



中国认可
国际互认
检测
TESTING
CNAS L3428

Test Report

Date : 2019-08-15
No. :DY19060319

Page 1 of 18

TEST FACILITY

STC (Dongguan)
68 Fumin Nan Road, Dalang,
Dongguan, Guangdong,
China. (Zip code 523770)

SPONSOR

STILO OPTICAL TECHNOLOGY
Yonglong industry park, Fumin Ind, Zone,
Tanglivilage, Fenggang Town, Dongguan City,
Guangdong Province, China.

CONFIDENTIAL

STUDY TITLE

Primary skin irritation Study in Rabbits

TEST ARTICLE NAME

FRAME

TEST ARTICLE IDENTIFICATION

CP-MD-1197

CSD NO: CL20190605262



STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 2 of 18

TABLE OF CONTENTS	Page
Summary	3
1. Introduction.....	4
2. Identification of Test and Control Articles	4
3. Test System.....	6
4. Animal Management	6
5. Method.....	8
6. Evaluation.....	10
7. Results	11
8. Conclusion.....	12
9. Records	12
10. ISO Compliance	12
11. References	13
Appendix 1 – Dermal Observations	14
Appendix 2 - Periodic Positive Control Study for Primary Skin Irritation Test	16
Appendix 3 – Photograph(s) of Test Articles.....	18

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 3 of 18

Summary

The test article, FRAME, was evaluated for primary skin irritation in rabbits. This study was conducted based on the requirements of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test articles were extracted in 0.9% sodium chloride injection and Soybean oil. Two 25 mm x 25 mm sections of absorbent gauze patches with 0.5ml test extracts/ control extracts were topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single application.

There was no erythema and no edema observed on the skin of the animals treated with the test extracts. The Primary Irritation Index for the test extracts was calculated to be 0.0. The response of the test article was categorized as negligible.

A handwritten signature in black ink that reads 'Tang'.

Authorized Signatory Approval: _____

Jonathan Tang



STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 4 of 18

1. Introduction

1.1 Purpose

The purpose of this study was to evaluate the test article for the potential to cause skin irritation in the rabbit.

1.2 Testing Guidelines

This study was based on the requirements of the International Organization for Standardization 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

1.3 Dates

Test Article Received:	2019.06.28
Treatment Started:	2019.08.03
Observations Concluded:	2019.08.09

2. Identification of Test and Control Articles

The test article provided by the sponsor was identified and handled as described below:

Table 1: Test Article

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 5 of 18

Name:	FRAME
Size:	N.A
CAS Code:	N.A
Model:	TRUEGRASSES
Lot:	N.A
Initial State:	Not Sterilized
Strength, Purity and Composition:	TRUEGRASSES
Color:	N.A
Physical Description of the Test Article:	Solid
Manufacture date:	N.A
Expiration Date:	N.A

Table 2: Negative Control Article

Name:	0.9% Sodium chloride injection (SC) Soybean oil (SO)
Purity, Composition, and Other Characteristics:	SC: Composition: 0.9% NaCl \pm 5.0% of label claim, balance is water; sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 SO: Composition: CAS No.: 8001-22-7

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770
Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group
This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.
For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 6 of 18

Table 3: Reagents

Name	Brand	Lot
SC	Yuyuan	H19050908
SO	Tianyushan	20180306

3. Test System

3.1 Test System

Species: Rabbit (*Oryctolagus cuniculus*)
Strain: New Zealand White
Source: Guangzhou baiyun district longgui xingke animal farm (广州市白云区龙归兴科动物养殖场)
Sex: Female
Body Weight Range: 2.0kg to 2.2kg at study selection
Age: Young adult
Acclimation Period: Minimum 5 days
Number of Animals: 6

3.2 Test System Management

The rabbit (animal) is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO testing standards. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is conventional system lab. The lab animal use permit No. SYXK(粤)2019-0159. The animal housing room temperature and relative humidity were

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 7 of 18

monitored daily. The temperature for the room was set to 19-26°C and the relative humidity was set to 40-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

Food: Laboratory animal formula feed (rabbit), Wuhan wanqian jiaxing biotechnology co. LTD (武汉市万千佳兴生物科技有限公司), was provided daily.

Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2006)

Food and water were sterile. No contaminants present in the feed and water impacted the results of this study.

4.3 Personnel

Associates involved in this study were appropriately qualified and trained.

4.4 Veterinary Care

Standard veterinary medical care was provided in this study.

4.5 IACUC

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.

4.6 Selection

Only healthy, animals free from irritation or other dermatological lesions that could interfere with the test were selected.

