

Number: GZHT02286443-S1

Report Ref:	GZHT02286443-S1	THIS IS TO SUPERSEDE REPORT NO. GZHT02286443 DATED May 09, 2020	
Date Received:	Apr 29, 2020	Date Issued:	Jun 04, 2020

Company Name:	AS ARBEITSSCHUTZ GMBH
Address:	ROOM 3104, MINHANG PLAZA
	6088 HUMIN ROAD, SHANGHAI
Contact Name:	Brandy Tang

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:		
End Uses :	Non-Sterile Medical Face Mask	
Ratings :	Type IIR	
Sample Name :	3-Ply Face Mask	
Size :	-	
Colour :	Blue/White	
Standard :	EN 14683:2019+AC:2019	
Date received/ Test Started :	Apr 29, 2020	
Ref :	Style No. 4331	

Prepared And Checked By:

For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin

General Manager

qin / pennytao



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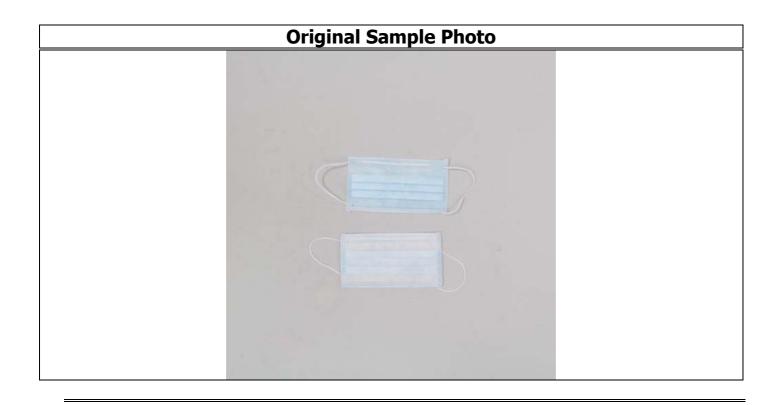
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## **Summary of testing:**

With reference to following standard:

EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type IIR

Materials Used in The Submitted Sample Were Found To Comply With The Type IIR Requirements of EN 14683:2019+AC:2019 with respect to Microbial Cleanliness, Bacterial Filtration Efficiency, Differential Pressure and Splash Resistance Pressure tests.

The tested component of the sample passes in Azocolourants Content Requirement with Reference to Annex XVII Item 43 and 72 of the REACH Regulation (EC) No. 1907/2006 & Its Amendments.

The tested components of the sample pass in Formaldehyde Content Requirement with Reference to Annex XVII Item 72 of REACH Regulation (EC) 1907/2006 and Its Amendment (EU) 2018/1513.

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Tests Conducted (As Requested By The Applicant)

#### 1 Microbial Cleanliness

As Per EN 14683:2019+AC:2019 Medical face masks-Requirements and test methods Annex D.

Toot Itom	Result ( cfu/g ) (1)					<u>Limit</u>
<u>Test Item</u>	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	<u>( cfu/g )</u>
Microbial cleanliness	28	22	26	25	27	Type IIR: ≤30

Remark:

cfu = Colony Forming Unit

 $\leq$  = Not More Than

Sample received condition: sample in closed plastic bag

**Tested Component:** 

(1) Blue / White Face Mask

2 Bacterial Filtration Efficiency (EN 14683:2019+AC:2019, Clause 5.2.2, Testing Refer To Annex B): Flow rate: 28.3L/min, Test area: 77 cm<sup>2</sup>, Test bacteria: Staphylococcus aureus ATCC 6538, Inside of the test mask was facing towards the challenge aerosol, The average plate count results of the positive controls: 2.7 X 10<sup>3</sup> CFU, The average plate count results of the negative controls: <1 CFU.

<u>Tested Sample</u>	Result (%)	<u>Performance</u>
		Requirement for
		<u>Medical Face Mask</u>
		<u>(%)</u>
		Type IIR : ≥ 98
Specimen (1)	99.2	
Specimen (2)	99.3	
Specimen (3)	99.3	
Specimen (4)	99.3	
Specimen (5)	99.3	

Remark: Test was conducted by external provider.

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Tests Conducted (As Requested By The Applicant)

3 Differential Pressure (EN 14683:2019+AC:2019 Annex C): Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm<sup>2</sup>.

Tested Sample	Result (Pa/cm²)	Performance Requirement for Medical Face Mask (Pa/cm²)
Specimen (1)	16.3	
Specimen (2)	18.9	Type IIR: < 60
Specimen (3)	13.4	
Specimen (4)	15.6	
Specimen (5)	16.9	
Average	16.2	

Remark: Test was conducted by external provider.

4 Detection of Amines Derived from Azocolourants and Azodyes:

By Gas Chromatographic - Mass Spectrometric (GC-MS) and High Performance Liquid Chromatographic Analysis (HPLC).

