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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Transfusion equipment for medical use —

Part 1:

Glass transfusion bottles, closures and caps

ITeH STANDARD PREVIEW

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Matériel de transfusion à usage médical —

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

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Reference number
ISO 1135-1: 1987 (E)

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 first edition of ISO 1135-1 : 1986, of which it constitutes a minor revision.

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

This part of ISO 1135 specifies dimensions and requirements for types of transfusion bottles for medical use in order to ensure 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.

2 References

ISO 718, *Laboratory glassware — Methods for thermal shock tests.*

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

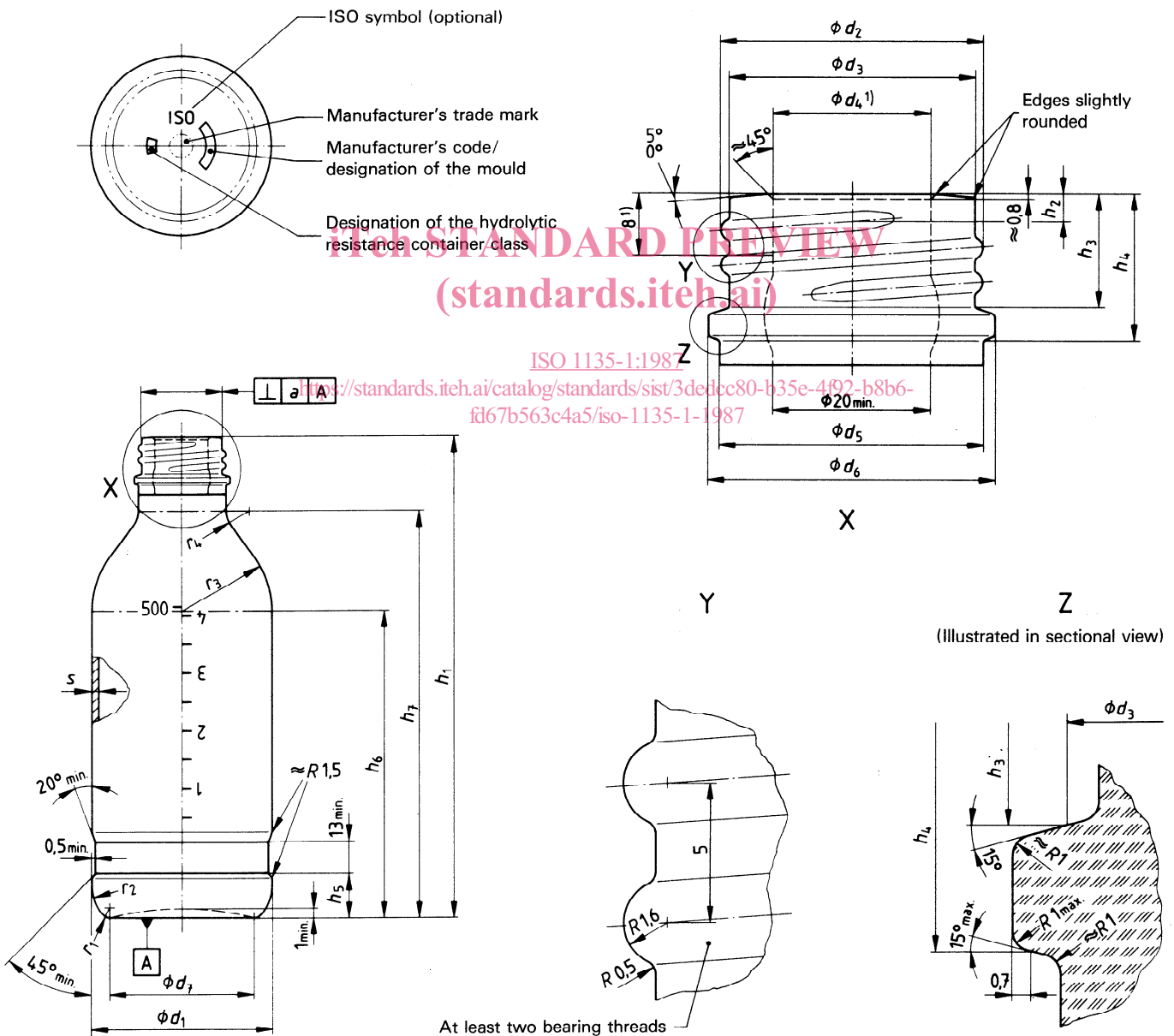
The dimensions for glass transfusion bottles as shown in figures 1 and 2 shall be as specified in tables 1 and 2.

