



**56893—
2016/
ISO/TS 17665-2:2009**

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17665-1

**ISO/TS 17665-2:2009
Sterilization of health products — Moist heat —
Part 2: Guidance on the application of ISO 17665-1
(IDT)**



2016

1 « » (»)
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2 383 «
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3 17 2016 . N? 157-
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4 ISO/TS 17665-2:2009 «
 2. 17665-1»

(ISO/TS 17665-2:2009 «Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1»).

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 (www.gost.ru)

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8	8	
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9.1	10	
9.2	(IQ).....	11	
9.3	(OQ).....	11	
9.4	(PQ).....	13	
9.5	14	
10	15	
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12	16	
12.1	16	
12.2	17	
12.3	17	
12.4	17	
12.5	17	
()	,	18	
()	,	24	
()	,	27	
D()	,	29	
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56893—2016

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11607-2.

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17665-1

Sterilization — health care products. Moist heat. Part 2. Guidance on the application of ISO 17665-1

— 2017—03—01

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17665-1:2006

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(ISO 17665-1:2006. Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices).

17665-1.

17665-1

17665*1
11607*2.

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3.1

(tests for sterility):

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11140-3. 11140-4.
11140-5. 11140-6" 285.
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6.1.3 .4.2).
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D. 0.5.

8.1

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8.6
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(. . . 11140-1).

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9.1.7
9.1.8 D.6.2.3 D.6.3.
9.2 (IQ)
9.2.1

9.2.2

9.2.3

61016-2*40.

9.3 (OQ)

0.6.1.

9.3.1

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b)
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11140-3. 11140-4 11140-5;

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- 9.4.5
- 9.4.6
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- 9.5.1
- 9.5.2 ():
- a)
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{ . . . 61010-2-040(24)}. . .

12.3.2

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285(25)

285 (

17665-1. 9.1.4).
13060(38).

265 13060.

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.3.3. .3.6 .7.

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27^{s5}.

185*⁵ r/².

30 *

20 * 30 *

40 % 60 %.

.3.4

220 * 300

.1.

.3.5

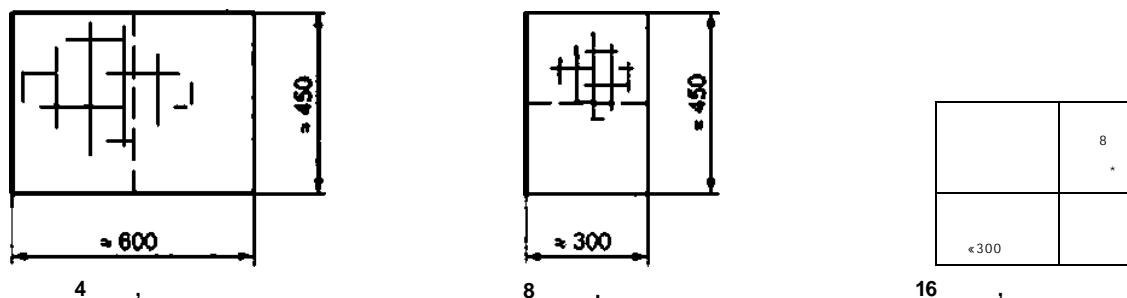
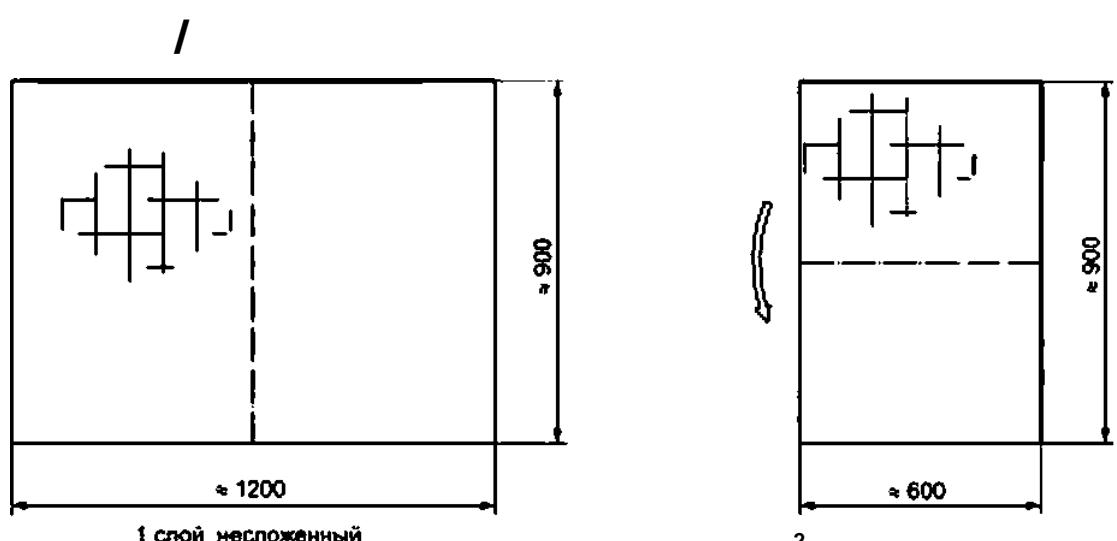
250 (

