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Plastic collapsible containers for human
blood and blood components

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Foreword

This Japanese Industrial Standard has been revised by the the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 3217 : 2016**), which has been technically revised.

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# Plastic collapsible containers for human blood and blood components

## Introduction

This Japanese Industrial Standard has been prepared based on **ISO 3826-1 : 2019**, Edition 3, with the following changes to reflect local conditions in Japan: exclusion of products containing anticoagulant and preservative solutions from the scope because these products require special approval for manufacture in Japan by Pharmaceuticals and Medical Devices Agency (PMDA); and replacement of bottle needle dimensions of **ISO 1135-4** and **ISO 1135-5** with those of relevant **JISs** that are compatible with transfusion sets distributed in Japan.

The vertical lines on both sides and dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

## 1 Scope

This Standard specifies requirements for plastics collapsible containers for the collection, storage, processing, transport, separation and administration of blood and blood components (hereafter referred to as plastics containers).

This Standard does not apply to products containing anticoagulant and preservative solutions.

**NOTE** The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 3826-1 : 2019 *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

The previous edition of this Standard, **JIS T 3217 : 2016**, remains valid for three years from the date of public notice of the revision of this Standard.

## 2 Normative references

Part or all of the provisions of the following standards, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS T 0993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

JIS T 3212-4 *Sterile blood transfusion set — Part 4: Sterile transfusion sets for*

*single use, gravity feed*

NOTE Normative reference in the corresponding International Standard: ISO 1135-4 *Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed*

JIS T 3212-5 *Sterile blood transfusion set — Part 5: Sterile transfusion sets for single use with pressure infusion apparatus*

NOTE Normative reference in the corresponding International Standard: ISO 1135-5 *Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus*

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 skin sensitization*

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

### 3 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.

#### 3.1

##### **plastics container**

bag used for collection, storage, processing, transport, separation or administration of blood and blood components, provided with an inlet for blood collection, an outlet for transfusion or outlet(s) of plasma and others

Note 1 to entry Those capable of direct collection of blood are called blood collection bags.

#### 3.2

##### **shelf life**

period between the date of sterilization and the use-by date (expiry date)

Note 1 to entry The plastics containers shall not be used after the shelf life.

#### 3.3

##### **sheeting**

plastics material intended for the production of empty containers

(Source: ISO 15747 : 2018[19], 3.12)

#### 3.4

##### **raw container**

empty container that has not yet been sterilized and has no identification

(Source: **ISO 15747** : 2018, **3.11**)

### 3.5

#### **empty container**

raw container with identification, which is suitable for the acceptance and storage of fluids where applicable and to be used for testing purposes

(Source: **ISO 15747** : 2018, **3.3**)

### 3.6

#### **gauge pressure**

pressure zero-referenced against local atmospheric pressure

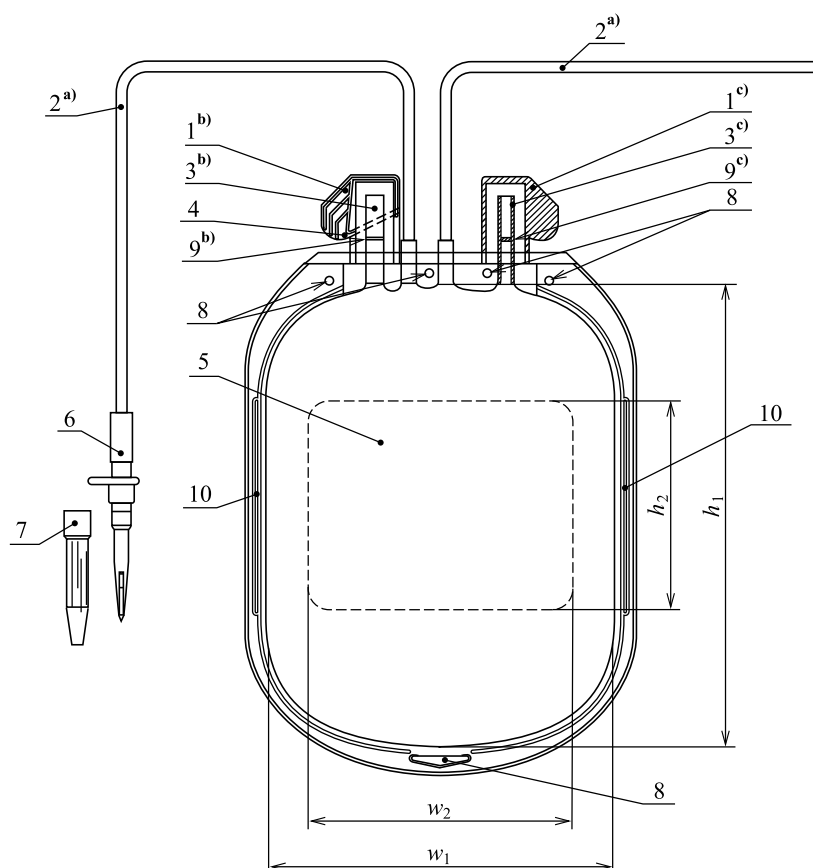
Note 1 to entry Container internal gauge pressure is positive when the container is pressurized above the surrounding atmospheric pressure, and is negative when the container is subjected to suction.

