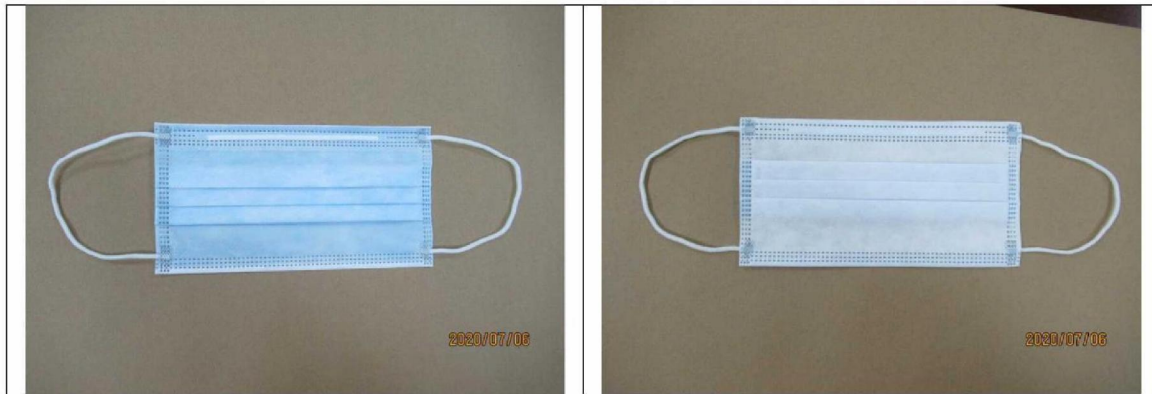


HQTS	INSPECTION REPORT Pre-Shipment Inspection	Report No: H-20076084
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INSPECTION INFORMATION			
Client	MEDIQ		
Supplier	BRANDBASE		
Factory	Weihai Shengjie Medical Technology Co., Ltd		
Inspection Instruction	GWI-H-004-HQT		
P.O. No.	LCH 2020-0211-3	P.O. Quantity	5.1.1c
Item No.	CM type 2R	Sampling Plan	ISO2859 : Single, Normal
Inspection Date	06/07/2020 to 07/07/2020	Inspection Level	G-II
Inspection Sequence	Original inspection	Sample Size	800 Pieces
Inspection Location	Weihai, China	AQL	Critical:0, Major:1.5, Minor:4.0
Product Description	TYPE IIR 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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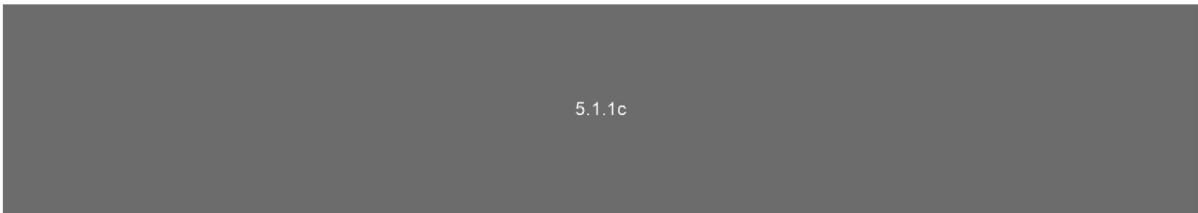
This report reflects the facts as recorded by HQTS at the time and place of inspection. It does not relieve the manufacturers from their contractual obligations nor prejudice client's right for compensation for any apparent and/or hidden defects not detected during our random inspection or occurring thereafter.

SPECIAL ATTENTION POINT (SAP)

1	Quantity	NIL
2	Workmanship	NIL
3	Style, Color & Documentation	NIL
4	Field Test & Measurement	NIL
5	Shipping Mark & Packaging	
5.1	Actually found the carton dimension printed on shipping mark was different from client's layout. While it was similar with the result of carton dimension check. For details, please refer to photos as below.	

SAP5.1-1-specification	SAP5.1-2-actual finding

INSPECTION DETAILS



2. Workmanship	Conform		
	Critical	Major	Minor
Defects Description			
Poor welding on ear rope		1	
Mask edge unfixed well		3	
Solder joint deviation on ear lobe		3	
Discrepancy on stack width of mask		1	
Fold mark on surface			4
Slant nasal bridge wire			8
Black dot on surface			2

Report No: H-20076084

Total Found:	0	8	14
Allowed:	0	21	21
Sample Size:	800	800	315

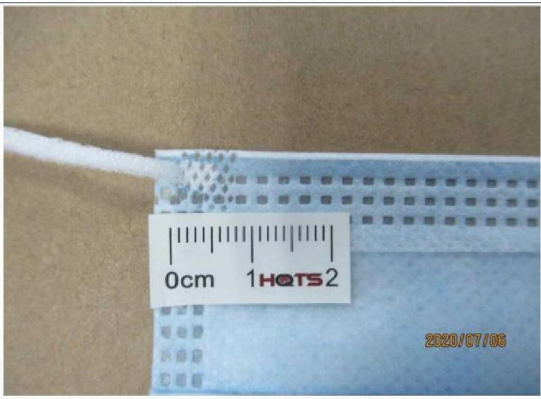
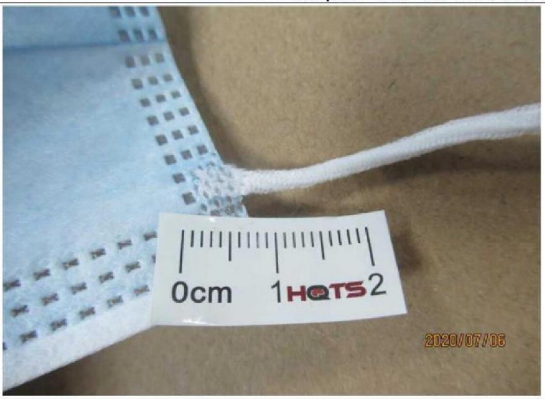
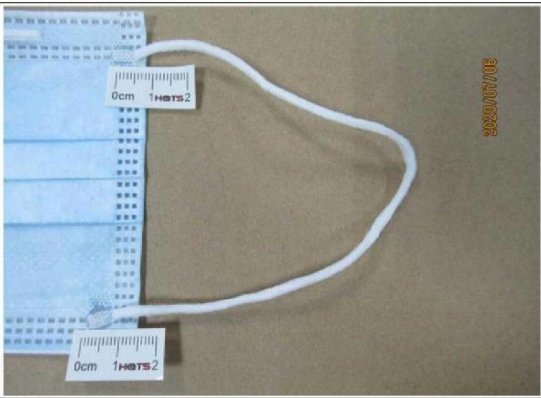
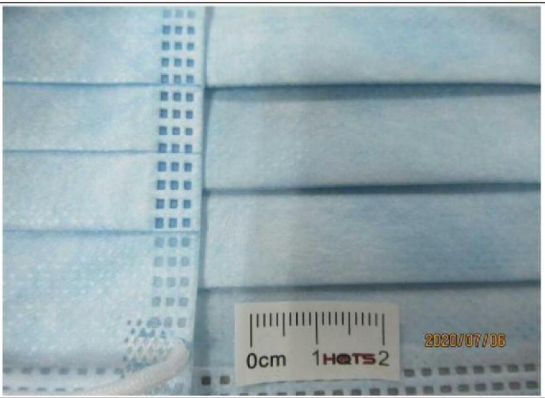


