



中国认可
国际互认
检测
TESTING
CNAS L2954

Final Report

Skin Irritation Test of double sides adhesive tape

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

Sponsor 

Address 



Sanitation & Environment Technology Institute, Soochow University

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

Website: www.sudatest.com

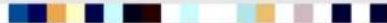
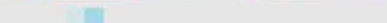
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Summary

1 Test Article

Test Article Name	double sides adhesive tape
Manufacturer	
Address	
Model	DSYY
Lot/Batch	RQ-2021

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: 

4 Conclusion

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

Test Report

1 Purpose

The extract of test article was evaluated for skin irritation and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2 Reference

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

ISO 10993-12:2021 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

ISO 10993-2:2006 Biological evaluation of medical devices — Part 2: Animal welfare requirements

3 Compliance

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954.

RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.



180015144061



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In Vitro Cytotoxicity Test of double sides adhesive tape

According to ISO 10993-5: 2009
MTT Method
MEM with 10%FBS extract

Sponsor: 

Address: 



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Summary

1 Test Article

Test Article Name	double sides adhesive tape
Manufacturer	
Address	
Model	DSYY
Lot/Batch	RQ-2021

2 Main Reference

ISO 10993-5: 2009 Biological evaluation of Medical Devices—Part 5: Tests for *in vitro* Cytotoxicity

3 Test Method

Potential toxicity of test article was evaluated using MTT in accordance with ISO 10993-5: 2009 Biological evaluation of Medical Devices—Part 5: Tests for *in vitro* Cytotoxicity.

Study protocol number: 

4 Conclusion

Under the conditions of this study, the test article extract did not show potential toxicity to L929 cells.

Test Report

1 Purpose

The purpose of the test is to determine the biological reactivity of a mammalian cell culture (mouse fibroblast L929 cells) in response to the test article.

2 Reference

ISO 10993-5: 2009 Biological evaluation of Medical Devices—Part 5: Tests for *in vitro* Cytotoxicity

ISO 10993-12: 2021 Biological evaluation of Medical Devices—Part 12: Sample preparation and reference materials

3 Compliance

ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954.

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Skin Sensitization Test of double sides adhesive tape

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

Sponsor: _____

Address: _____



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Summary

1 Test Article

Test Article Name	double sides adhesive tape
Manufacturer	
Address	
Model	DSYY
Lot/Batch	RQ-2021

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:

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.

Test Report

1 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2 Reference

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

ISO 10993-12:2021 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials

ISO 10993-2:2006 Biological evaluation of medical devices — Part 2: Animal welfare requirements

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