

# ZIBO EASTMED HEALTHCARE PRODUCTS CO LTD

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## Sterile Latex Surgical Gloves

# Certificate of Analysis

Product Name		Powder Latex Surgical Gloves	Product Standard		EN455-1, -2-3-4
Lot No.		20200706	Type, Size		7.5#
Mfg date		20200706	Exp. Date		20250705
Lot Quantity		100000pairs	Sample Quantity		50 pairs
Sampling		06-07-20~18-07-20	Test Date		12-07-20~19-07-20
Sampler		Mike Lee	Identifier		Mike Lee
Test Item		Index	Test Level	Test Result	Result
Before Aging	Force at break	≥9 N	S-2 AQL 4.0	12.25~14.0, 0/13	Pass
	Tensile Strength (Mpa)	≥24 Mpa	S-2 AQL 4.0	24.5~28, 0/13	Pass
	Ultimate elongation	≥750%	S-2 AQL 4.0	780-840,0/13	Pass
	Stress at 500 % elongation	≤5.5Mpa	S-2 AQL 4.0	4.2-4.8,0/13	Pass
Aged	Force at break	≥9 N	S-2 AQL 4.0	10.2~13.0, 0/13	Pass
	Ultimate elongation	≥560%	S-2 AQL 4.0	630-680,0/13	Pass
	Tensile Strength (Mpa)	≥18Mpa	S-2 AQL 4.0	19-23,0/13	Pass
7.5#	<b>Length</b>	≥270 mm	S-2 AQL 4.0	273~276, 0/13	Pass
	<b>Width</b>	95±5mm	S-2 AQL 4.0	93~99, 0/13	Pass
	<b>Finger Thickness</b>	≥0.1mm	S-2 AQL 4.0	0.36~0.39, 0/13	Pass
	<b>Palm Thickness</b>	≥0.1mm	S-2 AQL 4.0	0.27~0.32, 0/13	Pass
	<b>Cuff Thickness</b>	≥0.1mm	S-2 AQL 4.0	0.22~0.27, 0/13	Pass
	<b>Weight</b>	≥9.g	S-2 AQL 4.0	9~9.5,0/13	pass
<b>Leachable Protein</b>		≤200µg/dm <sup>2</sup>	3 pcs	80.0 µg/dm <sup>2</sup>	Pass
<b>Freedom from holes</b>			G-1 AQL1.5	0/50	Pass
<b>Labeling</b>			S-2 AQL 1.5	0/50	Pass
<b>POWDER RESIDUE</b>			≤2mg	0.5-1 mg	pass
<b>sterilize result</b>			N-5		Pass
<b>Biological Test</b>			Non-Irritation to Rabbit's Skin and Non-sensitization to Guinea Pig's Skin.		
<b>Determinant Compliance</b>			<b>This lot conforms to the requirements established by the specifications of EN455-1, EN455-2,EN 455-3,ASTM D412 ,ASTM D573, ASTMD5712, ASTMD6124, ASTMD 3577-09</b>		

David Qiu

Approved By \_\_\_\_\_  
David Qie/ QC Dept.

