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NEWAY TESTING LABORATORY

Testing Report

Skin Sensitization Test ISO 10993-10:2010

Closed-patch test（Buehler test）

Report No.: WT20010538-6

Test Sample: Conductive Hydrogel

Sponsor: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD

Manufacturer: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD

纽唯 Neway TESTING

Remarks

1. The results shown in this test report refer only to the sample(s) tested.
2. The content of this report is invalid if it is not presented as the entire report.
3. Any unauthorized alteration, forgery or falsification of the content or appearance of this report is unlawful and offenders may be prosecuted fully of the law.

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ABSTRACT

Sponsor / Client: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD.

Address: 3 YONGFA EAST ROAD, QISHI TOWN, DONGGUAN CITY, GUANGDONG, CHINA.

Manufacturer: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD.

Address: 3 YONGFA EAST ROAD, QISHI TOWN, DONGGUAN CITY, GUANGDONG, CHINA.

Test Sample: Conductive Hydrogel, prepared two samples a pair(6.25cm^2 a piece), and subjected to animal skin sensitization test according to ISO 10993-10:2010.

20 guinea pigs (10 for test, 5 for Negative control and 5 for Positive control) for Closed-patch test were used. After induction phase, the prepared sample patches were applied to the animals for (6±0.5) h.

The skin reactions for erythema and oedema were graded according to "Magnusson and Kligman Scale" and recorded at (24±2) h and (48±2) h after removal of the dressings.

Conclusion:	The frequency of positive challenge results in sample and Negative control animals are 0%, the Positive control is 100%.

Study Director: _____ Date: NOV. 13. 2020

Xu Fengxia

Report Reviewer: _____ Date: Nov. 13, 2020

Wang Meng

Authorized Signatory: _____ Approval Date: NOV. 13, 2020

Xu Honglei

Report issued by:

GUANGDONG NEWAY QUALITY TECHNOLOGY SERVICE CO., LTD.

(Testing Stamp)

QUALITY ASSURANCE STATEMENT

These tests were audited by Quality Assurance (QA) personnel of NEWAY. The QA inspection includes review of study plan, result of a study-based audit and results of audit of raw data and study report.

The findings were reported to Study Director and NEWAY management.

QA manager:

Xu Honglei

NOV. 13, 2020

Date Completed

Inspection Type	Inspection Date	Testing Phase	Date to Facility Manager & Study Director
Study base	Sep. 21, 2020	Draft Protocol	Sep. 21, 2020
Study base	Oct. 07, 2020	Induction phase	Oct. 07, 2020
Study base	Nov. 07, 2020	Challenge Phase	Nov. 07, 2020
Study base	Nov. 10, 2020	Raw Data & Draft Final Report	Nov. 10, 2020

PURPOSE AND SCHEDULE

According to its nature and duration of the anticipated contact with human tissues when in use, medical device should be tested for biocompatibility to avoid potential physiological damage from hypersensitive substances produced or contaminated during manufacturing.

In this study, guinea pig skin sensitization study (Closed-patch test) was performed to evaluate the possibility of skin sensitization after topical applications of the test sample on the skin of guinea pig. These results provide practical information for assessing the risk of skin sensitization of the medical device.

Study schedule is as below:

