

CE Technical Documentation Review Report

Applicant: **Jiangxi AICARE Medical Technology Co., Ltd.**
South Side of South Ring Road, Le'an County, Fuzhou
City 344300, Jiangxi Province, China (Building No.1,
New Era Home Group, Le'an County)

Report Number: 60362246-001

Examination intent: Examination the completeness of the Technical
Documentation according to the requirements of
REGULATION (EU) 2017/745, Annex II

Product(s): Disposable Medical Face Mask

Type(s)/Model(s): A6001, B6006

Classification: Class I
(according to manufacturer's declaration)

Examination period: Apr.30.2020

Date of expiry: Apr.29.2025

Review result: During the examination of the provided Technical
Documentation (No.: JXZH/YF-01, Version A/0,
Dated 04.29.2020), no Non-compliance according to
the requirements of REGULATION (EU) 2017/745,
Annex II was detected.



Yuhong CHEN
Vice General Manager | Medical Greater China
TÜV Rheinland (China) Ltd.

We hereby declare that in accordance with the contents of CE Technical Documentation Review Report, the assessments carried out are the voluntary nature based on applicant request and are not equivalent to the mandatory conformity assessment procedures carried out by TÜV Rheinland LGA Products GmbH, Notified Body 0197 to the aforementioned Regulation.

To verify the report validity, please send email to: service-gc@tuv.com



Inspection Report (PSI)

R -20200610-1

PRODUCT DESCRIPTION

**Client Name: HUIDA****Product Name:**

Disposable Face Mask

Inspection location: JIANGXI FUZHOU**Inspection date:** 10 / June /2020**Expected shipment date:** 11 / June /2020**Your internal reference number:**

Disposable Face Mask

Reference # / SKU #

A6001

P/O number:**Supplier:**

Jiangxi AICARE Medical Technology Co., LTD

Order quantity: 50,00000 Pcs**Pcs ready for inspection:** 50,00000 pcs,100%**Reference sample available:**

N/A

Factory cooperation	Factory organization	Inspector's opinion on the factory
Average	Average	Average

OVERALL INSPECTION RESULT:**Passed****(Client has the final decision to Reject or Approve)**



INSPECTION RESULT SUMMARY					
	Result	Findings/Remarks			
WORKMANSHIP (defectives list)	Within AQL		CRITICAL	MAJOR	MINOR
		Found	0	6	8
		Max	0	21	21
		Checked	2000	2000	2000
		<u>Most serious defects found:</u> Loosened article due to Poor connection 1 piece Askew assembly of article 5 Wrinkle 8 pieces			
TESTS	Passed				
QUANTITY	OK				
PRODUCT COLOR	OK				
STYLE / CONSTRUCTION	OK				
PRODUCT DIMENSIONS & WEIGHT	OK				
ARTWORKS / LABELS	OK				
PACKING & PACKAGING	OK				
SHIPPING MARKS	OK				
OTHER REMARKS					
1, All product finished and packed for inspection					
2, No approval sample available for inspection on site.					



INSPECTION STANDARDS	
Inspection type	Pre-Shipment Inspection
Sampling standard	ISO 2859-1 (Mil Std 105E)
Sampling level	II
AQL for Critical defective	Not Allowed
AQL for Major defective	2.5
AQL for Minor defective	4.0
Sampling size for Cri/Maj/Min	2000 / 2000 / 2000 Pcs
Nb of inspected pieces	2000 Pcs
Total quantity of cartons in your shipment	2000 Cartons
Quantity of cartons available for inspection	2000 Cartons
Nb of cartons inspected	45 Cartons
Nb on the inspected cartons	N/A

Nb of Mandays spent: 3	
	
Inspector by : .Asiaseainspection	Report Approver: Frank Yuan

深圳市亚海产品质量检验有限公司(盖章)	报告发行人: 袁新灵

QUALITY CRITERIA
1. Quantity



Expected Result	Result	Actual Picture / Comments
80%of the total order quantity must be finished and packed-order qty: 5000000 Pcs	OK	All products finished and packed for inspection

Lanyard without vinyl pouch

Item	Ordered		Ready		Inspected		Pcs/ inbox	Pcs/ Ctn
	Qty	Ctn	Qty	Ctn	Qty	Ctn		
Disposable Face Mask	5000000	2000	5000000	141	2000	2000	50	2500
TOTAL	5000000	2000	5000000	141	2000	2000	50	2500

Quantity of packed products:	5000000 pieces
Quantity of finished & unpacked products:	0 pc
Quantity of semi-finished products:	0 pc

Additional Pictures:

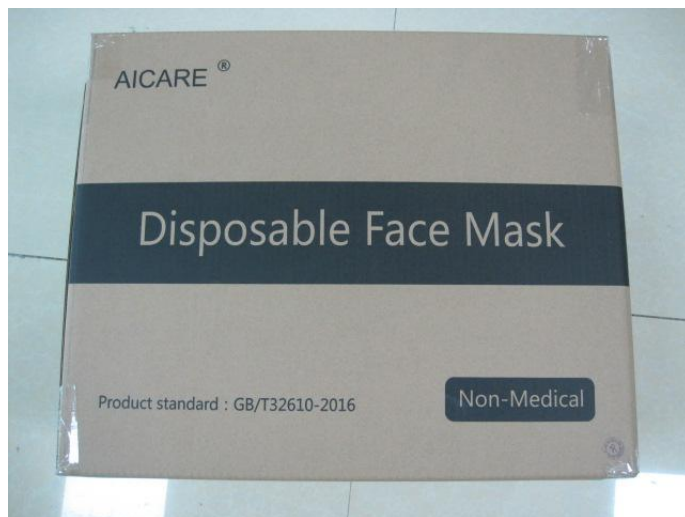


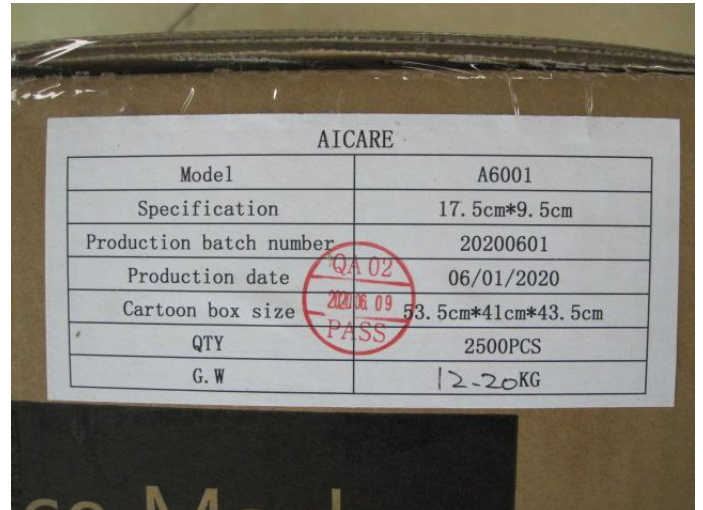
2. Colours

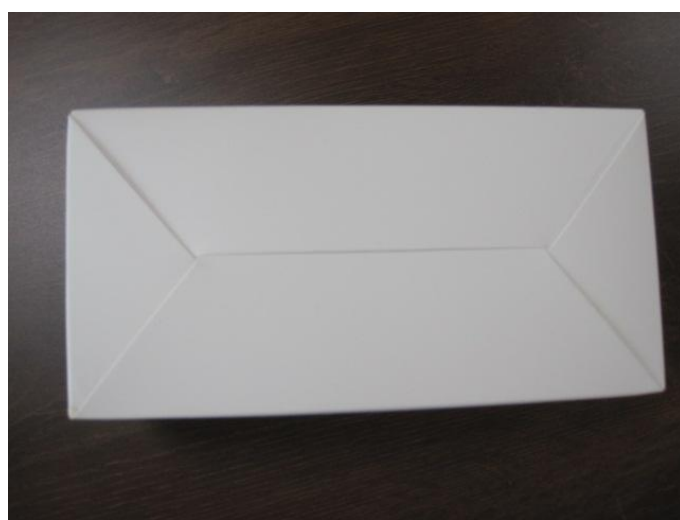
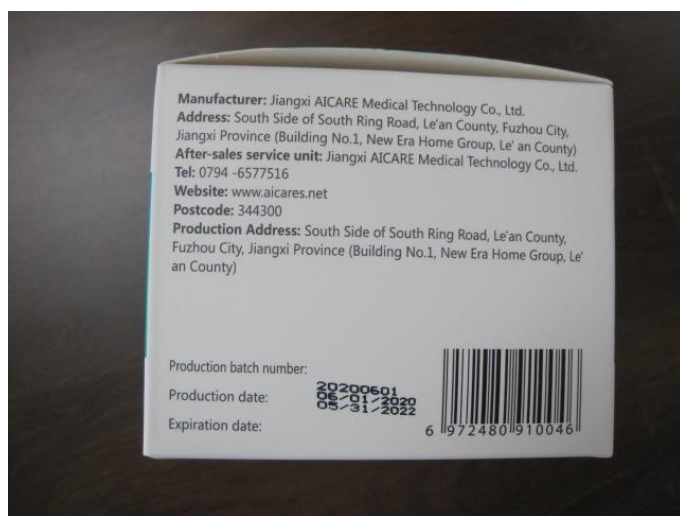
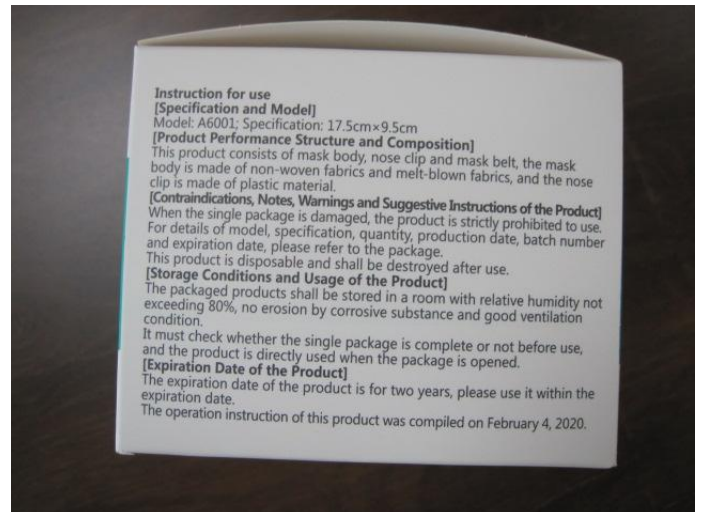


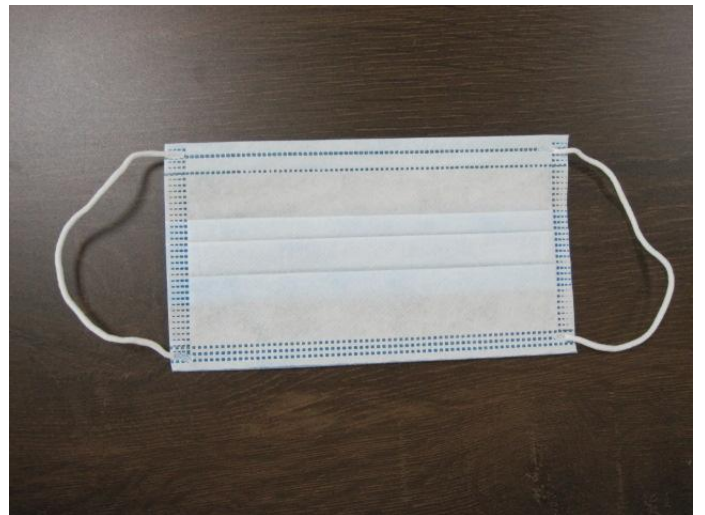
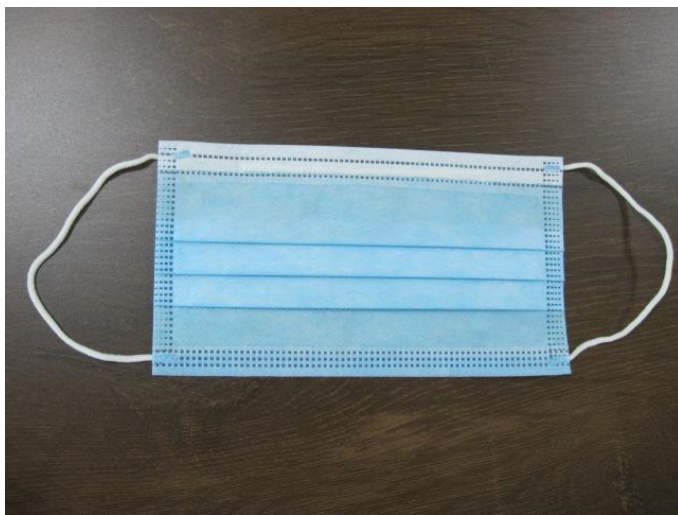
Expected Result	Result	Pantone code	Comments
	N/A		See below sheet and pictures
Client's comments:			

