立讯检测股份
LCS Testing Lab
股 票 代 码：871117

TEST REPORT
测试报告

Report No.(报告编号): LCS200407004AR Date(日期): 2020.04.11 Page(页码): 1 of 6

Applicant	:	Guangdong Ruishi Wire Cable Co., Ltd
申请商	:	广东瑞狮电线电缆有限公司
Address	:	Longshi Industrial Zone, Longshi community, Dongsheng Street, Rongcheng District, Jieyang City, Guangdong, China
地址	:	广东省揭阳市榕城区东升街道龙石社区龙石工业区

Report on the submitted samples said to be:
委托检测的样品及申请者对样品的说明如下 ：

Sample Name	:	NOSE STRIP OF MAK/口罩鼻梁条
样品名称	:	
Material	:	N/A
材料	:	
Testing Period	:	April 09, 2020 ~ April 11, 2020
测试周期	:	2020 年 04 月 09 日~2020 年 04 月 11 日
Results	:	Please refer to next page(s).
测试结果	:	参见后续页。

TEST REQUEST 测试要求	CONCLUSION 结论
According to the customer's request, based on the performed tests on submitted sample, the result of Lead(Pb), Cadmium(Cd), Mercury(Hg), Hexavalent Chromium(Cr(VI)), PBBs, PBDEs, Dibuyl Phthalate(DBP), Benzylbutyl Phthalate(BBP), Bis(2-ethylhexyl) Phthalate(DEHP), Diispbutyl phthalate(DIBP) content comply with the limit requirements as set of RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU. 根据客户的要求，提交样品测试铅(Pb)、镉(Cd)、汞(Hg)、六价铬(Cr(VI))、多溴联苯(PBBs)、多溴联苯醚(PBDEs)、邻苯二甲酸二丁酯 (DBP)、邻苯二甲酸丁苄酯(BBP)、邻苯二甲酸(2-乙基已基酯)(DEHP)、邻苯二甲酸二异丁酯(DIBP)含量结果符合欧盟 RoHs 指令 2011/65/EU 及其修正指令 EU) 2015/863 的限值要求	Pass （合格）

Signed for and on behalf of LCS

Center of Testing Service * APPROVED *

Daniel

Shenzhen LCS Compliance Testing Laboratory Ltd.
深圳立讯检测股份有限公司

Add: F&G, 23/F.,Technology Building, Quanzhi Science and Technology
地址：深圳市宝安区沙井街道后亭茅洲山工业园工业大厦全至科技创新园
Innovation Park, Industrial Building, Maozhoushan Industrial Park,
科创大厦 23 层 F、23 层 G
Houting,Shajing Street , Bao'an District, Shenzhen, Guangdong,China

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Tested part(s)测试部位:

(1) White plastic 白色塑料.

Results 测试结果:

Test method:

Lead(Pb) & Cadmium(Cd) Content:
With reference to IEC 62321-5:2013, by acid digestion and analysis was performed by inductively coupled plasma atomic emission spectrometer (ICP-OES)

Mercury(Hg) Content:
With reference toIEC 62321-4:2013+AMD1:2017 CSV, by acid digestion and analysis was performed by inductively coupled plasma atomic emission spectrometer (ICP-OES)

Hexavalent Chromium(Cr(VI)) Content:
With reference to IEC 62321-7-2:2017, by alkaline digestion and analysis was performed by UV-visible spectrophotometer (UV-Vis)

PBBs & PBDEs Content:
With reference to IEC 62321-6:2015, by solvent extraction and analysis was performed by gas chromatographic-mass spectrometer (GC-MS)

DBP, BBP, DEHP, DIBP Content

With reference to IEC 62321-8:2017, by solvent extraction and analysis was performed by gas chromatographic-mass spectrometer (GC-MS)

测试方法:

铅(Pb)和镉(Cd)含量:

参考 IEC 62321-5:2013 测试方法，样品用酸消解，然后用电感耦合等离子体发射光谱仪(ICP-OES)进行检测

汞(Hg)含量:
参照 IEC 62321-4:2013+AMD1:2017 CSV，用酸消解然后用电感耦合等离子体发射光谱仪(ICP-OES)进行检测

六价铬(Cr(VI))含量:
参考 IEC 62321-7-2:2017 测试方法，用碱液提取法，然后用紫外-可见分光光度计(UV-Vis)进行检测

多溴联苯(PBBs)、多溴联苯醚(PBDEs)含量:
参考 IEC 62321-6:2015 测试方法，样品采用有机溶剂萃取，气相色谱质谱联用仪(GC-MS)进行检测

邻苯二甲酸二丁酯(DBP)、邻苯二甲酸丁苄酯(BBP)、邻苯二甲酸(2-乙基己基酯)(DEHP)、邻苯二甲酸二异丁酯(DIBP)含量
参考 IEC 62321-8:2017 测试方法，样品采用有机溶剂萃取，气相色谱质谱联用仪(GC-MS)进行检测

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Items 项目	Unit 单位	MDL 方法检出限	Results 测试结果 (1)	Limit 限量
Lead(Pb) Content 铅含量	mg/kg	5	N.D.	1000
Cadmium(Cd) Content 镉含量	mg/kg	5	N.D.	100
Mercury(Hg) Content 汞含量	mg/kg	5	N.D.	1000
Hexavalent Chromium(Cr(VI)) 六价铬含量	mg/kg	5	N.D.	1000
Dibuyl Phthalate(DBP)Content 邻苯二甲酸二丁酯(DBP)含量	mg/kg	100	214	1000
Benzylbutyl Phthalate(BBP)Content 邻苯二甲酸丁苄酯(BBP)含量	mg/kg	100	N.D.	1000
Bis(2-ethylhexyl) Phthalate(DEHP)Content 邻苯二甲酸(2-乙基己基酯)(DEHP)含量	mg/kg	100	N.D.	1000
Diispbutyl phthalate(DIBP)Content 邻苯二甲酸二异丁酯(DIBP)含量	mg/kg	100	N.D.	1000
Polybrominated Biphenyls 多溴联苯(PBBs)				
Monobromobiphenyl (一溴联苯)	mg/kg	5	N.D.	
Dibromobiphenyl (二溴联苯)	mg/kg	5	N.D.	
Tribromobiphenyl (三溴联苯)	mg/kg	5	N.D.	
Tetrabromobiphenyl(四溴联苯)	mg/kg	5	N.D.	
Pentabromobiphenyl (五溴联苯)	mg/kg	5	N.D.	
Hexabromobiphenyl (六溴联苯)	mg/kg	5	N.D.	
Heptabromobiphenyl (七溴联苯)	mg/kg	5	N.D.	
Octabromobiphenyl (八溴联苯)	mg/kg	5	N.D.	
Nonabromodiphenyl (九溴联苯)	mg/kg	5	N.D.	
Decabromodiphenyl (十溴联苯)	mg/kg	5	N.D.	
Total content (总含量)	mg/kg	/	N.D.	1000
Polybrominated Diphenylethers 多溴联苯醚(PBDEs)(Mon-Deca)				
Monobromodiphenyl ether (一溴联苯醚)	mg/kg	5	N.D.	
Dibromodiphenyl ether (二溴联苯醚)	mg/kg	5	N.D.	
Tribromodiphenyl ether(三溴联苯醚)	mg/kg	5	N.D.	
Tetrabromodiphenyl ether (四溴联苯醚)	mg/kg	5	N.D.	
Pentabromodiphenyl ether (五溴联苯醚)	mg/kg	5	N.D.	
Hexabromodiphenyl ether (六溴联苯醚)	mg/kg	5	N.D.	
Heptabromodiphenyl ether (七溴联苯醚)	mg/kg	5	N.D.	
Octabromodiphenyl ether (八溴联苯醚)	mg/kg	5	N.D.	
Nonabromodiphenyl ether (九溴联苯醚)	mg/kg	5	N.D.	
Decabromodiphenyl ether (十溴联苯醚)	mg/kg	5	N.D.	
Total content (总含量)	mg/kg	/	N.D.	1000