The following field test included in workmanship check

Labeling check

Pull check for ear loop

Defect Photos

<p>Defect- Poor welding on ear rope-ma</p>	<p>Defect- Mask edge unfixed well-ma</p>
<p>Defect- Mask edge unfixed well-ma</p>	<p>Defect- Mask edge unfixed well-ma</p>

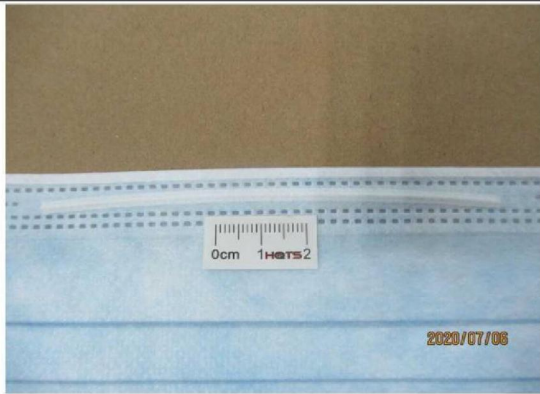
	
<p>Defect- Solder joint deviation on ear lope-ma</p>	<p>Defect- Solder joint deviation on ear lope-ma</p>
	
<p>Defect- Solder joint deviation on ear lope-ma</p>	<p>Defect- Discrepancy on stack width of mask-ma</p>
	