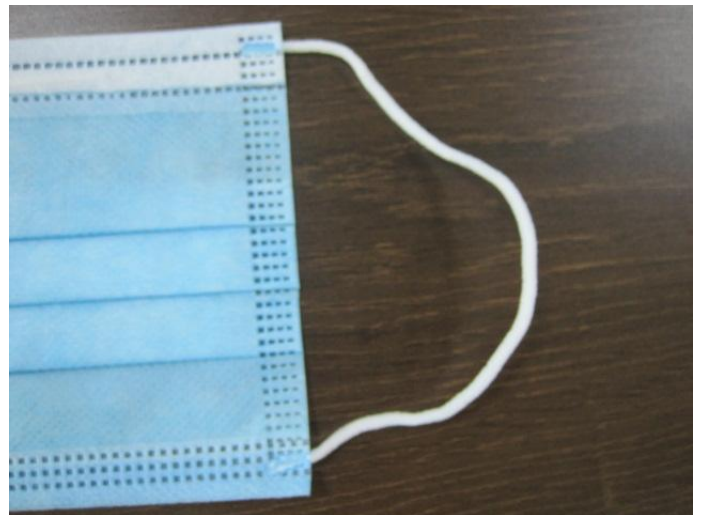
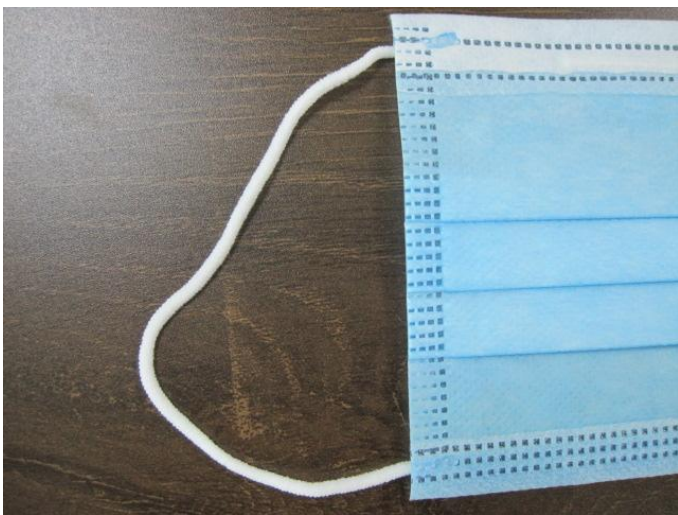
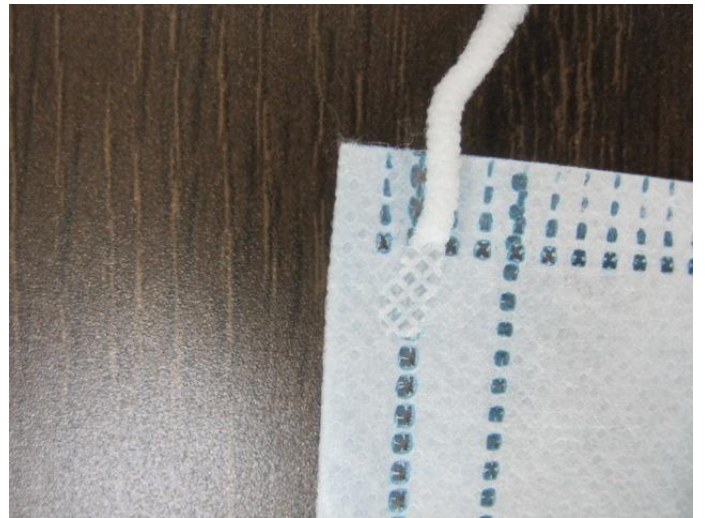
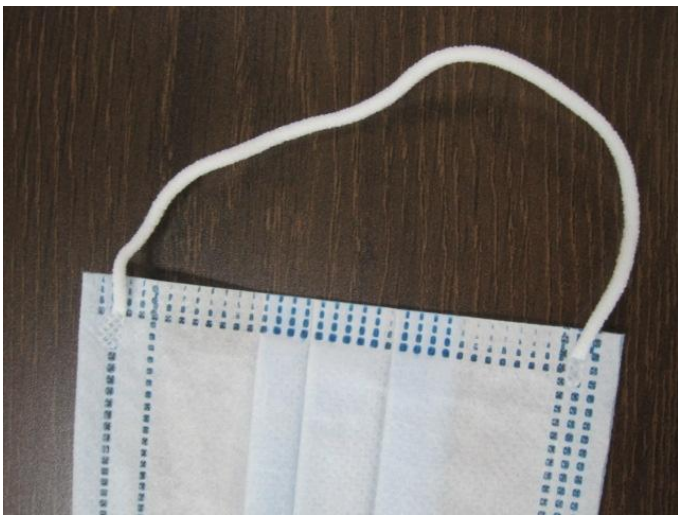
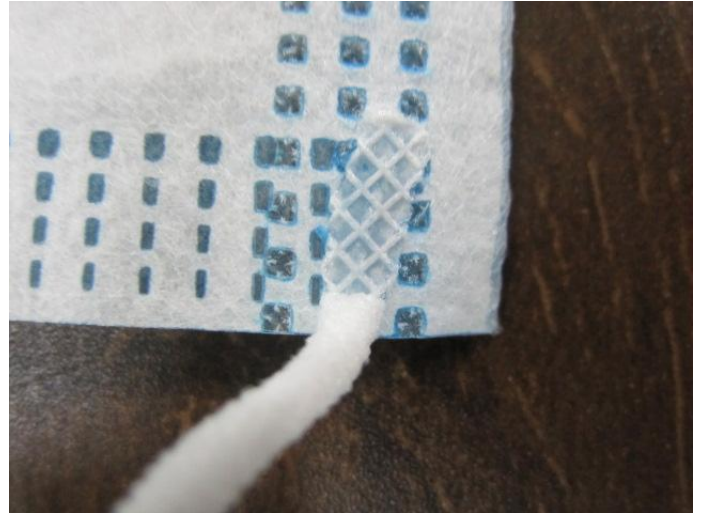
Additional Pictures:

