

**SHIPMENT INSPECTION REPORT**

MANUFACTURER	SENTIENX SDN.BHD									
PRODUCT	FINESIS ZERO FLEXYLON									
DESCRIPTION	Sterile Surgical Gloves Powder Free									
DATE :	23 <sup>th</sup> November 2022									
PURCHASE ORDER NO. :	06/22/SU/JG									
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	22	11	7	N/A	125	
No. of defect gloves (pinholes)	0	2	0	0	1	1	0	N/A	2	
<b>B. Major defects (cuts, tears)</b>										
Total defects (A+B)	0	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	22	11	7	N/A	125	
No. of defect gloves	0	0	1	0	1	0	1	N/A	3	
Accepted :	10									

Total conclusion by QC : **DEVI** Approved by : **DEVI** 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	N/A	
Length in mm (specification min 285 mm ± 5 mm)	290	285	297	297	296	297	295	N/A	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	N/A	
- Palm (mm), minimum	0.20	0.20	0.20	0.20	0.20	0.20	0.20	N/A	N/A	
- Cuff (mm), minimum	0.19	0.19	0.19	0.19	0.19	0.19	0.19	N/A	N/A	

<b>E1. Physical Properties</b>										
According to EN 455-2 ; Median of 13 pcs										
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	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	N/A	

<b>E2 Physical Properties</b>										
According to ASTM D 3577 ; Inspection level S 2 ; AQL 4.0										
Tensile Strength (Mpa), unaged, min. 18 Mpa	22.7	18.9	20.9	22.3	22.0	20.5	19.2	N/A	N/A	
Elongation at break in %, unaged, min. 700%	1020	862	990	922	1030	907	905	N/A	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	N/A	
Elongation at break in %, aged, min. 500%	841	873	871	850	891	941	874	N/A	N/A	

<b>F. Biocompatibility</b>										
Following ASTM D 3577 no Talcum (Magnesiumsilicate)										
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	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	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							

Total conclusion by LAB : **DEVI** Approved by : **DEVI** Date : 24 NOV 2022

Remarks for summary : **DEVI** Released by QA : **DEVI** Date : 24 NOV 2022