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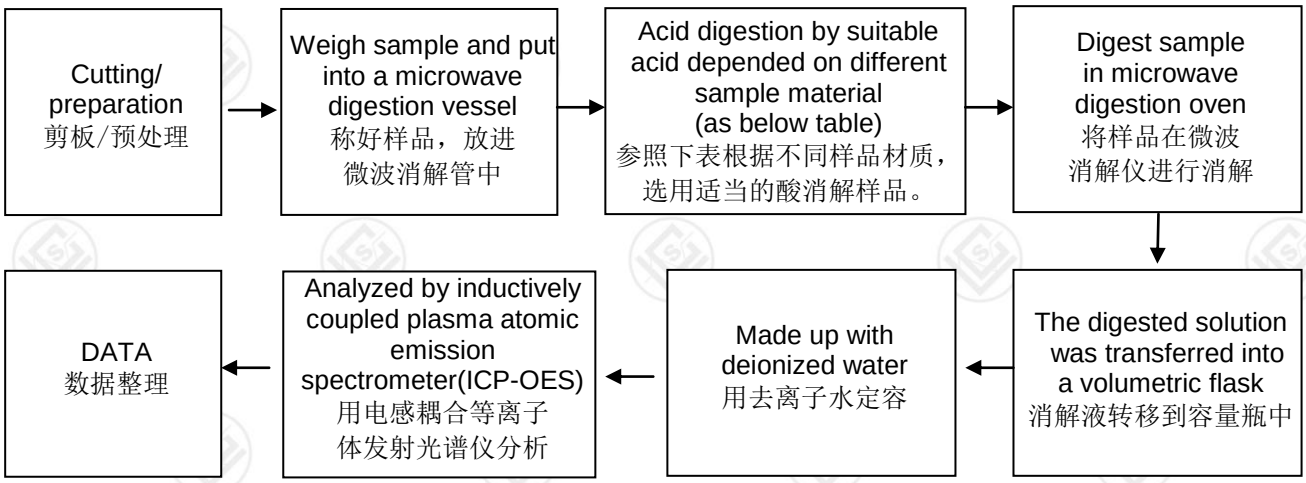
Note 注释:

- N.D. = Not Detected or less than MDL
  N.D. = 未检出或低于检出限
- MDL = Method Detection Limit
  MDL = 方法检出限
- mg/kg = ppm
  毫克每千克 = ppm
- The sample had been dissolved totally tested for Lead, Mercury and Cadmium.
  样品完全溶解测试铅，汞，镉含量
- Flow chart is included.
  附测试流程图
- Photo appendix is included.
  样品照片见附录。

Test Flow: These samples were dissolved totally by pre-conditioning method according to below flow chart.
测试流程： 测试样品按照以下流程图的前处理方法完全溶解

1. Test Flowchart for Pb/Cd/Hg contents
   铅/镉/含量汞测试流程图



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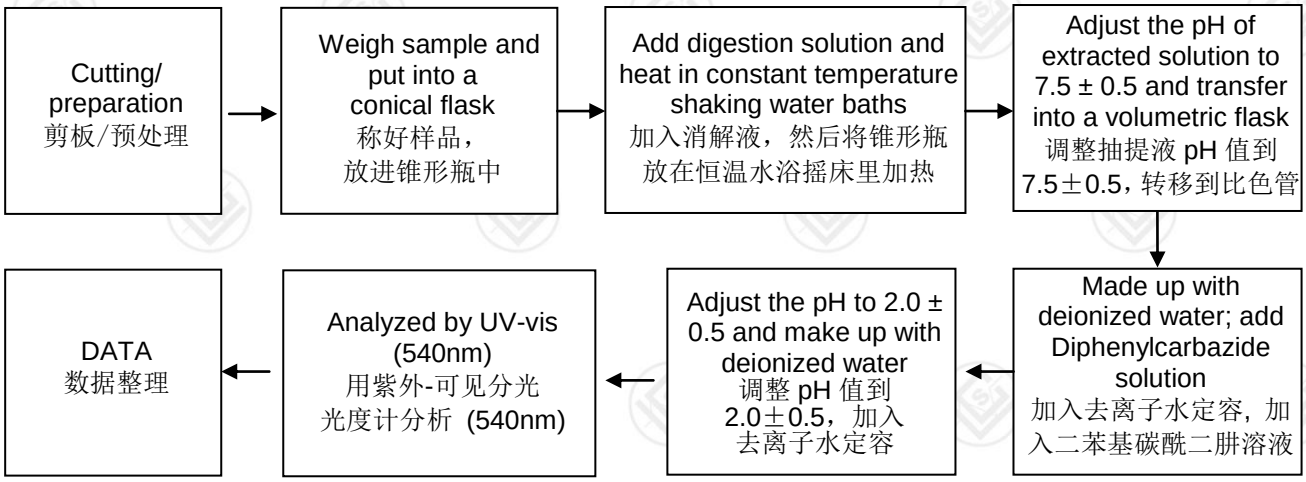
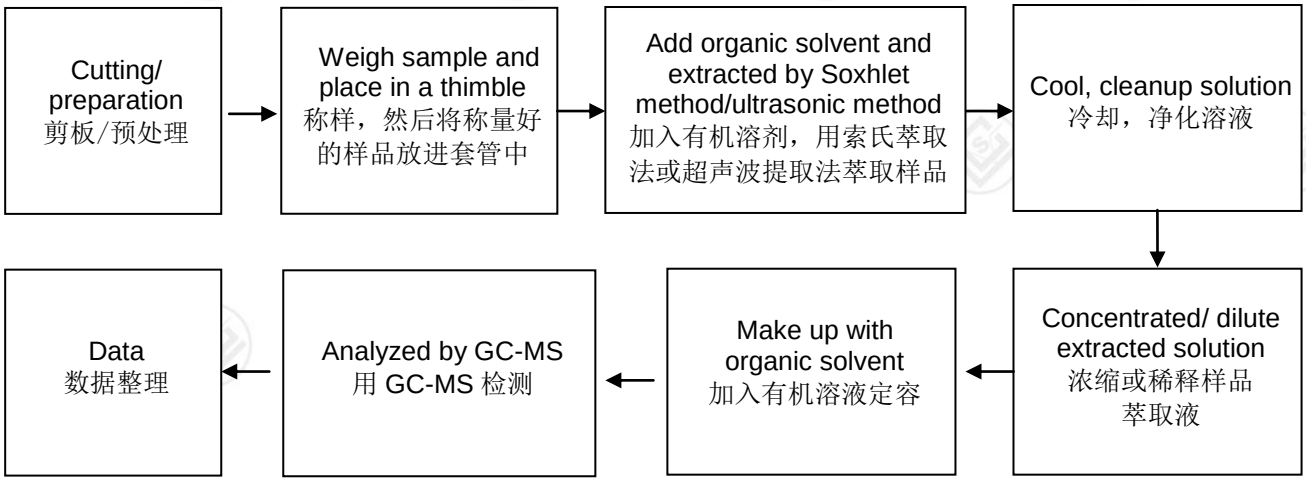
2. Test Flowchart for Cr(VI) content(For non-metallic material)
六价铬(Cr(VI))(非金属)测试流程图



3. Test Flow chart for PBBs & PBDEs, DBP, BBP, DEHP, DIBP content
多溴联苯(PBBs)、多溴联苯醚(PBDEs)、邻苯二甲酸二丁酯含量(DBP)、邻苯二甲酸丁苄酯含量(BBP)、邻苯二甲酸(2-乙基己基酯)含量(DEHP)、邻苯二甲酸二异丁酯(DIBP)含量测试流程图



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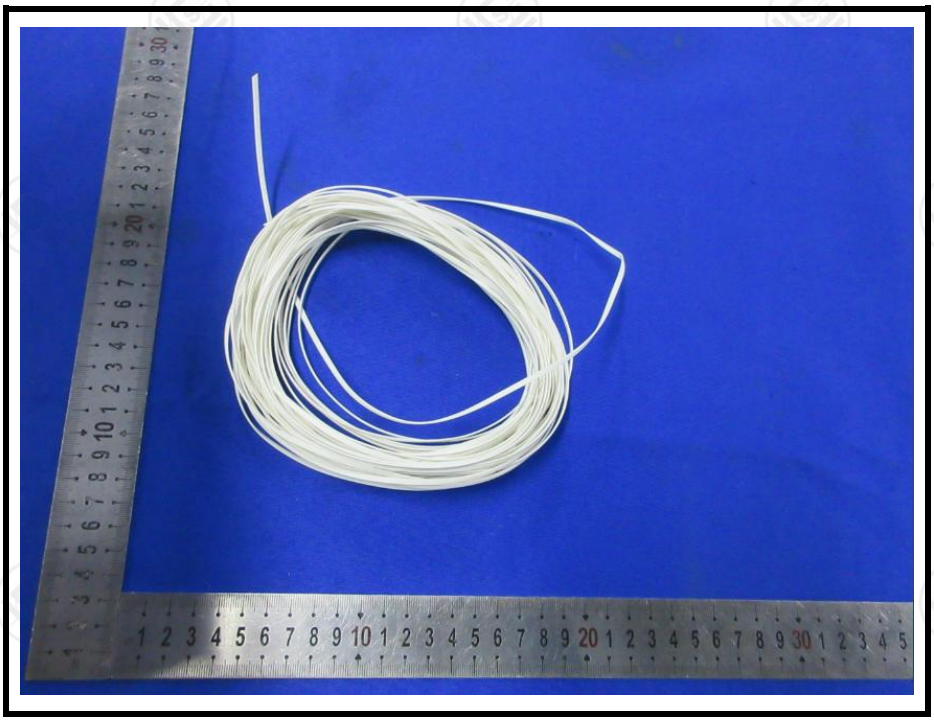
The photo of the sample
样品图片



LCS authenticate the photo on original report only
此图片仅限于随 LCS 正本报告使用

*** End of Report ***
*** 报告结束 ***

Statement 声明:

1. The test report is considered invalidated without approval signature, special seal on the perforation.
   检测报告无批准人签字、加盖公司报告专用章无效。
2. The result(s) shown in this report refer only to the sample(s) tested.
   本报告检测结果仅对受测样品负责。
3. Without written approval of LCS, this report can't be reproduced except in full.
   未经 LCS 书面同意，不得部分复制本报告。
4. The sample(s) and sample information was/were provided by the client who should be responsible for the authenticity which LCS hasn't verified.
   未经 LCS 验证，由客户提供的样品和样品信息，客户应对其真实性负责。
5. In case of any discrepancy between the English version and Chinese version of the testing reports(if generated), the Chinese version shall prevail.
   如果英文版本和中文版本的测试报告有任何差异（如产生），则以中文版本为准。

Testing Report	Security website：www.fcl-sz.org.cn Security code：2832226377
Report No：ZFLJ2650944A	Page 1 of 4

Applicant Information

Applicant Name : Guangdong YADE Industry Co.,Ltd.
Applicant Address : Zhulin Village,Ziyun Gaoxin District,Meiyun town,Roncheng District,Jieyang City,Guangdong Province,China
Manufacturer : Guangdong YADE Industry Co.,Ltd.

