Certificate HK20/42007

The management system of

Synertech International Limited

Rm 09, 13/F & Rm 03, 22/F, Laurels Industrial Centre, 32 Tai Yau Street,
San Po Kong, Kln, HK

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of single use non-sterile medical face mask

This certificate is valid from 1 September 2020 until 31 August 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 22 August 2023
Issue 1. Certified since 1 September 2020

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

CERTIFICATE OF COMPLIANCE

This is to certify that

The Cleanroom at

Room 3, 22/F, Laurels Industrial Centre, 32 Tai Yau Street, San Po Kong, Kowloon, Hong Kong

of Ownership

Synertech International Limited

Complies with the Acceptance Criteria of

BS EN ISO 14644-1:1999: Class 8

As detailed in

Test Report No.: 204260HP200148 **Date of Certification:** Aug. 14, 2020

Date of expiry: Aug. 14, 2021

Certified by: _____ **Date of issue:** Aug. 27, 2020

Approved Signatory: Cheng Hon Kai, Arthur
Project Manager

FUGRO TECHNICAL SERVICES LIMITED

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检测
TESTING
CNAS L10463

FINAL REPORT

Study Name: Medical Face Mask-Skin Sensitization Test

Study Number: MED202004001-08-EN

Testing Facility

Name: Epin Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

Sponsor

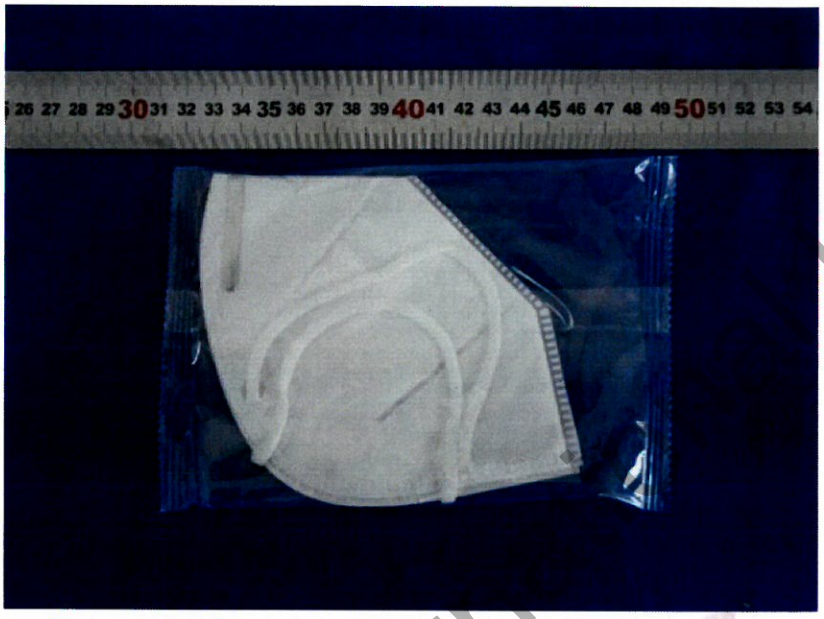
Name: Synertech International Limited

Address: Rm 9, 13/F., Laurels Industrial Centre, 32 Tai Yau St., San Po Kong, Kowloon, Hong Kong

SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days after receiving the report if there is any objection.
2. Any erasure or without specific testing seal the report is invalid.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result is only for the tested articles.
5. The report shall not be partly reproduced without the written approval by the institute.

SAMPLE CONFIRMATION AND SIGNATURE



Edited by: Aileen Zhang Date: 2020-05-25
Aileen Zhang

Checked by: Tina Tian Date: 2020.05.25
Tina Tian

Approved by: Date: 2020-05-25
William Guo (Facility Manager)

GLP COMPLIANCE STATEMENT

This study was performed in compliance with a quality management system according to ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories), which has been established at Epin Suzhou Ltd.

This quality management system includes the quality requirements prescribed by the international guidelines for Good Laboratory Practice (GLP).

Study Director: Tina Tian Date: 2020-05-25

Tina Tian

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of EPIN, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to EPIN's Management.