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25

150

30 3.6), — 4.0 ± 0.16 (17 7.0 ± 0.14 (250 7.14)
 30 * 3.7 40 % 60 %. 150 , 4.16 .
 30 3.6 , ,
 (. . . 11140-4(56)).
Размеры в мм



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.4.1

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6.

EN 265.

.4.1.2

a)

3* :

15

b)

600

30

c) 80 , , , , 5 *

60 . , 2* , ,

d) , , , ,

e) 134* 15 , 2* (. 3 6.1.2). 121 *

126 .4.2 ,

.4.2.1 ,

.4.2.2 ,

.5 ,

.5.1 ,

11140-3 (55). [44].

.5.2 , , ,

11140-4 [56].

.6 , , , .2. 4 .5.

(60) , , 0.13 / (1.3 /) 6

.7 (. .) ,

.7.1 ,

(. .4.1) (. .4.2). ,

.7.2 ,

(. .) , , , .4.1 .4.2).

.6 — , , ,

, , , 1% , , 0.2%

.9 , , ,

61010-2-040 [24].

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.10 , , ,

3- , , , 1000 / (10 /).

20

.11

.11.1

(. .4).

.11.2

285,

- a)
 b) 90% (10%) 95% (5%) 3.5%
 c) 25% , :
 d) .1 .2;
 e) , (± 10%) .1.

.1 —

(St O ^A)	£ 0.1 /
	£ 0.1 /
	£ 0.005 /
	£ 0.05 /
,	£ 0.1 /
(~)	£ 0.1 /
(2)	£ 0.1 /
(25*)	£ 3 pS/
pH()	5 7
()	, ,
(X)	£ 0.02 /
—	285. 22.4.

.2 —

	R»
(NH _d)	\$ 0.2 /
	\$ Ra(/)
	£ 0.1 /
(~)	\$ 0.5 /
(NO _j)	£ 0.2 /
(SO _d)	£ R ^a (/)
	£ R ^a (/)
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<St O _j)	£ 0.1 /
(P ₂ O _s)	£ 0.1 /
(25')	£ 35 pS/CM

.2

	S0,25 /
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.12

15 * . {£),
 0.7 / 2.0 / . , , ,

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600 800 (5 7),
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 25 . , , ,

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	285		-	-	*
	11	XX	—	—	
(11):					
• :	13.3.2.22.1	—	X	—	X d
• :	13.3.3.22.2	—	X	—	X d
• :	13.3.4.22.3	—	X	—	X d
• "(1 2)	.2	—	X	—	X d
(.4):					
• (4.1);	0.3.1.2.16.1	—	XX	—	X
• (.4.2)	8.3.1.2.16.2	—	XX	—	X d
(.2)	8.2.5.15	—	XX	—	X d
- (.5)	8.3.2.17	—	XX	—	X
(6)	8.3.3.18	—	XX	—	X
(.7):					
• :	8.3.4.2, 19.2	—	XX	—	X d
• ;	8.3.4.3. 19.3	—	XX	—	X d
•	8.3.4.4, 19.4	—	XX	—	X *

	EH 26S	w	-	-	»
(.8):					
• ();	8.4.1.20.1	—	X	—	—
• ();	8.4.2.20.2	—	X	—	—
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(.10)	10.23	—	—	—	
	—	—	—	X9	X^d
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^d					
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17665-1.