Test Method: EN ISO 14362-1: 2017 for Textile Material

EN ISO 17234-1: 2015 for Leather Material

EN ISO 14362-3: 2017 & EN ISO 17234-2: 2011 for p-Aminoazobenzene

<u>No.</u>	Forbidden Amine	Cas No.	<u>Resu</u>	<u>ult (mg/kg)</u>
			Method T	Method D
			(2)	(2)
1.	4-Aminodiphenyl	92-67-1	ND	ND
2.	Benzidine	92-87-5	ND	ND
3.	4-Chloro-o-Toluidine	95-69-2	ND	ND
4.	2-Naphthylamine	91-59-8	ND	ND
5.	o-Aminoazotoluene	97-56-3	ND	ND
6.	2-Amino-4-Nitrotoluene	99-55-8	ND	ND
7.	p-Chloroaniline	106-47-8	ND	ND
8.	2,4-Diaminoanisole	615-05-4	ND	ND
9.	4,4'-	101-77-9	ND	ND
	Diaminodiphenylmethane			

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10.	3,3'-Dichlorobenzidine	91-94-1	ND	ND
11.	3,3'-Dimethoxybenzidine	119-90-4	ND	ND
12.	3,3'-Dimethylbenzidine	119-93-7	ND	ND
13.	3,3'-Dimethyl-	838-88-0	ND	ND
	4,4'diaminodiphenylmethane			
14.	p-Cresidine	120-71-8	ND	ND
15.	4,4'-Methylene-Bis(2-	101-14-4	ND	ND
	Chloroaniline)			
16.	4,4'-Oxydianiline	101-80-4	ND	ND
17.	4,4'-Thiodianiline	139-65-1	ND	ND
18.	o-Toluidine	95-53-4	ND	ND
19.	2,4-Toluylenediamine	95-80-7	ND	ND
20.	2,4,5-Trimethylaniline	137-17-7	ND	ND
21.	2-Methoxyaniline	90-04-0	ND	ND
22.	4-aminoazobenzene	60-09-3	ND	ND
23.	2,4-Xylidine	95-68-1	ND	ND
24.	2,6-Xylidine	87-62-7	ND	ND
25.	4-chloro-o-toluidinium	3165-93-3	ND	ND
	chloride (detection by 4-			
	Chloro-o-toluidine)			
26.	2-Naphthylammoniumacetate	553-00-4	ND	ND
	(detection by 2-			
	Naphthylamine)			
27.	4-methoxy-m-phenylene	39156-41-7	ND	ND
	diammonium sulphate			
	(detection by 4-methyl-m-			
	phenylenediamine)			
28.	2,4,5-trimethylaniline	21436-97-5	ND	ND
	hydrochloride (detection by			
	2,4,5-trimethylaniline)			
	•			

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Tests Conducted (As Requested By The Applicant)

Remark: ND = Not Detected

Detection Limit = 5 mg/kg Client's Requirement = 30 mg/kg

Method T: Direct buffer extraction as per EN ISO 14362-1: 2017 Section 10.2

Method D: Colourant extraction with Xylene as per EN ISO 14362-1: 2017 Section 10.1

Method L: EN ISO 17234-1: 2015

The Result of Additional Amines (23-24) are Reported for Reference Only.

**Tested Component:** 

(2) Blue non-woven fabric (face)

5 Formaldehyde Content

With Reference to EN ISO 14184-1:2011, Followed by UV-Visible Spectrophotometer (UV-Vis).

<u>Tested Sample/Component</u> <u>Result (mg/kg)</u> <u>Requirement (mg/kg)</u>

(2+3+4) ND 75

Remark: Detection Limit = 16 mg/kg

ND = Not Detected

**Tested Components:** 

- (2) Blue non-woven fabric (face)
- (3) White non-woven fabric (lining)
- (4) White elastic string (strap)

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Tests Conducted (As Requested By The Applicant)

Splash Resistance Pressure (ISO 22609:2004): Synthetic Blood Surface Tension: 0.040 N/m, Distance Between Blow Head Front End And Target Area: 300 mm, Artificial Blood Volumes: 2 mL, Test Pressure: 16.0 kPa, Velocity: 550 cm/s, Use A Fixed Target.

Tested Sample	<u>Result (kPa)</u>	Performance Requirement for Medical Face Mask Type IIR: No penetration at 16.0 kPa
Specimen (1)	None seen	
Specimen (2)	None seen	
Specimen (3)	None seen	
Specimen (4)	None seen	
Specimen (5)	None seen	
Specimen (6)	None seen	
Specimen (7)	None seen	
Specimen (8)	None seen	
Specimen (9)	None seen	
Specimen (10)	None seen	
Specimen (11)	None seen	

None seen

None seen

Remark: Test was conducted by external provider.

End of Report

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Specimen (12)

Specimen (13)

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To: AS ARBEITSSCHUTZ GMBH

Attention: Brandy Tang Date: Jun 04, 2020

Re: Report Revision Notification

Labtest Report Number GZHT02286443 date MAY 09, 2020

Please be informed that all the content recorded in the above captioned report will be void. This captioned report is now superseded by a revised Labtest Report, Number GZHT02286443-S1 , issued on Jun 04, 2020 .

Thank you for your attention

Prepared And Checked By:

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