Inspections	Date of Inspections	Date of Reported
Study protocol	2020-04-16	2020-04-16
Sample preparation	2020-04-21	2020-04-21
Intradermal induction phase dosing process	2020-04-24	2020-04-24
Topical induction phase dosing process	2020-05-01	2020-05-01
Challenge phase dosing process	2020-05-15	2020-05-15
Observing process	2020-05-17	2020-05-17
Raw data + Final report	2020-05-25	2020-05-25

Quality Assurance Unit: Bill Yu

Bill Yu

Date: 2020-05-25

CONTENTS

SUMMARY

1. Purpose

To evaluate the potential of test article extracts to cause skin sensitization in the guinea pig.

2. Experimental Process

Test article was whole sampling by 3 cm^2: 1 mL, extraction condition was 37℃ for 72 h. Extraction solvents were 0.9% sodium chloride (SC) and sesame oil (SO).

A pair of 0.1 mL intradermal injections was made into each animal in the clipped intrascapular region. At 7 d after completion of the intradermal induction phase, administered the test article extracts by topical application to the intrascapular region of each animal, used a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secured with an occlusive dressing. Removed the dressings and patches after (48±2) h. Treated the negative control animals similarly, used the negative liquid alone. If the test article extracts did not produce irritation, pretreated the area with 10% sodium dodecyl sulfate massaged into the skin (24±2) h before the patch was applied.

At 14 d after completion of the topical induction phase, challenged all animals with the test extract. Administered all animals by topical application to sites that were not treated during the induction stage, used absorbent gauze (2.5 cm×2.5 cm) soaked. Secure with an occlusive dressing. Removed the dressings and patches after (24±2) h.

Observed the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Described and scored the skin reactions for erythema and oedema according to the Magnusson and Kligman grading.

3. Result

The positive rate of all test groups was 0%.

The positive rate of all negative control groups was 0%.

No abnormal clinical symptoms were observed in all animals except skin reactions.

4. Conclusion

Under the conditions of this study, the sample extract showed no signification evidence of causing skin sensitization in the guinea pig.

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

Medical Face Mask-Skin Sensitization Test (MED202004001-08-EN).

1.2. Study Purpose

To evaluate the potential of test article extracts to cause skin sensitization in the guinea pig.

1.3. Referred Standard

- ISO 10993-10: 2010

  Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization

- ISO 10993-12: 2012

  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

1.4. Compliance

- Good Laboratory Practice Regulations, 21 CFR, Part 58

1.5. Testing Facility

Name:	Epin Suzhou Ltd.
Address:	No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

1.6. Sponsor

Name:	Synertech International Limited
Address:	Rm 9, 13/F., Laurels Industrial Centre, 32 Tai Yau St., San Po Kong, Kowloon, Hong Kong
ATTN:	Andy Kum
Contact Information:	+852-2687 6828/andykum@synertech.com.hk

1.7. Quality Guarantee

Quality Assurance Unit:	Bill Yu

The methods and raw data involved in this test were inspected and this report should be reviewed by the Quality Assurance Unit (QAU). The key practices during the procedure were inspected regularly by QAU required by related SOP.

1.8. Study Protocol Alteration Treatment

Before the study start, the study protocol was approved by Study Director, Facility Manager and Sponsor. Meanwhile, QAU finished the protocol review in accordance with the requirements for GLP. Any study alteration should be applied by Study Director and approved by QAU and Facility Manager.

1.9. Deviation and Accident Treatment

If deviation or accident occur during the test, the related information would be recorded timely and deviation report should be submitted with the final report to interpretate the specific effect on the final result caused by the deviation or accident.

1.10. Major Laboratory Personnel

Study Director:	Tina Tian
Main Operation Personnel:	Ann Feng, Alisa Wang, Cheery Zhou

1.11. Schedule of the Study

Sample Received Date:	2020-04-15
Protocol Effective Date:	2020-04-16
Technical Initiation Date:	2020-04-24
Technical Completion Date:	2020-05-18
Final Report Completion Date:	2020-05-25

2. TEST MATERIAL

2.1. Test Article

2.1.1. Test article information

Name:	Medical Face Mask
Initial State:	Non-sterile
CAS/Code#:	Not Supplied by Sponsor (N/S)
Size:	230X125MM

Model:	SC1001M
Lot/ Batch#:	001-04/2020
Physical State:	Solid
Color:	White
Density:	N/S
Stability:	N/S
Solubility:	N/S
Storage Condition:	Room temperature, Keep out of sun
Test Article Material:	Non woven fabric
Packaging Material:	OPP Bag + Paper Colour Box
Expiry Date:	2023/04/30
Manufacturer Name:	Synertech International Limited
Manufacturer Address.:	Rm 9, 13/F., Laurels Industrial Centre, 32 Tai Yau St., San Po Kong, Kowloon, Hong Kong

Note: The information about the test article was supplied by the sponsor. The sponsor was responsible for all test article characterization data as specified in the GLP Regulations.