<p>Defect- Fold mark on surface-mi</p>	<p>Defect- Fold mark on surface-mi</p>



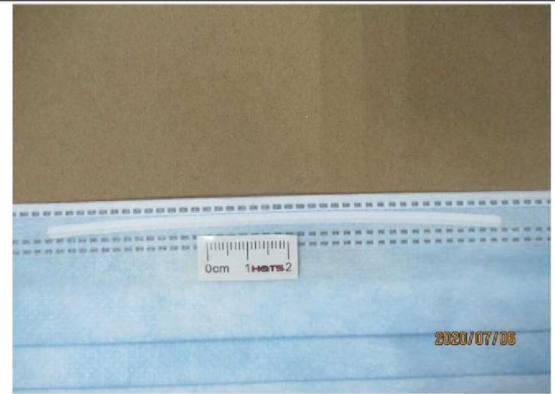
Defect- Fold mark on surface-mi



Defect- Fold mark on surface-mi



Defect- Slant nasal bridge wire-mi



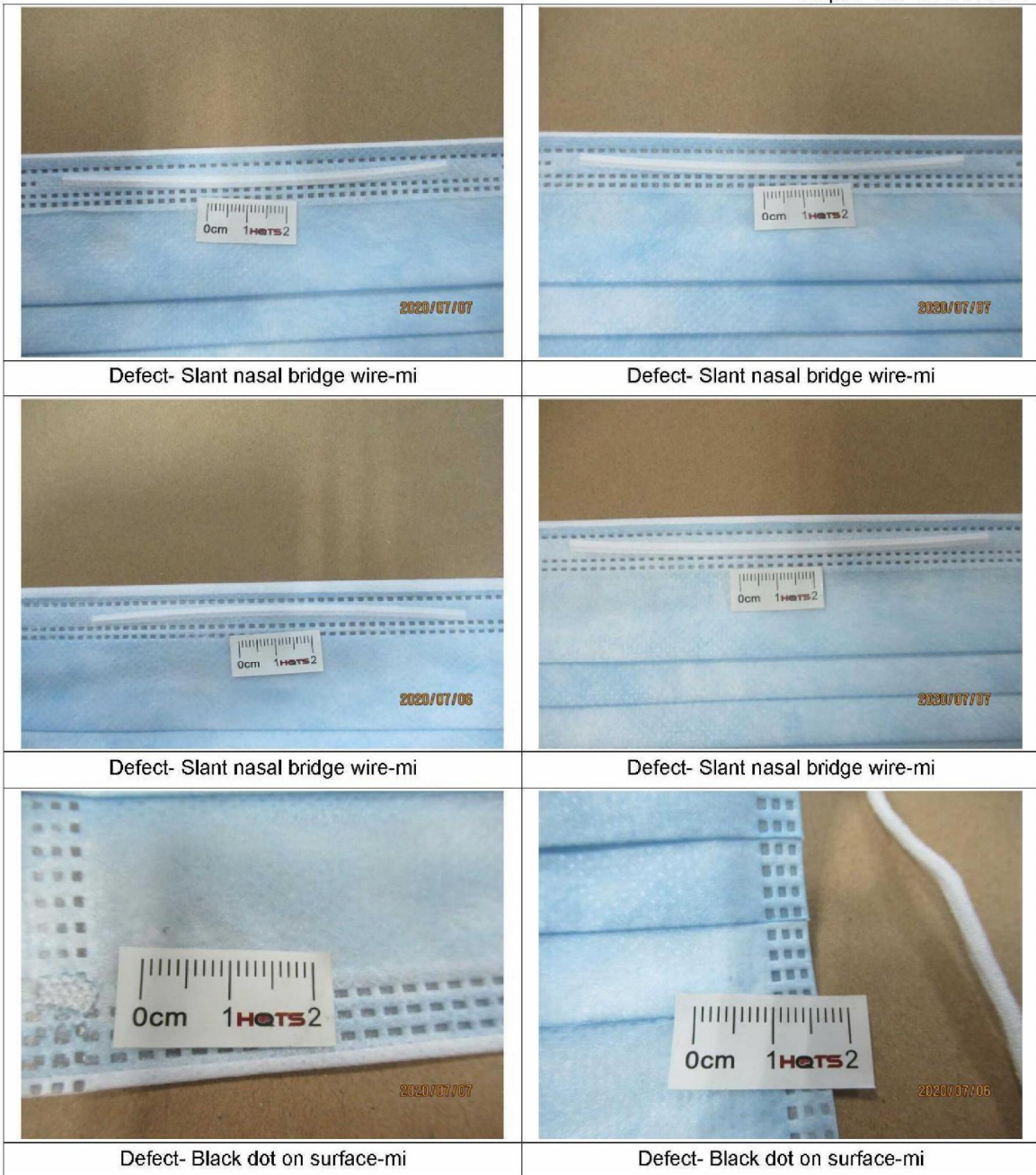
Defect- Slant nasal bridge wire-mi



Defect- Slant nasal bridge wire-mi



Defect- Slant nasal bridge wire-mi



3. Style, Color & Documentation	Conform		
DESCRIPTION	Conform	Not Conform	Pending
The inspected samples were consistent with	-	-	-
Product Specification	X		
Digital photo	X		
Instruction manual and Document Verification	-	-	-

Report No: H-20076084

Instruction manual in English.	X		
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4. Field Test & Measurement			Conform		
Item	Specification	Sample Size	Conform	Not Conform	Pending
4.1	Wear check	5 samples	X		
4.2	Product dimension check	5 samples	X		
4.3	Product net weight check	5 samples	X		
4.4	Smell check	5 samples	X		
4.5	Rub test	5 samples	X		
4.6	Quantity per box check	All selected cartons	X		
4.7	Carton dimension check	1 carton	X		
4.8	Carton gross weight check	1 carton	X		
4.9	Carton drop check	1 carton	X		
4.10	Test for strength of belt	2 samples	X		
4.11	Bacterial filtration efficiency test	2 samples	X		
4.12	Nacl particulate matter filtration efficiency test (PFE)	2 samples	X		
4.13	Synthetic blood penetration test	2 samples	X		
4.14	Differential pressure test	2 samples	X		
4.15	Microbial cleanliness test	1 sample	X		
4.16	Fire proof to melt-blown fabric test	2 samples	X		
4.17	Material structure check	2 samples	X		

Checking Item	Specification	Result
Carton dimension check (cm) +/-5%	Shipping mark: 53.5x38.5x38.5cm Specification: 56x37x37cm	53.2x38.9x40.0cm
Carton gross weight check (kg)+/-10%	10kg	9.50kg
Color box dimension check(cm)	-	18.1x10.0x9.0cm
Color box gross weight check (g)	-	212.76g
Unit dimension check(cm)	17.5x9.5cm	17.4x9.5, 17.4x9.5, 17.4x9.5, 17.4x9.5, 17.4x9.5cm
Unit net weight check(g)	-	3.02, 3.00, 3.02, 3.06, 2.99g
Fabric weight check(GSM)	-	Shell: 26gsm Middle layer: 27gsm Inside layer: 24gsm
Differential pressure test (Pa/(cm ²))	<60	43.34, 50.2
Nacl particulate matter filtration efficiency test(0.3um)	-	99.171%, 99.014%
Test for strength of belt (N)	>10N	20.02, 16.53 N
Microbial cleanliness test	≤30cfu/g	6.7cfu/g
Bacterial filtration efficiency test	≥98%	99.16,99.21,99.23,99.27,99.18%

5. Shipping Mark & Packaging **Pending**

5.1 Shipping mark photos



5.2 Packaging photos



Packaging Description:

- 10 pieces of products were packed into a polybag .
- 5 polybags were packed into an inner box.
- 40 inner boxes were packed into a 5-ply corrugated export carton.
- Export carton was sealed with adhesive tape.

6. Reference Note

6.1	Carton numbers selected for sampling were 1630, 1693, 1169, 1296, 1249, 1080, 1003, 1608, 1591, 451, 553, 726, 51, 634, 926, 178, 774, 581,1317, 1479, 1531, 676, 1411, 1382, 1450, 494, 805, 1041, 307, 35, 232, 382, 2058, 1754, 858, 1728, 2095, 992, 2032, 1877, 1997, 1961, 2457, 2242, 2285, 2403, 2332, 2368, 2115, 2174
6.2	Our inspector required the factory to repair all defective samples before shipment.
6.3	Draft report has been provided to the factory and defective points have been explained as well.
6.4	Regarding those check items that no data or specification had been provided by the client, only measured data, which were generally judged as conformed, were listed in the data sheet for your reference.

7. Photos



Warehouse (1)



Warehouse (2)



Item CM type 2R (1)



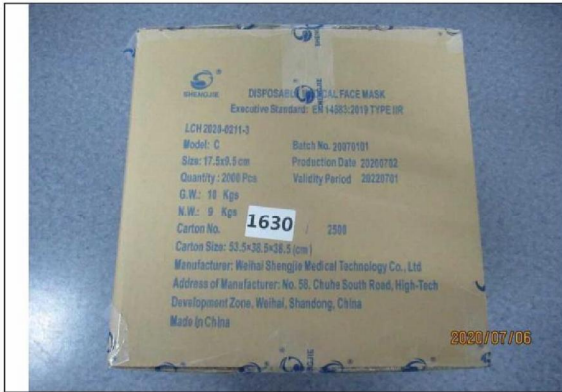
Item CM type 2R (2)



Item CM type 2R (3)



Item CM type 2R (4)



Item CM type 2R (5)



Item CM type 2R (6)



Item CM type 2R (7)



Item CM type 2R (8)