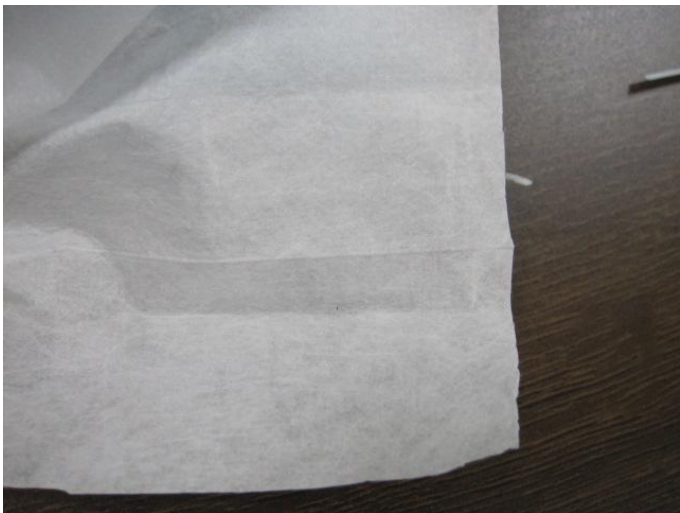


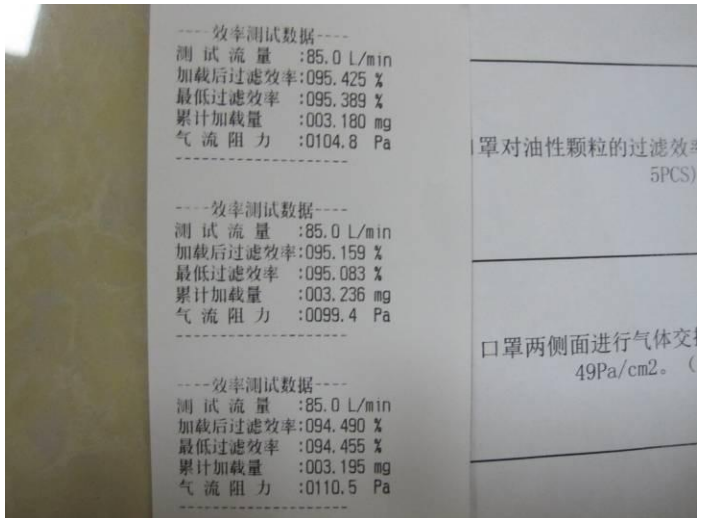
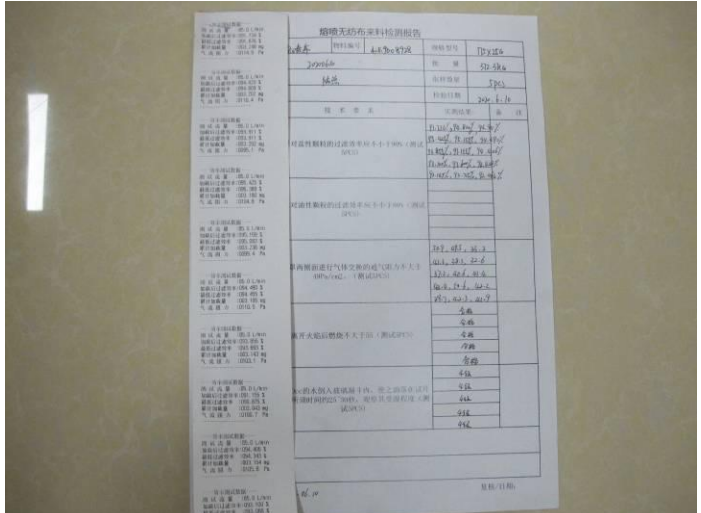
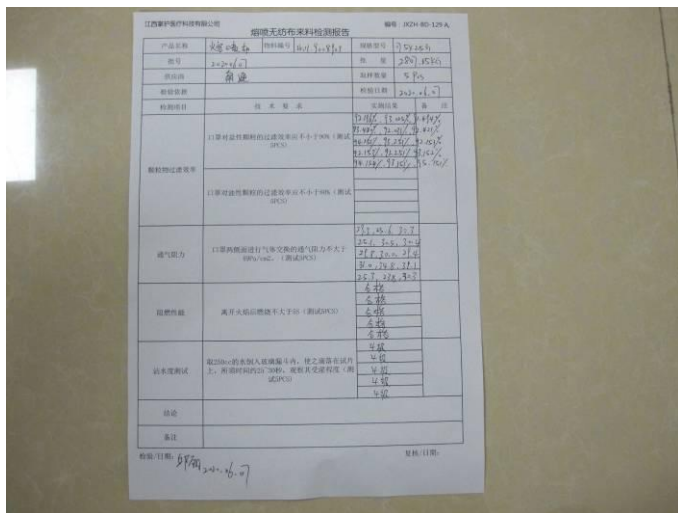
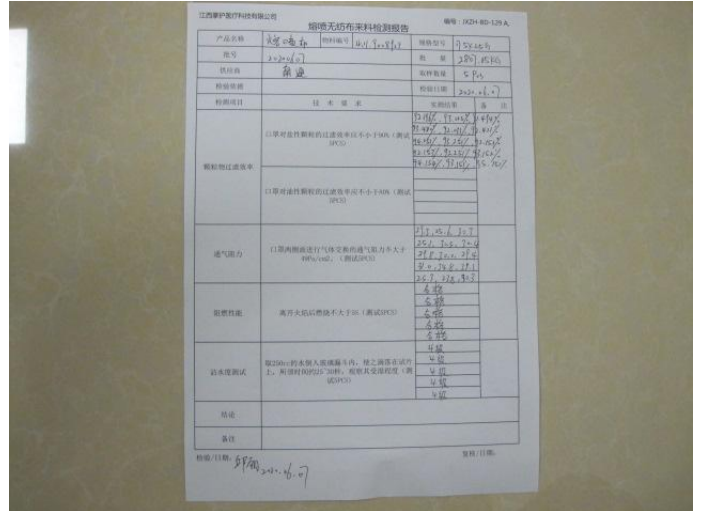


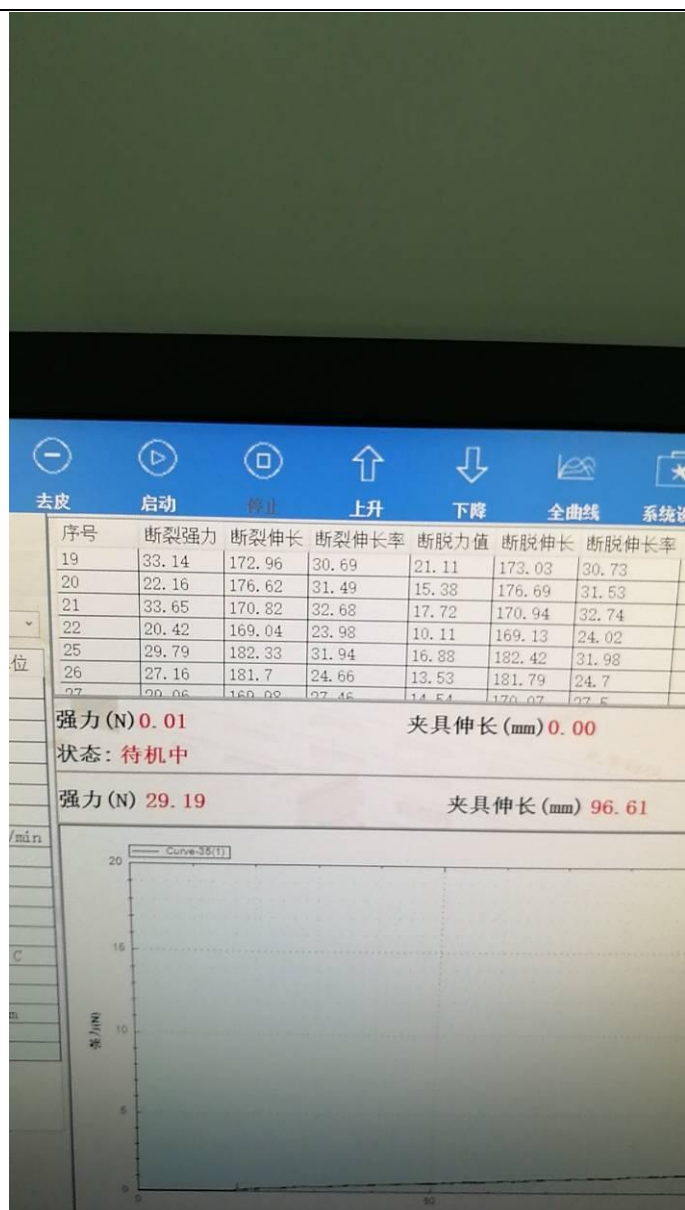
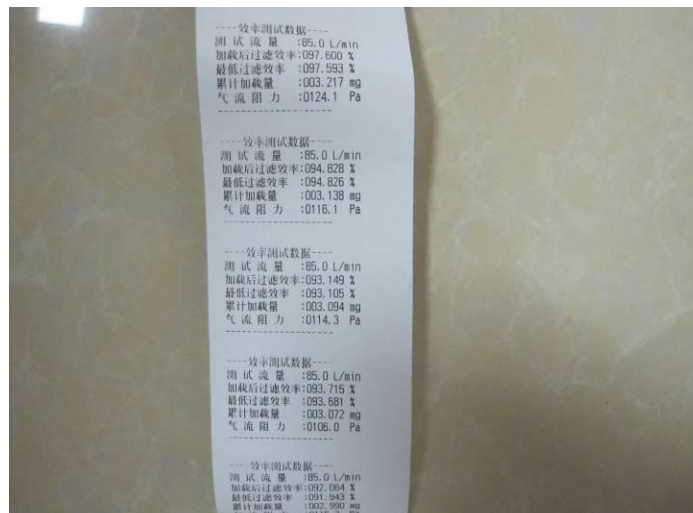
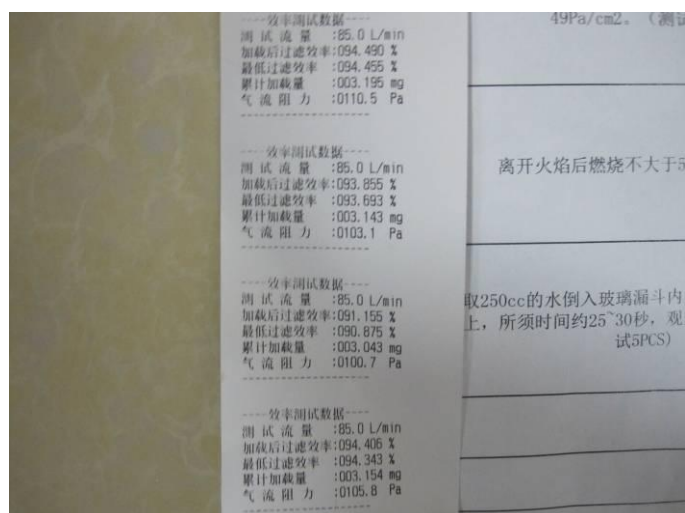












