

HQTS	INSPECTION REPORT Pre-Shipment Inspection	Report No: H-20078127
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INSPECTION INFORMATION			
Client	MEDIQ		
Supplier	Hangzhou Qianyuan Technology Co., Ltd		
Factory	JIANG SU NAN FANG MEDICAL CO., LTD		
Inspection Instruction	GWI-H-004-HQT, SWI-2099-HQT-MEDI		
P.O. No.	2020024-6	P.O. Quantity	5.1.1c
Item No.	LCH-2020-0207-06	Sampling Plan	ISO2859 : Single,Normal
Inspection Date	17/07/2020	Inspection Level	G-II
Inspection Sequence	Original inspection	Sample Size	800 Pieces
Inspection Location	WuJin,China	AQL	Critical:0, Major:1.5, Minor:4.0
Product Description	DISPOSABLE MEDICAL SURGERY MASK		



INSPECTION RESULT SUMMARY			
Category	Conform	Not Conform	Pending
1.Quantity	X		
2.Workmanship	X		
3.Style, Color & Documentation	X		
4.Field Test & Measurement			X
5.Shipping Mark & Packaging	X		
OVERALL CONCLUSION	Pending to client's requirement		

Approved by HQTS Supervisor:	5.1.2e
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This report reflects the facts as recorded by HQTS at the time and place of inspection. It does not relieve the manufacturers from their contractual obligations nor prejudice client's right for compensation for any apparent and/or hidden defects not detected during our random inspection or occurring thereafter.

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SPECIAL ATTENTION POINT (SAP)	
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1	Quantity	NIL
2	Workmanship	NIL
3	Style, Color & Documentation	NIL
4	Field Test & Measurement	
4.1	The product dimension was out of specification, please refer to the data sheet with red mark.	
4.2	Differential Pressure test was not conducted since relevant apparatus was not available by the factory.	
5	Shipping Mark & Packaging	NIL

INSPECTION DETAILS

5.1.1c

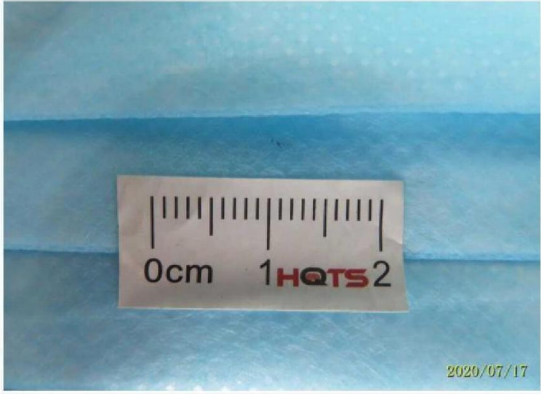


2. Workmanship	Conform		
Defects Description	Critical	Major	Minor
Item#: LCH-2020-0207-06			
Poor adhesion of ear loop	0	4	0
Pleat on surface	0	2	0
Impurities on the product surface (about 1mm)	0	0	3
Total Found:	0	6	3
Allowed:	0	21	21
Sample Size:	800	800	315

The following field test included in workmanship check

Function check

Defect Photos



	
<p>Defect-Impurities on the product surface (about 1mm) -mi</p>	<p>Defect-Impurities on the product surface (about 1mm) -mi</p>
	<p>NA</p>
<p>Defect-Impurities on the product surface (about 1mm) -mi</p>	

3. Style, Color & Documentation	Conform		
DESCRIPTION	Conform	Not Conform	Pending
The inspected samples were consistent with	-	-	-
Purchase Order	X		
Product Specification	X		

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4. Field Test & Measurement				Pending		
Item	Specification	Sample Size	Conform	Not Conform	Pending	
4.1	Carton dimension check	-	1 Carton	X		
4.2	Carton gross weight check	-	1 Carton	X		
4.3	Carton drop test	-	1 Carton	X		
4.4	Quantity per carton check	-	2 Cartons	X		
4.5	Product dimension check	-	5 Samples			X
4.6	Product weight check	-	5 Samples	X		
4.7	Wearing test	-	5 Samples	X		
4.8	Waterproof check	-	5 Samples	X		
4.9	Rub test	-	5 Samples	X		
4.10	Tension test on ear strings	10N	5 Samples	X		
4.11	Bacterial filtration efficiency(BFE) check	≥98%	5 Samples	X		
4.12	Differential pressure test	-	5 Samples			X
4.13	Synthetic blood splash resistant test	-	5 Samples	X		
4.14	Microbial cleanliness	-	5 Samples	X		
4.15	PFE test	-	5 Samples	X		
4.16	Fabric weight check	-	1 Sample	X		
4.17	Fire proof to melt-blown fabric test	-	5 Samples	X		

