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# INTERNATIONAL STANDARD



# 3825

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## Glass transfusion bottles for medical use — Chemical resistance

*Flacons de transfusion en verre à usage médical — Résistance chimique*

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## 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.

International Standard ISO 3825 was developed by Technical Committee ISO/TC 76, *Transfusion equipment for medical use*, and was circulated to the member bodies in July 1975.

It has been approved by the member bodies of the following countries :

|                |                       |                |
|----------------|-----------------------|----------------|
| Australia      | Germany               | Switzerland    |
| Belgium        | Iran                  | Thailand       |
| Canada         | Italy                 | Turkey         |
| Czechoslovakia | New Zealand           | United Kingdom |
| Denmark        | Romania               | U.S.A.         |
| France         | South Africa, Rep. of | U.S.S.R.       |

No member body expressed disapproval of the document.

# Glass transfusion bottles for medical use – Chemical resistance

## 0 INTRODUCTION

The purpose of this International Standard is to specify the chemical resistance of glass transfusion bottles for medical use. The provisions of the specification are complementary to the various other physical and performance requirements given in ISO/R 1135, *Transfusion equipment for medical use*.

## 1 SCOPE AND FIELD OF APPLICATION

This International Standard specifies limits and methods of test for the chemical resistance of two classes of glass transfusion bottles. The two classes are defined in clause 3.

## 2 REFERENCE

ISO/R 720, *Determination of the hydrolytic resistance of glass grains at 121 °C*.

## 3 CLASSIFICATION

Glass transfusion bottles covered by this International Standard shall be classified as one of the following according to composition or surface preparation :

- a) borosilicate glass;
- b) surface-treated soda-lime-silica glass.

Where particular bottles are to be used more than once, then borosilicate glass only shall be specified.

## 4 REQUIREMENTS

The total amount of alkali metal oxides, calculated as equivalent sodium oxide ( $\text{Na}_2\text{O}$ ), when tested in accordance with the relevant test procedures specified in clause 6, shall not exceed the following limits :

- a) borosilicate glass — when tested in accordance with 6.1, the amount of alkali extracted shall not exceed  $62 \mu\text{g}$  of  $\text{Na}_2\text{O}$  per 1 g of powdered glass or the titration shall not exceed 0,2 of 0,01 N acid per 1 g of powdered glass and when tested in accordance with 6.2, the amount of the alkali extracted per 100 ml of leaching agent shall not exceed the limits given in the table;
- b) surface-treated soda-lime-silica glass — when tested in accordance with 6.2, the amount of alkali extracted per 100 ml of leaching agent shall not exceed the limits given in the table.

TABLE — Limiting amount of alkali oxides

| Nominal capacity of container (volume corresponding to 90 % of overflow volume) | $\text{Na}_2\text{O}$ per 100 ml of test liquid | 0,01 N acid solution to titrate 100 ml of test liquid |
|---------------------------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------|
| ml                                                                              | $\mu\text{g}$                                   | ml                                                    |
| 125                                                                             | 124                                             | 0,40                                                  |
| 400 to 500                                                                      | 92                                              | 0,28                                                  |
| 1 000                                                                           | 64                                              | 0,20                                                  |

## 5 SAMPLING

The samples shall be representative of the whole consignment. The number of samples to be taken from a batch of bottles should be agreed between the interested parties; in the absence of such agreement, it is recommended that not fewer than six bottles be taken.

## 6 METHODS OF TEST

### 6.1 Powdered glass test

Carry out this test using the method described in ISO/R 720.

### 6.2 Whole article test

#### 6.2.1 Principle

The containers to be tested are filled with specially prepared water to a specified capacity and heated under specified conditions. The degree of the attack is measured by analysis of the extract solution.

#### 6.2.2 Reagents

Use only reagents of recognized analytical grade.

##### 6.2.2.1 Specially prepared water.

Use distilled or deionized water, of high purity complying with the following requirements : when tested immediately before use, it shall be free from dissolved gases and heavy metals, particularly copper, as shown by the dithizone test; it shall have an electrolytic conductivity not exceeding  $1 \times 10^{-4} \text{ S/m}$  at  $20^\circ\text{C}$  and it shall have a pH value of about 5,5.