3. Style / Construction

Expected Result	Result	Actual Picture / Comments
	OK	See above sheet and pictures



4. Product dimensions

a. Dimensions

Expected Result	Result	Actual Picture / Comments
	OK	See below sheet and pictures

b. Weight

Expected Result	Result	Actual Picture / Comments
	OK	See below sheet and pictures

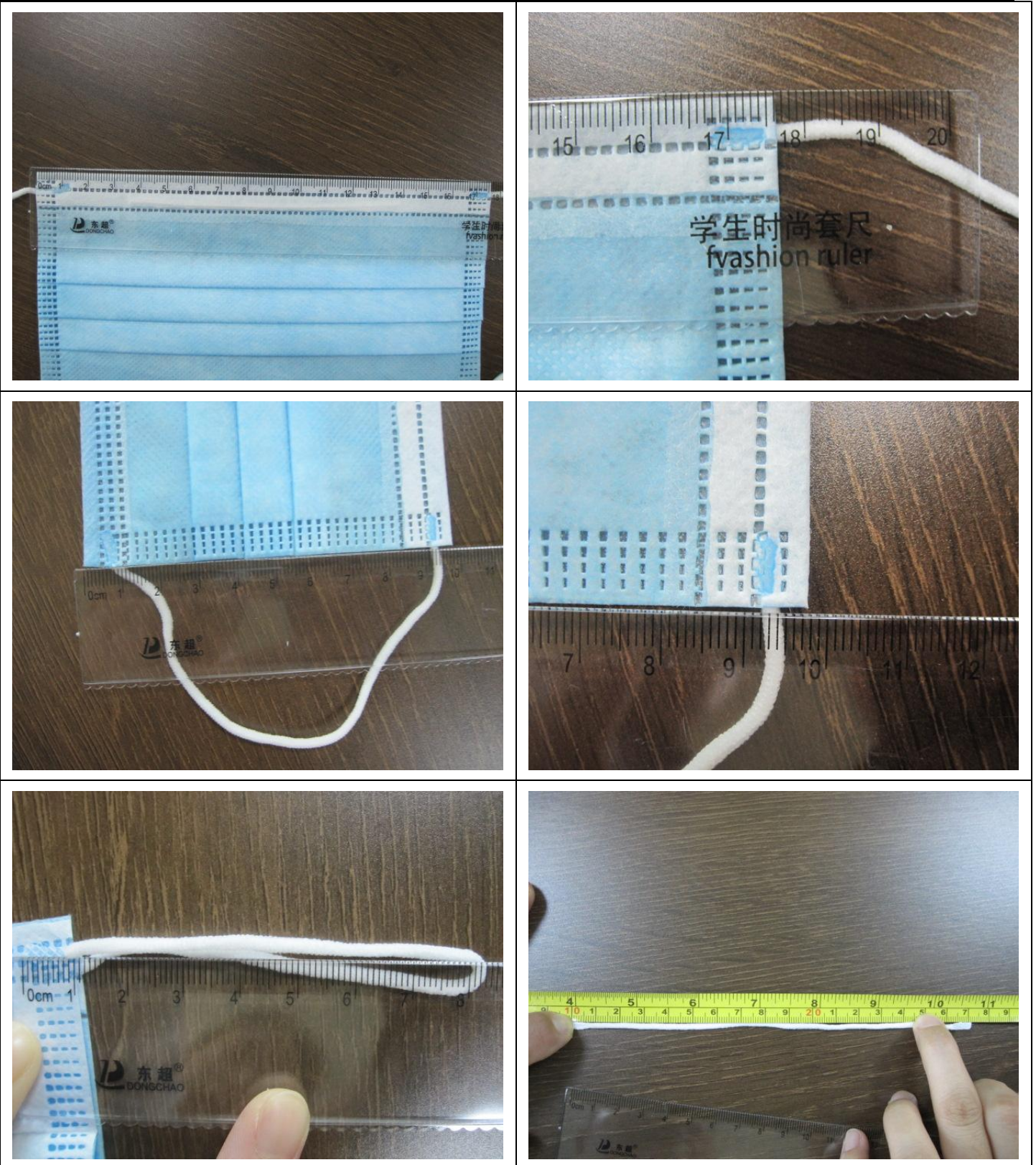
Client's comments:

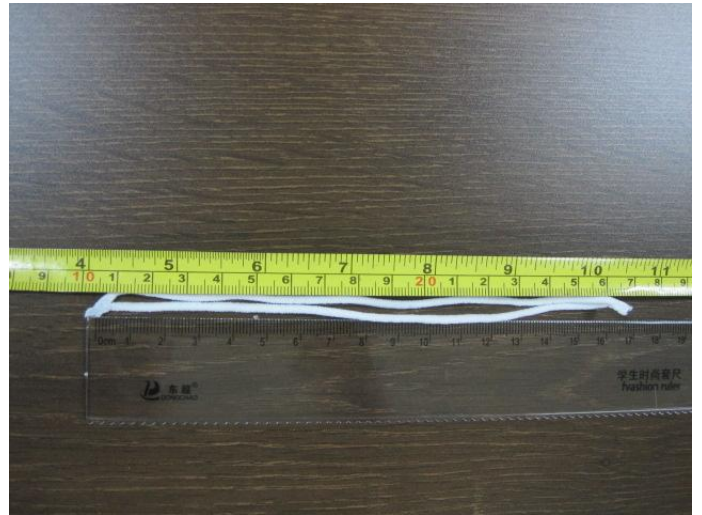
MEASUREMENT TABLE - Actual Finding

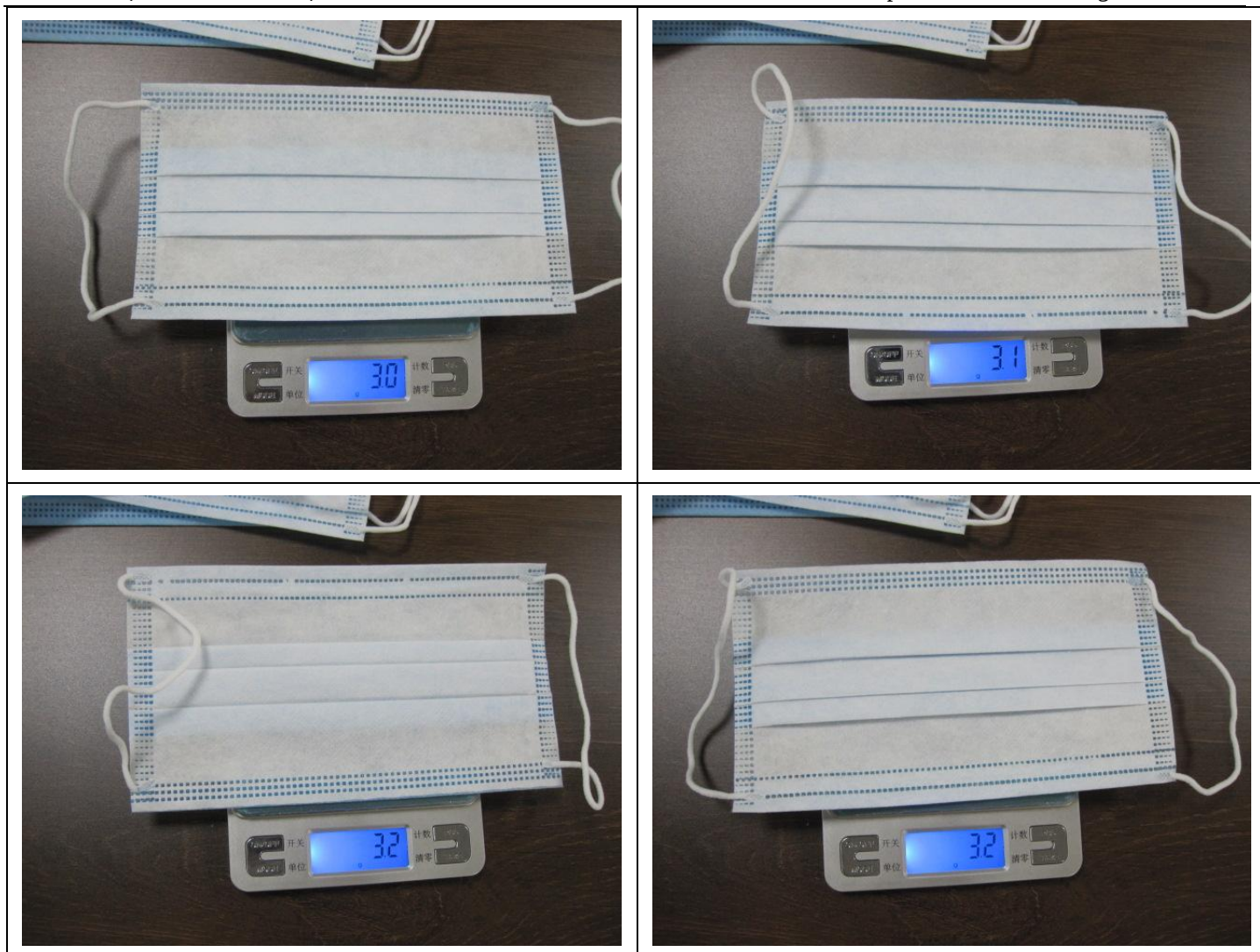
Expected		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
17.5 x9.5 cm 3 g		17.5 x9.5 cm 3 g	17.5 x9.5 cm 3 g	17.5 x9.5 cm 3 g	17.5 x9.5 cm 3 g	17.5 x9.5 cm 3 g

Additional Pictures:









5. Artworks / Labels

Logo

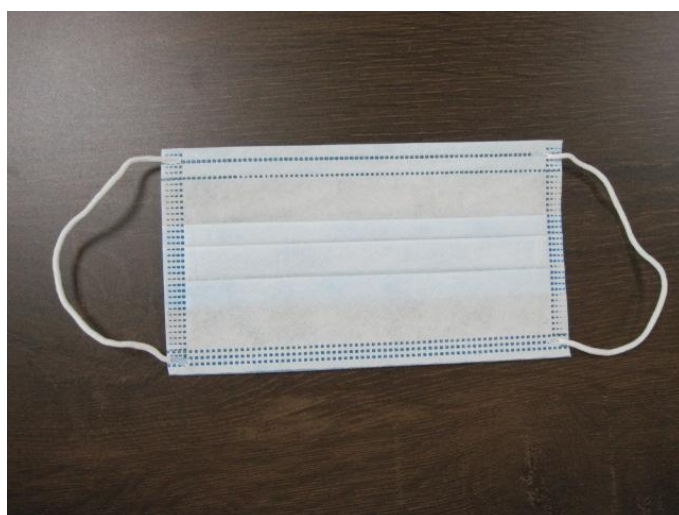
Client's comments:

Did you get an artwork or physical reference of the logo in your hand during Inspection ?

NO

N/A

Pictures:



Artwork or Sample

Bulk product

a. Logo quality

Expected Result	Result	Actual Picture / Comments
General quality and design	OK	See below sheet and pictures
Spelling	OK	
Font type	OK	
Boldness	OK	

Additional Pictures:



b. Logo colors

Expected Result	Result	Actual Picture / Comments
	OK / N/A / Not OK	See above sheet and pictures

c. Logo Dimension, Positioning and Alignment



Expected Result	Result	Actual Picture / Comments
Dimension (width x height) (Trace the smallest rectangle which can include the logo & measure the height and width of the rectangle surrounding the logo)	OK	See below sheet and pictures
Positioning (from the top edge of the rectangle to the top edge of the product)	OK	
Positioning (from the side edge of the rectangle to the side edge of the product)	OK	
Alignment and parallelism (draw a line at the bottom of the logo and check the parallelism of this line with the product side edge or bottom)	OK	

Additional Pictures:



d. Label

Expected Result	Result	Actual Picture / Comments
	OK	See color part with pictures above

6. Packing and packaging

a. Unit packing:

Expected Result	Result	Actual Picture / Comments
	OK	See below sheet and pictures

Additional Pictures:



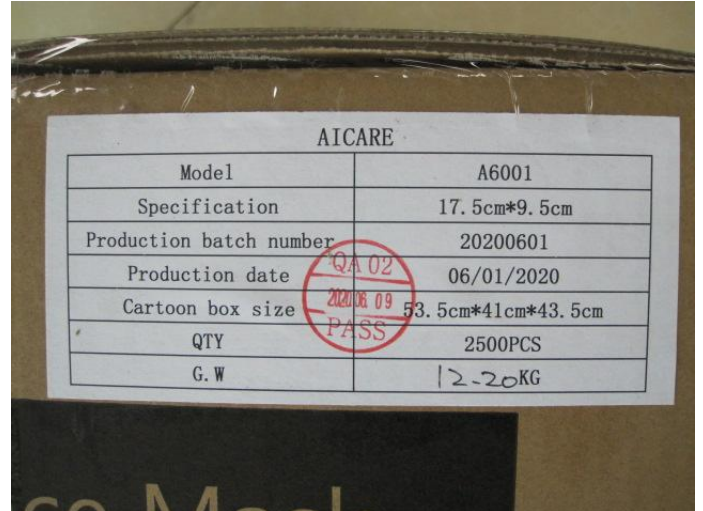
b. Inner packing:

Expected Result	Result	Actual Picture / Comments
	N/A	50 pieces per plastic bag 2500 pieces per inner box

c. Outer packing:

Expected Result	Result	Actual Picture / Comments		
	OK	See below sheet and pictures		
Sealing method (Ex: staples - adhesive - plastic band - metal band):	OK	Adhesive, 5-ply		
Number of pieces per carton (on 5 cartons)	OK	Carton #	Reference #	# of pieces
		N/A	2500	2500
		N/A	2500	2500
		N/A	2500	2500
		N/A	2500	2500
Client's comments:				

Additional Pictures:



d. Dimensions of export cartons: (on 5 cartons)



Expected Result	Result	Actual Picture / Comments	
L: 53.5cmxW: 41cm x H:43.5cm	OK	Carton number	L x W x H (cm)
		N/A	53.0 x 42.0 x 44.5
		N/A	53.0 x 42.0 x 44.5
		N/A	53.0 x 42.0 x 44.5
		N/A	53.0 x 42.0 x 44.5
		N/A	53.0 x 42.0 x 44.5

Additional Pictures:





e. Weight of cartons: (on 5 cartons)

Expected Result	Result	Actual Picture / Comments	
Maximum weight of Export Cartons: 24 kgs	OK	Carton number	Weight (kg)
		N/A	12.4
		N/A	12.4
		N/A	12.4
		N/A	12.4
		N/A	12.4

(1 kg = 2.2 Lbs / 1 lb = 0.45 kg)

Additional Pictures:



7. Shipping Marks

**a. Carton Front Mark**

Expected Result	Result	Actual Picture / Comments
	OK	See below sheet and pictures

b. Carton Side Mark

Expected Result	Result	Actual Picture / Comments
	OK	See below sheet and pictures

