

Test Report

Number: GZHT02306194-S1

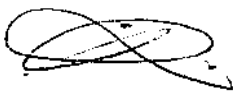
Report Ref:	GZHT02306194-S1	THIS IS TO SUPERSEDE REPORT NO. GZHT02306194 DATED Jul 06, 2020	
Date Received:	Jun 23, 2020	Date Issued:	Jul 10, 2020

Company Name:	
Address:	
Contact Name:	Wella Wu

Sample Description:	
The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
Sample Name	: Surgical Gown Material: SMMS
Size(s) Range	: -
Color	: Blue
Classifications Claimed	: Standard performance
End Uses	: Non-Sterile Surgical Gowns
Standard	: EN 13795-1:2019
Manufacturer	:
Country Of Original	:
Date received/ Test Started	: Jun 23, 2020
Date Final Information Confirmed	: -

Testing was conducted on specific items, at our client's request.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch



Lin Lin
General Manager



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WEN / hilaryxu

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Original Sample Photo



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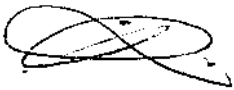
Conclusion:

Tensile Strength As Received	M
Bursting Strength As Received	M
Hydrostatic Head Test As Received	M
Cleanliness Microbial / Bioburden	M
Lint And Other Particles Generation In The Dry State	M
The Resistance To Dry Microbial Penetration (CFU)	M
The Resistance To Wet Bacterial Penetration	M

Note : M = Meet Standard's Requirement
= No Comment

F = Below Standard's Requirement
N/A = Not Applicable

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Tests Conducted (As Requested By The Applicant)

1 Tensile Strength As Received (EN 29073-3:1992, 5-cm Cut Strip Test, Tensile Testing Machine, CRE):

	Dry	Wet	<u>Requirement</u>
I. Fabric			
<u>Length Direction</u>			
Specimen 1	94.6 N	98.7 N	
Specimen 2	97.4 N	99.9 N	
Specimen 3	97.9 N	105.6 N	
Specimen 4	99.7 N	113.5 N	
Specimen 5	107.5 N	115.2 N	
Median (M _d)	97.9 N	105.6 N	
Lower Quartile Value (L _q)	97.4 N	99.9 N	≥20N
<u>Width Direction</u>			
Specimen 1	51.3 N	47.7 N	
Specimen 2	52.0 N	50.6 N	
Specimen 3	52.3 N	50.7 N	
Specimen 4	53.1 N	51.3 N	
Specimen 5	55.5 N	53.1 N	
Median (M _d)	52.3 N	50.7 N	
Lower Quartile Value (L _q)	52.0 N	50.6 N	20N
II. Seam			
<u>Parallel to seam</u>			
Specimen 1	91.8 N	93.4 N	
Specimen 2	95.6 N	101.4 N	
Specimen 3	97.7 N	105.8 N	
Specimen 4	115.2 N	129.3 N	
Specimen 5	115.7 N	129.9 N	
Median (M _d)	97.7 N	105.8 N	
Lower Quartile Value (L _q)	95.6 N	101.4 N	20N

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Tests Conducted (As Requested By The Applicant)

Perpendicular to seam

Specimen 1	24.9 N	27.7 N	
Specimen 2	25.6 N	28.0 N	
Specimen 3	25.7 N	30.4 N	
Specimen 4	26.3 N	34.5 N	
Specimen 5	40.9 N	35.6 N	
Median (M _d)	25.7 N	30.4 N	
Lower Quartile Value (L _q)	25.6 N	28.0 N	20N

Remark : N = Newton

- 2 Bursting Strength As Received (EN ISO 13938-1:1999, Mullen Type Burster, Modified Test Area, 30.5 mm Diameter):

	Dry	Wet	<u>Requirement</u> ≥ 40 kpa
Specimen 1	112.0 kpa	128.0 kpa	
Specimen 2	113.0 kpa	140.0 kpa	
Specimen 3	112.0 kpa	133.0 kpa	
Specimen 4	126.0 kpa	126.0 kpa	
Specimen 5	147.0 kpa	112.0 kpa	
Median (M _d)	113.0 kpa	128.0 kpa	
Lower Quartile Value (L _q)	112.0 kpa	126.0 kpa	

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Tests Conducted (As Requested By The Applicant)

3 Hydrostatic Head Test As Received (EN ISO 811:2018, Pressure Gradient At 10 cm/min Water Pressure):

	<u>Fabric</u>	<u>Requirement</u>
Specimen 1	> 20.0 cm H ₂ O	Critical Product Area ≥ 20 cm H ₂ O (Surgical Gown: Standard Performance Critical Product Area) (EN 13795-1:2019)
Specimen 2	> 20.0 cm H ₂ O	
Specimen 3	> 20.0 cm H ₂ O	
Specimen 4	> 20.0 cm H ₂ O	
Specimen 5	> 20.0 cm H ₂ O	
Median (M _d)	> 20.0 cm H ₂ O	
Lower Quartile Value (L _q)	> 20.0 cm H ₂ O	
	<u>Sleeve Seam</u>	<u>Requirement</u>
Specimen 1	> 20.0 cm H ₂ O	Critical Product Area ≥ 20 cm H ₂ O (Surgical Gown: Standard Performance Critical Product Area) (EN 13795-1:2019)
Specimen 2	> 20.0 cm H ₂ O	
Specimen 3	> 20.0 cm H ₂ O	
Specimen 4	> 20.0 cm H ₂ O	
Specimen 5	> 20.0 cm H ₂ O	
Median (M _d)	> 20.0 cm H ₂ O	
Lower Quartile Value (L _q)	> 20.0 cm H ₂ O	

