

SHIPMENT INSPECTION REPORT

MANUFACTURER	TERANG NUSA SDN.BHD.									
PRODUCT	NUZONE X2									
DESCRIPTION	Synthetic Surgical Gloves Powderfree									
DATE :	29 May 2019									
PURCHASE ORDER NO :	01/19/SU/AD									
LOT NO.	3483055, 3483060, 3483065, 3483070, 3483075, 3483080, 3483085& 3483090									
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)	2,000	24,000	52,000	84,000	62,400	44,000	24,000	8,000	N/A	300,400

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	3	40	87	140	104	73	40	13	N/A	500
No. of defect gloves (pinholes)	0	0	0	3	2	2	0	0	N/A	7
B. Major defects (cuts, tears)										
Total defects (A+B)	0	0	0	3	2	2	0	0	N/A	7
Accepted :	14									
C. Minor defects										
Inspection level : G1 ; AQL 4.0 ; Double sampling plan according to ISO 2859-1										
No. of gloves tested	2	25	55	88	66	46	25	8	N/A	315
No. of defect gloves	0	0	2	0	2	3	3	0	N/A	10
Accepted :	21									
Total conclusion by QC :										
Approved by :										Date : 29/5/2019

D. Dimension in mm										
According to EN 455-2 ; n = 13 pcs per size										
Width in mm (minimum measured in this lot)	73	80	86	91	96	106	110	116	N/A	
Length in mm (specification min. 295 mm)	296	297	297	296	297	298	297	298	N/A	
Double-wall thickness										
- Finger (mm) , specification	0.46	0.44	0.44	0.44	0.44	0.46	0.46	0.46	N/A	
- Palm (mm) , specification	0.38	0.36	0.36	0.36	0.38	0.38	0.36	0.38	N/A	
- Cuff (mm) , specification	0.32	0.32	0.32	0.32	0.34	0.34	0.32	0.34	N/A	
E1. Physical Properties										
According to EN 455-2 ; Median of 13 pcs										
Force at break (N), unaged, Median, min. 11N	14.1	14.2	14.2	14.4	14.7	14.2	14.2	14.4	N/A	
Force at break (N), aged, Median, min. 9 N	13.2	13.7	13.6	13.2	13.5	13.6	13.3	13.2	N/A	
E.2 Physical Properties										
According to ASTM D 3577 ; Inspection level S 2 ; AQL 4.0										
Tensile Strength (Mpa), unaged, min. 17 Mpa	26.6	25.7	25.0	25.5	23.8	25.5	25.2	26.4	N/A	
Elongation at break in %, unaged, min. 650%	912	920	916	912	917	926	918	922	N/A	
Tensile Strength (Mpa), aged, min. 12 Mpa	25.8	24.4	23.9	24.4	23.1	24.7	24.6	25.7	N/A	
Elongation at break in %, aged, min. 490%	901	905	902	901	905	912	906	911	N/A	
F. Biocompatibility										
Following ASTM 3577 no Talcum (Magnesiumsilicate)										
pH – inside the glove, Median (spec. 7.5 ± 1.0)	7.50	7.50	7.50	7.50	7.50	7.60	7.50	7.50	N/A	
Residual powdered (specification max.2.0 mg/glove) method ASTM D 6124	0.20	0.20	0.40	0.20	0.20	0.40	0.40	0.40	N/A	
Protein content (µg/g) according to EN 455-3, modified Lowry method mean (specification: N/A)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	

Total conclusion by LAB :
Gloves are complaint with: EN 455-1,2,3,4

Date : 29/5/2019

Remarks for summary :

Released by QA :



Date : 29/5/2019