Checking Item	Specification	Result
Carton dimension (cm)	55x35x44	56x36x45
Carton gross weight (kg)	10.5	10.35
Product dimension (cm)	17.5x9.5	18x9.5, 17.8x9.5, 17.5x9.5, 17.6x9.5, 17.5x9.5
Product weight (g)	-	4.4, 4.4, 4.4, 4.3, 4.3
Length of ear strings (cm)	-	39, 41, 40, 40, 40.5
PFE test (%) (Only for 0.3um)	-	98.728, 98.664, 97.517, 98.253, 96.738
Fabric weight (gsm)	-	Blue non-woven fabric:32 Melt-blown filter:27 White non-woven fabric:30
Microbial cleanliness test	≤30cfu/g	8,12,12,16,12 cfu/g
Bacterial filtration efficiency test	≥98%	99.07,99.15,98.18, 98.94,98.31%

5. Shipping Mark & Packaging **Conform**

5.1 Shipping mark photos



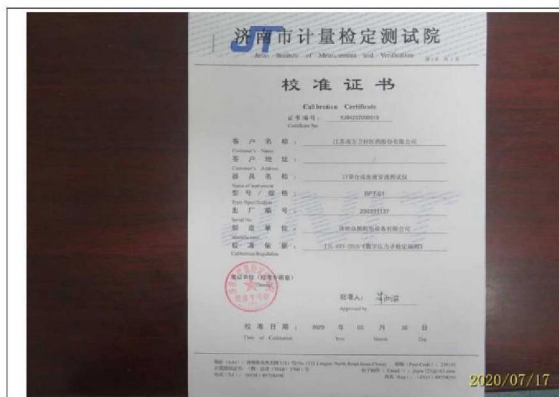
5.2 Packaging photos



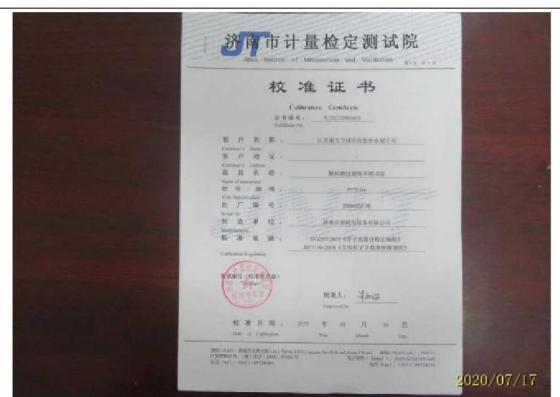
Packaging Description:

- 20 pieces of products were packed into a polybag but no silica gel bag or tissue paper was found.
- 10 polybags were packed into a big polybag.
- 1 polybag was packed into a 5-ply corrugated export carton.
- Export carton was sealed with gummed tape and secured by nylon straps.

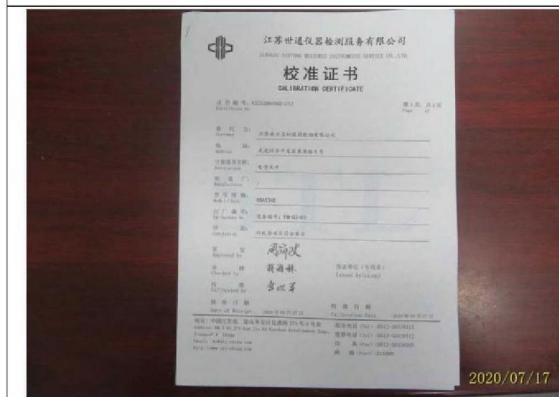
6. Reference Note	
6.1	It was found that the factory did not adopt mildew prevention measures on the packaging to reduce the risk of product mildew during transportation and storage.
6.2	The inspected cartons were not sealed because the factory did not repack them immediately after inspection.
6.3	Our inspector required the factory to repair all defective samples before shipment.
6.4	Draft report has been provided to the factory and defective points have been explained as well.
6.5	Both of Bacterial Filtration Efficiency(BFE) test and Microbial cleanliness test were not conducted during inspection since they needed bacterial and microbial culture. Per to factory's explain, about 4 days were needed to finish these 2 tests. Inspector sampling to factory during inspection, the test process will not be supervised by our inspector and the result would be provided later by the factory.
6.6	The calibration certificates of Synthetic Blood Penetration test, Particulate matter filtration efficiency test and weight apparatus were provided by factory, for other test apparatus, calibration certificates were not available. Below for reference.
6.7	Excutive standard was EN 14683:2019 type IIR.