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 8 of 18

5. Method

5.1 Test and Control Article Preparation

The test articles were measured and calculated. The preparations of the test article and the negative control were subjected to the extraction conditions as described below. The extracts were continuously agitated during extraction.

Table 4: Extraction

Vehicle	Treatment Group	Extraction Ratio	Article Amount	Volume of Vehicle	Extraction Condition
SC	Test	0.2g:1 mL	17.878g	89.4mL	50±2°C for 72±2 hours
	Control	N. A	N. A	20mL	
SO	Test	0.2g:1 mL	18.389g	91.9mL	
	Control	N. A	N. A	20mL	

The following table contains a description of the test and control article extracts before and after extraction.

Table 5: Condition of Extracts

Vehicle	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
SC	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
SO	Before Extraction	Test	Colorless	Oily	None
		Control	Colorless	Oily	None
	After Extraction	Test	Colorless	Oily	None
		Control	Colorless	Oily	None
	Prior to Use	Test	Colorless	Oily	None
		Control	Colorless	Oily	None

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.

STC (Dongguan) Company Limited



Test Report

Date: 2019-08-15
No. : DY19060319

Page 9 of 18

The test article extracted in SC and SO remained unchanged during the extraction process. The extracts were maintained at ambient temperature <24 hours before use for all phases. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

5.2 Test Procedure

The animals were weighed and the fur on the back of each animal was clipped with an electric clipper 24 hours prior to treatment. On the day of treatment, four sites, two on each side of the back and positioned cranially and caudally, were designated on each animal. The sites were free of blemishes that could interfere with the interpretation of results. The appropriate extracts were applied to the 2.5 cm × 2.5 cm absorbent gauze patches. 0.5 ml extract was used to saturate the gauze. A control patch of gauze moistened with the extract vehicle was applied as well. And then all the application sites were covered with a bandage (semi-occlusive or occlusive) for a minimum of 4 h. Animals were returned to their cages after treatment. After the 4-hour exposure, the binders, tape, and patches were removed. The sites were gently wiped with a gauze sponge dampened with deionized water in an attempt to remove any remaining residue.

5.2.1 Laboratory Observations

1. Animals were observed daily for general health.
2. Body weights were recorded for each animal at pretreatment.
3. Dermal observations for erythema and edema were recorded at 1, 24, 48 and 72 hours after patch removal in accordance with the criteria in Appendix 1.

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stcgroup Website : www.stcgroup.com

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 10 of 18

Table 6 Classification System for Skin Reaction

Erythema and Eschar Formation	Numerical Grading	Edema Formation	Numerical Grading
No erythema	0	No edema	0
Very slight erythema (barely perceptible)	1	Very slight edema (barely perceptible)	1
Well-defined erythema	2	Well-defined edema (edges of area well-defined by definite raising)	2
Moderate erythema	3	Moderate edema (raised approximately 1 mm)	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4	Severe edema (raised more than 1 mm and extending beyond exposure area)	4
Total possible score for irritation			8

Table 7 Irritation Response Categories in the Rabbit

Irritation Response Categories in the Rabbit	
Response Category	Mean Score
Negligible	0-0.4
Slight	0.5-1.9
Moderate	2.0-4.9
Severe	5-8

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or STC standard operating procedures.

6. Evaluation

The Primary Irritation Index of the test was calculated following test completion for each animal. The erythema and edema scores obtained at the 24, 48 and 72-hour intervals were added together

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770
Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group
This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.
For Conditions of Issuance of this test report, please refer to the overleaf and Website.





Test Report

Date: 2019-08-15
No. : DY19060319

Page 11 of 18

and divided by the total number of observations. This calculation was conducted separately for the test and control article for each animal. The score for the control was subtracted from the score for the test article to obtain the Primary Irritation Score. The Primary Irritation Score for each animal was added together and divided by the number of animals to obtain the Primary Irritation Index. The Primary Irritation Index was characterized based on the definitions.

7. Results

All the animals were clinically normal throughout the study. Individual results of dermal scoring are presented in Appendix 1. No irritation was observed on the skin of the animals. The Primary Irritation Index of the test article was calculated to be 0.0. The irritation calculations are shown below:

Table 8 Irritation Calculations of SC group

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category
2019080207	0	-	0	0	0	0	Negligible
2019080208	0	-	0	0			
2019080209	0	-	0	0			

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 12 of 18

Table 9 Irritation Calculations of SO group

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category
2019080210	0	-	0	0	0	0	Negligible
2019080211	0	-	0	0			
2019080212	0	-	0	0			

8. Conclusion

There was no erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Indexes for the test article extracts were both calculated to be 0.0. The response of the test article extracts was categorized as negligible.