2.1.2. Reserve sample

Reserve Sample Volume:	5 pcs
Storage Location:	Sample Reserve Room

2.1.3. The remaining samples

Remaining after the Test Complete:	Destroy and waste
Remaining after the Study Complete:	Destroy and waste

2.2. Negative Control

2.2.1. Polar control information

Name:	0.9% Sodium Chloride (SC)
Size:	500 mL
Lot/ Batch#:	190709 2A, 190722 5A

Physical State:	Liquid
Color:	Colorless
Storage Condition:	Room Temperature
Manufacturer:	Double Crane Pharmaceutical Co., Ltd.

2.2.2. Non-polar control information

Name:	Sesame Oil (SO)
Size:	500 mL
CAS:	8008-74-0
Lot/ Batch#:	191028, 200302
Physical State:	Puce oily liquid
Storage Condition:	Room temperature, keep out of sun
Manufacturer:	PERFEMIKER

2.3. Positive Control

Denomination:	2, 4-Dinitrochlorobenzene (DNCB)
Size:	100 g
Content:	98%
Lot/ Batch#:	160310
CAS:	97-00-7
Physical State:	Pale yellow solid
Storage Condition:	Room temperature
Manufacturer:	PERFEMIKER
Induction Concentration:	0.5%
Challenge Concentration:	0.1%

2.4. Animal

2.4.1. Animal information

Species:	Hartley Guinea Pig
Microbial Levels:	Conventional
Number/Sex:	30/Male

Weight:	＞300 g
Manufacturer:	Suzhou Zhenhu
Production License#:	SCXK(Su)2015-0007
Quality Certificate#:	No.202001630, No.202001956

2.4.2. Animal feeding conditions

Breeding Density:	5 animals per cage
Cages:	Plastic cage
Animal Identification:	Stain with neutral magenta and identified by a cage card
Acclimation Period:	At least 5 days under the same conditions as for the actual test
Fodder:	Name: Guinea pig maintain feed Manufacturer: Beijing Keao Xieli Feed Co.,Ltd. Daily 40 g quantitative uptake per animal
Padding:	Name: Corn cob Manufacturer: Suzhou Anweierkang Periodic replacement
Vegetable/ Fruit:	Manufacturer: Supermarket Every afternoon rationing

2.4.3. Animal room environmental conditions

Temperature:	18℃-29℃
Relative Humidity:	40%-70%RH
Ventilation Rate:	≥8/h
Lights:	12 hours light/dark cycle, full spectrum fluorescent lights

2.5. Main Instruments and Reagents

2.5.1. Main instruments

Name	No.	Manufacturer
Electronic Balance	EPB-036	Shanghai Yueping
Shaking Bath	EPB-184	Shanghai Yiheng
Clean Bench	EPB-143	BIOBASE

2.5.2. Main reagents

Name	Lot/ Batch#	Manufacturer
FCA	SLCB 3232	SIGMA
Sodium Dodecyl Sulfate	20170712	Sinopharm Chemical Reagent Co., Ltd

2.6. Justification of the Test System

The albino guinea pig has been used historically for sensitization studies. The guinea pig is believed to be the most sensitive animal model for this type of study. 2, 4-Dinitrochlorobenzene (DNCB) is recommended as the positive substance by guiding principle. 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at EPIN Suzhou LTD once every 3 months with this method.

3. TEST DESIGN

3.1. Extract Preparation

3.1.1. Extraction process

Test phase	Sampling Manner	Actual Sampling*	Ratio	Solvent	Amount	Conditions
Intradermal induction	Whole	440 cm^2	3 cm^2: 1 mL	SC	146.6 mL	37℃, 72 h
		440 cm^2	3 cm^2: 1 mL	SO	146.6 mL	37℃, 72 h
Topical induction		440 cm^2	3 cm^2: 1 mL	SC	146.6 mL	37℃, 72 h
		440 cm^2	3 cm^2: 1 mL	SO	146.6 mL	37℃, 72 h
Challenge		440 cm^2	3 cm^2: 1 mL	SC	146.6 mL	37℃, 72 h
		440 cm^2	3 cm^2: 1 mL	SO	146.6 mL	37℃, 72 h

Note: The vehicle (without the test article) was similarly prepared to serve as the negative control.

