

SHIPMENT INSPECTION REPORT

MANUFACTURER	TERANG NUSA SDN.BHD.										
PRODUCT	SENSIFLEX PLUS										
DESCRIPTION	Latex Surgical Gloves Powderfree										
DATE :	06 June 2019										
PURCHASE ORDER NO :	02/19/SU/AD										
LOT NO.	3483155,3483160, 3483165, 3483170, 3483175, 3483180, 3483185 & 3483190										
MANUFACTURING DATE :	2019-05										
EXPIRY DATE :	2024-04										
Sizes breakdown	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	Total	
Quantities (in pairs)	10,000	40,000	64,000	100,000	92,000	52,000	24,000	10,000	N/A	392,000	

A. Water Leaks Test (according to EN 455-1)	Inspection level : G1 ; AQL 0.65 ; Double sampling plan according to ISO 2859-1										
No. of gloves tested	13	51	62	128	117	66	30	13	N/A	500	
No. of defect gloves (pinholes)	1	1	1	1	2	1	1	0	N/A	8	
B. Major defects (cuts, tears)											
Total defects (A+B)	1	1	1	1	2	1	1	0	N/A	8	
Accepted :	14										
C. Minor defects	Inspection level : G1 ; AQL 4.0 ; Double sampling plan according to ISO 2859-1										
No. of gloves tested	8	32	52	80	74	42	19	8	N/A	315	
No. of defect gloves	1	3	2	2	2	2	1	2	N/A	15	
Accepted :	21										

Total conclusion by QC : 4 Approved by : 4 Date : 6/06/2019

D. Dimension in mm	According to EN 455-2 ; n = 13 pcs per size										
Width in mm (minimum measured in this lot)	74	80	86	92	98	105	110	116	N/A		
Length in mm (specification min. 295 mm)	295	295	297	297	296	298	297	298	N/A		
Double-wall thickness											
- Finger (mm), specification	0.46	0.46	0.46	0.48	0.48	0.46	0.48	0.48	N/A		
- Palm (mm), specification	0.42	0.42	0.42	0.42	0.42	0.42	0.42	0.42	N/A		
- Cuff (mm), specification	0.34	0.34	0.34	0.36	0.36	0.36	0.36	0.36	N/A		
E1. Physical Properties	According to EN 455-2 ; Median of 13 pcs										
Force at break (N), unaged, Median, min. 12 N	16.4	16.5	16.8	16.8	16.3	16.9	16.5	16.9	N/A		
Force at break (N), aged, Median, min. 11 N	15.6	15.8	15.9	15.9	15.6	15.6	15.7	15.8	N/A		
E.2 Physical Properties	According to ASTM D 3577 ; Inspection level S 2 ; AQL 4.0										
Tensile Strength (Mpa), unaged, min. 24 Mpa	29.9	30.1	28.4	28.7	29.3	29.0	29.5	29.2	N/A		
Elongation at break in %, unaged, min. 750%	968	958	979	925	952	957	942	925	N/A		
Tensile Strength (Mpa), aged, min. 18 Mpa	29.1	29.1	28.2	28.4	28.9	28.7	28.9	29.0	N/A		
Elongation at break in %, aged, min. 560%	924	916	939	917	916	914	912	915	N/A		
F. Biocompatibility	Following ASTM D 3577 no Talcum (Magnesiumsilicate)										
pH – inside the glove, Median, spec. 7.5 ± 1.0)	7.50	7.50	7.40	7.50	7.50	7.50	7.50	7.50	N/A		
Residual powdered (specification max. 2.0 mg/glove) method ASTM D 6124	0.20	0.40	0.40	0.20	0.40	0.40	0.40	0.20	N/A		
Protein content (µg/g) according to EN 455-3, med. Lowry (specification: max 20 µg/g)	9	9	2	5	8	9	9	8	N/A		

Total conclusion by LAB : 4 Approved by : 4 Date : 6/06/2019
Gloves are complaint with: EN 455-1,2,3,4

Remarks for summary :

TERANG NUSA SDN BHD
 Kota Bharu, Kelantan
 Malaysia
 Date : 6/06/2019
 Released by QA : 6