Product Specification for	Microflex Ultraform UF-524	Doc. Ref. No.	PS-UF-524/DG
		Revision No.	00
		Revision Date	19 Nov 2024

Product Name and Style #

Product Name (brand) and Equivalent(s)	Style #	Base/Equivalent/PL	Region and/or Countries
1.1 Microflex Ultraform	UF-524	Base	N. America
1.2 Micro-Touch Micro-Thin Nitrile	313014	Equivalent	N. America

2. Product Description /Attributes

Product Category/Structure	Disposable
Product Grade	Medical
Material	Nitrile
Powdering	Powder Free
Glove Design	Ambidextrous
Fingers Design	Straight fingers
Color	Cobalt Blue Pantone: 072C
Texture	Outer/application surface: Fingertips textured
Cuff	Beaded
Inner Surface Treatment/Coating	Online: Chlorination Chlorine concentration, ppm: 500 – 1200ppm Offline: Not applicable
Outer Surface Treatment/Coating	Online: Powder Free Coagulant Offline: Not applicable
Sterility	Non-sterile
Shelf Life	3 years

3. Product Compliant

Manufacturing Quality System	ISO 13485 and ISO 9001	
Product Regulations and Standard (s) **current version*	☒ ASTM: D6319 ☐ Health Canada ☐ ISO: Not applicable ☐ AS/NZS: Not applicable ☐ JIS: Not applicable ☐ GB: Not applicable ☐ EAC ☐ SIRIM ☐ TGA MD CE marked product only: ☐ MD Regulation (EU) 2017/745 ☐ EN 455-1,2,3 ☐ EN 455-4 PPE CE Marked product only: ☐ PPE Regulation (EU) 2016/425 ☐ EN ISO 21420 / EN 420 ☐ EN 421 ☐ EN 388 ☐ EN ISO 374-1 Type A ☐ EN ISO 374-1 Type B ☐ EN ISO 374-1 Type C ☐ EN ISO 374-5 ☐ EN ISO 374-5 VIRUS ☐ ISO 18889 ☐ UKCA	☒ REACH ☒ California Proposition 65 ☒ FDA 21CFR177.2600 ☐ Regulation (EC) 1935/2004 (materials to come into contact with food) ☐ Regulation (EC) 2023/2006 (GMP for materials to come into contact with food) ☐ UL NFPA 1999 ☒ Chemotherapy Drugs ASTM D6978 ☒ Biocompatibility – ISO 10993-10 Skin Sensitization ☒ Biocompatibility – ISO 10993-23 Skin Irritation ☒ Biocompatibility – ISO 10993-5 In-Vitro cytotoxicity ☒ Viral Penetration ASTM F1671 ☐ Viral Penetration ISO 16604 ☒ Bioburden – ISO 11737 ☐ Anti-static – EN 1149 *(refer to 5.11)* ☐ EUDR ☐ Others:
Additional Compliant **current version* *(to be completed & confirmed by PPM and RA)*	☒ US Ergonomics ☐ Low Dermatitis Claim ☐ Low Protein Claim ☐ Low Endotoxin Claim ☐ Silicone free / Silicone free (not monitored) ☐ Compostable	☐ Others:
US FDA 510(k) #	K202536	Owned by manufacture partner
US FDA MDL #	D454053	Owned by manufacture partner

4. Manufacturing Ingredient List/Formulation

Component /Function	Chemical Name	CAS #
Base Material-Elastomers	Acrylonitrile-butadiene methacrylic acid copolymer	9010-81-5
pH Adjuster/Stabilizer	Ammonia Hydroxide	1336-21-6
	Potassium Hydroxide	1310-58-3
Crosslinker	Zinc Oxide	1314-13-2
Secondary Crosslinker	Sulphur	7704-34-9
Vulcanization accelerators	Zinc Diethyl Dithiocarbamate	14324-55-1
	Zinc Dibutyl Dithiocarbamate	136-23-2
Surfactant	Sodium Alkyl Benzenesulfonate	68411-30-3
	Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt	9084-06-4
Antioxidant	Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene	68610-51-5
Defoamer	Distillates (Petroleum), Hydrotreated Light Paraffinic Oil	64742-55-8
Functional Additive	Hydrated Aluminium Silicate	1332-58-7
Base Pigment	Titanium Dioxide	13463-67-7
Blue Pigment	Copper Phthalocyanine Blue	147-14-8
	Carbazole Violet	6358-30-1

