INTERNATIONAL STANDARD

ISO 1135-1

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

Transfusion equipment for medical use -

Part 1:

Glass transfusion bottles, closures and caps EVIEW

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Matériel de transfusion à usage médical —

Partie 1: Flacons de transfusion en verre, bouchons et capsules

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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.

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. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 1135-1 was prepared by Technical Committee ISO/TC 76, Transfusion, infusion and injection equipment for medical use.

This second edition of ISO 1135-1 cancels and replaces the 5first 9 edition of ISO 1135-1: 1986, of which it constitutes a minor revision log/standards/sist/3dedcc80-b35e-4f92-b8b6-fd67b563c4a5/iso-1135-1-1987

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Transfusion equipment for medical use —

Part 1:

Glass transfusion bottles, closures and caps

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1 Scope and field of application

2 References

ISO 1135-1:1987

This part of ISO 1135 specifies dimensions and requirements ds/sist(\$0.718, Laborator) glassware — Methods for thermal shock for types of transfusion bottles for medical use in order to enso-113 tests 987 sure functional interchangeability of the equipment.

Secondary aims of this part of ISO 1135 are to provide

- a) specifications relating to the quality and performance of materials used in transfusion equipment;
- b) a unified presentation of terms and designations for such equipment.

Transfusion bottles with rubber closures should not yield, in normal conditions of use, substances having undesirable effects on the contents or producing harmful effects on the patient receiving the contents. No tests have yet been developed to assess these effects and therefore no requirements have been included.

This part of ISO 1135 specifies requirements applicable to sterilized glass transfusion bottles for single use.

ISO 719, Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification.

ISO 3302, Rubber — Dimensional tolerances of solid moulded and extruded products.

ISO 4802, Glassware — Hydrolytic resistance of the interior surfaces of glass containers —

Part 1: Determination by titration method and classification.

Part 2: Determination by flame spectrometric methods and classification.

ISO 7458, Glass containers — Internal pressure resistance test — Test methods.

ISO 8872, Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods.¹⁾

¹⁾ At present at the stage of draft.

3 Glass transfusion bottles

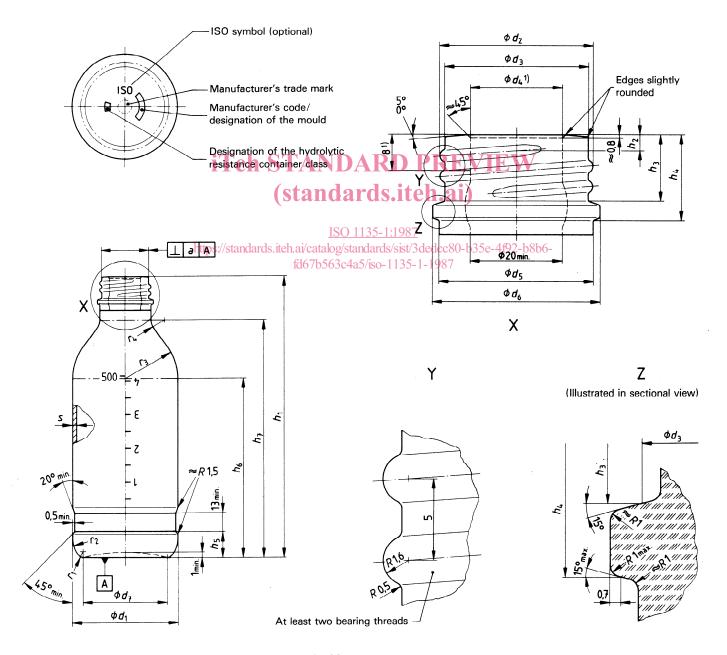
3.1 Dimensions

The dimensions for glass transfusion bottles as shown in figures 1 and 2 shall be as specified in tables 1 and 2.

NOTES

- 1 Figures 1 and 2 illustrate examples of the configuration of widely used transfusion bottles with nominal internal neck diameters of 22,5 mm and 30 mm, respectively, but they do not form part of the requirements for glass transfusion bottles specified in this part of ISO 1135; only the dimensions given in tables 1 and 2 are binding.
- 2 Table 3 specifies approximate radii dimensions for transfusion bottles which are important for the design of moulds; the radii dimensions do not form part of the requirements specified in this part of ISO 1135.

Dimensions in millimetres



1) The dimension d_4 shall be maintained over a minimum depth of 8 mm.

Figure 1 — Glass transfusion bottle with a nominal internal neck diameter of 22,5 mm

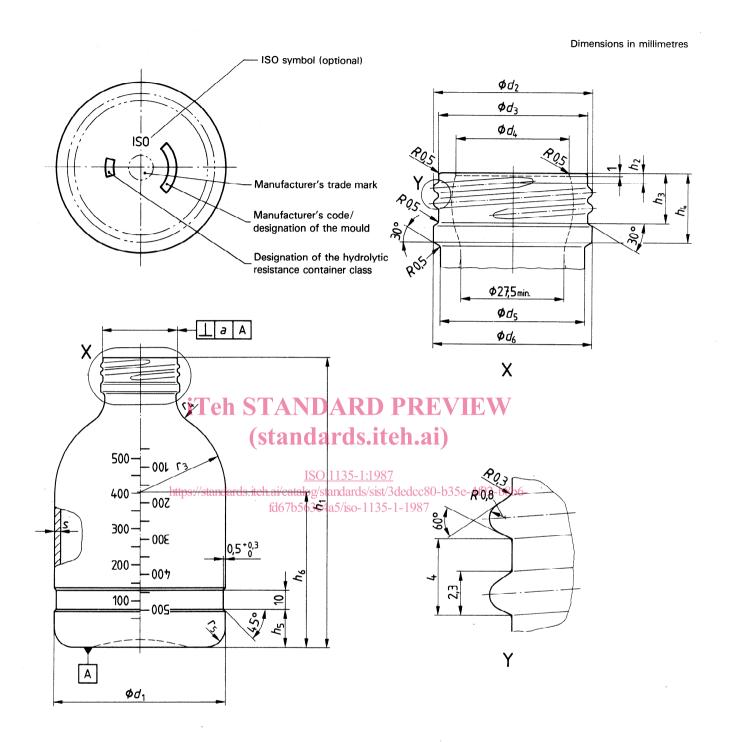


Figure 2 — Glass transfusion bottle with a nominal internal neck diameter of 30 mm