*: The surface is 440cm^2 per sample (provided by sponsor).

3.1.2. Final extract treatment

Final extract	Presence of particles or Not	Color and Clear or Not	Additional processing prior to the testing or Not
SC	Not	Colorless and Clear	Not
SO	Not	Puce and Clear	Not

Note: Used the final extracts within 24h.

3.2. Grouping

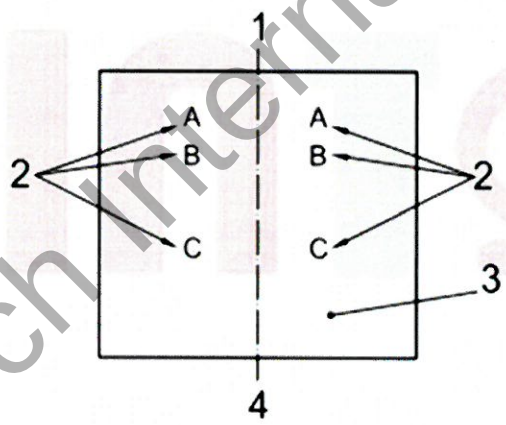
Took 30 guinea pigs and divided them into four groups.

Group No.	Group Name	Amount	Sex	Numbered list
1	Negative control (SC)	5	♂	1101-1105
2	Test group (SC)	10	♂	2106-2115
3	Negative control (SO)	5	♂	3116-3120
4	Test group (SO)	10	♂	4121- 4130

3.3. Experimental Process

3.3.1. Intradermal induction phase I

A pair of 0.1 mL intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in **Figure 1** in the clipped intrascapular region.



1. Cranial end 2. 0.1 mL intradermal injections 3. Clipped intrascapular region 4. Caudal end
Site A: 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.
Site B: The test article extract, the negative control animals were injected with the solvent alone.
Site C: The test article extract, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%), the negative control animals were injected with an emulsion of the negative liquid with adjuvant.

Figure 1 Location of intradermal injection sites

3.3.2. Topical induction phase II

At 7 d after completion of the intradermal induction phase, administered the test article extract by topical application to the intrascapular region of each animal, used a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secured with an occlusive dressing. Removed the dressings and patches after (48±2) h. Treated the negative control animals similarly,

used the negative liquid alone. If the test article extract did not produce irritation, pretreated the area with 10% sodium dodecyl sulfate massaged into the skin (24±2) h before the patch was applied.

3.3.3. Challenge phase

At 14d after completion of the topical induction phase, challenged all animals with the sample extract. Administered all animals by topical application to sites that were not treated during the induction stage, used absorbent gauze (2.5 cm×2.5 cm) soaked. Secured with an occlusive dressing. Removed the dressings and patches after (24±2) h.

3.3.4. Observation of animal

Observed the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Described and graded 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.

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

3.3.5. Other observed endpoints

Clinical symptoms except dermal reactions were observed every day.
Weighting all the test animals at the beginning and end of the test.

4. EVALUATION CRITERION

(1) Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

(2) If grades of 1 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.

(3) If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

(4) Occasionally, the test group has a greater number of animals showing a response than the controls, although the intensity of the reaction is not greater than that exhibited by the controls. In these instances, a rechallenge might be necessary to define the response clearly. A rechallenge shall be carried out 1

week to 2 weeks after the first challenge. The method used shall be as described for the first challenge, using a naive side on the animal.

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

5. ALTERATION AND DEVIATION

At the request of the sponsor. Changed the product name from "Surgical Face Mask" to "Medical Face Mask". Changed the Model from "FM-001A-01" to "SC1001M" and changed the ATTN and Contact Information from "Larry Zhong, +86 2161278307/Larry.zhong@intertek.com" to "Andy Kum, +852-26876828/andykum@synertech.com.hk". The sponsor was responsible for all test article characterization data as specified in the GLP Regulations.

No deviation happened in this study.

6. RESULTS

The positive rate of all test groups was 0%.