Sample Information

Sample Description : surgical mask
Specification : 17.5*9.5CM
Sample Quantity : 70 pieces
Model : KYD06

- Sample Receiving Date : 2020-10-07
- Report Date : 2020-10-19
- The original sample is sticked on the last paper.

Test Performed

Judgement according to:
EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type ⅡR
- Selected test(s) as requested by applicants. For details, refer to attached page(s).

Pronounce

The results shown in this report refer only to sample(s) tested unless otherwise stated.
All the items are performed in the standard conditions, except the noted cases.
Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.

Signed for and on behalf of
CNTAC Testing Service Co.,Ltd.(Foshan)
Approved by

张志荣 （ Except for microbiological project ）

罗桂通 （ Microbiological project）

佛山中纺联检验技术服务有限公司 检验检测专用章 (02)

Testing Report	Security website：www.fcl-sz.org.cn Security code：2832226377
Report No：ZFLJ2650944A	Page 2 of 4

--- Test Result ---

	Test Result	Requirements	Judgement
1. Resistance to Penetration by Synthetic Blood *ISO 22609:2004* Synthetic blood surface tension: 0.040N/m, Distance between blow head front end and target area：300mm， Synthetic blood volumes: 2mL, Test pressure: 16.0kPa, Injection velocity: 550cm/s, Use a fixed target board.			
sample 1#	None seen	Pass Pressure at 16.0kPa	Pass
sample 2#	None seen		
sample 3#	None seen		
sample 4#	None seen		
sample 5#	None seen		
sample 6#	None seen		
sample 7#	None seen		
sample 8#	None seen		
sample 9#	None seen		
sample 10#	None seen		
sample 11#	None seen		
sample 12#	None seen		
sample 13#	None seen		
sample 14#	None seen		
sample 15#	None seen		
sample 16#	None seen		
sample 17#	None seen		
sample 18#	None seen		
sample 19#	None seen		
sample 20#	None seen		
sample 21#	None seen		
sample 22#	None seen		
sample 23#	None seen		
sample 24#	None seen		
sample 25#	None seen		
sample 26#	None seen		
sample 27#	None seen		
sample 28#	None seen		
sample 29#	None seen		
sample 30#	None seen		
sample 31#	None seen		
sample 32#	None seen		

Testing Report	Security website：www.fcl-sz.org.cn Security code：2832226377
Report No：ZFLJ2650944A	Page 3 of 4

	Test Result	Requirements	Judgement
2. Differential Pressure *EN 14683:2019+AC:2019 Appendix C*			
Air flow: 8L/min, Test area diameter 25mm, Test area: 4.9cm^2			
Unit: <**Pa/cm²**>			
sample 1#	42.0	< 60	Pass
sample 2#	39.5		
sample 3#	41.4		
sample 4#	42.7		
sample 5#	41.1		
Average	41.3		

3. Bacterial Filtration Efficiency *EN 14683:2019+AC：2019 Appendix B*

Flow rate: 28.3L/min, Test area: 77cm^2, Test bacteria culture: Staphylococcus aureus ATCC 6538, Particle Diameter: 3.0μm, Inside of the test mask was facing towards the challenge aerosol, The average plate count results of the positive controls: 2.5×10^{3}CFU, The average plate count results of the negative controls: <1CFU

Unit: <**%**>

sample 1#	99.9	≥ 98	Pass
sample 2#	99.9		
sample 3#	99.9		
sample 4#	99.9		
sample 5#	99.9		

佛山中纺联检验技术服务有限公司 检验检测专用章 (02)

Testing Report	Security website：www.fcl-sz.org.cn Security code：2832226377
Report No：ZFLJ2650944A	Page 4 of 4

Original Sample

======= End of Report ======

Testing Report	Security website：www.fcl-sz.org.cn Security code：6012363548
Report No：ZFLJ2652456A	Page 1 of 3

Applicant Information

Applicant Name : Guangdong YADE Industry Co.,Ltd.
Applicant Address : Zhulin Village, Ziyun Gaoxin District, Meiyun town, Roncheng District, Jieyang City, Guangdong Province,China
Manufacturer : Guangdong YADE Industry Co.,Ltd.

Sample Information

Sample Description : surgical mask
Specification : 17.5*9.5CM
Sample Quantity : 15 pieces
Model : KYD06

- Sample Receiving Date : 2020-10-16
- Report Date : 2020-10-24
- The original sample is sticked on the last paper.

Test Performed

Judgement according to:
EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type ⅡR
- Selected test(s) as requested by applicants. For details, refer to attached page(s).

Pronounce

The results shown in this report refer only to sample(s) tested unless otherwise stated.
All the items are performed in the standard conditions, except the noted cases.
Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.

Signed for and on behalf of
CNTAC Testing Service Co.,Ltd.(Foshan)
Approved by

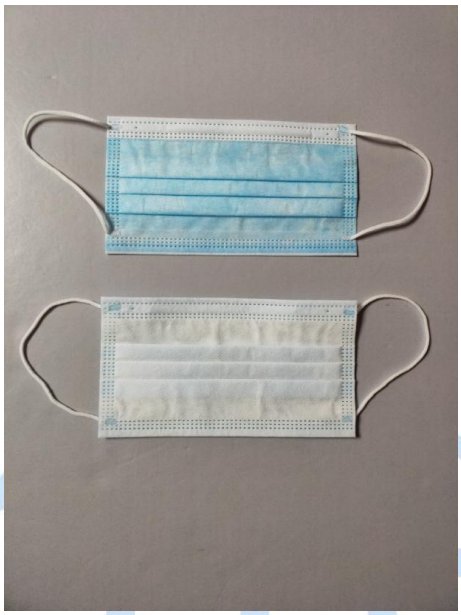
Testing Report	Security website：www.fcl-sz.org.cn Security code：6012363548
Report No：ZFLJ2652456A	Page 2 of 3

--- Test Result ---

	Test Result	Requirements	Judgement
1. Microbial Cleanliness Test *EN 14683:2019+AC:2019 Appendix D*			
Unit: <**CFU/g**>			
sample 1#	5	≤ 30	Pass
sample 2#	5		
sample 3#	6		
sample 4#	6		
sample 5#	4		
Maximum	6		

Testing Report	Security website：www.fcl-sz.org.cn Security code：6012363548
Report No：ZFLJ2652456A	Page 3 of 3

Original Sample



======= End of Report ======

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Life Science Services Laboratory

T:021-61152161, 60645151 F:021-64951517
中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼
7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

Test Report

Date: 26th Mar. 2020

Client name: GUANGDONG TIANHUA NONWOVEN FABRIC INDUSTRIAL CO.,LTD

Client address: BEIYANG,BEIHUAN ROAD,XIASHAN STREET,CHAONAN DISTRICT,SHANTOU CITY

Assignment ID: 14A1906755

Sample No.: 14S19025551-02 v.2

Report on the submitted sample identified by the client as below:

Product Name	NONWOVEN
Quantity Received	1 bag
Sample Receiving Condition	Room temperature
Sample Receiving Date	18th Nov.2019
Testing Period	12th Dec.2019 –13th Dec.2019

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The above sample was submitted and identified by the client. The test was carried out by SGS subcontractor certified ISO17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

Sia Tong

Sia Tong
Life Science Quality Assurance
Authorized Signature

Attachment 1: Test for in vitro cytotoxicity (MTT cytotoxicity test)

SUMMARY

An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article: NONWOVEN, based on the International Organization for Standardization ISO 10993-5:2009: Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity; ISO 10993-12:2012: Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.

Four concentrations (100%, 75%, 50%, and 25%) of the test article extracts, the blank, 100% of the negative control and the positive control were prepared using Minimum Essential Medium (MEM) supplemented with 10% fetal bovine serum. The semi-confluent monolayers of L-929 mouse fibroblast cells were incubated with the test extract, the blank and two controls in a 96-well microplate respectively at 37°C under the condition of 5% CO_2. After 24 h, the MTT colorimetric assay was employed and the plate was read on a microplate reader at 570 and 650nm. Then the viability of cells was calculated.