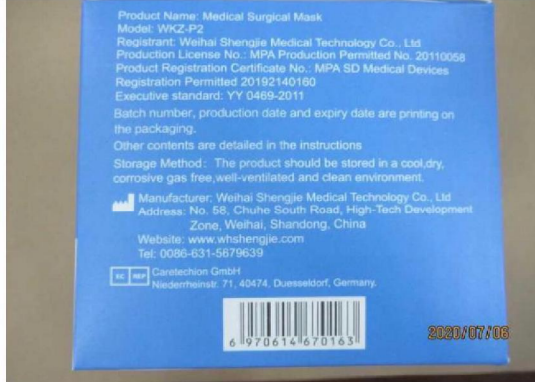

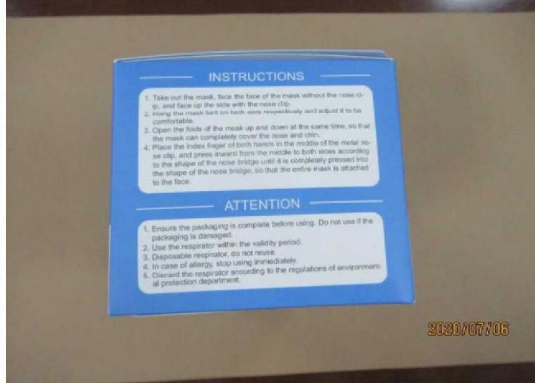
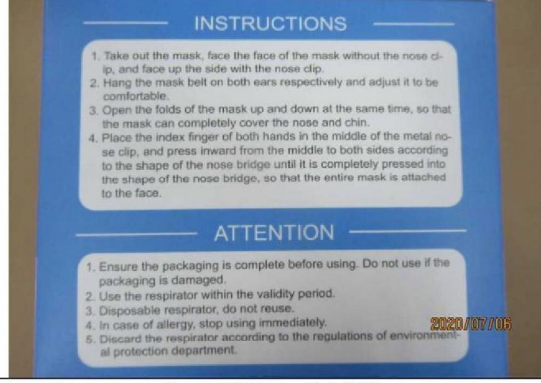
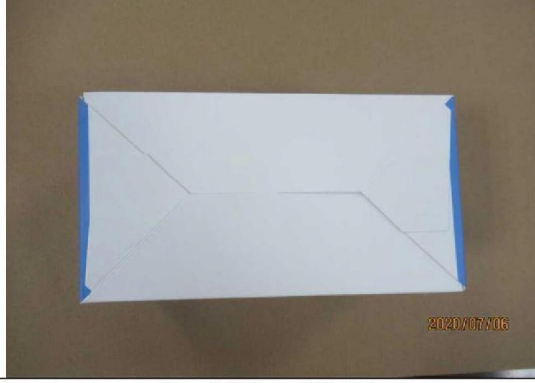
Item CM type 2R (9)



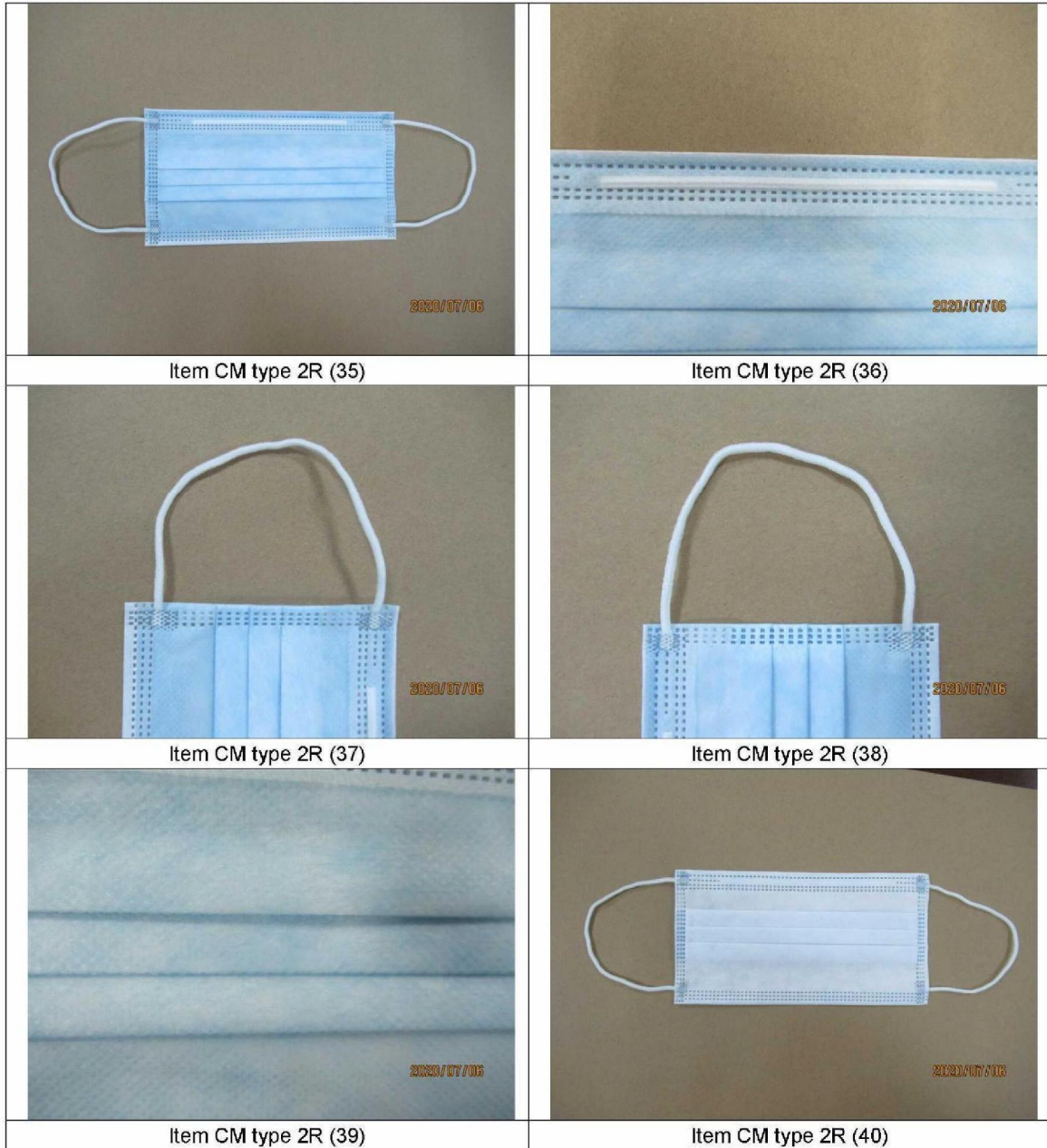
Item CM type 2R (10)

