

CLIENT 10991



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REPORT DATE

17 Mar 2020

SUMMARY REPORT

Test Article Name:	Figure 4 MED-WHT 10
Physical Description:	Solid
Lot Number:	XH324N21
Part Number:	Bio_Comp_MW_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-WHT 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: 19D0184H-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: 19D0184H-X02G

Intracutaneous (Intradermal) Reactivity Test in New Zealand White Rabbits
Pacific BioLabs Report Number: 19D0184H-X04G

CONCLUSION

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

PACIFIC BIOLABS

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18 Mar 2020

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

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