Under the conditions of this study, the viability of 100% extract of the test article was 81 %. It can be considered that the test article extracts had not a cytotoxic potential.

MATERIALS

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

Test Article:	NONWOVEN
Sterilization Status:	Non-sterile
Storage Conditions:	Room temperature
Extract Vehicle:	GIBCO's Minimum Essential Medium supplemented with L-glutamine and 10% fetal bovine serum.
Test Extract Preparation:	According the requirement of the sponsor, the test articles were sterilized by ethylene oxide two weeks before the treatment. Based on the ISO 10993-12:2012, the ratio of 6 cm^2:1 ml (Surface area of the test sample to volume of extraction vehicle), 126 cm^2 of the test articles were covered with 21 ml extraction vehicle under aseptic

conditions for preparing the test extract at 37 ℃ for 24 hours. The extract was used immediately after extraction.

Blank Preparation: The extraction vehicle not containing the test sample, retained in a vessel identical to that which holds the test article and subjected to conditions identical to those to which the test sample is subjected during its extraction.

Negative Control Preparation: Current SBRTC negative control, the ratio of 3 cm^2 high-density polyethylene: 1 ml (surface area of the test article to volume of extraction vehicle) was used and extracted at 37°C for 24 hours.

Positive Control Preparation: Current SBRTC positive control, the ratio of 6 cm^2 Polyurethane film containing 0.1% zinc diethyldithiocarbamate (ZDEC): 1 ml (surface area of the test article to volume of extraction vehicle) was used and extracted at 37 ℃ for 24 hours.

Condition of Extracts: All the extracts of the test and controls were clear and without any special treatments.

METHODS

Test System Management:

Mouse fibroblast cells (L-929, from the cell bank of Shanghai Institutes for Biological Sciences), were cultured in MEM with L-glutamine supplemented with 10% fetal bovine serum at 37 ℃ in a gaseous environment of 5% carbon dioxide (CO_2). A 96-well microplate method was employed for the MTT colorimetric assay. Each well was seeded 100 μL suspension of 1×10^4 cells, and incubated at 37 ℃ in 5% CO_2 atmosphere for 24 hours prior to use.

Experimental Procedure:

After incubation, the growth medium was replaced with 100 μL four concentrations (100%, 75%, 50%, and 25%) of the test extract, 100% of the negative control and the positive control, the blank (row 2 and 11) respectively. Six replicates were prepared for each group. The 96-well plate was incubated at 37 ℃ in 5% CO_2 for 24h.

After 24 h treatment, the culture medium was removed carefully from the plates. 50μL of the MTT (Sigma, 1mg/mL) solution was then added to each test well and the plates were further incubated for 2 h at 37 ℃ in a 5% CO_2 atmosphere. Then the MTT solution was removed and 100μL isopropanol per well was added and shake for 10 min gently. The plate was read on a microplate reader at 570nm (reference wavelength 650nm). The viability of the cells was calculated according to the formula below:

Viab.%= $100 \times OD_{570e}/OD_{570b}$

Where

OD_{570e} is the mean value of the measured optical density of the extracts of the test sample;

OD_{570b} is the mean value of the measured optical density of the blanks.

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks. If the viability of the test sample was reduced to <70% of the blank, it had a cytotoxic potential. The 50% extract of the test sample should have at least the same or a higher viability than the 100% extract; otherwise the test should be repeated.

RESULTS

Group	The optical density (570nm-650nm)	Viab.%
100% of the negative control	0.772±0.020	100
100% of the test extract	0.626±0.015	81
75% of the test extract	0.662±0.017	86
50% of the test extract	0.687±0.021	89
25% of the test extract	0.718±0.019	93
100% of the positive control	0.034±0.004	4
The blank (row 2)	0.776±0.014	/
The blank (row 11)	0.772±0.019	/

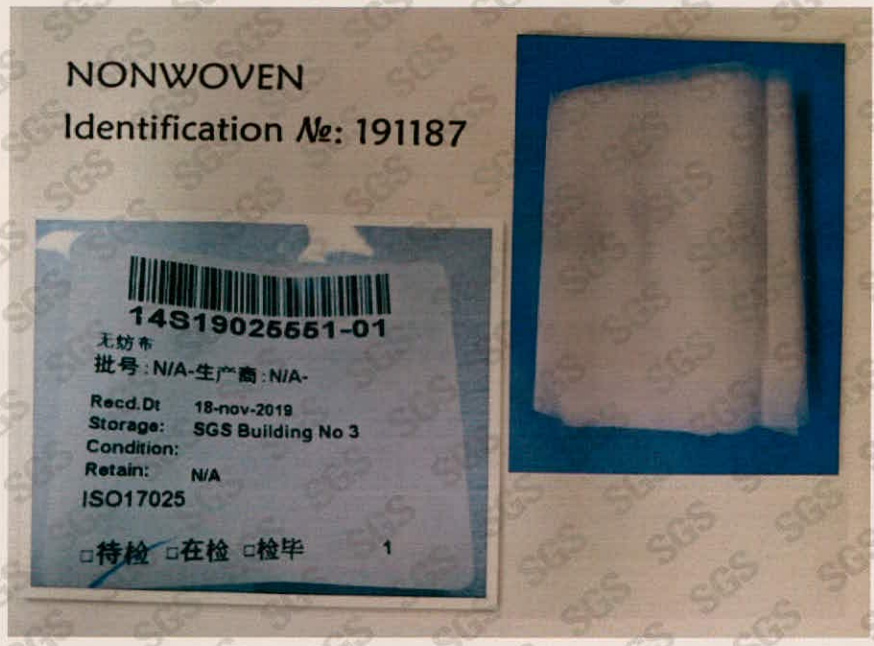
Note: n=6

The mean value of optical density of the blank was 0.774±0.016; both the left (row 2) and the right (row 11) mean of the blanks were less than 15% from the mean of all blanks.

CONCLUSION

Under the conditions of this study, the viability of 100% extract of the test article was 81 %. It can be considered that the test article extracts had not a cytotoxic potential.

PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Life Science Services Laboratory

T:021-61152161, 60645151 F:021-64951517
中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼
7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

Test Report

Date: 26th Mar. 2020

Client name: GUANGDONG TIANHUA NONWOVEN FABRIC INDUSTRIAL CO.,LTD

Client address: BEIYANG,BEIHUAN ROAD,XIASHAN STREET,CHAONAN DISTRICT,SHANTOU CITY

Assignment ID: 14A1906755

Sample No.: 14S19025551-01 v.2

Report on the submitted sample identified by the client as below:

Product Name	NONWOVEN
Quantity Received	1 bag
Sample Receiving Condition	Room temperature
Sample Receiving Date	18th Nov.2019
Testing Period	06th Dec.2019 –13th Dec.2019

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The test was carried out by SGS subcontractor certified ISO17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

Sia Tong

Sia Tong
Life Science Quality Assurance
Authorized Signature

Attachment 1: Test for irritation (Animal skin irritation test)

SUMMARY

The animal skin irritation test of the test article, NONWOVEN, was conducted to assess the potential of the material to produce irritation. This study was conducted based on the requirements of the International Organization for Standardization 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.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract and corresponding reagent control was contacted on animal skin directly. Observations for erythema and edema were conducted at 24, 48 and 72 hours after contact.

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.

MATERIALS

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

Test Article:	NONWOVEN
Sterilization Status:	Non-sterile
Storage Conditions:	Room temperature
Extraction Vehicle:	0.9% sodium chloride injection (SC) Cotton seed oil (CSO)
Test Article Preparation:	According the requirement of the sponsor, the test articles were sterilized by ethylene oxide two weeks before the treatment. Based on the ISO 10993-12:2012, the ratio of 6 cm^2:1 ml (Surface area of the test sample to volume of extraction vehicle), 90 cm^2 of the test articles were covered with 15 ml of extraction vehicle under aseptic conditions for preparing

the SC and CSO test extract at 37℃ for 72h respectively. The extracts were used after extraction.

Reagent Control: The extraction vehicles (without test article) were similarly prepared to serve as the reagent control.

Condition of extracts: All the extract of the test and controls were clear and without any special treatments.

In addition, according ISO 10993-10 requirement, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study (2019.09.23~2019.09.27). Complete data is traceable in laboratory records.

METHODS

Test System:

Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Half males and half females
Body weight range:	2.3 kg ~ 2.6 kg
Age:	Young adult
Number of animals:	Six

Animal Management:

Husbandry: Conditions conformed to “Laboratory animal-Requirements of environment and housing facilities”.

Food: Diet was provided from Shanghai Pu Lu Teng Biological Technology Co., Ltd.

Housing: Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment，and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No of the test article and first treatment date.

