INTERNATIONAL STANDARD

ISO 3826-3

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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

Reference number
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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.

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