

SHIPMENT INSPECTION REPORT

MANUFACTURER:	TOP GLOVE SDN. BHD.					
PRODUCT:	GLOVTEC EXT BLUE (PPE&MDR)					
DESCRIPTION:	Examination Gloves Powder free (Blue)					
DELIVERY DATE:	22 nd June 2021					
PURCHASE ORDER NO.:	01/21/EX/TG					
LOT NO.:	142283S, 142283M, 142283L, 142283XL,					
MANUFACTURING DATE :	2021-05					
EXPIRE DATE (according to EN 455-4):	2026-04					
Sizes breakdown	Extra-Small	Small	Medium	Large	X-Large	Total
Quantities (in pcs)	N/A	70,000	400,000	430,000	280,000	1,180,000

A. Water Leaks Test (according to EN 455-1)	Inspection level: GI ; AQL 1.5 ; Single sampling plan according to ISO 2859-1					
No. of gloves tested	N/A	30	169	182	119	500
No. of defect gloves (pinholes)	N/A	3	6	2	2	13
B. Major defects (cuts, tears)						
No. of defects gloves (cuts, tears)	N/A	0	0	0	0	0
Total defects (A+B)	N/A	3	6	2	2	13
Accepted :	14					
C. Minor defects	Inspection level: GI ; AQL 4.0 ; Single sampling plan according to ISO 2859-1					
No. of gloves tested	N/A	19	107	114	75	315
No. of defect gloves	N/A	0	4	5	2	11
Accepted :	21					
Total conclusion by QC:	Approved by: Nisallini			Date: 22 nd June 2021		

D. Dimension in mm	According to EN 455-2 ; n = 13 pcs per size					
Width in mm (minimum measured in this lot)	N/A	86	94	106	115	
Specification (± 5 mm)						
Length in mm (specification min. 290 mm)	N/A	295	297	297	298	
Single-wall thickness (specification min.0.10 mm)						
- Finger (mm) , minimum	N/A	0.14	0.15	0.15	0.16	
- Palm (mm), minimum	N/A	0.09	0.10	0.11	0.12	
- Cuff (mm), minimum	N/A	0.08	0.08	0.08	0.08	
E1. Physical Properties	According to EN 455-2 ; Median of 13 pcs					
Force at break (N), unaged, Median, min. 6 N	N/A	6.5	6.1	6.3	6.8	
Force at break (N), aged, Median, min. 6 N	N/A	6.6	6.3	6.4	6.9	
E.2 Physical Properties	According to ASTM D 6319; Inspection level S 2; AQL 4.0					
Tensile Strength (Mpa), unaged, min. 14 Mpa	N/A	N/A	N/A	N/A	N/A	
Elongation at break in %, unaged, min. 500%	N/A	N/A	N/A	N/A	N/A	
Tensile Strength (Mpa), aged, min 14 Mpa	N/A	N/A	N/A	N/A	N/A	
Elongation at break in %, aged, min. 400%	N/A	N/A	N/A	N/A	N/A	
F. Biocompatibility	Following ASTM D 6319 no talcum (Magnesiumsilicate)					
pH – inside the glove, Median, spec. 7.5 ± 1.0)	N/A	6.93	6.44	6.57	6.73	
Powder residues (mg/glove) according to EN-455-3 (specification max. 2.0 mg/glove)	N/A	0.29	0.32	0.33	0.35	
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	

Total conclusion by LAB: Gloves are compliant with: EN 455-1,2,3,4	Approved by: Nisallini	Date: 22 nd June 2021
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mark for summary:	Release by QA: Mr. Wong	Date: 22 nd June 2021
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