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INTERSTATE COUNCIL FOR STANDARDIZATION, METROLOGY AND CERTIFICATION
(ISC)

ISO 10993-12- 2015

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(ISO 10993-12:2012, IDT)



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 evaluation of medical devices — Part 12: Sample preparation and reference materials (12.).
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 ISO 10993-12—2011

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Medical devices. Biological evaluation of medical devices. Part 12. Sample preparation and reference materials

— 2016—06—01

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ISO 10993 () Biological evaluation of medical devices ()
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- a) $(37 \pm 1)'$ $(72 \pm 2) ;$
- b) $(50 \pm 2) ^\circ\text{C}$ $(72 \pm 2) ;$
- c) $(70 \pm 2) ^\circ\text{C}$ $(24 \pm 2) ;$
- d) $(121 \pm 2) ^\circ\text{C}$ $(1 \pm 0,1) .$

— $(37 \pm 1) ^\circ\text{C}$ (24 ± 2)

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1) High-density polyethylene (Negative Control Plastic RS) can be obtained from the US Pharmacopeia, Rockville, MD 20852, USA.

2* HDPE film, RM-C: Hatano Research Institute/Food and Drug Safety Center, 729-5 Ochiai Hadano, Kanagawa 257-8523, Japan.

3> HDPE sheet, RM-D: Hatano Research Institute/Food and Drug Safety Center, 729-5 Ochiai Hadano, Kanagawa 257-8523, Japan.

4> HDPE rod, RM-E: Hatano Research Institute/Food and Drug Safety Center, 729-5 Ochiai Hadano, Kanagawa 257-8523, Japan.

5* PE 140 tubing: RAUMEDIC AG, Postfach 501,95205 Munchberg, Germany. PE film is available from Hoechst AG, 6230 Frankfurt 80, Germany.

6* Biomaterials Program, Devices and Technology Branch, National Heart, Lung and Blood Institute, NIH Building,7550 Wisconsin Ave., Bethesda, MD20892, USA.

7* SIK 8363 tubing: RAUMEDIC AG, Postfach 501,95205 MOnchberg, Germany.

8* PVC 7506 and PVC 7536 tubing: RAUMEDIC AG, Postfach 501,95205 Munchberg, Germany. PVC-DEHP and PVC-TEHTM film is available from Hoechst AG, 6230 Frankfurt 80, Germany.

9* PUR 2541 tubing: RAUMEDIC AG, Postfach 501,95205 Munchberg, Germany. PU film is available from Frontline Filmblasning, 60003 Norrkoping, Sweden.

10> PP146 tubing: RAUMEDIC AG, Postfach 501,95205 Munchberg, Germany. PP film is available from Hoechst AG, 6230 Frankfurt 80, Germany.

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¹¹⁾ Positive Control Material, code 499-300-000-000: Portex Limited (same as positive control RS which can be obtained from the US Pharmacopeia, Rockville, MO 20852, USA).

¹²⁾ Polyurethane rod — ZDEC: RM-F, Hatano Research Institute/Food and Drug Safety Center. 729-5 Ochiai Hadano, Kanagawa 257-8523, Japan.

¹³⁾ Polyurethane film — ZDEC: RM-A, Hatano Research Institute/Food and Drug Safety Center, 729-5 Ochiai Hadano, Kanagawa 257-8523, Japan.

¹⁴⁾ Polyurethane film — ZDBC (SPU-ZD8C): RM-B, Hatano Research Institute/Food and Drug Safety Center. 729-5 Ochiai Hadano, Kanagawa 257-8523, Japan.

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ISO 10993-1:2003 1. -	IDT	ISO 10993-1—2011 1.	. -
ISO 10993-2:2006 2.	—	*	
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ISO 10993-4:2002 4. -	IDT	ISO 10993-4—2011 4.	. - -
ISO 10993-5:1999 5. <i>in vitro</i>	IDT	ISO 10993-5—2011 5. <i>in vitro</i>	. - -
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ISO 10993-10:2002 10. -	IDT	ISO 10993-10—2011 10.	. -
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ISO 10993-12—2015

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ISO 10993-17:2002	17.	-	IDT	ISO10993-17—2011 17.
ISO 10993-18:2005	18.	-	IDT	ISO 10993-18—2011 18.
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ISO/TS 10993-20:2006	20.	-	IDT	ISO/TS 10993-20—2011 20.
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<p>*</p> <p>— 8 —</p> <p>: - IDT —</p>				

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