<p>Instructions of Disposable Medical Face Mask</p> <p>Product Name: Disposable Medical Face Mask</p> <p>Model: C</p> <p>Manufacturer: Weihai Shengjie Medical Technology Co., Ltd.</p> <p>Address: No. 58, Chube South Road, High-Tech Development Zone, Weihai, Shandong, China</p> <p>Product License No.: MPA Production Permitted No. 20110058</p> <p>Product Registration Certificate No.: MPA SD Medical Devices Registration Permitted 20192140160</p> <p>Product Technical Requirements: SD Medical Devices Registration Permitted 20192140160</p> <p>EN 14683:2019 Type II R</p> <p>The Disposable Medical Face Mask is composed of mask body (bottom layer, surface layer and middle layer), nose clip and mask earloop. The bottom layer and surface layer of the mask body are composed of non-manufacturing cloth, and the middle layer is composed of polypropylene melt blown. The nose clip is composed of aluminum strip and polypropylene material, and the mask earloop is woven of polyester and spandex or composed of non-woven.</p> <p>This Disposable medical face mask is suitable for the wearer in the general medical environment where there is no risk of bodily fluids and spillage.</p> <p>Use with caution if you are allergic to nonwovens.</p> <p>Precautions, Warnings and Suggestive notes</p> <p>Before use, check whether the package is in good condition, confirm the</p> <p>2020/07/06</p>	<p>Instructions of Disposable Medical Face Mask</p> <p>Product Name: Disposable Medical Face Mask</p> <p>Model: C</p> <p>Manufacturer: Weihai Shengjie Medical Technology Co., Ltd.</p> <p>Address: No. 58, Chube South Road, High-Tech Development Zone, Weihai, Shandong, China</p> <p>Product License No.: MPA Production Permitted No. 20110058</p> <p>Product Registration Certificate No.: MPA SD Medical Devices Registration Permitted 20192140160</p> <p>Product Technical Requirements: SD Medical Devices Registration Permitted 20192140160</p> <p>EN 14683:2019 Type II R</p> <p>The Disposable Medical Face Mask is composed of mask body (bottom layer, surface layer and middle layer), nose clip and mask earloop. The bottom layer and surface layer of the mask body are composed of non-manufacturing cloth, and the middle layer is composed of polypropylene melt blown. The nose clip is composed of aluminum strip and polypropylene material, and the mask earloop is woven of polyester and spandex or composed of non-woven.</p> <p>This Disposable medical face mask is suitable for the wearer in the general medical environment where there is no risk of bodily fluids and spillage.</p> <p>Use with caution if you are allergic to nonwovens.</p> <p>Precautions, Warnings and Suggestive notes</p> <p>Before use, check whether the package is in good condition, confirm the</p> <p>2020/07/06</p>
<p>Item CM type 2R (11)</p> <p>Development Zone, Weihai, Shandong, China</p> <p>Tel of Manufacturer: +86-631-5679639</p> <p>Production License No.: MPA Production Permitted No. 20110058</p> <p>Product Registration Certificate No.: MPA SD Medical Devices Registration Permitted 20192140160</p> <p>Product Technical Requirements: SD Medical Devices Registration Permitted 20192140160</p> <p>Executive standard: EN 14683:2019 Type IIR</p> <p>Product Structure: Disposable Medical Face Mask is composed of mask body (bottom layer, surface layer and middle layer), nose clip and mask earloop. The bottom layer and surface layer of the mask body are composed of non-manufacturing cloth, and the middle layer is composed of polypropylene melt blown. The nose clip is composed of aluminum strip and polypropylene material, and the mask earloop is woven of polyester and spandex or composed of non-woven.</p> <p>Application: This Disposable medical face mask is suitable for the wearer in the general medical environment where there is no risk of bodily fluids and spillage.</p> <p>Contraindications: Use with caution if you are allergic to nonwovens.</p> <p>Precautions, Warnings and Suggestive notes</p> <p>Before use, check whether the package is in good condition, confirm the</p> <p>2020/07/06</p>	<p>Item CM type 2R (12)</p> <p>external package identification, production date and validity period, and use it within the validity period.</p> <p>If the package is damaged before use.</p> <p>This product is disposable. Do not reuse it.</p> <p>Those who are allergic to non-woven should use it with caution. In case of allergy, please stop wearing it immediately.</p> <p>Please use the product as soon as possible after unpacking. Do not touch the inner side of the mask with your hands.</p> <p>Tolerance for the size of the product is $\pm 5\%$.</p> <p>Label Identification Sample</p> <p>Disposable Refer to instructions for use</p> <p>Instructions</p> <p>1. Take out the mask, face the face of the mask without the nose clip, and face up the side with the nose clip.</p> <p>2. Hang the mask belt on both ears respectively and adjust it to be comfortable.</p> <p>3. Open the folds of the mask up and down at the same time, so that the mask can completely cover the nose and chin.</p> <p>4. Place the index finger of both hands in the middle of the metal nose clip, and press inward from the middle to both sides according to the shape of the nose bridge until it is completely pressed into the shape of the nose bridge, so that the entire mask is attached to the face.</p> <p>Storage Method: The product should be stored in a cool, dry, corrosive gas free, well-ventilated and clean environment.</p> <p>Production Date: See the Printing Code</p> <p>Date of Preparation or Revision: June 11, 2020</p> <p>2020/07/06</p>
<p>Item CM type 2R (13)</p> <p>external package identification, production date and validity period, and use it within the validity period.</p> <p>If the package is damaged before use.</p> <p>This product is disposable. Do not reuse it.</p> <p>Those who are allergic to non-woven should use it with caution. In case of allergy, please stop wearing it immediately.</p> <p>Please use the product as soon as possible after unpacking. Do not touch the inner side of the mask with your hands.</p> <p>Tolerance for the size of the product is $\pm 5\%$.</p> <p>Label Identification Sample</p> <p>Disposable Refer to instructions for use</p> <p>Instructions</p> <p>1. Take out the mask, face the face of the mask without the nose clip, and face up the side with the nose clip.</p> <p>2. Hang the mask belt on both ears respectively and adjust it to be comfortable.</p> <p>3. Open the folds of the mask up and down at the same time, so that the mask can completely cover the nose and chin.</p> <p>4. Place the index finger of both hands in the middle of the metal nose clip, and press inward from the middle to both sides according to the shape of the nose bridge until it is completely pressed into the shape of the nose bridge, so that the entire mask is attached to the face.</p> <p>Storage Method: The product should be stored in a cool, dry, corrosive gas free, well-ventilated and clean environment.</p> <p>Production Date: See the Printing Code</p> <p>Date of Preparation or Revision: June 11, 2020</p> <p>2020/07/06</p>	<p>Item CM type 2R (14)</p> <p>external package identification, production date and validity period, and use it within the validity period.</p> <p>If the package is damaged before use.</p> <p>This product is disposable. Do not reuse it.</p> <p>Those who are allergic to non-woven should use it with caution. In case of allergy, please stop wearing it immediately.</p> <p>Please use the product as soon as possible after unpacking. Do not touch the inner side of the mask with your hands.</p> <p>Tolerance for the size of the product is $\pm 5\%$.</p> <p>Label Identification Sample</p> <p>Disposable Refer to instructions for use</p> <p>Instructions</p> <p>1. Take out the mask, face the face of the mask without the nose clip, and face up the side with the nose clip.</p> <p>2. Hang the mask belt on both ears respectively and adjust it to be comfortable.</p> <p>3. Open the folds of the mask up and down at the same time, so that the mask can completely cover the nose and chin.</p> <p>4. Place the index finger of both hands in the middle of the metal nose clip, and press inward from the middle to both sides according to the shape of the nose bridge until it is completely pressed into the shape of the nose bridge, so that the entire mask is attached to the face.</p> <p>Storage Method: The product should be stored in a cool, dry, corrosive gas free, well-ventilated and clean environment.</p> <p>Production Date: See the Printing Code</p> <p>Date of Preparation or Revision: June 11, 2020</p> <p>2020/07/06</p>
<p>Item CM type 2R (15)</p>	<p>Item CM type 2R (16)</p>