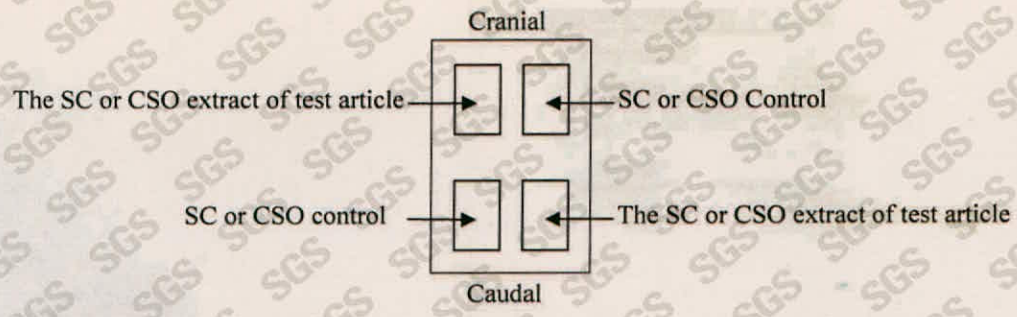
Environmental: The room temperature and humidity was monitored daily.

The room temperature range was from 20℃ to 26℃. The room humidity range was from 50% to 70%.

Personnel Selection: Associates involved were appropriately qualified and trained. Only healthy, previously unused rabbits were selected.

Experimental Procedure:

On the day before the test, the rabbits were closely clipped the fur on the backs of the animals, and both sides of the spinal for application and observation of all test sites, approximately 10 cm x15 cm. A 25 mm ×25 mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to the test sites. The extract of test article and the reagent control were directly applied to the region as illustrated below:



The application sites were covered with a gauze patch and then the application sites were wrapped with a semi-occlusive bandage for 24 h. At the end of the contact time, the dressings were removed. A natural lighting was used to visualize the skin reactions. The skin reactions for erythema and oedema were described and scored at 1, 24, 48 and 72 hours.

The tissue reaction for erythema and oedema were graded according to the classification system given below for each site and at each time observed, and the results were recorded.

Reaction	Primary Irritation Score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-define by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4

Only the 24, 48 and 72hours observations were used for calculation. For each animal, the score both erythema and oedema at each time point were added together separately for each test article and the negative control. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (2 test sites x 3 time points). All the primary irritation scores of individual animals were added and divided by the number of animals, and then the primary irritation scores for each test article were obtained. A similar calculation was made with the negative control. The primary irritation index was obtained by subtracting the score of the negative control from the test article score and the response categories were given as below:

Mean score	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

RESULTS

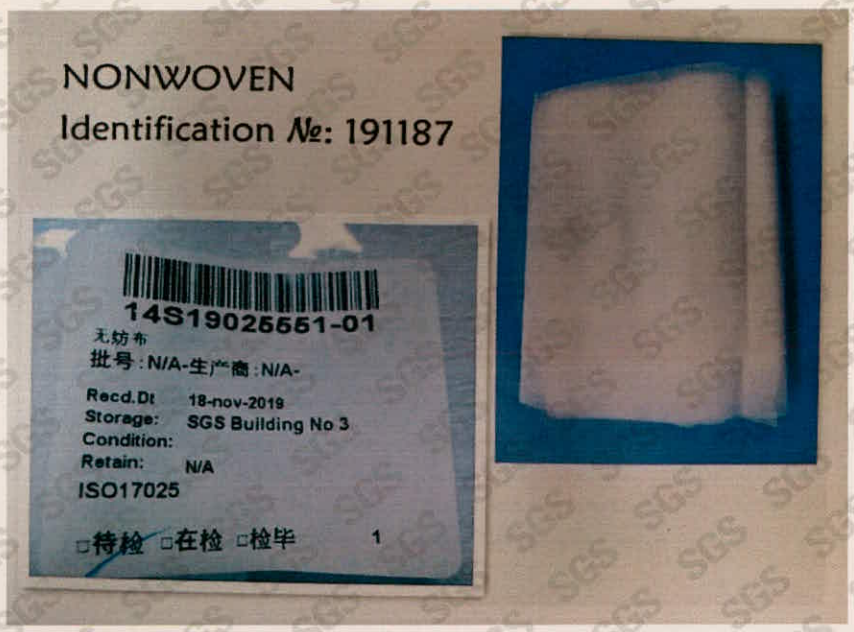
All animals appeared clinically normal throughout the study. All sites of the test extract and the reagent control appeared normal following removal the patches; the score of the test extract and the reagent control all were 0.

The Primary Irritation Index (PII) of the test article was all 0.0.

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.

PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Life Science Services Laboratory

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中国.上海.徐汇区宜山路 889 号 3 号楼 7 楼
7/F, the 3rd Building, Yishan Road , Xuhui District, Shanghai, China 200233

Test Report

Date: 08th Apr. 2020

Client name: GUANGDONG TIANHUA NONWOVEN FABRIC INDUSTRIAL CO.,LTD

Client address: BEIYANG,BEIHUAN ROAD,XIASHAN STREET,CHAONAN DISTRICT,SHANTOU CITY

Assignment ID: 14A1906755

Sample No.: 14S19025551

Report on the submitted sample identified by the client as below:

Product Name	NONWOVEN
Quantity Received	1 bag
Sample Receiving Condition	Room temperature
Sample Receiving Date	18th Nov.2019
Testing Period	11th Jan.2020 –08th Feb.2020

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The test was carried out by SGS subcontractor certified ISO 17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

Racy Li

Racy Li
Life Science Quality Assurance
Authorized Signature

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中国上海徐汇区宜山路889号3号楼 邮编：200233 t(86-21)61152197 f(86-21)64951517 e sgs.china@sgs.com

Attachment 1: Test for skin sensitization (Maximization test)

SUMMARY

A guinea pig maximization test of the test article, NONWOVEN, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices part 10: Tests for irritation and skin sensitization; ISO10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five reagent control guinea pigs (per vehicle). Following a recovery period, the test and reagent control animals were received a challenge patch of the appropriated test article extract and the reagent control. All sites were scored at 24 h and 48 h after patch removal.

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

MATERIALS

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

Test Article:	NONWOVEN
Sterilization Status:	Non-sterile
Storage Conditions:	Room temperature
Extraction Vehicle:	0.9% sodium chloride injection (SC) Cotton seed oil (CSO)
Test Article Preparation:	According the requirement of the sponsor, the test articles were sterilized by ethylene oxide two weeks before the treatment. Based on the ISO 10993-12:2012, the ratio of 6 cm^2:1 ml (Surface area of the test sample to volume of extraction vehicle), 90 cm^2 of the test articles were covered with 15 ml of extraction vehicle under aseptic

conditions for preparing the SC and CSO test extract at 37 ℃ for 72 h respectively for each phase. The extracts were used after extraction.

Reagent Control: The vehicles (without test article) were similarly prepared to serve as the reagent control.

Condition of extracts: All the extract of the test and controls were clear and without any special treatments.

Additional materials: Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the vehicle.

A 10% (w/w) sodium dodecyl sulphate suspension in paraffin.

In addition, according ISO10993-10 requirement, 5% mercaptobenzothiazole (dissolved in DMSO) as a positive control was used previously for another study. Complete data is traceable in laboratory records.

METHODS

Test System

Species:	Albino guinea pig
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FEILD
Sex:	Half melas and half females
Body Weight Range:	307.8 g to 345.3 g
Age:	Young adult
Number of animals:	Thirty

Animal Management:

Husbandry: Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".

Food: Diet was provided from Shanghai Pu Lu Teng Biological Technology Co., Ltd.

Housing: Healthy animals were acclimatized to the laboratory conditions for 5 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No. of the test article and first treatment date.

Environmental: The room temperature and humidity were monitored daily. The temperature range for the room was from 20 ℃ to 26 ℃. The room humidity range was from 50 % to 70 %.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, unused animals were selected.

Experimental Procedure:

1. Intradermal induction phase (induction I):

The day prior to treatment, the fur was clipped on all treatment sites with an electric clipper. The 1st day, the test animals were injected with the fresh extracts of test article and the control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2 cm x 4 cm boundary of the fur clipped area as illustrated below:

Test Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
b) 0.1ml of test extract
c) 0.1ml of 50:50(v/v) mixture of a and b

Control Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the vehicle
b) 0.1ml of vehicle
c) 0.1ml of 50:50(v/v) mixture of a and b

2. Topical induction phase (Induction II):

At 7th day after completion of the intradermal induction phase, the same area was clipped free of fur and treated with 10% sodium dodecyl sulphate suspension in paraffin. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered.

At 8th day, a 20mm×40mm section of absorbent gauze patch, saturated with freshly prepared the extract of the test article, and then was topically applied to the previously injected sites of the test

animals. The control animals were similarly patched with the appropriate reagent control. Each patch was secured with an occlusive dressing. The dressings and patches were removed after 48h.

3. Challenge phase

At 22nd days, the fur was clipped and shaved from the left flank areas. At 23rd day, absorbent gauze patches were soaked with the corresponding solution at the concentration of site C, and patched on the left upper flank of each animal in test and reagent control group. Then the animals were secured with an occlusive dressing. The dressings and patches were removed after 24 h.

