




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	192,600		

A. Water Leaks Test (according to EN 455-1)											
No. of gloves tested	3	33	92	65	57	33	16	16	Inspection level : G1 ; AQL 0.65 ; Double sampling plan according to ISO 2859-1		
No. of defect gloves (pinholes)	0	0	0	0	2	1	0	0	315		
B. Major defects (cuts, tears)											
Total defects (A+B)	0	0	0	0	2	1	0	0	3		
Accepted : 10											
C. Minor defects											
No. of gloves tested	3	33	92	65	57	33	16	16	Inspection level : G1 ; AQL 4.0 ; Double sampling plan according to ISO 2859-1		
No. of defect gloves	0	1	0	0	1	0	0	1	315		
Accepted : 21											
Total conclusion by QC : Approved by :  Date : 08/08/2019											

D. Dimension in mm											
Width in mm (minimum measured in this lot)	75	80	86	92	96	105	110	115	According to EN 455-2 ; n = 13 pcs per size		
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			
- Palm (mm), specification	0.32	0.32	0.33	0.32	0.32	0.34	0.34	0.33			
- Cuff (mm), specification	0.30	0.32	0.32	0.32	0.32	0.30	0.32	0.30			
According to EN 455-2 ; Median of 13 pcs											
E1. Physical Properties											
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			
According to ASTM D 3577 ; Inspection level S 2 ; AQL 4.0											
E.2 Physical Properties											
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			
Following ASTM D 3577 no Talcum (Magnesiumsilicate)											
F. Biocompatibility											
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 :											
Gloves are complaint with: EN 455-1,2,3,4											
Approved by :  Date : 08/08/2019											

Remarks for summary :											
Released by QA :  Date : 08/08/2019											