
**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.

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.

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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*