4. Observation of animals

The appearance of the challenge skin sites of the test and control animals was observed respectively at 24 h and 48 h after removal of the dressing. The skin reactions for erythema and swelling were described and graded in according with the criteria shown below:

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

If the grades of less than 1 are seen in reagent control animals, grades of 1 or greater in the test group were generally indicated sensitization.

RESULTS

Clinical Observation:

All animals appeared clinically normal throughout the study.

Dermal Observations:

No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase shown below:

Client name: GUANGDONG TIANHUA NONWOVEN FABRIC INDUSTRIAL CO.,LTD
Client address: BEIYANG,BEIHUAN ROAD,XIASHAN STREET,CHAONAN DISTRICT,SHANTOU CITY

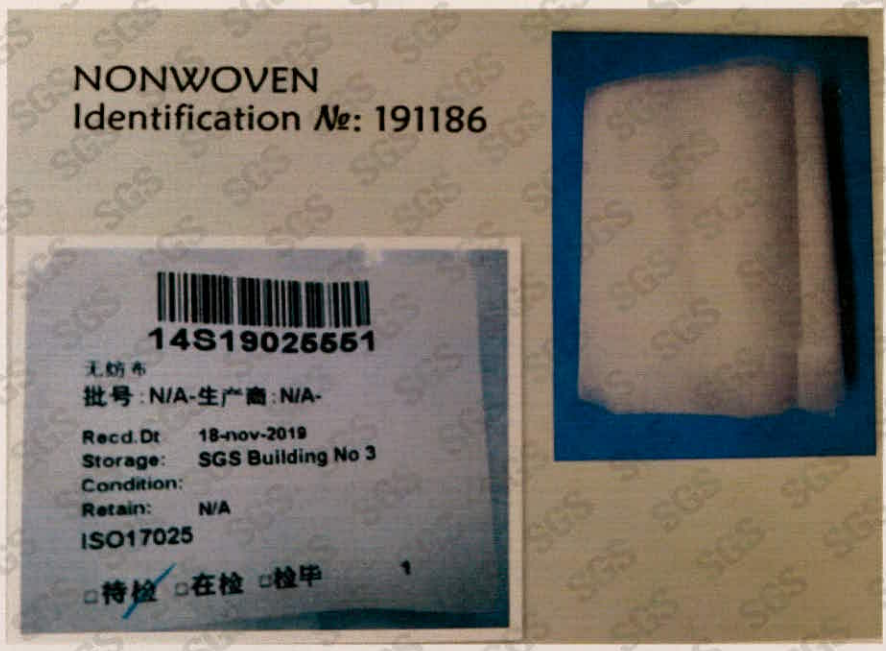
Assignment ID: 14A1906755
Sample No.: 14S19025551

	Hours following patch removal			
Time	24 h		48 h	
Vehicle	SC	CSO	SC	CSO
Test article	0	0	0	0
Reagent Control	0	0	0	0

CONCLUSION

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

PHOTOGRAPH OF THE TEST ARTICL



Remark: Results and conclusions apply only to the test article sample tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***

EC DECLARATION OF CONFORMITY
DECLARACIÓN CE DE CONFORMIDAD

The manufacturer
El fabricante

GUANGDONG YADE INDUSTRY CO. LTD.

**(ZHULIN VILLAGE) ZIYUNGAOXIN DISTRICT,
MEIYUN OFFICE, RONGCHENG, JIEYANG CITY,
GUANGDONG, P.R.C.**

With the next authorized representative
Con el siguiente representante autorizado

SUNGO Europe B.V
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Declares hereby that the following product is in compliance with the **annex VII of European Directive 93/42/EEC** concerning medical devices and European Directive 2007/47/EC, which corrects the previous one, and meets the requirements of the following harmonized standards:

*Declara por la presente que el siguiente producto es conforme con el **anexo VII de la Directiva Europea 93/42/CEE** relativa a los dispositivos médicos así como con la Directiva Europea 2007/47/CE que corrige a la anterior, cumpliendo, además, con los requerimientos de las siguientes normas armonizadas:*

EN ISO 14971:2019	EN ISO10993-5:2009	ISO 10993-1:2018
EN 1041:2008+A1:2013	EN ISO 15223-1:2016	EN ISO 10993-10:2013
EN 14683:2019+AC:2019		

Product trade name / *Nombre comercial del producto*

Disposable Surgical Face Mask TYPE IIR / Mascarilla Quirúrgica No Reutilizable TIPO IIR

Product Model(s) / *Referencia(s) de producto*

KYD06

Class regarding EN 14683:2019 / *Clase con respecto a la EN 14683:2019*

TYPE IIR / TIPO IIR

Class regarding Directive 93/42/EEC / *Clase con respecto a la Directiva 93/42/CEE*

CLASS I / *CLASE I*

Classification done by the **Rule 1 at Annex IX** of European Directive 93/42/EEC.
*Producto clasificado mediante la **Regla 1 del Anexo IX** de la Directiva 93/42/CEE.*

Signed by / *Firmado por:*
Guangdong Yade

Signed by / *Firmado por:*

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Report No.: ZF2003130060

Testing reports

Customer and Sample Information	Entrusted Unit	Puning Kangli Weaving Co., Ltd		
	Address of entrusting unit	First East Side of Liu Sha Dong Liu Dou Po Jin Hang Building, Puning City, Guangdong Province		
	Production units	Puning Kangli Weaving Co., Ltd		
	Address of production unit	First East Side of Liu Sha Dong Liu Dou Po Jin Hang Building, Puning City, Guangdong Province		
	Sample name	Mask ear strap (loose strap)	Client	———————
	Sample size	One pack	Trademarks	KEN TOP of Jinhang
	Specification Type	———————	Color	———————
	Order Number	———————	Paragraph number	———————
	End-use	———————	Composition	———————
	Security technology category	B category	Quality rating	———————
Type of detection		Commissioned testing	Sample status	Compliance with testing requirements
Time to sample		13 March 2020	Time of issue	16 March 2020
Testing basis		GB18401-2010 National Technical Specification for Basic Safety of Textile Products		

Address :4th Floor, North Gate, Zhongfang City Convention and
Tel :0571-82771633 Mailbox:mffzjc@163.c Website:www.mfzts.co

Conclusion	See next page.
Sample	The sample or picture is shown on the last page of this report.
Remarks	———————

Reports issued: 李清政

Special Chapter of Test Report

Address :4th Floor, North Gate, Zhongfang City Convention and
Tel :0571-82771633 Mailbox:mffzjc@163.c Website:www.mfzts.co

Report No.: ZF2003130060

Test data:

Testing projects		Unit	Test requirements	Test results	Single decision	Methodological criteria
Fibre content (DG)		%	/	Nylon 74.4 Spandex 25.6	/	GB/T2910.7-2009FZ/T01057.2-2007FZ/T01057.3-2007 FZ/T01057.4-2007
Water fastness	Discoloration	Level	≥3	4-5	Compliance	GB/T 5713-2013
	Colour		≥3	4-5	Compliance	
Colour fastness to acid perspiration	Discoloration	Level	≥3	4-5	Compliance	GB/T 3922-2013
	Colour		≥3	4-5	Compliance	
Colour fastness to alkaline perspiration	Discoloration	Level	≥3	4-5	Compliance	GB/T 3922-2013
	Colour		≥3	4-5	Compliance	
Colour fastness to rubbing	Ganmo	Level	≥3	4-5	Compliance	GB/T3920-2008

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odour	/	No smell	No smell	Compliance	GB 18401-2010 6.7
Formaldehyde	mg/kg	≤75	(<20)	Compliance	GB/T2912.1-2009
pH	/	4.0-8.5	7.1	Compliance	GB/T 7573-2009
Decomposition of carcinogenic aromatic amine dyes	mg/kg	disable	(<5)	Compliance	GB/T 17592-2011

Address :4th Floor, North Gate, Zhongfang City Convention and
Tel :0571-82771633 Mailbox:mffzjc@163.c Website:www.mfzts.co

Report No.: ZF2003130060

24 decomposable carcinogenic aromatic amine dyes:

Serial number	CAS	Chemical name
1	92-67-1	4- aminobiphenyl 4- aminobiphenyl
2	92-87-5	benzidine benzidine
3	95-69-2	4- chloro-o-toluidine 4- chloromethylamine
4	91-59-8	2- naphthylamine 2- naphthalene amine
5	97-56-3	o-aminoazotoluene o-aminoazobenzene
6	106-47-8	p-chloroaniline chlorphenamine
7	615-05-4	2,4- diaminoanisole 2,4- diphenyl ether
8	101-77-9	4,4'- diaminobiphenymethane 4,4′ - diaminodiphenyltrichloroethane
9	91-94-1	3,3'- dichlorobenzidine 3,3′ - dichlorobenzidine
10	119-90-4	3,3'- dimethoxybenzidine 3,3′ - dimethoxybenzidine
11	119-93-7	3,3'- dimethylbenzidine 3,3′ - dimethyl benzidine
12	838-88-0	3,3'- dimethyl-4,4′ -diaminobiphenylmethane 3,3'-dimethyl-4,4'-diaminodibenzomethane
13	120-71-8	p-cresidine 2- methoxy-5-methylaniline
14	101-14-4	4,4'- methylene-bis-(2-chlorolaniline) 4,4'-methyl-di-(2-chlorophenylamine)
15	101-80-4	4,4'- oxydianiline 4,4′ - diaminodiphenyl ether
16	139-65-1	4,4'- thiodianiline 4,4′ - diaminodisulfide
17	95-53-4	o-toluidine o-toluidine
18	95-80-7	2,4- toluylenediamine 2,4- diphenyl
19	137-17-7	2,4,5- trimethyianiline 2,4,5- trimethylaniline
20	90-04-0	o-anisidine o-aminobenzyl ether
21	95-68-1	2,4- xylidine 2,4- dimethylaniline
22	87-62-7	2,6- xylidine 2,6- dimethylaniline
23	99-55-8	2- amino-4-nitrotoluene 2- amino-4 nitrotoluene
24	60-09-3	4- aminoazobenzene 4- aminoazobenzene

Address :4th Floor, North Gate, Zhongfang City Convention and
Tel :0571-82771633 Mailbox:mffzjc@163.c Website:www.mfzts.co

Report No.: ZF2003130060

Sample for inspection

********** end of ********** report

Address :4th Floor, North Gate, Zhongfang City Convention and
Tel :0571-82771633 Mailbox:mffzjc@163.c Website:www.mfzts.co

Instrucciones de Uso Mascarillas Quirúrgicas Tipo IIR

Nombre del Producto: Mascarilla Quirúrgica IIR.
Referencia del producto: KYD06
Medidas: 17,5cm x 9,5cm.
Composición:

pieza	***material***
Capa Interna	Tela no tejida blanca (partículas plásticas de PP)
Capa Media	Polipropileno (PP)
Capa Externa	Tela no tejida azul (partículas plásticas de PP)
Gomas	2x140d nylon + 210D spandex
Clip Nasal	Poliolefina + varilla de hierro fina

Indicaciones de uso:

1- Lávese las manos con agua y jabón o una solución hidroalcohólica antes de manipular la mascarilla.
2- Ajuste la mascarilla cubriendo la nariz y la boca y ajuste la pinza nasal.
3- Coloque las comas detrás de las orejas, sin cruzarlas, y baje la parte inferior hasta la barbilla.
4- Ajuste la pinza nasal pellizcando con ambas manos y verifique el sellado y ausencia de molestias.
5- Se recomienda no tocar la mascarilla durante su uso. Si fuese imprescindible, lávese las manos con jabón y agua o soluciones hidroalchólicas antes y después de su manipulación.
6- Retírese la mascarilla sin manipular la parte frontal y deséchala tal y como se indica posteriormente.

Desechar la mascarilla (SND/271/2020)

¿Padeces síntomas o eres positivo por COVID?
Introducir la mascarilla en una bolsa y cerrar la misma. Introducir esta bolsa junto a los guantes y mascarilla del cuidador/a en una segunda bolsa y cerrar la misma. Depositar esta segunda bolsa junto al resto de deshechos en el contenedor gris perteneciente a los “Restos”.

¿No padeces síntomas?
Las mascarillas se desecharan de forma habitual depositando las mascarillas en el contenedor gris perteneciente a los “Restos”.

Advertencias y Precauciones

- No utilizar si el embalaje y/o el producto se encuentran deteriorados.
- Por cuestiones de comodidad e higiene, no se recomienda su uso por un tiempo superior a 4 horas.
- En caso de humedad o deterioro en la mascarilla, se recomienda su sustitución.

- No reutilizar el producto.
- El producto se debe almacenar en un lugar seco.

Guandong Yade Industry Co., Ltd.
Zhulin Village, Ziyungaoxin District, Meiyun Office, Rongcheng,
Jieyang City, Guandong, Popular Republic of China

EC REP

SUNGO Europe B.V
Olympisch Stadion 24,
1076DE Amsterdam, Netherlands

ATAL INNOVATIONS,S.L

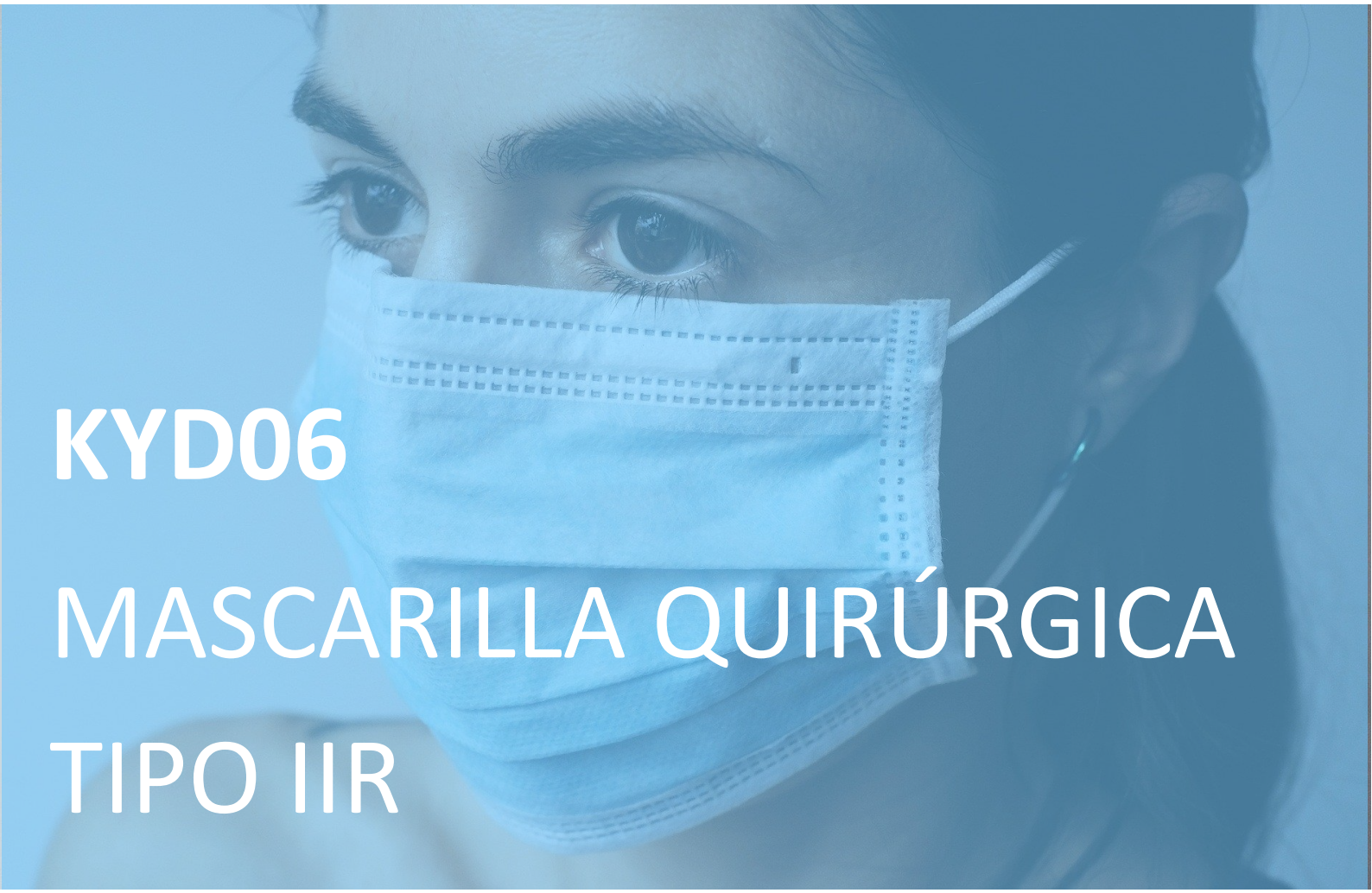
ATAL INNOVATION S.L. (Importador)
C/ Iturriondo Nº18 Nave 11C, 48940 Leioa, Bizkaia

Versión del 30/10/2020

CE

50 uds (5 packs x 10 uds)

ATAL INNOVATIONS,S.L



KYD06

MASCARILLA QUIRÚRGICA TIPO IIR

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CARACTERÍSTICAS

- Mascarilla con 3 capas protectoras con un 99,9% de Filtración Bacteriana (BFE).
- Gomas para un adecuado ajuste y colocación en los pabellones auditivos.
- Ajuste mecánico nasal mediante una pinza moldeable.
- Mascarilla no reutilizable.
- Talla única
- Color Azul
- Referencia del fabricante **KYD06**
- Paquete o blíster con cierre

ESPECIFICACIONES

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Eficacia de Filtración Bacteriana (BFE) %	≥ 95%	≥ 98%	≥ 98%
Respirabilidad – Presión diferencial (Pa/cm^2)	< 40 Pa/cm^2	< 40 Pa/cm^2	< 60 Pa/cm^2
Resistencia a las salpicaduras (kPa)	-	-	≥ 16 kPa
Limpieza Microbiana (ufc/g)	≤30 ufc/g	≤30 ufc/g	≤30 ufc/g

Las mascarillas quirúrgicas **Tipo IIR** están destinadas a limitar la transmisión de agentes del personal a los pacientes durante los procedimientos quirúrgicos. Además, previene la respiración de partículas sólidas y líquidas del aire y frena las salpicaduras de sangre y/o saliva.

