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Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO/DIS 3826-1:2018)

Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel (ISO/DIS 3826-1:2018)

Poches en plastique souple pour le sang et les composants du sang - Partie 1: Poches conventionnelles (ISO/DIS 3826-1:2018)

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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

ICS: 11.040.20

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 3826-1:2013), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Clause 'Terms and definitions' has been enhanced by four new entries;

— Clause 'Dimensions' has been reduced by the designation example;

— Clause 'Design' has been reviewed, especially in regard of the pilot samples, collection and transfer tube(s), blood-taking needle and outlet port(s);

— Clause 'Physical requirements' has been slightly amended;

— Clause 'Labelling' has been reviewed and amended by barcoding information;

— 'Normative references' and 'Bibliography' have been updated.

A list of all parts in the ISO 3826 series can be found on the ISO website.

Introduction

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 document is considered as a basic for other standards which include technical innovations.

The requirements in this document 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 or ISO 1135-5,

d) provide a package with appropriate resistance to breakage and deterioration.

Plastics collapsible containers for human blood and blood components —

Part 1: Conventional containers

1 Scope

This document specifies requirements, including performance requirements, for plastics collapsible, non-vented, sterile containers complete with collecting tube outlet port(s), integral needle, and with optional transfer tube(s), for the collection, storage, processing, transport, separation, and administration of blood and blood components. The plastics containers may contain anticoagulant and/or preservative solutions, depending on the application envisaged.

This document is also applicable to multiple units of plastics containers, e.g. to double, triple, quadruple, or multiple units.

Unless otherwise specified, all tests specified in this document apply to the plastics container as prepared ready for use.

This document is not applicable to plastics containers with an integrated filter.

NOTE In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use*

ISO 1135-5, *Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
plastics container
bag, of plastics material, complete with collecting tube and needle, port(s), anticoagulant, and/or preservative solutions, and transfer tube(s) and associated container(s), where applicable

3.2
shelf life
period between the date of sterilization and the use by date (expiry date) after which the plastics container(s) should not be used for the collection of blood

3.3
sheeting
plastics film or foil intended for the production of raw containers

3.4
raw container
unfilled container that has not yet been sterilized and has no base label attached

3.5
empty container
raw container with a base label attached, which is suitable for the acceptance and storage of fluids where applicable and to be used for testing purposes

3.6
gauge pressure
pressure zero-referenced against local atmospheric pressure

Note 1 to entry: Container internal gauge pressure is positive when the container is pressurized above the surrounding atmospheric pressure and is negative when the container is subjected to suction.

4 Dimensions

Figure 1 illustrates the components of a plastics container. The values of the dimensions shown in Figure 1 are binding and form part of the requirements of this document; the dimensions given in Table 1 are for guidance only.

5 Design

5.1 General

The design and manufacture of the plastics container shall provide for the safe and convenient collection, storage, processing, transport, separation, and administration of whole blood and blood components. The plastics container shall permit the collection of blood and the preparation of plasma or centrifuged or resuspended cellular components with a minimal hazard of contamination by microorganisms. The plastics container shall be functionally compatible with the transfusion set specified in ISO 1135-4 or ISO 1135-5. Its design shall also ensure that it can be used in a centrifuge cup.

5.2 Air content

5.2.1 The total volume of air contained in the plastics container system divided by the number of containers shall not exceed 15 ml.

NOTE Typical plastics container systems are described in ISO 3826-3.

5.2.2 When used in accordance with the manufacturer's instructions, the plastics container shall be capable of being filled with blood without air being introduced.

5.3 Emptying under pressure

The plastics container, when filled with a volume of water at a temperature of (23 ± 5) °C equal to its nominal capacity and connected to a transfusion set as specified in ISO 1135-4 or ISO 1135-5 inserted in an outlet port (see 5.8), shall empty without visual leakage (see Note in 6.2.7) within 2 min when gradually squeezed between two plates to a gauge pressure of 50 kPa.

