

SHIPMENT INSPECTION REPORT

MANUFACTURER	TERANG NUSA SDN.BHD.									
PRODUCT	MAXITEX NEURO PF									
DESCRIPTION	Latex Surgical Gloves Powderfree									
DATE :	29 July 2019									
PURCHASE ORDER NO :	04/18/SU/AD									
LOT NO.	3510355, 3510360, 3510365, 3510370, 3510375, 3510380, 3510385 & 3510390									
MANUFACTURING DATE :	2019-07									
EXPIRY DATE :	2024-06									
Sizes breakdown	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	Total	
Quantities (in pairs)	2,000	20,000	56,000	40,000	34,600	20,000	10,000	10,000	10,000	192,600

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	33	92	65	57	33	16	16	16	315
No. of defect gloves (pinholes)	0	0	0	0	2	1	0	0	0	3

B. Major defects (cuts, tears)										
Total defects (A+B)	0	0	0	0	2	1	0	0	0	3
Accepted :	10									

C. Minor defects	Inspection level : G1 ; AQL 4.0 ; Double sampling plan according to ISO 2859-1									
No. of gloves tested	3	33	92	65	57	33	16	16	16	315
No. of defect gloves	0	1	0	0	1	0	0	0	1	3
Accepted :	21									

Total conclusion by QC : Approved by :  Date : 08/08/2019

D. Dimension in mm	According to EN 455-2 ; n = 13 pcs per size									
Width in mm (minimum measured in this lot)	75	80	86	92	96	105	110	115		
Length in mm (specification min. 295 mm)	295	299	300	298	299	295	300	300		
Double-wall thickness										
- Finger (mm), specification	0.34	0.36	0.34	0.36	0.34	0.36	0.36	0.36	0.36	0.36
- Palm (mm), specification	0.32	0.32	0.33	0.32	0.32	0.34	0.34	0.34	0.34	0.33
- Cuff (mm), specification	0.30	0.32	0.32	0.32	0.32	0.32	0.32	0.32	0.32	0.30

E1. Physical Properties	According to EN 455-2 ; Median of 13 pcs									
Force at break (N), unaged, Median, min. 11 N	14.1	14.8	14.2	14.8	14.4	14.1	14.8	14.2		
Force at break (N), aged, Median, min. 9 N	13.6	13.9	13.7	13.9	13.6	13.4	13.7	13.8		
E.2 Physical Properties	According to ASTM D 3577 ; Inspection level S 2 ; AQL 4.0									
Tensile Strength (Mpa), unaged, min. 24 Mpa	25.4	24.8	28.8	29.2	29.8	27.1	29.5	27.5		
Elongation at break in %, unaged, min. 750%	912	926	937	919	921	937	960	925		
Tensile Strength (Mpa), aged, min. 18 Mpa	23.8	22.9	26.3	26.8	26.8	25.8	27.6	26.9		
Elongation at break in %, aged, min. 560%	905	911	920	907	910	925	932	912		

F. Biocompatibility	Following ASTM D 3577 no Talcum (Magnesiumsilicate)									
pH – inside the glove, Median, (spec. 7.5 ± 1.0)	7.55	7.60	7.81	7.62	7.45	7.30	7.42	7.48		
Residual powdered (specification max. 2.0 mg/glove) method ASTM D 6124	0.20	0.30	0.40	0.40	0.20	0.40	0.20	0.40		
Protein content (µg/g) according to EN 455-3, modified Lowry method mean (specification: max.20 µg/g)	17	15	11	17	12	14	15	12		

Total conclusion by LAB : Approved by :  Date : 08/08/2019

Gloves are complaint with: EN 455-1,2,3,4