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

Dimensions in millimetres

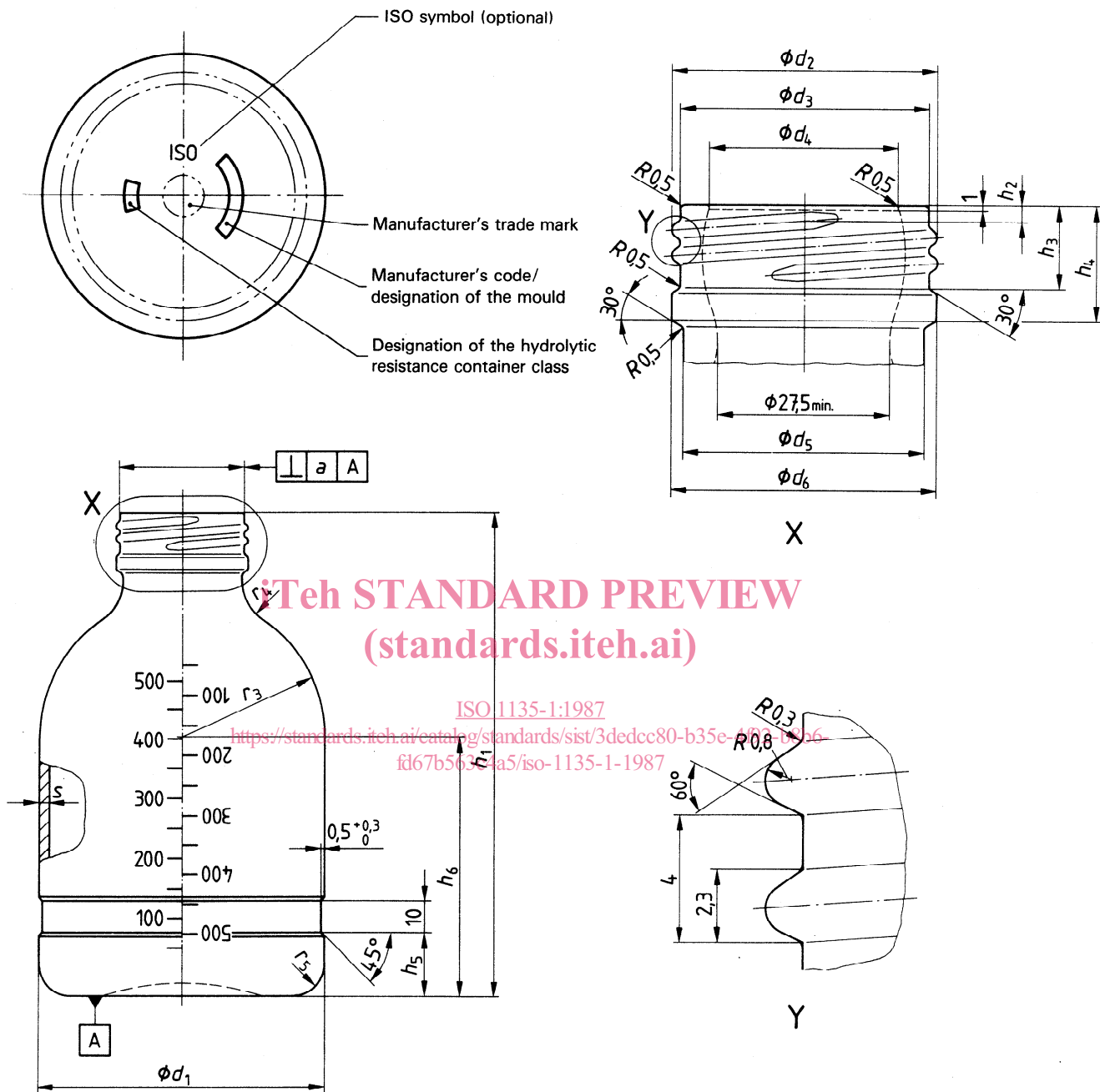


Figure 2 – Glass transfusion bottle with a nominal internal neck diameter of 30 mm

Table 1 – Overall dimensions and capacity of transfusion bottles

Dimensions in millimetres

Nominal internal neck diameter	Nominal capacity ml	a	d ₁		h ₁		s ¹⁾	
				tol.		tol.		tol.
22,5	120	2	49	±1	140	±1	3,5	±1,8
	300		78	±1,5				
	500	2,5			207	±1,3		
30	250	2	67	±1	152	±1,1	—	
	500	2,5	90,5	±1				
	1 000				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 neck diameter	d ₂		d ₃		d ₄		d ₅		d ₆		h ₂	h ₃		h ₄	
	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	4	17	16	21,3	20,7
30	42,2	41,6	39,9	39,3	30,4*	29,6*	38,3	—	42,2	41,6	5	13,2	12,8	18,4	17,6

* See 3.3.2.

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Table 3 – Dimensions of radii

Dimensions in millimetres

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

1) See note 2 in 3.1.