5.4 Pilot samples

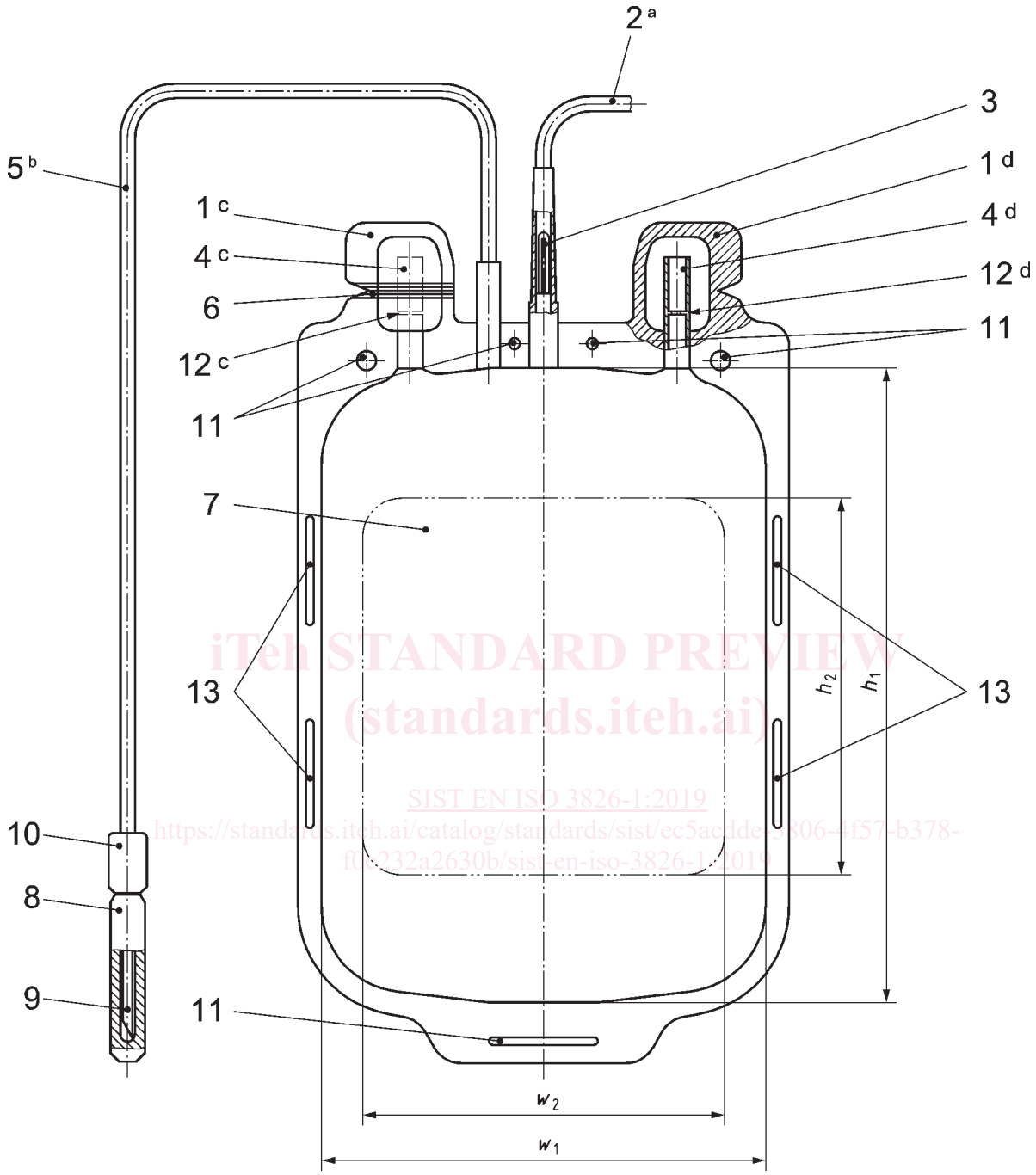
The plastics container shall be designed so that pilot samples of unmistakable identity can be collected for the performance of compatibility tests without the closed system of the plastics container being penetrated. This may be accomplished, e.g. by using an unmistakable numbering system on the tubing.

The tubing shall be designed so that stripping of the tubing up to 5 times with a tube stripper is possible and if applicable will not remove the existing numbering system when following the plastics containers instruction for use concerning tube stripping.

5.5 Rate of collection

The plastics container shall be designed so that it is capable of being filled to its nominal capacity in less than 8 min when tested in accordance with B.2.

Dimensions in millimetres



Key

1	tamper evident protector(s)	8	tamper evident protective cap
2	transfer tube	9	blood-taking needle
3	means of closure (optional)	10	needle hub
4	outlet port(s)	11	eyelets
5	collection tube	12	puncturable non-resealable closure(s)
6	tear line of protector	13	side slits
7	label area		

a Length ≥ 200 mm, internal diameter ≥ 2,7 mm, wall thickness ≥ 0,5 mm.

b Length ≥ 800 mm if used for gravitational collection, internal diameter ≥ 2,7 mm, wall thickness ≥ 0,5 mm.

c External view..