Note-6-6-Calibration certificate



Note-6-6-Calibration certificate



Note-6-6-Calibration certificate

NA

7. Photos



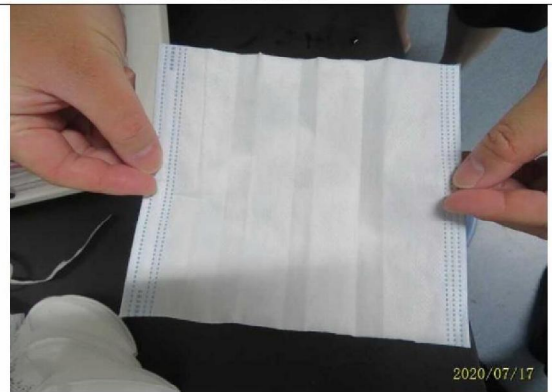
Warehouse



Warehouse



Synthetic Blood Penetration test



Synthetic Blood Penetration test



Tension test on ear loop



Tension test on ear loop



PFE test

PFE test



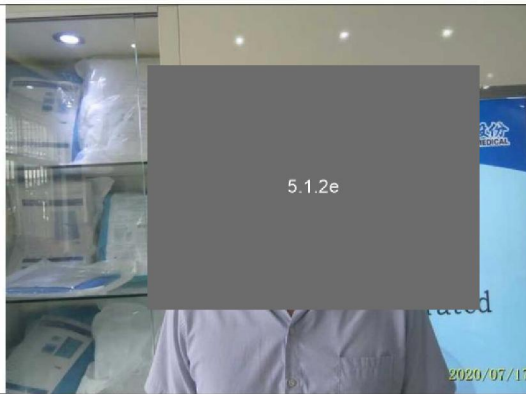

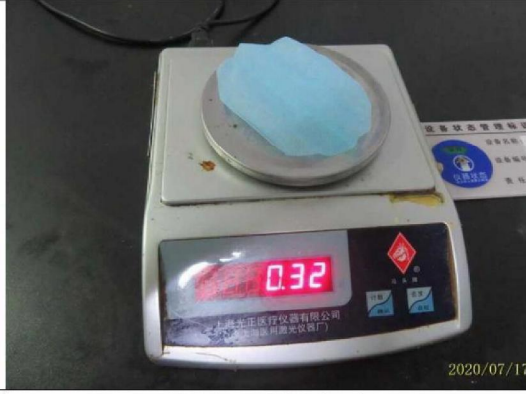


Water proof test

Barcode readability check



Wearing check

Wearing check

 <p>5.1.2e</p> <p>2020/07/17</p>	 <p>2020/07/17</p>
<p>Wearing check</p>	<p>Color shade check</p>
 <p>0.32</p> <p>2020/07/17</p>	 <p>0.27</p> <p>2020/07/17</p>
<p>Fabric weight check</p>	<p>Fabric weight check</p>
 <p>0.30</p> <p>2020/07/17</p>	 <p>2020/07/17</p>
<p>Fabric weight check</p>	<p>Item LCH-2020-0207-06</p>

