

# INTERNATIONAL STANDARD



# 1135

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

## Transfusion equipment for medical use

*Matériel de transfusion à usage médical*

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**Descriptors** : medical equipment, blood transfusion, specifications.

## FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

Prior to 1972, the results of the work of the technical committees were published as ISO Recommendations; these documents are in the process of being transformed into International Standards. As part of this process, Technical Committee ISO/TC 76, *Transfusion equipment for medical use*, has reviewed ISO Recommendation R 1135-1969 and found it technically suitable for transformation. International Standard ISO 1135 therefore replaces ISO Recommendation R 1135-1969, to which it is technically identical.

ISO Recommendation R 1135 had been approved by the member bodies of the following countries :

|           |                |                       |
|-----------|----------------|-----------------------|
| Australia | India          | Norway                |
| Austria   | Ireland        | South Africa, Rep. of |
| Canada    | Israel         | Spain                 |
| Chile     | Italy          | Sweden                |
| Denmark   | Korea, Rep. of | United Kingdom        |
| Germany   | Netherlands    |                       |
| Greece    | New Zealand    |                       |

The member body of France had also approved parts I (excluding clause 5.4.1), II and III of the draft, but had disapproved part IV as it was not in favour of having sets for repeated use.

The member body of Japan had opposed the approval of the draft mainly because the capacity of the glass bottle described in part I and the diameter of the blood-taking needle described in part II were considered too large for use for the population of Japan.

The member body of the following country disapproved the transformation of the Recommendation into an International Standard :

Germany

# Transfusion equipment for medical use

## 0 INTRODUCTION

It is recognized that some countries may not wish to include in their national standards all the types of equipment covered by this International Standard. It is hoped that countries which at present employ forms of equipment that would not satisfy the criterion of interchangeability, as between different countries, will abandon these as soon as possible.

In a number of countries the only giving sets prescribed in national standards are of the single-use type. It is recognized that this type is to be preferred but, in order to assist countries that are not able to insist that only single-use sets should be permitted, a specification for giving sets for repeated use is also included in this International Standard.

The primary purpose of this International Standard is to specify such requirements, for types of transfusion equipment for medical use, as will ensure functional interchangeability of the equipment irrespective of the country of origin.

Subsidiary purposes of this International Standard are to provide

- a) specifications for quality and performance of materials used in transfusion equipment;
- b) unification of terms and designations for such equipment.

## 1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies requirements for transfusion equipment, as follows :

- Section one : Glass bottle, means of suspension and closure.
- Section two : Taking sets for blood.
- Section three : Giving sets for single use with blood and blood derivatives.

Section four : Giving sets for single use with medical fluids other than blood and blood derivatives.

Section five : Giving sets for repeated use with blood and blood derivatives.

Section six : Giving sets for repeated use with medical fluids other than blood and blood derivatives.

Diagrammatic illustrations of taking and giving sets are also included. In addition, certain test methods are given in annexes, as follows :

Annex A : Test for thermal shock resistance of glass bottle.

Annex B : Test for efficiency of filter.

Annex C : Limit test for pyrogens.

Annex D : Tests for toxicity.

Annex E : Tests for sterility.

NOTE — The term "transfusion equipment for medical use" connotes equipment which is used to transfuse human blood and its derivatives or other infusion fluids, but does not include syringes for injection and special mechanical devices. Section one is concerned with glass bottles intended primarily for use with blood and blood derivatives.

## 2 REFERENCES

ISO/R 594, *Conical fittings for syringes, needles and other medical equipment — Definition and dimensional characteristics for conical fittings with a 6 % and a 10 % taper.*

ISO/R 596, *Hypodermic needles.*

ISO/R 718, *Methods for thermal shock tests on laboratory glassware.*

ISO 3825, *Glass transfusion bottles for medical use — Chemical resistance.*

ISO 3826, *Plastics, collapsible containers for blood and blood components.*<sup>1)</sup>

1) At present at the stage of draft.

## SECTION ONE

GLASS BOTTLE, MEANS OF SUSPENSION AND CLOSURE<sup>1)</sup>

## 3 GLASS BOTTLE

## 3.1 General

The glass bottle shall be transparent and substantially colourless. It shall not yield, under normal conditions of use, substances having undesirable effects upon the contents or harmful effects on the patient receiving the contents.<sup>2)</sup>

## 3.2 Thermal resistance

The bottle shall withstand the temperatures encountered during normal conditions of use, including :

**3.2.1 Sterilization** of the empty bottle by autoclaving in saturated steam at temperatures up to 134 °C.

**3.2.2 Heating** of the empty bottle in air to 250 °C.

**3.2.3 Cooling** of the bottle, filled to 70 % of its graduated capacity and closed under normal conditions of use, by immersion in a mixture of solid carbon dioxide and acetone.

