Second edition
2013-06-01

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

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 3826-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 3826-1:2003), of which it constitutes a minor revision with the following changes:

— 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;

— subclause 5.6.5 on requirements for sterile connection transfer tubing has been added;

— subclause 5.8.1 on the outlet port(s) has been amended by a specification for placement of the septum and by a Note 2;

— subclauses 5.8.3 and 5.8.4 on further requirements for the outlet port(s) have been added;

— 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 have been made throughout 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*

The following parts are under preparation:

— *Part 4: Aphaeresis 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.