The positive rate of all negative control groups was 0%.

No abnormal clinical symptoms were observed in all animals except skin reactions.

See **Attached Table 1-2.**

7. CONCLUSION

Under the conditions of this study, the sample extract showed no significant evidence of causing skin sensitization in the guinea pig.

8. ARCHIVING

All correspondence, an original copy of the protocol, an original copy of the test report, and a documentation of all raw data generated during the conduct of the study are stored in the archives of the Epin Suzhou Ltd.

9. ATTACHED TABLE

9.1. Attached Table 1 Sensitization Dermal Reactions

Group	Animal Number	(24±2) h before Phase II Patch Application		Hours Following Challenge Phase		Positive Rate after Challenge Phase
		Left	Right	(24±2) h	(48±2) h	
Negative control (SC)	1101	0	0	0	0	0%
	1102	0	0	0	0	
	1103	0	0	0	0	
	1104	0	0	0	0	
	1105	0	0	0	0	
Test group (SC)	2106	0	0	0	0	0%
	2107	0	0	0	0	
	2108	0	0	0	0	
	2109	0	0	0	0	
	2110	0	0	0	0	
	2111	0	0	0	0	
	2112	0	0	0	0	
	2113	0	0	0	0	
	2114	0	0	0	0	
	2115	0	0	0	0	
Negative control (SO)	3116	0	0	0	0	0%
	3117	0	0	0	0	
	3118	0	0	0	0	
	3119	0	0	0	0	
	3120	0	0	0	0	
Test group (SO)	4121	0	0	0	0	0%
	4122	0	0	0	0	
	4123	0	0	0	0	
	4124	0	0	0	0	
	4125	0	0	0	0	
	4126	0	0	0	0	
	4127	0	0	0	0	
	4128	0	0	0	0	
	4129	0	0	0	0	
	4130	0	0	0	0	

9.2. Attached Table 2 Weight Change and Clinical Observation

Group	Animal Number	Weight (g)		Clinical Observation except Dermal Reactions
		Test Begin	Test End	
Negative control (SC)	1101	327	415	Normal
	1102	318	402	Normal
	1103	336	434	Normal
	1104	316	409	Normal
	1105	334	416	Normal
Test group (SC)	2106	323	403	Normal
	2107	322	414	Normal
	2108	310	405	Normal
	2109	339	428	Normal
	2110	348	421	Normal
	2111	321	419	Normal
	2112	335	413	Normal
	2113	314	406	Normal
	2114	323	437	Normal
	2115	327	418	Normal
Negative control (SO)	3116	342	431	Normal
	3117	334	415	Normal
	3118	335	418	Normal
	3119	343	424	Normal
	3120	325	402	Normal
Test group (SO)	4121	326	413	Normal
	4122	337	417	Normal
	4123	343	426	Normal
	4124	324	439	Normal
	4125	352	445	Normal
	4126	345	434	Normal
	4127	328	402	Normal
	4128	326	413	Normal
	4129	332	427	Normal
	4130	310	401	Normal

9.3. Attached Table 3 Sensitization Dermal Reactions of Positive Group

Group	Animal Number	(24±2) h before phase II patch application		Hours following Challenge phase		Positive rate after challenge phase
		Left	Right	(24±2) h	(48±2) h	
Negative control (DNCB)	5131	0	0	0	0	0%
	5132	0	0	0	0	
	5133	0	0	0	0	
	5134	0	0	0	0	
	5135	0	0	0	0	
Positive control (DNCB)	6136	2	1	1	2	100%
	6137	2	1	2	3	
	6138	1	2	3	3	
	6139	2	1	2	2	
	6140	2	1	2	2	

Note: The data of positive control came from MED201912263-08 (Completed Date: 2020-03-12).

9.4. Attached Table 4 Weight Change and Clinical Observation of Positive Group

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Test began	Test end	
Negative control (DNCB)	5131	464	519	Normal
	5132	450	510	Normal
	5133	486	544	Normal
	5134	474	523	Normal
	5135	459	507	Normal
Positive control (DNCB)	6136	475	511	Normal
	6137	450	508	Normal
	6138	445	508	Normal
	6139	483	560	Normal
	6140	457	514	Normal

Note: The data of positive control came from MED201912263-08 (Completed Date: 2020-03-12).

End of Report