## 3.3 Thermal shock resistance

Transfusion bottles shall not break, crack or chip when subjected to a thermal shock resistance test at a temperature difference agreed between the purchaser and the vendor, but not less than 40 °C. The test shall be conducted in accordance with the procedure described in annex A.

## 3.4 Resistance to internal pressure

The bottle when completely filled with water shall withstand an internal gauge pressure of not less than the following :

1 030 kPa<sup>3)</sup> for bottles with a 22,5 mm neck;

860 kPa for bottles with 30 mm neck.

The test pressure shall be reached in not more than 5 s and maintained for 1 min.

## 3.5 Mechanical strength

The bottle, charged with water to the total graduated capacity and itself immersed in water up to the 500 ml mark, in a suitable centrifuge cup, shall withstand centrifuging, such as to produce an acceleration equivalent to 2 000 times that due to gravity in the plane of the base of the bottle, for at least 30 min.

## 3.6 External form of neck

The transfusion bottle may be provided with a screw thread on the neck. Whether or not there is a screw thread, the neck shall be provided with a bead which will permit the fitting of a cap to act either as the main closure or as an additional closure when the neck has a screw thread. If a screw thread is used,<sup>4)</sup> the overall diameter should preferably be less than that of the bead to facilitate the fitting of an additional closure. The dimensions of the bead shall be as shown in figure 1 a) or 1 b), according to the neck diameter.

## 3.7 Graduation marks

There shall be two moulded scales marked at 100 ml intervals; if desired, the intermediate 50 ml intervals may also be marked. At least the 100 ml graduation marks shall be numbered. One scale serves for the collection of fluid, the numbers being upright when the container stands on its base; the other scale serves for the delivery of fluid, the numbers being upright when the container is inverted. The marks shall not project more than 1 mm from the surface of the cylindrical portion of the bottle.

## 3.8 Internal neck diameter

The nominal internal diameter of the neck shall be either

- a) 22,5 mm, or
- b) 30 mm

1) See ISO 3826 for specifications for plastics containers for blood.

2) For tests for chemical resistance, see ISO 3825.

3) 1 kPa = 1 kN/m<sup>2</sup>

4) Screw threads for glass containers and closures are being studied, and any recommendations will be taken into consideration when available.

### 3.9 Overall dimensions and graduated capacity

The overall dimensions and graduated capacity shall comply with the appropriate requirements of the following table, according to the internal diameter of the bottle used.

TABLE — Dimensions and graduated capacity of the transfusion bottle

|                                      |    |                  |          |
|--------------------------------------|----|------------------|----------|
| Internal neck diameter               | mm | 22,5 ± 0,7       | 30 ± 0,4 |
| Graduated capacity                   | ml | 500 (see note 3) | 500      |
| Overall height, max.                 | mm | 220              | 153      |
| Overall diameter, max.               | mm | 80               | 91,5     |
| Projection of graduation marks, max. | mm | 1                | 1        |

#### NOTES

1 The requirements given in this table specify the leading dimensions of well established types of bottle. It is recommended that one or other of the specified sizes should be adopted on a national basis by countries where transfusion services using glass containers are to be organized.

2 The tolerance on the internal neck diameter shall hold in all parts of the neck in contact with the closure.

3 The bottle may be marked additionally at the 540 ml level, if required.

### 4 MARKING

Marks enabling the manufacturer, the mould number and the month and year of manufacture to be identified shall be moulded on the base of the bottle.

### 5 MEANS OF SUSPENSION

Means of suspending the bottle securely in an inverted position shall be provided.

### 6 CLOSURE

#### 6.1 Design

The design of the closure and the material from which it is made shall be such that the closure is easy to clean and makes an airtight seal when fitted to the bottle concerned. The closure shall have an overall height between the limits 15 and 20 mm, and the thickness of the flange shall be not less than 4 mm. The thickness of the piercing areas (see 6.2) shall be not less than 5 mm except for one or both of the areas marked "2" which may have a small circular portion having a thickness of 3 mm. If an internal air tube is fitted, it shall be attached to the closure under one of the areas marked "2".

#### 6.2 Marking

The upper surface of the rubber closure shall be marked for piercing at four different areas. Two diagonally opposite

areas shall be marked with the numeral 1 for the collection of fluid, and two diagonally opposite areas shall be marked with the numeral 2 for the delivery of fluid.

#### 6.3 Material

The closure shall be made of self-sealing elastomeric material such that, having been aged for 168 h at 70 °C and then fitted to a transfusion bottle, it will withstand a temperature of -79 °C and the temperatures encountered during sterilization by autoclaving in saturated steam at 121 ± 1 °C for 1 h, without impairment of its function under conditions of normal use. The material before ageing shall have a hardness of 40 to 50 IRHD.<sup>1)</sup>

The closure, under normal conditions of use, shall not produce undesirable effects upon the contents of the bottle or harmful effects upon the patient receiving the contents.