 <p>2020/07/06</p>	 <p>2020/07/06</p>
<p>Item CM type 2R (17)</p>	<p>Item CM type 2R (18)</p>
 <p>2020/07/06</p>	 <p>2020/07/06</p>
<p>Item CM type 2R (19)</p>	<p>Item CM type 2R (20)</p>
 <p>2020/07/06</p>	 <p>2020/07/06</p>
<p>Item CM type 2R (21)</p>	<p>Item CM type 2R (22)</p>

 <p>Product Name: Medical Surgical Mask Model: WKZ-P2 Registrant: Weihai Shengjie Medical Technology Co., Ltd Production License No.: MPA Production Permitted No. 20110058 Product Registration Certificate No.: MPA SD Medical Devices Registration Permitted 20192140160 Executive standard: YY 0469-2011 Batch number, production date and expiry date are printing on the packaging. Other contents are detailed in the instructions Storage Method: The product should be stored in a cool, dry, corrosive gas free, well-ventilated and clean environment. Manufacturer: Weihai Shengjie Medical Technology Co., Ltd Address: No. 58, Chuhe South Road, High-Tech Development Zone, Weihai, Shandong, China Website: www.whshengjie.com Tel: 0086-531-5679639 Caretechion GmbH Niederstr. 71, 40474, Dusseldorf, Germany</p> <p>2020/07/06</p>	 <p>Product Name: Medical Surgical Mask Model: WKZ-P2 Registrant: Weihai Shengjie Medical Technology Co., Ltd Production License No.: MPA Production Permitted No. 20110058 Product Registration Certificate No.: MPA SD Medical Devices Registration Permitted 20192140160 Executive standard: YY 0469-2011 Batch number, production date and expiry date are printing on the packaging. Other contents are detailed in the instructions Storage Method: The product should be stored in a cool, dry, corrosive gas free, well-ventilated and clean environment. Manufacturer: Weihai Shengjie Medical Technology Co., Ltd Address: No. 58, Chuhe South Road, High-Tech Development Zone, Weihai, Shandong, China Website: www.whshengjie.com Tel: 0086-531-5679639 Caretechion GmbH Niederstr. 71, 40474, Dusseldorf, Germany</p> <p>2020/07/06</p>
<p>Item CM type 2R (23)</p>	<p>Item CM type 2R (24)</p>
 <p>DISPOSABLE MEDICAL FACE MASK+ EN 14683:2019 TYPE II R 50 Pcs Model C Made in China SIZE:17.5*9.5cm</p> <p>2020/07/06</p>	 <p>INSTRUCTIONS</p> <ol style="list-style-type: none"> 1. Take out the mask, keep the back of the mask without the nose clip, and face up the side with the nose clip. 2. Hang the mask belt on both ears respectively and adjust it to be comfortable. 3. Open the folds of the mask up and down at the same time, so that the mask can completely cover the nose and chin. 4. Place the index finger of both hands in the middle of the metal nose clip, and press inward from the middle to both sides according to the shape of the nose bridge until it is completely pressed into the shape of the nose bridge, so that the entire mask is attached to the face. <p>ATTENTION</p> <ol style="list-style-type: none"> 1. Ensure the packaging is complete before using. Do not use if the packaging is damaged. 2. Use the respirator within the validity period. 3. Disposable respirator, do not reuse. 4. In case of allergy, stop using immediately. 5. Discard the respirator according to the regulations of environmental protection department. <p>2020/07/06</p>
<p>Item CM type 2R (25)</p>	<p>Item CM type 2R (26)</p>
 <p>INSTRUCTIONS</p> <ol style="list-style-type: none"> 1. Take out the mask, face the face of the mask without the nose clip, and face up the side with the nose clip. 2. Hang the mask belt on both ears respectively and adjust it to be comfortable. 3. Open the folds of the mask up and down at the same time, so that the mask can completely cover the nose and chin. 4. Place the index finger of both hands in the middle of the metal nose clip, and press inward from the middle to both sides according to the shape of the nose bridge until it is completely pressed into the shape of the nose bridge, so that the entire mask is attached to the face. <p>ATTENTION</p> <ol style="list-style-type: none"> 1. Ensure the packaging is complete before using. Do not use if the packaging is damaged. 2. Use the respirator within the validity period. 3. Disposable respirator, do not reuse. 4. In case of allergy, stop using immediately. 5. Discard the respirator according to the regulations of environmental protection department. <p>2020/07/06</p>	 <p>2020/07/06</p>
<p>Item CM type 2R (27)</p>	<p>Item CM type 2R (28)</p>