Additional Pictures:**8. Additional Comments on Product Specifications**

Expected result	Result	Actual Picture / Comments
		See below sheet and pictures

9. Special request for this service from Sale in charge

Expected result	Result	Actual Picture / Comments
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See below sheet and pictures

TESTS AND SPECIAL REQUIREMENTS

Test description	Comments from Inspector	Result
Was the inspector allowed to perform the sampling size expected by client fully randomly ? If yes, the result is passed, If not, the result is failed	Yes	passed
		
Perform a carton drop test on the export cartons:Yes	ok	passed
		

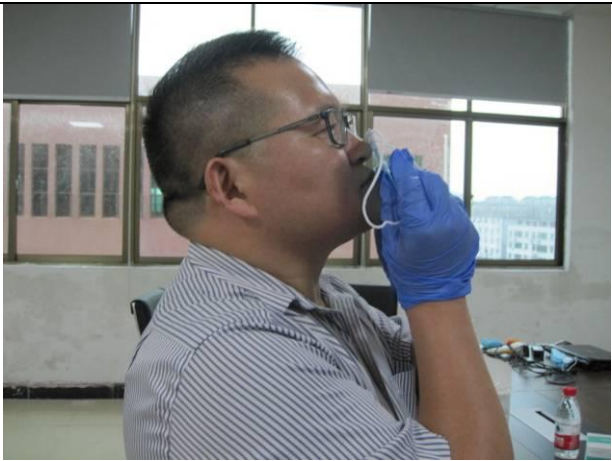


1, Pull on all metal parts attached to the bag and handle (lock, ring, etc.) □ □2, Check the seam strength on each part/pocket, especially on the handle or shoulder strap-1, Make sure all metal parts are correctly attached/stitched to the fabric of the bag. Pull on the handle/metal part with force to make sure all parts are well fixed and the seam of the handle is not too close to the handle's end. □2, Check the quality of the seaming. Check the bartacks / backstitch / re-enforcement should be made on all the connect areas. When pulling by force, the inspector must find no breaking. □3, Pull on the shoulder strap /belt /handle with a force of 1kg. After the test, the item should not break and should not have a stretched appearance.-II (2000 Pcs)	ok	passed
		
		



		
		
		
The importer information label must not be modified either by hand or by extra sticker.--II (2000 Pcs)		passed

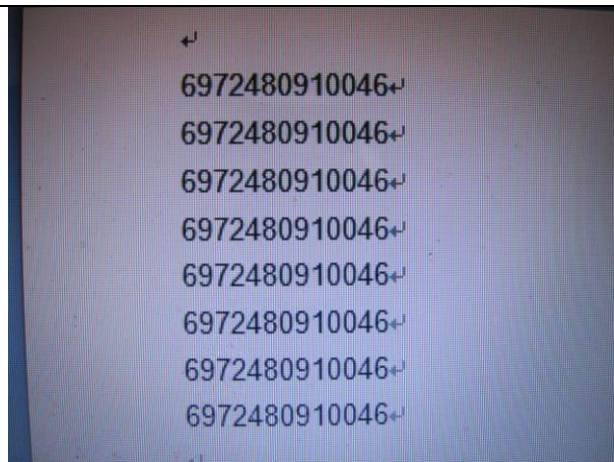


		
Count and record the number of stitches per inch--S1 (5 Pcs)	Not applicable	N/A
Check the item for any strong or offensive odors-The bags must not have a strong or bad smell.-II (125 Pcs)	ok	passed
		
Fatigue test for all adjustable parts found on each of the sample (i.e., zippers, velcro and snaps). - Do this 20 times-20 pcs (Pcs)	ok	passed
		

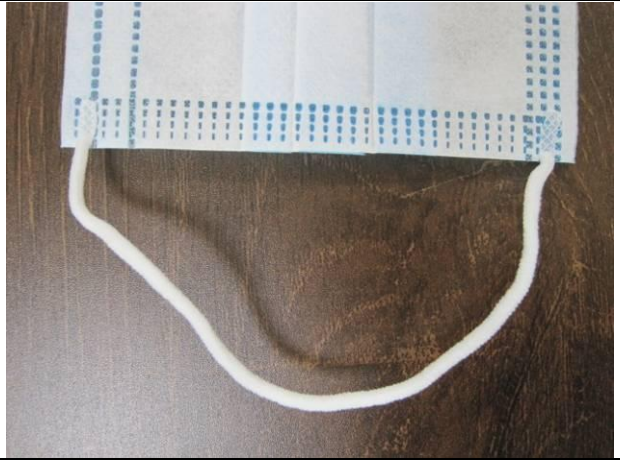


1. Color shading check within the same piece: put the same color parts side by side and identify the different dye lot. □2. Color shading check among all of the inspected pieces: place them side by side as per picture "color shading check attached" and identify the different dye lot.-Minimum grey scale 4-5 is acceptable for color shading in the same piece and minimum grey scale 4 is acceptable for color shading among the different pieces.-II (2000 Pcs)	ok	passed
		
Printing / Edge painting check-Check if painting uneven, crack, peel off -II (2000 Pcs)	ok	passed
		



Barcode scanning Test-The sample size for each type of the barcode should be scanned as following: ☐- Barcode label on products: the minimum sample size as client's requirements / sampling level of AI standard or 1 piece per each barcode if total # of barcodes are more than the sample size. (For example: bulks consist with 3 colorways & 5 sizes with totally 15 barcode no#, but the sample size is 13 pcs so inspector needs to scan 15 barcode (1 pce per each barcode) instead of 13 pcs accordingly) ☐ ☐- Barcode label per carton: 1 piece per each barcode ☐ ☐The barcode must match the client's specifications. It should be readable and have the correct number-S2 (8 Pcs)	ok	passed
		
Compare with approval sample and technical files(spec)(including bag shape, material/color of fabric, accessories, glue, hangtag/ labels, packing, logo/markings, workmanship & sewing construction, washing effect,hand feel.)-- 2pcs per color --S2 (8 Pcs)	N/A	N/A

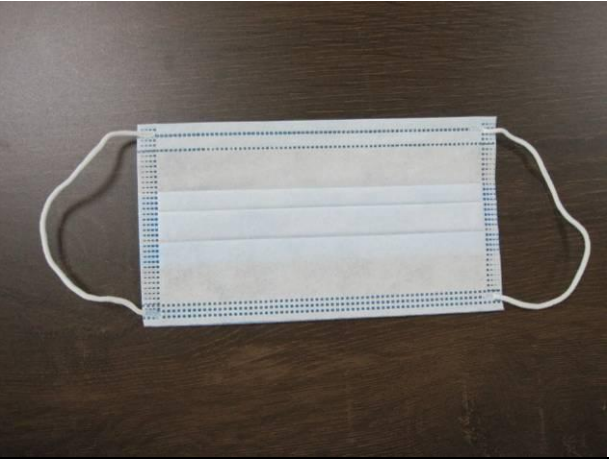


1,Fabric-weight check for non-woven fabric , with the GSM tester or cut fabric and convert to 1sqm and weigh in the weigh scale (unit: grams per square meter). ☐Do not neglect this test.This must be Performed from three places on one sample. -2, Check the weight of the unit product without unit packing-S1 (5 Pcs)-3 pcs (Pcs)	No equipment to do	N/A
Check the binding-The binding webbing should wrap the pannel tight, no empty space inside the webbing.-II (2000 Pcs)	ok	N/A
		
