

SHIPMENT INSPECTION REPORT

MANUFACTURER:	TERANG NUSA (MALAYSIA) SDN. BHD.									
PRODUCT:	MAXITEX ORTHO									
DESCRIPTION:	LATEX SURGICAL POLYMER POWDERFREE GLOVE (BROWN)									
DELIVERY DATE:	21 st November 2022									
PURCHASE ORDER NO.:	06/22/SU/TG									
LOT NO.:	01543165, 01543170, 01543175, 01543180 & 01543185									
MANUFACTURING DATE:	2022-10-27									
EXPIRY DATE (according to EN 455-4):	2027-10-26									
Sizes breakdown	5.5	6	6.5	7	7.5	8	8.5	9	Total	
Quantities (in pairs)	N/A	N/A	4,800	4,800	4,800	4,800	4,800	N/A	24,000	

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	N/A	N/A	40	40	40	40	40	N/A	200	
No. of defect gloves (pinholes)	N/A	N/A	0	0	0	0	0	N/A	0	
B. Major defects (cuts, tears)										
Total defects (A+B)	N/A	N/A	0	0	0	0	0	N/A	0	
Accepted :	3									
C. Minor defects	Inspection level : G1 ; AQL 4.0 ; Double sampling plan according to ISO 2859-1									
No. of gloves tested	N/A	N/A	40	40	40	40	40	N/A	200	
No. of defect gloves	N/A	N/A	0	0	0	0	0	N/A	0	
Accepted :	14									

Total conclusion by QC :  Approved by : _____ Date : 21/11/2022

D. Dimension in mm	According to EN 455-2 ; n = 13 pcs per size									
Width in mm (minimum measured in this lot)	N/A	N/A	85	90	97	104	111	N/A		
Length in mm (specification 295 mm ± 5 mm)	N/A	N/A	295	293	296	297	290	N/A		
Double-wall thickness (specification min 0.20 mm)										
- Finger (mm), minimum	N/A	N/A	0.61	0.60	0.58	0.60	0.55	N/A		
- Palm (mm), minimum	N/A	N/A	0.55	0.58	0.54	0.54	0.52	N/A		
- Cuff (mm), minimum	N/A	N/A	0.43	0.44	0.44	0.43	0.41	N/A		

E1. Physical Properties
According to EN 455-2 ; Median of 13 pcs

Force at break (N), unaged, Median, min. 9 N	N/A	N/A	17.77	20.01	20.53	21.96	16.78	N/A		
Force at break (N), aged, Median, min. 9 N	N/A	N/A	17.18	20.56	17.53	21.11	12.64	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	N/A	N/A	25.9	25.7	25.8	28.0	27.2	N/A		
Elongation at break in %, unaged, min. 750%	N/A	N/A	766	757	760	797	807	N/A		
Tensile Strength (Mpa), aged, min. 18 Mpa	N/A	N/A	27.1	24.8	22.5	25.8	24.3	N/A		
Elongation at break in %, aged, min. 560%	N/A	N/A	731	668	699	685	673	N/A		

F. Biocompatibility
Following ASTM D 3577 no Talcum (Magnesiumsilicate)

pH – inside the glove, Median, spec. 7.5 ± 1.0)	N/A	N/A	7.20	7.28	7.24	7.32	7.33	N/A		
Powder residues (mg/glove) according to EN-455-3 (specification max. 2.0 mg/glove)	N/A	N/A	0.92	0.12	0.3	0.28	0.26	N/A		
Protein content (µg/g) according to EN 455-3 modified Lowry method mean (specification: 30 max µg/g)	N/A	N/A	6.98	6.26	19.98	10.05	27.46	N/A		

Total conclusion by LAB: _____ Approved by :  Date : 21/11/2022
Gloves are compliant with: EN 455-1,2,3,4

Remarks for summary : _____
Released by QA :  TERANG NUSA (MALAYSIA) SDN. BHD.
Date : 21/11/2022