D).

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121

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121*

12-log.

15

b)

.1.5

(. . .1).

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.2.1

(SAL),

10ⁿ®.

10^{*1}.

10ⁿ®.

.2.2
 » «)» (. 17665-1. D).

.2.2.1
 (. 17665-1. 0.4).

.2.4
Geobacillus stearothermophilus.
 { . 11138-1. 11138-3 17665-1. D.4.1).

.3.3
 .3.1 100 %

.3.2 (. AAMI ST 79(59)).
) , /

.3.3
 10~*.
 10~*.
 0.21⁴ 1 « = 12 », « 10* (. 12-log
 .3.4 , , Pflug [53]).
) 3%.

.4
 .4.1

.4.2
 .4.1 (. 11140-5).

.4.4 100 %

.4.5 100 % (. 11140-5).

.4.6

pack ,

.4.7 .1

.1 —

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,	X	—	—	—	—	—
•	:	X	—	—	X	X

.1

-	-	-	-	-	-	-
-	-	X		X	X	X
{)	-	-	-	-	-	
-	-	X	X	X	X	
,	-	X	X	X	X	
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-	-	X	X	X	X	
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	-	«X»		()

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(. 17665-1. 6.1.2,)
(.1.)

.1—

	*	*	7 27 .27 6	*
1 014,2	100	0,10142	99.9971	-0,00287
1 050,9	101	0,10509	100.9981	*0,00185
1 088,7	102	0,10887	101.9993	-0,00071
1 127,7	103	0,11277	103.0025	0,002456
1 167,8	104	0,11678	104.0044	0,004372
1 209	105	0,1209	105.0045	0,004526
1 251,5	106	0,12515	106.0071	0,007106
1 295,1	107	0,12951	107.0068	0,006789
1 340,1	108	0,13401	108.0098	0,009813
1 386,3	109	0,13863	109.0110	0,011046
1 433,8	110	0,14338	110.0121	0,012132
1 482,6	111	0,14826	111.0125	0,012517
1 532,8	112	0,15328	112.0137	0,013662
1 584,3	113	0,15843	113.0130	0,013041
1 637,3	114	0,16373	114.0140	0,013976
1 691,8	115	0,16918	115.0158	0,015808
1 747,7	116	0,17477	116.0162	0,01617
1 805,1	117	0,18051	117.0164	0,016372
1 864	118	0,1864	118.0159	0,015913
1 924,5	119	0,19245	119.0160	0,015968
1 986,7	120	0,19867	120.0176	0,017586
2 050,4	121	0,20504	121.0171	0,017056
2 115,8	122	0,21158	122.0171	0,017072
2 182,9	123	0,21829	123.0171	0,017112
2 251,7	124	0,22517	124.0167	0,016702
2 322,2	125	0,23222	125.0154	0,015407
2 394,6	126	0,23946	126.0156	0,01556
2 468,8	127	0,24688	127.0153	0,015271
2 544,8	128	0,25448	128.0141	0,014123
2 622,7	129	0,26227	129.0130	0,013003
2 702,6	130	0,27026	130.0127	0,01271
2 784,4	131	0,27844	131.0115	0,011547
2 868,2	132	0,28682	132.0103	0,010329

.1

®	. . ‘ ®	®	7 , 273.27 ®	4
2 954.1	133	0.29541	133.0098	0.009792
3042	134	0.3042	134.0084	0.008352
3 132	135	0.3132	135.0068	0.006761
3 224.2	136	0.32242	136.0057	0.005699
3 318.5	137	0.33185	137.0037	0.003686
3415.1	138	0.34151	138.0024	0.00244
3 513.9	139	0.35139	139.0005	0.000526
3615	140	0.3615	139.9986	-0.00142