<p>Standard: EN14683:2019 TYPE IIR MODEL M</p> <p>C.C.C.EUROPE</p> <p>Surgical Mask</p> <p>LCH-2020-0207-06 Order number: 2020024-6 Mediq Nederland B.V. Acting as part of: the Landelijk Consortium Hulpmiddelen (LCH) Rijnzathe 10 3454 PV Utrecht The Netherlands</p> <p>Surgical Mask CARTON NO 2127-2500 MADE IN CHINA</p> <p>江苏南方卫材医药股份有限公司 Jiangsu Nanfang Medical Co.,Ltd.</p> <p>2020/07/17</p>	<p>Standard: EN14683:2019 TYPE IIR MODEL: M</p> <p>2020/07/17</p>
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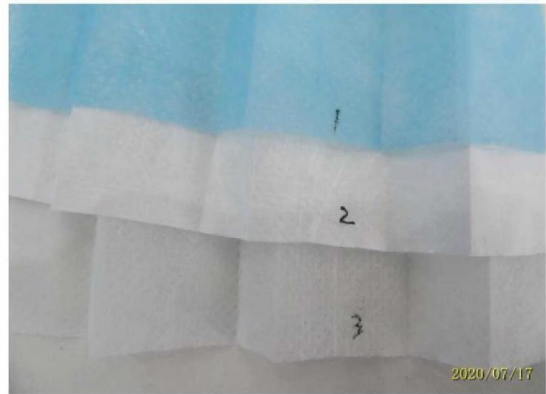
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 <p style="text-align: right; color: yellow; font-size: small;">2020/07/17</p>	<p style="text-align: center;">江苏南方卫材医药股份有限公司检验报告单 JIANGSU NAN FANG MEDICAL CO., LTD. CERTIFICATE OF ANALYSIS</p> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <tr> <td>Name of Sample</td> <td>Surgical Mask</td> <td>Specification</td> <td>17.5cm×9.5cm</td> </tr> <tr> <td>Lot No.</td> <td>20200705</td> <td>Test Date</td> <td>2020.07.16</td> </tr> <tr> <td>Quantity</td> <td>2000000Pcs</td> <td>Date of report</td> <td>2020.07.20</td> </tr> </table> <p style="text-align: center; font-size: x-small;">Check Standard: SCP-Q9223-633</p> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th>Item</th> <th>Item Tested</th> <th>Technical Requirement</th> <th>Testing data</th> <th>Result</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td rowspan="2">Appearance</td> <td>The appearance of the mask should be neat and intact, and there should be no damage or stain on the surface.</td> <td>Pass</td> <td>OK</td> </tr> <tr> <td>After wearing the mask, it should be able to cover the user's nose, mouth and jaw. The size of the mask should conform to the design size. After wearing the mask, it should cover the user's nose, mouth and jaw and ensure the tightness of the mask.</td> <td>Pass</td> <td>OK</td> </tr> <tr> <td>2</td> <td>Basic Size</td> <td>Length: 17.5cm ± 5% Height: 9.5 cm ± 5%</td> <td>17.5cm 9.5cm</td> <td>OK</td> </tr> <tr> <td rowspan="4">3</td> <td rowspan="4">Bacterial filtration efficiency (BFE)</td> <td rowspan="4">The bacterial filtration efficiency of the mask should be not less than 98%.</td> <td>99.07%</td> <td rowspan="4">OK</td> </tr> <tr> <td>99.15%</td> </tr> <tr> <td>98.18%</td> </tr> <tr> <td>98.31%</td> </tr> <tr> <td>4</td> <td>Splash resistance</td> <td>The splash resistance of the medical face mask shall more than 10Kpa.</td> <td>Pass</td> <td>OK</td> </tr> <tr> <td rowspan="4">5</td> <td rowspan="4">Microbial cleanliness (Bioburden)</td> <td rowspan="4">The bioburden of the medical mask shall be: ≤30 cfu/g</td> <td>8cfu/g</td> <td rowspan="4">OK</td> </tr> <tr> <td>12cfu/g</td> </tr> <tr> <td>16cfu/g</td> </tr> <tr> <td>12cfu/g</td> </tr> </tbody> </table> <p style="font-size: x-small;">Conclusion: This batch of products were inspected according to the standard SCP-Q9223-633 and the results are in conformity with the requirements.</p> <p style="font-size: x-small;">Inspector: 梅石林 Review: 袁国刚</p>	Name of Sample	Surgical Mask	Specification	17.5cm×9.5cm	Lot No.	20200705	Test Date	2020.07.16	Quantity	2000000Pcs	Date of report	2020.07.20	Item	Item Tested	Technical Requirement	Testing data	Result	1	Appearance	The appearance of the mask should be neat and intact, and there should be no damage or stain on the surface.	Pass	OK	After wearing the mask, it should be able to cover the user's nose, mouth and jaw. The size of the mask should conform to the design size. After wearing the mask, it should cover the user's nose, mouth and jaw and ensure the tightness of the mask.	Pass	OK	2	Basic Size	Length: 17.5cm ± 5% Height: 9.5 cm ± 5%	17.5cm 9.5cm	OK	3	Bacterial filtration efficiency (BFE)	The bacterial filtration efficiency of the mask should be not less than 98%.	99.07%	OK	99.15%	98.18%	98.31%	4	Splash resistance	The splash resistance of the medical face mask shall more than 10Kpa.	Pass	OK	5	Microbial cleanliness (Bioburden)	The bioburden of the medical mask shall be: ≤30 cfu/g	8cfu/g	OK	12cfu/g	16cfu/g	12cfu/g
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End of Report			