

## SHIPMENT INSPECTION REPORT

MANUFACTURER	SENTIENX SDN.BHD										
PRODUCT	FINESIS ZERO FLEXYLON										
DESCRIPTION	Sterile Surgical Gloves Powder Free										
DATE :	23 <sup>rd</sup> November 2022										
PURCHASE ORDER NO :	06/22/SU/TG										
LOT NO.	01543160, 01543165, 01543170, 01543175, 01543180, 01543185, 01543190										
MANUFACTURING DATE :	2022-10-27										
EXPIRY DATE :	2025-10-26										
Sizes breakdown	6	6.5	7	7.5	8	8.5	9	9.5	Total		
Quantities (in pairs)	600	3000	2000	2000	2000	1000	600	N/A			11,200

  

<b>A. Water Leaks Test (according to EN 455-1)</b>											
Inspection level : G1 ; AQL 0.1 ; Double sampling plan according to ISO 2859-1											
No. of gloves tested	7	34	22	22	11	7	N/A			125	
No. of defect gloves (pinholes)	0	2	0	0	1	0	N/A			2	
<b>B. Major defects (cuts, tears)</b>											
Total defects (A+B)	0	0	0	0	0	0	N/A			0	
Accepted :	0										
<b>C. Minor defects</b>											
Inspection level : G1 ; AQL 4.0 ; Double sampling plan according to ISO 2859-1											
No. of gloves tested	7	34	22	22	11	7	N/A			125	
No. of defect gloves	0	0	1	0	0	1	N/A			3	
Accepted :	10										
Total conclusion by QC : <i>DEVI</i> Approved by : <i>DEVI</i> Date : 23 NOV 2022											

  

<b>D. Dimension in mm</b>											
According to EN 455-2 ; n = 13 pcs per size											
Width in mm (minimum measured in this lot)	80	86	92	99	105	111	116			N/A	
Length in mm (specification min 285 mm ± 5 mm)	290	285	297	297	296	297	295			N/A	
Double-wall thickness (specification min 0.20 mm)											
- Finger (mm), minimum	0.22	0.22	0.22	0.22	0.22	0.22	0.22			N/A	
- Palm (mm), minimum	0.20	0.20	0.20	0.20	0.20	0.20	0.20			N/A	
- Cuff (mm), minimum	0.19	0.19	0.19	0.19	0.19	0.19	0.19			N/A	
According to EN 455-2 ; Median of 13 pcs											
<b>E1. Physical Properties</b>											
Force at break (N), unaged, Median, min. 9 N	16.4	16.3	16.6	16.4	13.5	16.9	14.5			N/A	
Force at break (N), aged, Median, min. 9 N	15.9	16.5	16.3	17.1	17.2	16.5	14.7			N/A	
According to ASTM D 3577 ; Inspection level S 2 ; AQL 4.0											
<b>E2 Physical Properties</b>											
Tensile Strength (Mpa), unaged, min. 18 Mpa	22.7	18.9	20.9	22.3	22.0	20.5	19.2			N/A	
Elongation at break in %, unaged, min. 700%	1020	862	990	922	1030	907	905			N/A	
Tensile Strength (Mpa), aged, min. 14 Mpa	20.4	21.2	20.4	21.2	20.8	19.7	22.7			N/A	
Elongation at break in %, aged, min. 500%	841	873	871	850	891	941	874			N/A	
Following ASTM D 3577 no Talcum (Magnesiumsilicate)											
<b>F. Biocompatibility</b>											
pH – inside the glove, Median, spec. 7.5 ± 1.0)	7.51	7.51	7.50	7.40	7.50	7.40	7.30			N/A	
Residual powdered (specification max. 2.0 mg/glove) method ASTM D 6124	0.60	0.80	0.77	0.76	0.65	0.65	0.75			N/A	
Protein content (µg/g) according to EN 455-3 modified Lowry method mean (specification: 20 max µg/g)	N/A	N/A	N/A	N/A	N/A	N/A	N/A			N/A	
Total conclusion by LAB : <i>DEVI</i> Approved by : <i>DEVI</i> Date : 24 NOV 2022											

  

Remarks for summary :		Released by QA : <i>DEVI</i> Date : 24 NOV 2022	
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