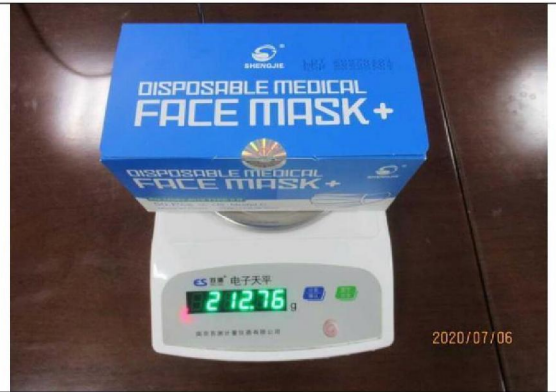




	
<p>2 carton dimension check</p>	<p>3 carton dimension check</p>
	
<p>4 carton dimension check</p>	<p>5 carton dimension check</p>
	
<p>6 carton dimension check</p>	<p>7 carton gross weight check</p>



8 carton gross weight check



9 color box gross weight check



10 color box dimension check



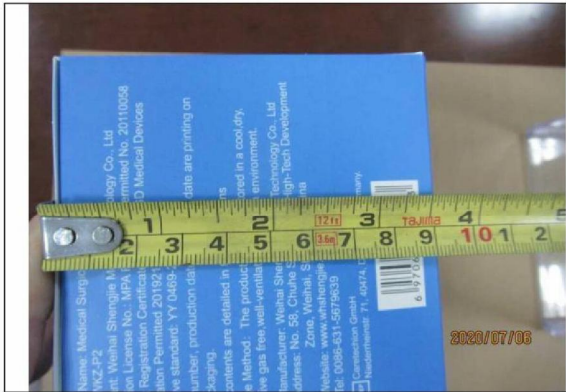
11 color box dimension check



12 color box dimension check



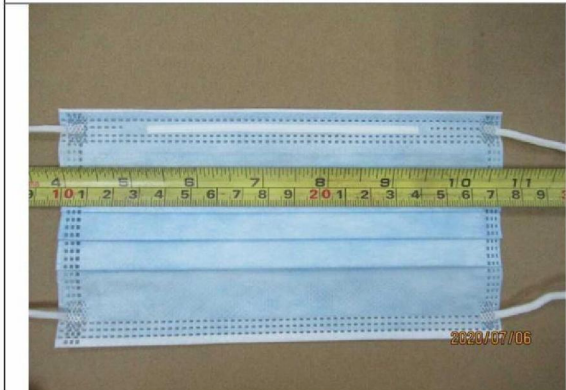
13 color box dimension check



14 color box dimension check



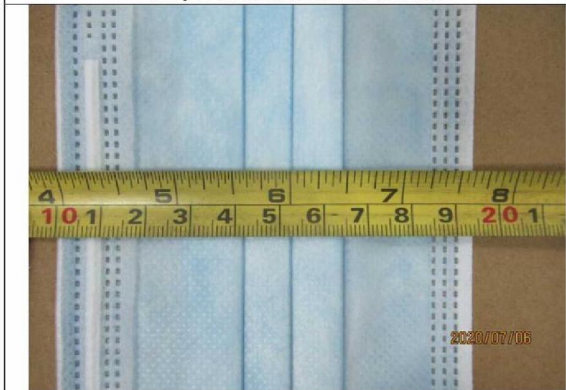
15 product weight check



16 product dimension check



17 product dimension check



18 product dimension check



19 product dimension check







32 synthetic blood penetration test



33 synthetic blood penetration test



34 synthetic blood penetration test



35 differential pressure test

威海盛洁医疗科技有限公司

日期	压力第1	压力第2	压力第3	压力第4	压力第5	平均值	备注
7/6	45.72	54.47	52.24	46.74	51.43	50.2	
	41.83	45.51	43.27	46.12	40.41	43.34	

2020/07/06

36 differential pressure test

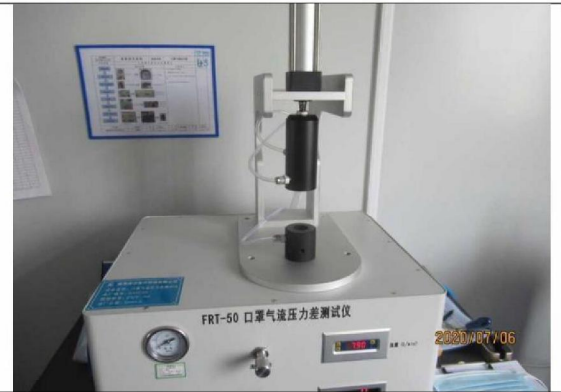


37 fire proof to melt-blown fabric test

<p>38 fire proof to melt-blown fabric test</p>	<p>39 GSM check</p>
<p>40 GSM check</p>	<p>41 GSM check</p>
<p>42 barcode readability check</p>	<p>43 barcode readability check</p>