(Source: **ISO 15747** : 2018, **3.4**)

## 4 Dimensions

The plastics container normally consists of a bag and tubes, and may be fitted with extra bag(s), transfer tube, bottle needle, blood-taking needle, male and female connectors (with or without lock), vent, backflow preventive valve, auxiliary bag, sampling port, etc. Figure 1 shows a typical construction of the plastics container, and Table 1, typical dimensions.

Figure 1 Typical construction of the plastics container



#### Key

- |                             |                                       |
|-----------------------------|---------------------------------------|
| 1: temper evident protector | 7: tamper evident protective cap      |
| 2: tube                     | 8: eyelets                            |
| 3: outlet port              | 9: puncturable non-resealable closure |
| 4: tear line of protector   | 10: side slits                        |
| 5: label area               |                                       |
| 6: bottle needle            |                                       |

Note <sup>a)</sup> Internal diameter  $\geq 2.7$  mm, wall thickness  $\geq 0.5$  mm.

Note <sup>b)</sup> External view.

Note <sup>c)</sup> Cross-sectional view.

**Figure 1 Schematic representation of typical construction of plastics container**

**Table 1 Typical dimensions for plastics containers, label areas, and nominal capacity**

Unit: mm

| Nominal capacity<br>ml | Inside width<br>$w_1$ | Inside height<br>$h_1$ | Size of label area |             |
|------------------------|-----------------------|------------------------|--------------------|-------------|
|                        |                       |                        | $w_2 \pm 5$        | $h_2 \pm 5$ |
| 100                    | 75                    | 120                    | 60                 | 85          |
| 250                    | 120                   | 130                    | 90                 | 85          |
| 400                    | 120                   | 170                    | 105                | 105         |
| 500 and 600            | 120                   | 185                    | 105                | 105         |

## 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 **JIS T 3212-4** or **JIS T 3212-5**.

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. This requirement does not apply to products such as ethylene oxide gas-sterilized containers that are designed to allow air circulation inside and outside the container for sterilization purposes.

**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  $23\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$  equal to its nominal capacity and connected to a transfusion set (without venous needle and with the flow controller closed) as specified in **JIS T 3212-4** or **JIS T 3212-5**, inserted in an outlet port (see **5.8**), shall empty at an average flow velocity of 250 ml/min or more without visible water leakage in any part of the transfusion set when gradually compressed 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 blood tests in the blood centre 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 a) or B.2 b)**.

### 5.6 Tubes

**5.6.1** The plastics container may be provided with one or more tube(s) to allow the collection and separation of blood and blood components.

If a transfer tube is present, and if necessary to avoid unexpected flow between containers, it shall be fitted with a device which first acts as a seal and then, when opened, permits the free flow of blood components.

**5.6.2** The tubes shall be such that they can be sealed hermetically and do not collapse under normal use.

**5.6.3** The plastics container, filled with water to its nominal capacity and sealed, and the tubes connected to the plastics container shall form a hermetic tight leakproof connection (see **6.2.7**) which will withstand, without leakage occurring, a tensile force of 20 N applied to the tubing for 15 s. The tensile force shall be applied at right angles to the edge of the joint and along the longitudinal axis of the plane of the plastics container at a temperature of  $23\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ .

There shall be no leakage at the connection and the plastics container shall also conform to the requirements specified in **6.2.7**.

**5.6.4** Under visual inspection, the tubing shall not display cracks, blisters, kinks, or other defects.

**5.6.5** Requirements for sterile connection of tubing are as follows.

- Tubing design shall allow the efficient transfer of blood and blood components between packs.
- Design should also allow the joining of tubes supplied by a single manufacturer or from different manufacturers using a sterile tube welding device.
- Typically, this is to enable the connection of separate satellite packs when preparing blood components by a 'secondary process'.
- Sterile tube welding devices join the two opposing ends of the tube while maintaining a sterile fluid pathway.
- Manufacturers of sterile tube welding devices typically specify acceptable tube dimensions (external and/or internal diameter and wall thickness) for use on their equipment.
- Blood bag manufacturers shall specify in their product documentation the material, internal and external diameters, and wall thickness of all their tubing to allow blood transfusion services to assess the suitability for tube welding.
- When a blood transfusion service wishes to weld tubing of different specifications,

a validation should be carried out before proceeding. A protocol is provided (see **B.5**) as a minimum requirement for such validations (see also Reference [5]).

