

TEST REPORT

ISO 10993-10:2010



中国认可
国际互认
检测
TESTING
CNAS L2954

Amendment Report

Report Number: SDWH-M202004118-2(E) Amd01
(Replace SDWH- M202004118-2 (E))

Skin Sensitization Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
Guinea Pig Maximization Test
0.9% Sodium Chloride Injection Extract

Sponsor: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

Address: No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing
yuan,Guangdong,China



Sanitation & Environment Technology Institute, Soochow University

Address: 199 Ren-Ai Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, P. R. China

Website: www.sudatest.com

Direct: +86 512 65880038

E-mail: med@sudatest.com

Free: 400 107 8828

Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

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

Study protocol number: SDWH-PROTOCOL-GLP-M202004118-2.

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.

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Amendment Report

Report Number: SDWH-M202004118-3(E) Amd01
(Replace SDWH- M202004118-3 (E))

Skin Sensitization Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
Guinea Pig Maximization Test
Sesame Oil Extract

Sponsor: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

Address: No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing
yuan,Guangdong,China



Sanitation & Environment Technology Institute, Soochow University

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Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

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

Study protocol number: SDWH-PROTOCOL-GLP-M202004118-3.

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.

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Amendment Report

Report Number: SDWH-M202004118-4(E) Amd01
(Replace SDWH- M202004118-4 (E))

Skin Irritation Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
0.9% Sodium Chloride Injection Extract

Sponsor: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

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yuan,Guangdong,China



Sanitation & Environment Technology Institute, Soochow University

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Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

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

3 Test Method

The extract of test article was evaluated for skin irritation. With ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- GLP-M202004118-4.

4 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

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Amendment Report

Report Number: SDWH-M202004118-5(E) Amd01
(Replace SDWH- M202004118-5 (E))

Skin Irritation Test of Single-use medical rubber examination gloves

According to ISO 10993-10:2010
Sesame Oil Extract

Sponsor: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

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yuan,Guangdong,China



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Summary

1 Test Article

Test Article Name	Single-use medical rubber examination gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 DeLong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007011

2 Main Reference

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

3 Test Method

The extract of test article was evaluated for skin irritation. With ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- GLP-M202004118-5.

4 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.