Check with tube in handle-if available-- no tube goes out of the handle ☐- finishing of the seam at the extremity is strong enough ☐- tubes are cut properly-II (2000 Pcs)	N/A	N/A
		



Adhesive test for all markings, printing and logos found-The printing, markings & logos easily peel off. For example: on surface of hardwares, heat transfer label, printing care label, etc-S1 (5 Pcs)	ok	passed
		
1.Rub test on all marking or printing ☐ ☐2.Rub test to check the color fastness of the fabric (including the lining) and all the accessories(Labels must be rubbed for this test). - 1, Check the durability of the marking/printing by rubbing it lightly for 15 seconds with a piece of cloth soaked with water. After drying the item, rub the marking/printing for a further 15 seconds with a piece of cloth soaked in petroleum spirits. If petroleum spirits is not available, use 95% alcohol. Expected result: After the test, the marking should be legible, the label(s) should not be easily removed or show any curling-S1 ☐ ☐2,Use a white cotton cloth to rub the material. Rub the item 10 times over a 10 cm distance with a force of 9N (1kg). Test with both a dry and a wet cloth. Expected result: There should be no color transfer greater than 4 on a grey scale (between the original white cloth and the colored one) after the dry test. There should be no color transfer greater than 3-4 on a grey scale (between the original white cloth and the colored one) after the wet test-S1 (5 Pcs)		



CLIENT'S IMPORTANT INSTRUCTIONS ON TESTS

Client's Instructions	Actual Finding / Comments
	See above sheet and pictures

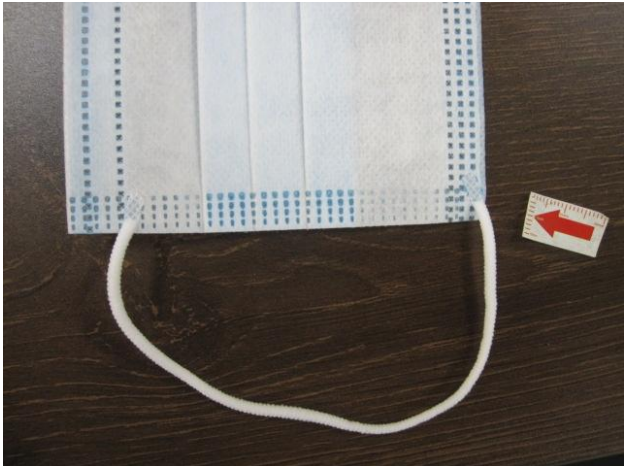
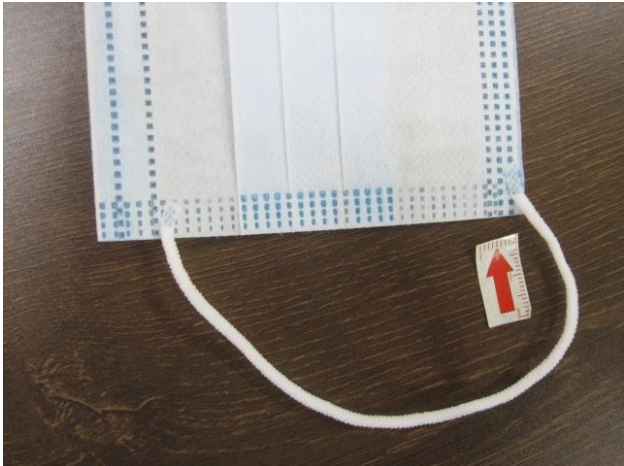
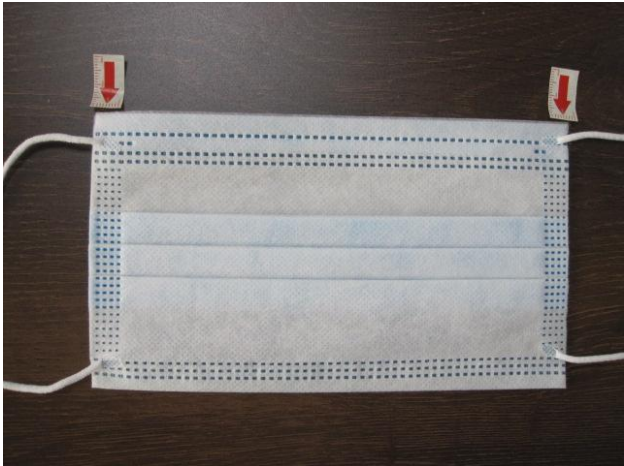
SAMPLE COLLECTION

[0] pcs of shipment samples were randomly collected by inspector for Lab Testing
[0] pcs of defective samples were collected by inspector for Client
[0] pcs of good samples were collected by inspector for Client
[0] pcs of samples were randomly collected by inspector for Client

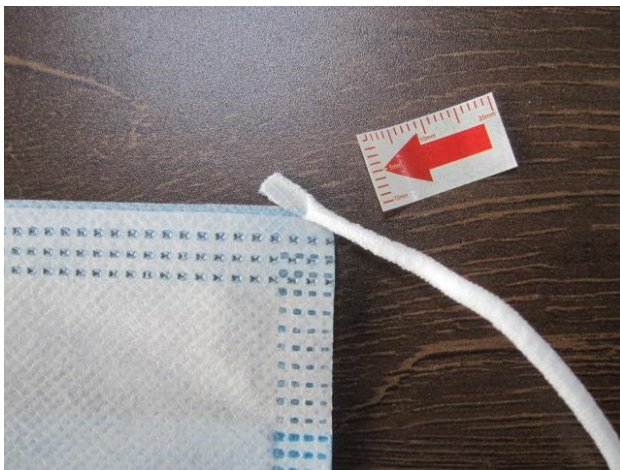


DEFECTIVES LIST					
		CRI	MAJ	MIN	Picture
Style / item: , Sample size:					
Style / item: HX01 , Sample size: 2000 pcs					
	Loosened article due to Poor connection	0	1	0	



	Askew assembly of article	0	5	0	
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	Wrinkle	0	0	8	

DEFECTIVES LIST SUMMARY				
	Cri	Maj	Min	AQL result
Number of Defectives found	0	6	8	Within AQL
Maximum Allowed	0	21	21	
No. of Inspected samples	2000	2000	2000	

- **CRI: defective 0 pieces found out of acceptable among 2000 pieces inspected at level Not Allowed**
- **MAJ: defective 6 pieces found out of acceptable among 2000 pieces inspected at level 2.5**
- **MIN: defective 8 pieces found out of acceptable among 2000 pieces inspected at level 4.0**

CLIENT'S IMPORTANT INSTRUCTIONS ON AQL	
Client's Instructions	<u>Actual Finding/ Comments</u>
	See above sheet and pictures



ADDITIONAL PICTURES

Your Product

Finished and packed products



Finished But not packed

Cartons

Total cartons

Inspected cartons



Factory Disclaimer

/

/

**Original signature from Factory Manager accepting AsiaInspection conditions
on Shipment authorization and bribery issues**

IMPORTANT NOTES

THE ABOVE RESULT(S) REFLECT(S) ASIASEAINSPCTION LIMITED'S FINDINGS AT THE TIME AND PLACE OF INSPECTION. THIS REPORT DOES NOT RELEASE THE BUYER OR SELLER FROM CONTRACTUAL RESPONSIBILITIES, NOR DOES IT PREJUDICE THE BUYER'S RIGHT OF CLAIM TOWARD THE SELLER/SUPPLIER FOR COMPENSATION FOR ANY APPARENT AND/OR HIDDEN DEFECTS NOT DETECTED DURING INSPECTION OR OCCURRING ANYTIME THEREAFTER.

End of the Report