood bag systems, containing the donor needle, and designed to prevent undesirable needle sticks after use of the donor needle

4 Dimensions and designation

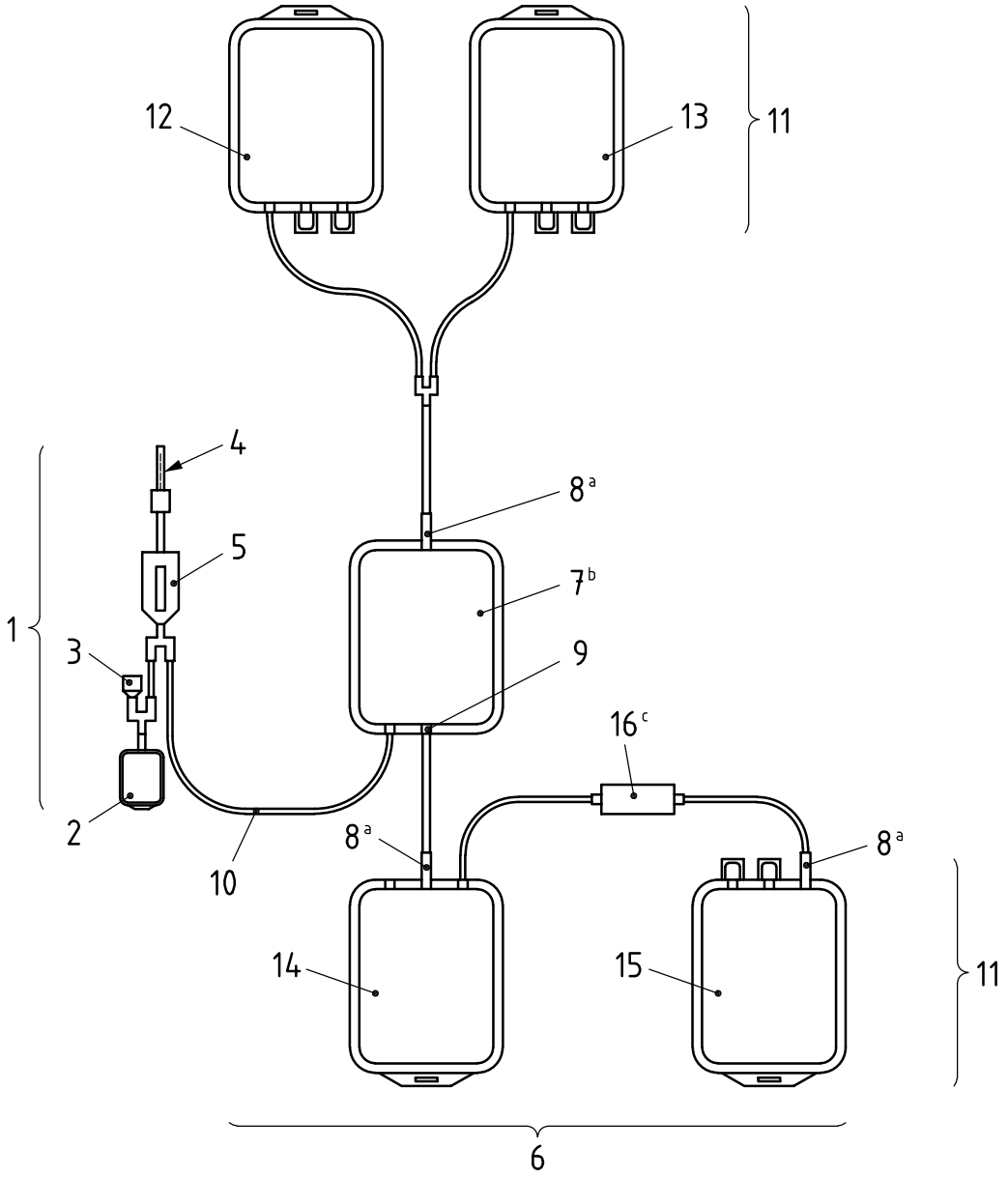
4.1 Dimensions

Figures 1 and 2 illustrate the components of a blood bag system with integrated features. The general drawings and the drawing of each feature are for guidance only. The dimensions shall be in accordance with those listed in ISO 3826-1:2003, 4.1, Figure 1.

4.2 Designation example

Plastics containers are designated using the descriptor words “Plastics container” followed by the number of this part of ISO 3826, in turn followed by the abbreviation of the relevant integrated feature given in Clause 3. For example, the designation of a plastics container with a leucocyte filter in accordance with this part of ISO 3826 is:

Plastics container ISO 3826-3 – LCF



Key

1	pre-donation sampling device (PDS)	9	bottom outlet
2	pre-donation sampling bag	10	collection tube
3	multiple sampling device	11	transfer bags
4	blood-taking needle	12	empty transfer bag
5	needle stick protection device (NPD)	13	platelet storage bag (PSB)
6	blood bag system	14	bottom empty transfer bag
7	top-and-bottom bag (TBB)	15	transfer bag with additive solution
8	(top) outlet	16	leucocyte filter (LCF)

a Means of closure. The means may be positioned at other sites.

b In the present configuration the TBB is the collection container and contains the anticoagulant.

c In the present configuration the LCF is a red cell concentrate filter.

Figure 1 — Schematic representation of components of a blood bag system with integrated features — Top-and-bottom bag system with integrated red cell filter, platelet storage bag and pre-donation sampling device