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs.

10. ISO Compliance

All procedures were compliance to ISO 17025.

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 13 of 18

11. References

Code of Federal Regulations (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices -Part 2: Animal welfare requirements (2006).

International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization (2010).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices -Part 12: Sample preparation and reference materials (2012).

International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories (2017).

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 14 of 18

Appendix 1 – Dermal Observations

Table 10 Dermal Observations of SC group

Animal number	Weight (g)	Group	Observation	Interval (hours)			
				1	24	48	72
2019080 207	2189	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
2019080 208	2081	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
2019080 209	2085	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 15 of 18

Table 11 Dermal Observations of SO group

Animal number	Weight (g)	Group	Observation	Interval (hours)			
				1	24	48	72
2019080 210	2066	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
2019080 211	2150	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0
2019080 212	2217	Test	Erythema	0	0	0	0
			Edema	0	0	0	0
		Control	Erythema	0	0	0	0
			Edema	0	0	0	0

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 16 of 18

Appendix 2 - Periodic Positive Control Study for Primary Skin Irritation Test

What was tested
sodium dodecyl sulfate (SDS)

Dates

Treatment Started: 2019.02.25
Observations Concluded: 2019.03.01

Purpose

A periodic positive control study was conducted for the Primary Skin Irritation Test to meet the following objectives: 1) confirm the methodology in ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization, 2) substantiate the potential of SDS to cause irritant effects, 3) verify proper training of the technicians performing these studies, and 4) substantiate the susceptibility of the rabbit strain to primary skin irritation test.

Methods

The test utilized young adult, nulliparous and not pregnant, male rabbit supplied by Guangzhou baiyun district longgui xingke animal farm (广州市白云区龙归兴科动物养殖场). The weight at study initiation ranged from 3kg to 4kg. Two 25 mm x 25 mm sections of absorbent gauze patches with 0.5ml 20% (w/w) concentration of SDS was topically applied to the skin of each of three rabbits and left in place for 4 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single application.

Results

All of the three sites demonstrated a positive skin irritation to the known skin irritant, SDS. None of the control sites of animals demonstrated an irritation response. The Irritation Calculations are shown below:

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770
Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.



Test Report

Date: 2019-08-15
No. : DY19060319

Page 17 of 18

Animal Number	Test Score Average	-	Control Score Average	Individual Primary Irritation Score	Combined Primary Irritation Score (CPIS)	Primary Irritation Index (CPIS/3)	Response Category
1	6.5	-	0	6.5	20	6.7	Severe
2	6.5	-	0	6.5			
3	7.0	-	0	7.0			

Conclusion

The known skin irritant SDS produced evidence of causing primary skin irritation in the New Zealand White strain of rabbit. Therefore, the following objectives were met: 1) the methodology in ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization was confirmed, 2) the potential for SDS to cause skin irritation was substantiated, 3) proper training of the technicians performing this study design was verified and 4) the susceptibility of the New Zealand White rabbit strain to skin irritation was substantiated.

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.

