INTERNATIONAL STANDARD

ISO 8362-1

Third edition 2009-12-15 **AMENDMENT 1** 2015-12-15

Injection containers and accessories —

Part 1: **Injection vials made of glass tubing**

AMENDMENT 1

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Recipients et accessoires pour produits injectables —

S Partie 1: Flacons en verre étiré

AMENDEMENT 1 ISO 8362-1:2009/Amd 1:2015

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The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use.*

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Page 2, <u>Table 1</u>

Replace the existing <u>Table 1</u> by the following one, where injection vials of the sizes 50R and 100R have been added and the masses of all injection vials have been amended.

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Table 1 — Dimensions, overflow capacity and mass

n or injec- ion vial		Overnow	a		d_1	d_2	d_3	d_4		h_1	h_2	_	h3	r_1	r_2		s_1	\$2	t	$\mathbf{Mass}^{\mathrm{a,b}}$
	capacity ml	ity	mm	-	шш	mm +0,2	mm max.	mm ± 0,2	u	mm	mm	п	mm	mm	mm		mm	mm	mm	XX
		tol.			tol.	-0,3				tol.	min.		tol.	n e	X		tol.		max.	
	4		,	,		,	, c	1	35		22			L	, L					4,4
	9	L	-	10	±0,15	13	10,5	`	45		32	∞		2,2	L,5			0,0		5,7
	10	۲0,5		C					40	L	56	L	L	L		7			1	6'2
	11,5		7	77			L		45	در h در h	31	α,5	₹0,5	3,5	c	-	±0,04		0,'0	8,7
	13,5	7	T,2	ć	7,0∓		16,5		45	ttps:	30	i			7					9,5
	19			47		20		12,6	09	//stai	45	Te		0,4				0,7		12,0
	26								55	ndar f	35	h								16,2
25R 3	32,5	±1,5	1,5	30	±0,25		17,5		65	+1	45	5	±0,75	5,5	2,5	1,2	±0,05		П	18,9
30R 3	37,5								75	<u>IS</u> eh.ai 9977	SES	TA								21,9
50R	62	+4	2,5	40	±0,4	20	17,5c	12,6	73	Q 8 (2) (4) (4)	4 1	þ	±0,75	0'9	4,0	1,5	±0,07	6'0	1,5	34,5
100R	123	7=	3,5	47	±0,5	20	17,5c	12,6	100	362 166/ 3/1sc	75	10	±0,75	6,5	4,0	1,7	±0,07	6'0	1,5	0'09
Mean values that can deviate about $10~\%$.	ıatcan	devia	te aboı	ut 10 9	%.					<u>-1:2</u> stand -83	ar	A								
ass spec ils made	ification of other	ons ap er glas	ply to s type	inject s (e.g.	ion vials amber g	s made glass or	of colou borosili	rless bo cate gla	rosilica† ss 3.3) n	The mass specifications apply to injection vials made of colourless borosilicate glass having a linear expansion coefficient of 5,1 x 10 ⁻⁶ K ⁻¹ s of vials made of other glass types (e.g. amber glass or borosilicate glass 3.3) needs to be calculated using the density of the particular glass.	vinga!	linear ited us	expansio ing the d	n coefficensity o	cient of f the pa	5,1 x rurticula	10-6 K-1 ar glass.	and a de	nsity of 2,3	The mass specifications apply to injection vials made of colourless borosilicate glass having a linear expansion coefficient of 5,1 x 10-6 K-1 and a density of 2,34 g/cm ³ . The sof vials made of other glass types (e.g. amber glass or borosilicate glass 3.3) needs to be calculated using the density of the particular glass.
olow bacl	k Type	B: 17,,	7 mm.	The sl.	ightly la	rger di	ameter i:	s necess	ary due	With blow back Type B: 17,7 mm. The slightly larger diameter is necessary due to the different hot forming process with more glass mass having to be formed	ferenth	ot-forr	ning proc	sess witl	n more	glassr	nass havi	ing to be	formed.	
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