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Final Report

Report Number: SDWH-M202005314-2(E)

Skin Sensitization Test of DISPOSABLE MEDICAL FACE MASK

According to GB/T 16886.10-2017
Guinea Pig Maximization Test
0.9% Sodium Chloride Injection Extract

Sponsor: XIANTAO HONGWEI NON-WOVEN FABRIC
PRODUCTS CO., LTD

Address: Taizihu Industrial Park, Xiantao, Hubei, China



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Summary

1 Test Article

Test Article Name	DISPOSABLE MEDICAL FACE MASK
Manufacturer	XIANTAO HONGWEI NON-WOVEN FABRIC PRODUCTS CO., LTD
Address	Taizihu Industrial Park, Xiantao, Hubei, China
Model	ELASTIC FACE MASK
Lot/Batch	200616

2 Main Reference

GB/T 16886.10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

3 Test Method

Potential skin sensitization of test article was evaluated using guinea pig maximization test in accordance with GB/T 16886.10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.

Study protocol number: SDWH-PROTOCOL -M202005314-2Amd01.

4 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.