Study Initiation Date: Sep. 21, 2020

Test Starting Date: Oct. 07, 2020

Test Completion Date: Nov. 10, 2020

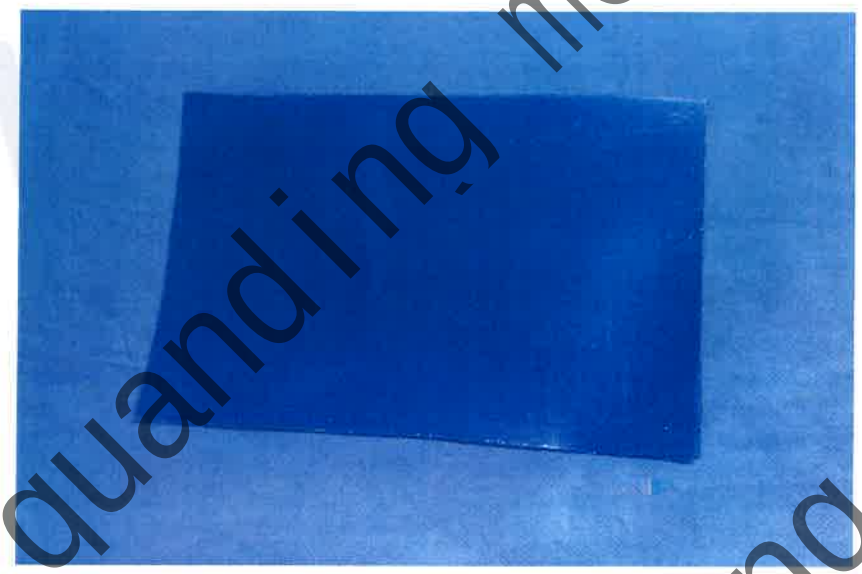

PHOTO OF TEST SAMPLE

1. MATERIALS INFORMATION

1.1 Test Sample

Test Sample information was provided by sponsor and showed as below:

Test Sample Description:	Conductive Hydrogel
Specify the test parts or materials:	Conductive Hydrogel
Major ingredients:	Conductive Hydrogel
Intended Use:	Conducting electric current to the skin surface or transmitting human EMG or ECG signals to the machine.
Batch/Lot No.:	20200915
Model No.:	QD0.9A
Stability:	Not entrusted
Production date:	Sep. 15,2020
Expiration Date:	Sep. 14,2022
Storage Condition:	Ambient temperature
External Features:	Solid
Sterilization Method:	Non-Sterilized
Pre-treatment:	Non

1.2 Reagents

1.2.1 0.9% Sodium Chloride (Guangdong KELUN Lot：H18111406)

1.2.2 DNCB（SIGMA Lot：BCBP8259V）

1.3 Equipment

1.3.1 Electronic Scale (Shanghai Yaohua, C2016-02-01)

1.4 Test Sample and Controls Preparation

Prepared two samples a pair (6.25cm^2 a piece) as the test sample apply to animal, the

absorbent gauze patches（2,5cm*2,5cm） containing 0.9% sodium chloride as the negative control and 0.1 % DNCB as the positive control.

2. EXPERIMENTAL DESIGN

2.1 Experimental System

2.1.1 Animals

a) Animal Species: Guinea Pig (Hartley strain)

b) Source: Guangzhou Huadu district huadong xinhua experimental animal farm, Experimental Animal Production Permit No.: SCXK(YUE) 2019-0023

c) Body Weights (Gender): Initial weight 300~500g (Male)

d) Health Status: Healthy, previously unused young adult

e) Quarantine/acclimation: Animals are subjected to quarantine and acclimated for a week before treatment. Guinea pigs are selected base on health status. The female guinea pigs were nulliparous and not pregnant.

f) Animal Identification: Ear Marking, 20 guinea pigs divided into 3 groups, test sample group (Guinea Pig 1# to 10#), negative control group (Guinea Pig 11# to 15#), positive control group (Guinea Pig 16# to 20#).

2.1.2 Animal Care and Management

a) Environment: Temperature 20-26℃, 40%-70% Relative Humidity

b) Housing: Animals are housed in groups in cages identified by a animal experiment information card.

c) Cage: Plastic Cage, 2 guinea pigs/cage

d) Feed: Guinea Pig Diet, Guangzhou Huadu district huadong xinhua experimental animal farm

e) Water: Drinking water met GB 5749 Standards for Drinking Water Quality

f) Lights: 12 hours light/dark cycle, full spectrum fluorescent lights.