* ASME 'International Steam Tables for Industrial Use',
 'Industrial Formulation 1997 for the Thermodynamic Properties of Water and Steam' (IAPWS-IF97).

b , .1.
 , .1 .

$$= 42.6776 + 1.38927(1 - 9.48654) - 273.27. \quad (.1)$$

$$= -0.20504 \quad 7 = 121^*$$

In -1.584550

$$\ln *(-9.48654) = -1.58455 < 9.48654 = -11.0710938927 / (-11.07109) = 351.6094$$

$$42.6776 + 351.6094 = 394.28705 = 394.28705 - 273.27 = 121.0171^*$$

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4.1)

17665-1.**0.2.1**

a)

b)

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17665-1.**12**

s)

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g)

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k)

l)

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D.2.4

a)

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6)

D.3.1

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D.3.1.1

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D.3.2

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17665-1,

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17665-1.

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D.4.1

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7.1

17665-1

D.4.2

17665-1,

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0.4.3 17665-1. 7.10

17664 [23],

D.5 (17665-1. 6)

0.5.1 17665-1. 8.1
0.5.1.1

D.5.1.2

D.5.1.3

0.5.1.4

17665-1. D, D.8.3.1 4.2).
0.5.1.5

0.5.2 17665-1. 8.3

D.5.3 17665-1. 8.4

0.5.4 17665-1. 6.12

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D.6.1.2
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D.6.2 () 17665-1,
9.4)

D.6.2.1 17665-1, 9.4.1
D.6.2.1.1

D.6.2.1.2

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D.6.2.1.3

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D.6.2.1.4

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D.6.2.1.5

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D.6.2.2

17665-1, 9.4.2

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17665-1, 9.4.4

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D.6.3 () 17665-1.
9.5.2)

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D.7.1 17665-1,

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17665-1.

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17665-1.

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17665*1

17665-1

/ 17665-2

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4	—	.1.2.4	—	—
4.1	—	.4.1	—	—
	13485			
4.2	—	.4.2	—	0.2
4.3	—	.4.3	—	—
	13485			
	10012			
4.4	—	.4.4	—	—
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5	—		5	—
5.1	—		5.1	—
5.2	—		5.2	—
5.3	—		5.3	—
5.4	—		5.4	—
6	—		6	—
6.1	—		6.1	
6.1.1	—		6.1.1	
6.1.2	—		6.1.2	0.3.1
6.1.3	—	.6	6.1.3	D.3.1
6.2	—		6.2	D.3.2
7	11607-1 11607-2 11737-1	.7	7	D.4

	17665-1:2006	17665-1:2006	17666- 1 2006.	- (/TS 17666-2 1-12)	- HCO; TS 17665-2. 0
	17665-1 - . D				
	11138-1				
	11138-3				
8	11140 11737-1 11737-2 17664		.8	8	D.5
9	—			9	0.6
9.1	—			9.1	—
9.2	()	—		9.2	—
9.2.1		—		9.2.1	—
9.2.2		—		9.2.2	—
9.2.3		—		9.2.3	—
9.3	- (OQ)	—		9.3	D.6.1
9.4	- (PQ)	17665-1:2006. 285	D	9.4	D.6.2
9.5	—			9.5	D.6.3
10	—		.10	10	D.7
11	—		.11	11	0.8
12	-	—		12	0.9
12.1	-	—		12.1	—
12.2		—		12.2	0.9.1
12.3	-	—		12.3	0.9.2
12.4		—		12.4	0.9.3
12.5		—		—	—

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17665-1		17665-1—2016 « 1. , - * -
• — : .	-	

- [1] 10993-1
 - 1. (Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system)
- [2] 10993-17
 - 17. (Biological evaluation of medical devices — Part 17: Establishment of allowable limits for teachable substances)
- [3J] 11138-1:2006
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