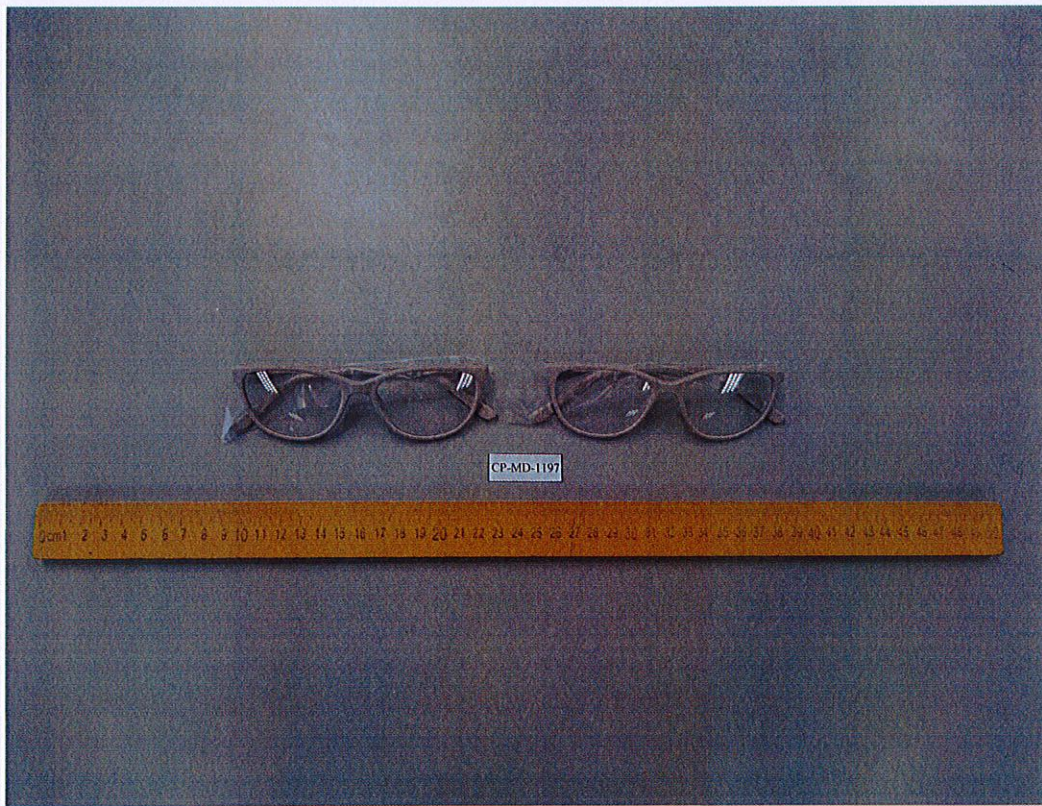


Test Report

Date: 2019-08-15
No. : DY19060319

Page 18 of 18

Appendix 3 – Photograph(s) of Test Articles



***** END OF TEST REPORT *****

STC (Dongguan) Company Limited

68 Fumin Nan Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

Tel : (86 769) 81119888 Fax : (86 769) 81116222 Email : dgstc@stc.group Website : www.stc.group

This report shall not be reproduced unless with prior written approval from STC (Dongguan) Company Limited.

For Conditions of Issuance of this test report, please refer to the overleaf and Website.

Conditions of Issuance of Test Reports

1. All samples and goods are accepted by The STC (Dongguan) Company Limited (the "Company") solely for testing and reporting in accordance with the following terms and conditions. The Company provides its services on the basis that such terms and conditions constitute express agreement between the Company and any person, firm or company requesting its services (the "Clients").
2. Any report issued by the Company as a result of this application for testing service (the "Report") shall be issued in confidence to the Clients and the Report will be strictly treated as such by the Company. It may not be reproduced either in its entirety or in part and it may not be used for advertising or other unauthorized purposes without the written consent of the Company. The Clients to whom the Report is issued may, however, show or send it, or a certified copy thereof prepared by the Company to his customer, supplier or other persons directly concerned. Subject to clause 3, the Company will not, without the consent of the Clients, enter into any discussion or correspondence with any third party concerning the contents of the Report, unless required by the relevant governmental authorities, laws or court orders.
3. The Company shall be at liberty to disclose the testing-related documents and/or files anytime to any third-party accreditation and/or recognition bodies for audit or other related purposes. No liabilities whatsoever shall attach to the Company's act of disclosure.
4. The Company shall not be called or be liable to be called to give evidence or testimony on the Report in a court of law without its prior written consent, unless required by the relevant governmental authorities, laws or court orders.
5. The results in Report apply only to the sample as received and do not apply to the bulk, unless the sampling has been carried out by the Company and is stated as such in the Report. The Clients provide the sample's relevant information, and the Company will not be liable for or accept responsibility for the truth of the sample information.
6. When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.
7. In the event of the improper use the report as determined by the Company, the Company reserves the right to withdraw it, and to adopt any other additional remedies which may be appropriate.
8. Sample submitted for testing are accepted on the understanding that the Report issued cannot form the basis of, or be the instrument for, any legal action against the Company.
9. The Company will not be liable for or accept responsibility for any loss or damage howsoever arising from the use of information contained in any of its Reports or in any communication whatsoever about its said tests or investigations.
10. Clients wishing to use the Report in court proceedings or arbitration shall inform the Company to that effect prior to submitting the sample for testing.
11. Subject to the variable length of retention time for test data and report stored hereinto as to otherwise specifically required by individual accreditation authorities, the Company will only keep the supporting test data and information of this test report for a period of six years. The data and information will be disposed of after the aforementioned retention period has elapsed. Under no circumstances shall we provide any data and information which has been disposed of after the retention period. Under no circumstances shall we be liable for damages of any kind, including (but not limited to) compensatory damages, lost profits, lost data, or any form of special, incidental, indirect, consequential or punitive damages of any kind, whether based on breach of contract of warranty, tort (including negligence), product liability or otherwise, even if we are informed in advance of the possibility of such damages.
12. Issuance records of the Report are available on the internet at www.stc.group. Further enquiry of validity or verification of the Reports should be addressed to the Company.