2.1.3 Justification of experimental system: Guinea Pig is specified as an appropriate animal model for evaluating potential skin sensitization by the current ISO 10993-10:2010 standards.

2.1.4 Facility: Experimental facility is accredited in accordance with ISO/IEC 17025 by CNAS

(China National Accreditation Service). CNAS registration Number: CNAS L9783.

2.1.5 Personnel: All relevant personnel are well trained and qualified.

2.1.6 Compliance: All activities of this study are carried out in compliance with the GLP (Good Laboratory Practices) for U.S. Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58 (1987).

2.2 Test Procedure

2.2.1 Preparation of animals

Prior to the study, the furs of animal's backside are clipped from neck to scapular area with an electric animal shaver. Animals with scratches or skin diseases on the clipped skin surfaces are rejected from the study. The clipped area is about 8 cm^2.

2.2.2 Induction phase

Apply the test sample patches by topical application to the clipped left upper back region of each animal. Remove the restrainer of any occlusive dressings and patches after (6 ± 0,5) h. Perform this procedure on three days a week for three weeks. Treat the control animals similarly, using the negative control and the positive control.

2.2.4 Challenge phase

At (14 ± 1) d after the last induction application, challenge all test and control animals with corresponding control solution. Apply the test sample patches by a single topical application to a clipped untested area of each animal. Remove the restrainer and occlusive dressings and patches after (6 ± 0,5) h.

2.3 Observation of Animals

Observe the appearance of the challenge skin sites of the test and control animals at (24±2) h and (48±2) h after removal of the dressings. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval. The skin reaction observation should be done without knowledge of the treatment.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

2.4 Evaluation of Results

2.4.1 Magnusson and Kligman grades of 1.0 or greater in the test group indicate sensitization, provided grades of less than 1.0 are seen in control animals.

2.4.2 If grades of 1.0 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

2.4.3 The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

3. TEST RESULTS

Refer to Table 2 and Table 3 for individual results of dermal scoring for the challenge.

Table2 Clinical Observation Record

Groups	Animal No.	Weight（g）		Clinical Observation except dermal reaction
		Before removal of hair	After Experiment	
test sample group	1	314	355	normal
	2	318	359	normal
	3	319	361	normal
	4	318	364	normal
	5	315	358	normal
	6	311	353	normal
	7	325	367	normal
	8	314	358	normal
	9	310	353	normal
	10	312	356	normal
negative control group	11	321	364	normal
	12	311	352	normal
	13	312	355	normal
	14	311	353	normal
	15	324	368	normal
positive control group	31	312	354	normal
	32	310	353	normal
	33	316	361	normal
	34	312	355	normal
	35	315	358	normal

Table 3 Guinea Pig Sensitization Dermal Reactions

Groups	Animal No.	A minimum of 2h after removal of hair	Hours after completion of challenge phase		Positive Rate
			24h	48h	
test sample group	1	0	0	0	0%
	2	0	0	0	
	3	0	0	0	
	4	0	0	0	
	5	0	0	0	
	6	0	0	0	
	7	0	0	0	
	8	0	0	0	
	9	0	0	0	
	10	0	0	0	
negative control group	11	0	0	0	0%
	12	0	0	0	
	13	0	0	0	
	14	0	0	0	
	15	0	0	0	
positive control group	16	0	2	2	100%
	17	0	2	2	
	18	0	2	2	
	19	0	2	2	
	20	0	2	2	

4. CONCLUSION

Under the conditions of this study, the frequency of positive challenge results in sample extract and Negative control animals are 0%, the Positive control is 100%.

5. ARCHIVING

All the study-related raw data, records, protocol and the final report will be kept in NEWAY for 6 years from report issue date. For studies of more than 4 weeks duration, the test samples will also be in kept in NEWAY for 6 years from report issue date.

All the records and test samples were handled according to GLP Guidance. Agent authorized by the sponsor can apply for review according to NEWAY policy.

广东纽唯质量技术服务有限公司

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