

# INTERNATIONAL STANDARD

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**AMENDMENT 1**  
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## Infusion equipment for medical use —

### Part 1: Infusion glass bottles

#### AMENDMENT 1

*Matériel de perfusion à usage médical —*

*Partie 1: Flacons en verre pour perfusion*

*AMENDEMENT 1*

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## Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 8536-1:2000 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*, to develop a further type of infusion bottle (model C) in order to meet the market actualities.



# Infusion equipment for medical use —

## Part 1: Infusion glass bottles

### AMENDMENT 1

Page 2, Clause 4

#### 4.1 Dimensions

Replace the present text with the following:

“The dimensions of the infusion glass bottles shall meet the requirements of Figure 1 and Tables 1, 2 and 3.”

#### 4.2 Designation

Change the existing word “EXAMPLE” to “EXAMPLE 1”

Add:

EXAMPLE 2 An infusion bottle (model C) with a nominal capacity of 500 ml, made of colourless glass (cl) of hydrolytic resistance container class HC 2 complying with the requirements laid down in this part of ISO 8536 is designated as follows:

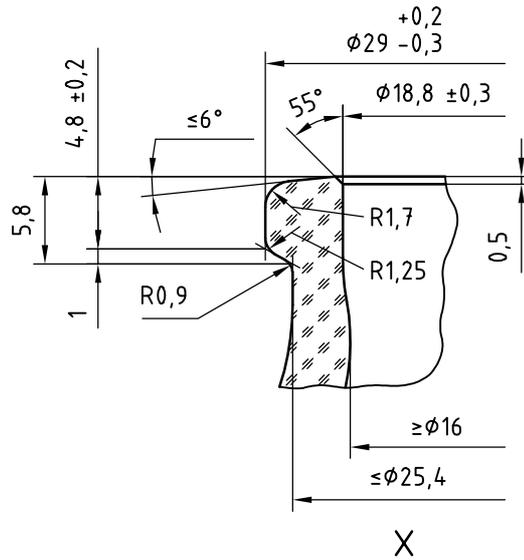
**Infusion bottle ISO 8536-1 - C - 500 - cl - HC 2**

Page 3, Figure 1

Change the existing figure title to read as follows:

**Figure 1 — Infusion glass bottle, showing three typical neck finishes**

Add the subfigure 1 c) as shown below:



c) Model C: Infusion bottle with 29 mm neck finish

Page 4

After the existing Tables 1 and 2, add new Table 3 given below.

Table 3 — Dimensions and capacity of infusion glass bottles with 29 mm neck finish (model C)

Dimensions in millimetres

Nominal capacity ml	Approx. brimful capacity		$\alpha^a$	$d_1$		$d_2$	$h_1$		$h_2$	$h_3$	$r_1$	$r_2$	$r_3$	$r_4$
	ml	tol.		tol.	tol.		tol.							
50	68	$\pm 5$	1	46	$\pm 0,8$	37	68	$\pm 0,7$	60,4	37,5	2	12	20,5	8
100	128	$\pm 5$	1,3	49	$\pm 0,8$	39	104	$\pm 0,8$	96,4	68,5	3	12	25	8
125	147	$\pm 5$	1,3	54,4	$\pm 0,8$	38,9	98,7	$\pm 0,8$	91,1	63,7	4,5	20	17	10
250	300	$\pm 8$	1,6	68	$\pm 1$	48,9	125	$\pm 1$	117,4	78	7	32	28	10
500	572	$\pm 8$	1,9	86	$\pm 1,2$	61,5	147	$\pm 1$	139,4	93,4	8	32	27	12
1000	1120	$\pm 15$	3	95	$\pm 1,5$	69,6	224,4	$\pm 1,3$	216,8	147,4	8,5	55	52	15

<sup>a</sup> The tolerance  $\alpha$  of the perpendicularity (defined as in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the bottle at the upper edge of the flange.