Table 1 — Overall dimensions and capacity of transfusion bottles

Dimensions in millimetres

Nominal internal neck diameter	Nominal capacity	а	ı	d ₁	,	^h 1	s1)		
	ml			tol.		tol.		tol.	
22,5	120	_	49	±1	440	±1			
	300	2	78	±1,5	140		3,5	±1,8	
	500	2,5	/6		207	±1,3			
30	250	2	67	±1					
	500	2.5			152	±1,1			
	1 000	2,5	90,5	±1	247	±1,4			

¹⁾ Dimension s is applicable only to the cylindrical part of the bottle, including the recess for the means of suspension, with a probability of 2 σ = 95 %. Owing to the manufacturing process it is not possible to specify tolerances for the thickness of the bottom wall.

Table 2 — Dimensions of the neck of transfusion bottles

Dimensions in millimetres

Nominal internal	d_2		d_3		d ₄		d_5		<i>d</i> ₆		h ₂	h	h ₃ h		14
neck diameter	max.	min.	max.	min.	max.	min.	max.	min.	max.	min.	min.	max.	min.	max.	min.
22,5	37,6	36,9	35,2	34,7	23	22	38		42	41	₇ 4	17	16	21,3	20,7
30	42,2	41,6	39,9	39,3	30,4*	29,6*	38,3	Kr	42,2	41,6	5	13,2	12,8	18,4	17,6

^{*} See 3.3.2.

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Dimensions in millimetres

Nominal internal neck diameter	Nominal capacity	d ₇ ≈	<i>h</i> 5 ≈	<i>h</i> ₆ ≈	<i>h</i> ₇ ≈	<i>r</i> ₁ ≈	<i>r</i> 2 ≈	<i>r</i> ₃ ≈	r ₄ ≈	* r ₅ ≈
22,5	120	40	11	97	112,5 175	3	12,5	10	10	
	300	62	16	69,5		4,5	20	39		· · —
	500		19	132						
30	250	_	20	98	_	_	<u>-</u>	33		
	500			81				45	14,5	10
	1 000			176						

¹⁾ See note 2 in 3.1.

3.2 Material

Colourless (cl) borosilicate glass or soda-lime-silica glass having either of the following hydrolytic resistance grain classes:

- ISO 719 HGB 1
- ISO 719 HGB 3

shall be used.

3.3 Neck of the bottle

3.4 Graduation marks

- **3.3.1** The neck shall be provided with a bead to allow a cap to be fitted as a main or an auxiliary protective cover. The overall diameter of the screw thread should preferably be less than that of the bead to facilitate the fitting of other protective covers.
- **3.3.2** The dimension for the internal neck diameter, d_4 , shall be maintained over the full depth for which it remains in contact with the closure for nominal diameters of 22,5 mm and over a depth of 1 mm for nominal diameters of 30 mm.

3.4.2 For transfusion bottles with a nominal internal neck diameter of 22,5 mm, the graduation marks shall comply with figure 3.

3.4.3 Transfusion bottles with a nominal internal neck diameter of 30 mm shall be provided with two moulded scales marked at 100 ml intervals; if necessary, the intermediate 50 ml intervals may also be marked.

3.5 Requirements and test methods

3.5.1 Hydrolytic resistance

When tested in accordance with ISO 4802, the hydrolytic resistance of the internal surface of transfusion bottles shall comply with the requirements specified for either of the following hydrolytic resistance container classes:

- ISO 4802 HC 1
- ISO 4802 HC 2

3.5.2 Thermal resistance

3.4.1 At least the graduation marks at 100 ml intervals shall be when tested in accordance with 3.5.2.2 to 3.5.2.4. numbered. One scale serves for the collection of fluid, the sumbers being unright when the container stands on its base.

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.

not project more than 1 mm from the surface of the cylindrical rds/sist/3de portion of the bottle.

3.5.2.2 Sterilize the empty bottle by autoclaving in saturated steam at a temperature of 134 °C.

ist/3dedcc80-b35e-4f92-b8b6-**3.3.5.2,3** Heat the empty bottle in air to 250 °C.

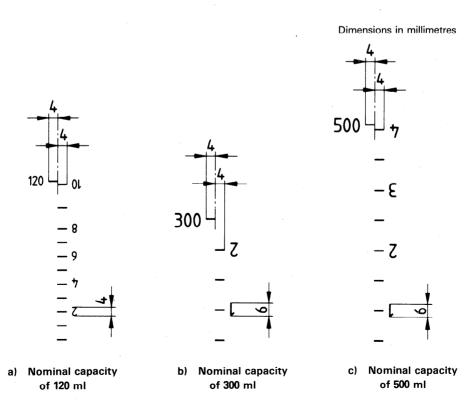


Figure 3 — Graduation marks for transfusion bottles with a nominal internal neck diameter of 22,5 mm