

**CLIENT** 10991



3D Systems Corporation  
26600 SW Parkway Ave.  
Bldg 61  
Wilsonville, OR 97070  
United States

**REPORT DATE**

17 Mar 2020

**SUMMARY REPORT**

Test Article Name:	Figure 4 MED-AMB 10
Physical Description:	Solid
Lot Number:	XG031N02
Part Number:	Bio_Comp_SG_EV39_040419
Other Identifier:	Not provided by Sponsor
Expiration Date:	4/4/21
Special Handling and/or Precautions:	None
Sterilization Data:	Non-Sterile
Storage Conditions:	Room Temperature
Final Intended Use/Application:	Medical Device

The Test Article “Figure 4 MED-AMB 10” met the ISO 10993 testing guidelines specific to each type of test.

ANSI/AAMI/ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5:*  
*Tests for in vitro cytotoxicity*

Cytotoxicity – MEM Elution Test  
Pacific BioLabs Report Number: 19D0183H-M01G

ISO 10993-10:2010 *Biological evaluation of medical devices. Part 10:*  
*Tests for irritation and skin sensitization*

Maximization Test for Delayed-Type Hypersensitivity in Hartley Guinea Pigs  
Pacific BioLabs Report Number: 19D0183H-X02G

Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits  
Pacific BioLabs Report Number: 19D0183H-X04G

## CONCLUSION

The test article “Figure 4 MED-AMB 10” met the requirements of ISO 10993-5:2009 and ISO 10993-10:2010 for tests as outlined above.

## PACIFIC BIOLABS

Multiple Study Coordinator: Zuzana Karjala, Ph.D., RLATg, Senior Scientist

18 Mar 2020

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I approve the content of this document.  
Signed by: Zuzana Karjala

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