## 5.7 Blood-taking needle

The blood-taking needle shall be integral with the tube and covered by a protective cap. The protective cap shall prevent leakage of fluid from the plastics container during storage, shall maintain the sterility of the fluid path, and shall be readily removable. The protective cap shall be tamper-evident and manufactured so that either it is impossible to replace or any attempt at manipulating it is blatantly obvious.

The internal and external surfaces of the blood-taking needle shall be clean and smooth. The bevel of the needle shall be sharp and free from ridges, burrs, and barbs.

The joint between the blood-taking needle and the needle hub shall withstand a static tensile (pull) force and compressive (push) force of 20 N for 15 s along the longitudinal axis.

The joint between the needle hub and the connected tubing shall withstand a static tensile (pull) force of 20 N for 15 s along the longitudinal axis.

The blood-taking needle may contain a needle-stick protection device.

## 5.8 Outlet port(s)

**5.8.1** The plastics container shall be provided with one or more outlet ports for the administration of blood and blood components through a transfusion set. The port(s), which shall have a puncturable non-resealable closure port septum, shall allow connection of a transfusion set having a closure-piercing device in accordance with **JIS T 3212-4** or **JIS T 3212-5** without leakage (see **6.2.7**) on insertion or during conditions of use, including emptying under pressure (see **5.3**).

Before the closure is pierced by the point of the closure-piercing device, the outlet port(s) shall be tightly occluded by the closure-piercing device. When used in accordance with manufacturer's instructions, the piercing device shall not damage the plastic film of the plastics container on insertion.

**NOTE** Dimensions of the closure-piercing device can be found in **JIS T 3212-4** or **JIS T 3212-5**.

When designing the outlet port to ensure good compatibility with closure-piercing devices, manufacturers should avoid the use of tubing that is highly inflexible. Thin-walled tubing (<1 mm) should also be avoided as this tends to twist and collapse on insertion.

**5.8.2** Each outlet port shall be fitted with a hermetically sealed, tamper-evident protector to maintain the sterility of the internal surface.

**5.8.3** When a closure-piercing device conforming to **JIS T 3212-4** or **JIS T 3212-5** is inserted into the blood bag port, this shall resist a static pull force of 15 N for 15 s and shall remain in place.

**5.8.4** When tested in accordance with **5.3**, the connection between the closure-piercing

device and the blood bag port shall show no visible evidence of leakage (see 6.2.7).

## 5.9 Suspension

The plastics container shall have adequate means of suspension or positioning (see, for example, 8 in Figure 1) which do not interfere with the use of the plastics container during collection, storage, processing, transport, and administration. The means of suspending or positioning the empty container shall be capable of withstanding a tensile force of 20 N applied along the longitudinal axis of the outlet port(s) for 60 min at a temperature of  $23\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$  without breaking.

## 6 Requirements

### 6.1 General

The plastics container shall be transparent, virtually colourless (see 6.2.4), flexible, sterile, non-pyrogenic, biologically safe (see 6.4), and non-frangible under conditions of use (see 6.2.5). It shall be compatible with the contents under normal conditions of storage. The plastics container shall meet the requirements for terminal sterilization and shall not become tacky during sterilization and storage for its shelf life at temperatures not exceeding  $40\text{ }^{\circ}\text{C}$ .

The plastics container shall be stable biologically, chemically, and physically with respect to its contents during its shelf life and shall not permit penetration of microorganisms. Any substances leached from the plastics container by the contained anticoagulant and/or preservative solution, blood, and blood components by either chemical interaction or physical dissolution, shall be within the limits specified.

In many countries, national pharmacopoeias specify formulations of different plastics materials, such as flexible poly(vinyl chloride) (PVC) with different plasticizers and other plastics materials, while government regulations or standards may detail suitable tests for assessing chemical or physical interactions.

### 6.2 Physical requirements

#### 6.2.1 Conditions of manufacture

All processes involved in the manufacture, assembly, and storage of the plastics container shall be carried out under clean and hygienic conditions. Every practicable precaution shall be taken at all stages to reduce the risk of adventitious contamination by microorganisms or foreign matter.

#### 6.2.2 Sterilization

**6.2.2.1** The plastics container shall have been sterilized by steam sterilization or any other validated method.

**6.2.2.2** The method of sterilization used shall not adversely affect the materials or contents, nor cause any loosening of joints and deterioration of welds in the plastics material nor any major alteration in the shape of the plastics container.

**6.2.2.3** The manufacturer shall be able to produce evidence of the effectiveness of the sterilization process actually used. If required, positive controls to check the effective-