INTERNATIONAL STANDARD

ISO 3826-1

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
ISO 3826-1:2013(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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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*