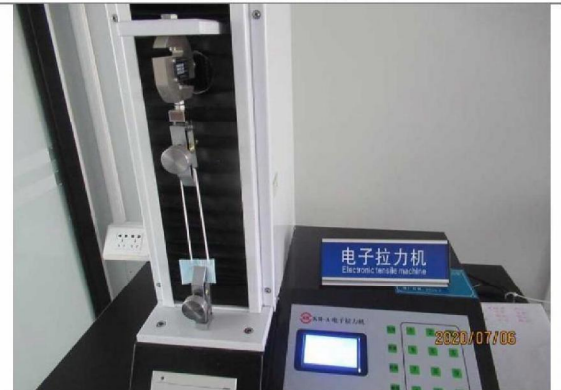
44 calibration certificate



45 calibration certificate



46 calibration certificate




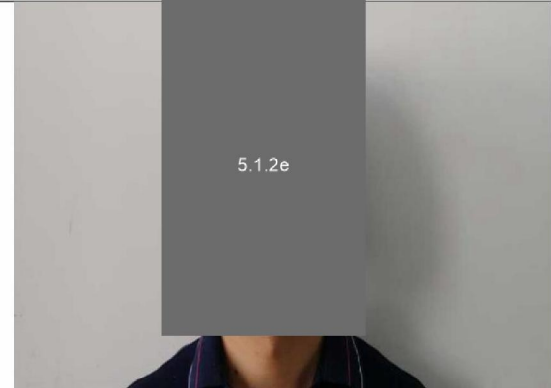

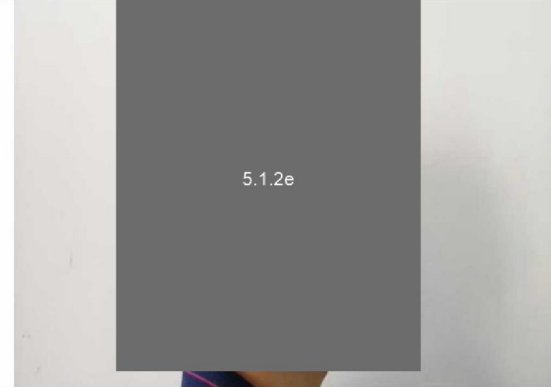
47 calibration certificate



48 calibration certificate



49 calibration certificate

	
<p>50 calibration certificate</p>	<p>51 wear check</p>
	
<p>52 wear check</p>	<p>53 wear check</p>

威海盛洁医疗科技有限公司

细菌过滤效率测试报告

编号: SJ-4/SOP-ZL-104-A/0

产品名称	Disposable Medical Face Mask	规格型号	Model C
产品批号	20070101	抽样数量	10pcs
样品状态	样品完好	检验类别	大货抽检
检测时间	2020.7.6~2020.7.8	检测依据	SJ-3/SOP-ZL-012-A/0

测试过程

1. 细菌悬浮液制备: 挑取一环金黄色葡萄球菌ATCC6538接种在适量胰蛋白胨大豆肉汤培养基中, 在 (37±2) °C 振荡培养 (24±2) h, 然后用1.5%的蛋白胨将上述培养物稀释至约5×10⁸cfu/ml.
2. 管路输出: 试验开始前首先检查一下系统管路是否连接正确, 确保管路没有漏气、堵气的地方.
3. 消毒: 在试管中加入适量70%酒精, 接入系统管路中, 进入“系统消毒”模式.
4. 打开检测仪的电源总开关, 打开控制面板上的电源开关按钮, 系统自动进入BSE控制系统初始界面. 打开仪器的照明灯和风机, 运行5min. 试验操作人员平坐或平站在仪器前方, 将双手分别放入手套内, 开始试验操作.
5. 培养: 正式试验结束后, 逐级取出培养皿并盖盖, 标记后倒置放入恒温培养箱中, 37 °C培养24h~48h.
6. 数据记录与统计: 培养结束后, 将培养皿取出, 使用菌落计数器进行计数, 并将每一级菌落数对应阳性孔转换表进行转换. 转换后的数据求和, 即得出总菌落数, 阳性孔转换范围应在 (2200±500) cfu之间.
7. 细菌过滤效率计算公式如下:
 $BFE = (C - T) / C \times 100\%$
 式中: C—阳性对照平均菌落数; T—试验组菌落总数.

	阳性对照 (A)	阳性对照 (B)	阴性对照	样品1#	样品2#	样品3#	样品4#	样品5#
1	49	62	0	0	0	0	0	0
2	113	80	0	0	0	0	0	0
3	150	160	0	0	0	0	0	0
4	460	400	0	4	2	1	1	6
5	670	820	0	5	3	8	10	7
6	905	780	0	6	8	9	6	6
总 (T), CFU	2347	2302	0	15	13	18	17	19
平均 (C), CFU	2325							
BFE%				99.16	99.21	99.23	99.27	99.18
要求				≥98%				

结论: 该样品按SJ-3/SOP-ZL-012-A/0《细菌过滤效率测试操作规程》检测, 检测结果合格.

检测人: 徐乐 日期: 2020.7.8 审批人: [Signature] 日期: 2020.7.8

威海盛洁医疗科技有限公司

初始污染菌检测报告

编号: SJ-4/SOP-ZL-079-A/0

产品名称	Disposable Medical Face Mask	规格型号	Model C
产品批号	20070101	抽样数量	10Pcs
样品状态	样品完好	检验类别	常规监控
检测时间	2020.7.6~7.8	检测依据	SJ-3/SOP-ZL-007-A/1

技术要求

检测结果	检测结果	单项判定
≤30cfu/g	6.7cfu/g	合格

结论: 该样品按SJ-3/SOP-ZL-007-A/1《初始污染菌检测操作规程》检测, 检测结果合格.

检测人: 徐乐 日期: 2020.7.8 审批人: [Signature] 日期: 2020.7.8

54 bacterial filtration efficiency test

威海盛洁医疗科技有限公司

初始污染菌检测原始记录

编号: SJ-4/SOP-ZL-066-A/0

试样名称	Disposable Medical Face Mask	规格型号	Model C
产品批号	20070101	抽样数量	10Pcs
检测依据	SJ-3/SOP-ZL-007-A/1 产品初始污染菌检测操作规程		

1. 供试液制备: 取待测产品, 根据产品特性的大小, 分别采用直接投入法或膜拭子擦拭法或冲洗法收集微生物. 制成1:10供试液. 保温于45°C水浴中5~10min, 并每隔一分钟振摇一次, 作为1:10的供试液.
2. 接种检验: 取上述供试液上清液作初始污染菌检测. 取4个培养皿, 每个稀释液各取1ml至每个灭菌平皿. 每个稀释液注2个平皿. 各稀释液平行做3份试样, 同时做阴性对照.
3. 培养: 将已经凝固的平板倒置于37°C培养箱中, 一般培养 48±2h. 计算平板上的细菌菌落数. 将已经凝固的平板倒置于20~25°C培养箱中, 一般培养 72±2h. 计算平板上的真菌菌落数.

检验结果

培养基名称	培养基名称	培养基名称	培养基名称	空白对照
1:10	1:10	1:100	1:100	1:100
细菌数	1#	2#	1#	2#
菌落	2	3	0	0
B	1	2	1	0
C	1	1	1	0
菌落均值	1.33	1.67	0.67	0.33
培养基名称	培养基名称	培养基名称	培养基名称	空白对照
1:10	1:10	1:100	1:100	1:100
菌落数	1#	2#	1#	2#
AD	0	0	0	0
BD	0	0	0	0
CD	0	0	0	0
菌落均值	0	0	0	0
菌落总数 (cfu/件次或g)	0.67×10 ⁶ / 10 = 6.7			

结论: 合格

检测人/日期: 徐乐 2020.7.8 复核人/日期: [Signature] 2020.7.8

55 microbial cleanliness test

NA

56 microbial cleanliness test

Inspector:	5.1.2e	Auditor:	5.1.2e
End of Report			