La mascarilla **KYD06** ha obtenido los siguientes resultados que la clasifican como Tipo IIR:

- Eficacia de filtración bacteriana(BFE)[1] 99,9%
- Respirabilidad – Presión Diferencial[1] 41,3 Pa/cm^2
- Resistencia a las salpicaduras[1] ≥ 16 kPa en 32 muestras analizadas
- Limpieza microbiana[2] entre 4 y 6 ufc/g

[1] Informe de ensayos nº ZFLJ2650944A realizado en CNTAC Testing Service Co., Ltd. (Foshan).
[2] Informe de ensayos nº ZFLJ2652456A realizado en CNTAC Testing Service Co., Ltd. (Foshan).

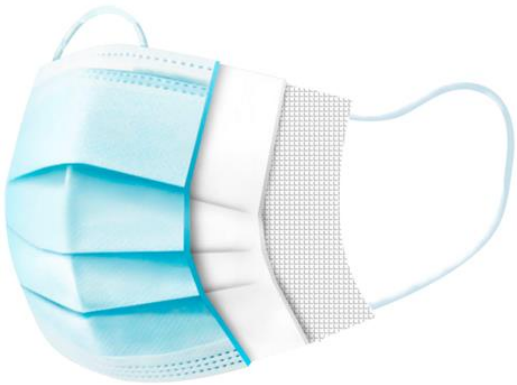
BIOCOMPATIBILIDAD DE MATERIALES

Se han realizado ensayos de biocompatibilidad de las mascarillas quirúrgicas tipo IIR con referencia KYD06. Los ensayos fueron realizados por los laboratorios de SGS-CSTC Standards Technical Services (Shangai). Se realizaron diferentes ensayos en base a la normativa de biocompatibilidad obteniendo los siguientes resultados:

- Los ensayos de Citotoxicidad en base a la norma ISO 10993-5:2009 que se recogen en el informe 14A1906755 ofrecen un resultado positivo mostrando que las mascarillas no tienen potencial citotóxico.
- Los ensayos de sensibilización de la piel en base a la norma ISO 10993-10:2010 se recogen en el informe 14A1906755. Los resultados recogidos muestran que no hay evidencia de sensibilización de la piel causada por el producto.
- Los ensayos de irritación de la piel se realizan en base a la norma ISO 10993-10:2010 y se recogen en el informe 14A1906755, ofreciendo unos resultados favorables al no obtener irritación en la piel causada por el producto.

PRESENTACIÓN Y DATOS TÉCNICOS

La mascarilla se presenta en talla única, válida tanto para el público infantil como para el público adulto.

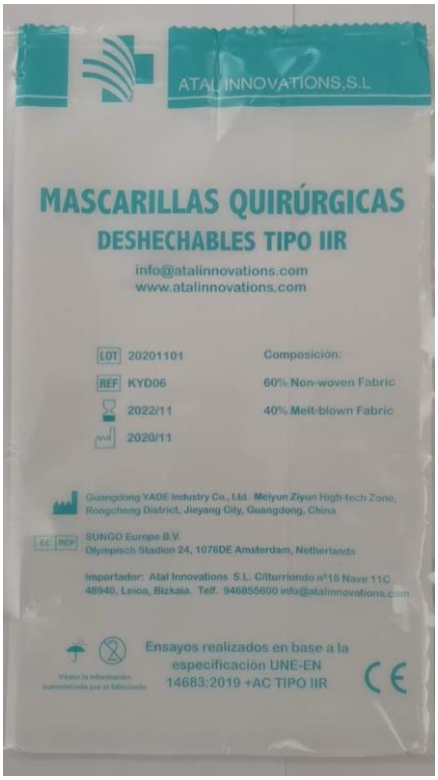


Los materiales de la mascarilla son los siguientes:

- **Capa interna:** Tela no tejida blanca (partículas plásticas de PP)
- **Capa intermedia:** Polipropileno (PP)
- **Capa externa:** Tela no tejida azul (partículas plásticas de PP)
- **Gomas:** 2x140d nylon + 210D spandex
- **Clip nasal:** Poliolefina + varilla de hierro fina

El producto se expone en una caja de 50 unidades dividida en 5 paquetes de 10 unidades por paquete, tal y como se expone a continuación.

Blíster



El paquete o blíster de 10 unidades que se encuentra dentro de la caja, dispone de toda la información que se presenta en la caja, permitiendo así que el usuario disponga de toda la información necesaria sin necesidad de transportar la caja. Estos blíster han sido diseñados de forma que consigan mantener las mascarillas en condiciones óptimas hasta su colocación por el usuario. Para conseguir eso, se ha incluido en el blíster una banda adhesiva de forma que, una vez el usuario coja una mascarilla, pueda volver a cerrar el blíster manteniendo las mascarillas en las mejores condiciones de higiene y preservación, manteniendo los niveles de contaminación de los productos al mínimo en todo momento.

Caja Externa

Estas cajas se encuentran diseñadas de forma que cumplen con la normativa y la regulación vigente en materia de la información que el fabricante aporta al usuario. En la caja externa se encuentra toda la información necesaria para el buen uso de las mascarillas, incluyendo instrucciones de uso y precauciones o advertencias para los usuarios. La información de contacto tanto del fabricante como de su representante autorizado se encuentra disponible en la propia caja externa. Además, la caja incluye la información de trazabilidad del producto necesaria como lote, referencia, fecha de fabricación y fecha de expiración, disponiendo de un código de barras generado en base al estándar GS1-128.

APLICACIONES

Las mascarillas quirúrgicas están destinadas a limitar la transmisión de agentes del personal a los pacientes durante los procedimientos quirúrgicos. Además, previene la respiración de partículas sólidas y líquidas del aire y frena las salpicaduras de sangre y/o saliva.

INDICACIONES DE USO

1. Lávese las manos con agua y jabón o una solución hidroalcohólica antes de manipular las mascarillas.
2. Ajuste la mascarilla en la cara cubriendo la nariz y la boca y ajuste la pinza nasal.
3. Coloque las gomas detrás de las orejas, sin cruzarlas, y baje la parte inferior hasta la barbilla.
4. Ajuste la pinza nasal pellizcando con ambas manos y verifique el sellado y ausencia de molestias.
5. Se recomienda no tocar la mascarilla durante su uso. En caso de ser imprescindible, lávese las manos con jabón y agua o una solución hidroalcohólica antes y después de la manipulación de la mascarilla.
6. Retírese la mascarilla sin manipular la parte frontal y deséchela tal y como se indica en los paquetes unitarios.

ADVERTENCIAS Y PRECAUCIONES

- No utilizar si el embalaje y/o el producto se encuentran deteriorados.
- Por cuestiones de comodidad e higiene, no se recomienda su uso por un tiempo superior a 4 horas.
- En caso de humedad o deterioro en la mascarilla, se recomienda su sustitución.
- No reutilizar el producto.
- El producto se debe almacenar en un lugar seco.

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DATOS DE CONTACTO

	Guandong Yade Industry Co., Ltd. Zhulin Village, Ziyungaoxin District, Meiyun Office, Rongcheng, Jieyang City, Guandong, Popular Republic of China
EC REP	**SUNGO Europe B.V** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
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NORMAS DE APLICACIÓN

- **Directiva 93/42/CEE:** Directiva del Consejo Europeo relativa a los productos sanitarios.
- **RD 1591/2009:** Real Decreto por el que se regulan los productos sanitarios.
- **EN-ISO 14971:2019:** Dispositivos médicos/productos sanitarios (MD). Aplicación de la gestión de riesgos a los MD.
- **EN 1041:2008+A1:2013:** Información proporcionada por el fabricante de productos sanitarios.
- **EN 14683:2019+AC:** Mascarillas quirúrgicas. Requisitos y métodos de ensayo.
- **EN ISO 10993-5:2009:** Evaluación biológica de productos sanitarios. Parte 5: Ensayos de citotoxicidad in vitro.
- **EN ISO 15223-1:2016:** Productos sanitarios. Símbolos a utilizar en las etiquetas, el etiquetado y la información a suministrar. Parte 1: Requisitos generales.
- **ISO 10993-1:2018:** Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
- **EN ISO 10993-10:2013:** Evaluación biológica de productos sanitarios. Parte 10: Ensayos de irritación y sensibilización cutánea.
- **ISO 22609:2004:** Clothing for protection against infectious agents -- Medical face masks -- Test method for rsistance against penetration by synthetic blood.