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Tests Conducted (As Requested By The Applicant)

4 Cleanliness Microbial / Bioburden

As Per BS EN 13795-1:2019 Surgical Clothing And Drapes – Requirements And Test Methods Part 1: Surgical Drapes And Gowns And EN ISO 11737-1:2018 Sterilization Of Health Care Products – Microbiological Methods – Part 1: Determination Of A Population Of Microorganisms On Products.

Test Item	Result (CFU/100cm ²)					Limit (CFU/100cm ²)
	(1)					
	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	
Cleanliness microbial / Bioburden	87	44	40	64	95	≤300

CFU = Colony Forming Unit

≤ = Not more than

Tested Component:

(1) Surgical Gown Material SMS In Blue

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Tests Conducted (As Requested By The Applicant)

- 5 Lint And Other Particles Generation In The Dry State:
(EN ISO 9073-10:2004, Size Of Particles Counted: 3µm~25µm)
(EN ISO 9073-10:2004 Idt ISO 9073-10:2003)

Coefficient Of Linting:	<u>Material</u>	<u>Requirement</u>
A: Face		Coefficient Of Linting ≤4.0 (Surgical Gown: Standard Performance Critical Product Area) (EN 13795-1:2019)
1#	2.6	
2#	2.9	
3#	2.7	
4#	2.5	
5#	3.0	
B: Face		
1#	2.8	
2#	2.4	
3#	2.6	
4#	2.3	
5#	2.9	

Coefficient Of Linting:	<u>Sleeve Seam</u>	<u>Requirement</u>
A: Face		Coefficient Of Linting ≤4.0 (Surgical Gown: Standard Performance Critical Product Area) (EN 13795-1:2019)
1#	2.7	
2#	2.7	
3#	2.6	
4#	2.4	
5#	2.9	
B: Face		
1#	2.8	
2#	2.7	
3#	2.4	
4#	2.3	
5#	2.9	

Remark: The test was performed by an approved third party subcontractor laboratory.

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Tests Conducted (As Requested By The Applicant)

- 6 The Resistance To Dry Microbial Penetration (CFU):
 (EN ISO 22612:2005, The Fourth Generation Of Spores Of Bacillus Subtilis ATCC 9372, The Concentration Of The Spores: 1.9×10^8 CFU/G Talcum Powder, Sample:12, Vibration Frequency:20800 Times/Min, Vibration Time: 30 Min)

	<u>Material</u>	<u>Requirement</u>
1#	4	≤300
2#	4	(Surgical Gown: Standard
3#	2	Performance Less
4#	8	Critical Product Area)
5#	6	(EN 13795-1:2019)
6#	7	
7#	7	
8#	3	
9#	2	
10#	5	

	<u>Sleeve Seam</u>	<u>Requirement</u>
1#	3	≤300
2#	3	(Surgical Gown: Standard
3#	8	Performance Less
4#	8	Critical Product Area)
5#	7	(EN 13795-1:2019)
6#	2	
7#	12	
8#	8	
9#	12	
10#	4	

Remark: The test was performed by an approved third party subcontractor laboratory.

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- 7 The Resistance To Wet Bacterial Penetration:
(EN ISO 22610:2006, Temp:24.5°C, RH:56.0 %, The Distance Of Agar To Plates Brim:3 mm,
Carrier Material:30 µm Polyurethane (PU))

Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
Concentration of bacterium: 2.2 x 10⁴ CFU/ml

The Barrier Index:

	<u>Material</u>	<u>Requirement</u>
1#	4.4	The Barrier Index ≥2.8 (Surgical Gown: Standard Performance Critical Product Area) (EN 13795-1:2019)
2#	4.4	
3#	4.3	
4#	4.3	
5#	4.3	

The Barrier Index:

	<u>Sleeve Seam</u>	<u>Requirement</u>
1#	4.2	The Barrier Index ≥2.8 (Surgical Gown: Standard Performance Critical Product Area) (EN 13795-1:2019)
2#	4.2	
3#	4.2	
4#	4.3	
5#	4.3	

Remark: The test was performed by an approved third party subcontractor laboratory.

End of Report

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To :
Attention : Wella wu Date : Jul 10, 2020

Re : Report Revision Notification
Labtest Report Number GZHT02306194 date JUL 06, 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 GZHT02306194-S1 , issued on Jul 10, 2020 .

Thank you for your attention

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin
General Manager

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