#### 6.4 Sealing test

**6.4.1** The design and material of the closure shall be such that, after ageing for 168 h at 70 °C and sterilizing (see 6.3), the closure is capable of maintaining airtightness of the container at room temperature at a pressure of 27 kPa (200 mmHg) below the prevailing atmospheric pressure for 72 h, after each piercing area 1 has been pierced with a non-coring needle of 2,4 mm external diameter and the needle has been left in the closure for 10 min and then withdrawn. This requirement test is deemed to be satisfied if any change in absolute pressure is within the limits 0 to + 1,3 kPa (10 mmHg).

NOTE — This test will reveal closures which are grossly unsatisfactory. Some failures in the test are also found with batches of closures which prove satisfactory in use, but the maximum percentage of failures that can be accepted has not yet been determined.

**6.4.2** The closure shall not show any signs of leakage when the bottle is inverted immediately after it has been filled with fluid through a taking set, the piercing needles have been withdrawn and the surface of the closure has been wiped clean.

NOTE — Closures which pass the above tests will not necessarily prevent bacteria from reaching the interior of a container. The risk of bacterial contamination should be avoided by taking other suitable precautions.

### 7 BOTTLE CAP

The bottle cap shall be made of aluminium alloy or other suitable material, the thickness and design being such that it will withstand the conditions of normal use without being deformed. It shall be provided with a suitable aperture or apertures for use with taking and giving sets, and shall be so designed that it retains, and prevents distortion of, the closure during normal use.

1) International rubber hardness degrees (ISO 48).

## SECTION TWO

### TAKING SETS FOR BLOOD

#### 8 GENERAL REQUIREMENTS

##### 8.1 Types of sets

Blood-taking sets may be either for repeated use or for single use (disposable). Alternatively some components may be disposable (for example tubing) and some components re-usable (for example needles). Any component of the equipment that is intended to be re-used shall be so designed that it can be cleaned.

Each taking set shall consist of the blood-collection assembly and the air-outlet assembly, which may be separate or combined. A diagram of a typical taking set is shown in figure 2.

##### 8.2 Blood-collection assembly

The blood-collection assembly shall consist of a needle for vein puncture (the blood-taking needle), connected by a length of tubing to a needle (the bottle needle) to be inserted through one of the areas marked "1" on the bottle closure (see 6.2). The overall length of this assembly should be such as is convenient for the particular method of collection used, but the tubing shall be not less 600 mm long.

##### 8.3 Air-outlet assembly

The air-outlet assembly shall consist of tubing carrying an air filter made of non-absorbent material and fitted to a needle (the air-outlet needle) for piercing the other area marked "1" on the bottle closure (see 6.2).

##### 8.4 Sterilization

It shall be possible to sterilize the assembled complete set, by autoclaving or some other method, without causing any loosening of joints or any important alteration in the shape of the set or in the consistency of the materials used. When sets are supplied sterile, the maker shall be able to produce evidence, acceptable to the user, of the efficacy of the actual process of sterilization used.

Positive controls to check the efficacy of sterilization shall be included with each batch submitted to sterilization and, if required, samples of the sets should be tested for sterility (see annex E).

##### 8.5 Maintenance of sterility

The set shall be so packed that the needles and the interior of the set remain sterile during storage.

NOTE — The conditions and duration of storage will govern how this requirement is to be interpreted between purchaser and vendor.

Sets shall be packed and sterilized in such a way that there are no flattened portions or kinks when the equipment is ready for use.

If the set is to be packed and distributed in such a way that the external surface may not remain sterile, all the extremities of the set shall be provided with protectors designed to maintain sterility of the internal parts of the set and the needles until the set is used. The protectors shall be easily removable.

##### 8.6 Pilot tubes

Means shall be available for collecting and retaining samples of the donor's blood without entering the bottle, and maintaining their unmistakable identity until the blood in the bottle has been used.

#### 9 MATERIALS

9.1 The materials from which the equipment is made shall not have undesirable effects upon the blood passing through the set under ordinary conditions of use, or on the fluids used in connection with the blood. They shall not produce any general toxic effects on the recipient of the blood, or any local reaction (see annex D).

9.2 Samples of the sterilized assembled sets shall satisfy tests for pyrogens and toxicity (see annexes C and D). The method of sampling shall be based on statistical practice.

#### 10 TUBING

The tubing used shall comply with such requirements of clause 20 as are appropriate. The use of opaque rubber tubing necessitates the introduction of a window in the blood collection assembly, about 5 to 8 cm from the blood-taking needle. No window is necessary with translucent tubing.

#### 11 NEEDLES

11.1 The tubing mounts of needles shall either comply with the requirements of clause 32, for use with re-usable tubing, or be specially designed for single use or repeated use with disposable tubing.

NOTE — As far as the bottle needle is concerned, the use of a retaining ring to ensure a leak-proof joint between disposable tubing and needle hub may be necessary.