5. Product Quality Requirements

Parameters	Requirements	Sampling Plan & Test Method (TM) [ISO 2859: Single-Normal]	Final Release Criteria
5.1 DIMENSION			
Glove Length, mm	Min: 230 Max: 260	S-2, AQL 4.0 *TM: D6319 & D3767*	Yes
Single-wall Thickness, mm			Yes
Finger	Target: 0.10 Tolerance: ± 0.03		
Palm	Target: 0.06 Tolerance: -0.01/+0.02		
Cuff	Target: 0.06 Tolerance: ± 0.02		
Palm Width, mm			Yes
☒ Ambidextrous / ☐ Hand Specific			
XXS 5.5	Target: N/A Tolerance: N/A		
XS 6.0	Target: 76 Tolerance: ± 4		
XS/S -	Target: 81 Tolerance: ± 3		
S 6.5	Target: 85 Tolerance: ± 4		
S/M -	Target: 91 Tolerance: ± 3		
M 7.0	Target: 95 Tolerance: ± 4		
M/L -	Target: 101 Tolerance: ± 3		
L 7.5	Target: 105 Tolerance: ± 4		
XL 8.0	Target: 115 Tolerance: ± 4		
XXL 8.5	Target: N/A Tolerance: N/A		
XXXL 9.0	Target: N/A Tolerance: N/A		
9.5			
Glove Weight, g/pc*		N=13 *for monitoring purpose only	No
☒ Ambidextrous / ☐ Hand Specific			
XXS 5.5	Target: N/A Tolerance: N/A		
XS 6.0	Target: 2.3 Tolerance: ± 0.3		
XS/S -	Target: TBD Tolerance: TBD		
S 6.5	Target: 2.6 Tolerance: ± 0.3		
S/M -	Target: TBD Tolerance: TBD		
M 7.0	Target: 2.9 Tolerance: ± 0.3		
M/L -	Target: TBD Tolerance: TBD		
L 7.5	Target: 3.2 Tolerance: ± 0.3		
XL 8.0	Target: 3.6 Tolerance: ± 0.3		
XXL 8.5	Target: N/A Tolerance: N/A		
XXXL 9.0	Target: N/A Tolerance: N/A		
9.5			
Cuff Bead Thickness, mm	N/A	S-2, AQL 4.0 *TM: ISO 11193 & 23529*	N/A

Untreated Band Width, mm	N/A	Sampling plan *TM: -*	N/A

Product Quality Requirements (continue)

Parameters		Requirements	Sampling Plan & Test Method (TM) [ISO 2859: Single-Normal]	Final Release Criteria
5.2 PHYSICAL PROPERTIES				
☒ ASTM	Tensile Strength, MPa Before Aging After Aging	 Min: 14 Min: 14	S-2, AQL 4.0 *TM: D412 & D573 Die-C*	Yes
	Ultimate Elongation, % Before Aging After Aging	 Min: 500 Min: 400		Yes
	Stress at 500% Elongation, MPa Before Aging *(NRL glove only)*	Max: N/A		N/A
	Modulus 300%, MPa Before Aging *(Synthetic latex glove only)*	Max: 8.0		Yes
☐ EN 455	Force at Break, N Before Aging *(fresh)* After Aging *(after challenge test)*	 Min: N/A Min: N/A	EMEA & ANZ only: N=13; Accept 1 Reject 2 *TM: EN 455-2 Die-D*	N/A
☐ ISO	Force at Break, N Before Aging After Aging	 Min: N/A Min: N/A	S-2, AQL 4.0 TM: ISO37 Die Type 2	N/A
	Elongation at Break, % Before Aging After Aging	 Min: N/A Min: N/A		N/A
	Force at 300% Elongation, N Before Aging	Max: N/A		N/A
☐ NFPA	Ultimate Elongation, % After IPA immersion *Acceptance criteria when tested by UL & Ansell*	Min: N/A	S-2, AQL 4.0 *TM: D412 & D573 Die-C*	N/A
5.3 BARRIER DEFECTS				
Freedom from Holes (AQL) **1000ml Watertight*		Barrier Defects	G-I, AQL 1.5 or sample size code letter 'L' per ISO 2859 in the case where sample size is < 200 pcs *TM: D5151 & EN455-1, EN 374-2 (for PPE only)*	Yes
5.4 VISUAL APPEARANCE				
Visual Inspection - Glove		Critical Defects Major Defects Minor Defects	G-I, AQL 1.0 G-I, AQL 2.5 G-I, AQL 4.0 *TM: OSQA-WI-001*	Yes Yes Yes
Visual Inspection - Packing & Packaging		Critical Defects Major Defects Minor Defects	Accept No Defect, AND G-I, AQL 2.5 G-I, AQL 4.0 *TM: OSQA-WI-002*	Yes Yes Yes
5.5 PROTEIN, POWDER RESIDUE AND MICROBIAL CLEANLINESS				
ASTM - Total Aqueous Extractable Protein Content, µg/dm^2 **NRL glove only*		N/A	N=3 *TM: D5712*	N/A
EN455-3 Leachable Protein, µg/g **NRL glove only*		N/A	N=8 *TM: EN 455-3*	N/A
Powder Free Residue, mg/glove **PF glove only*		Max. 2	N=5 *TM: D6124 & EN 455-3*	Yes
Powder Content, mg/dm^2 **Powdered glove only*		N/A	N=2 *TM: D6124 & EN 455-3*	N/A
Antigenic Protein, µg/mL **NRL glove only*		N/A	N=1 *TM: D6499*	N/A
Microbial cleanliness - bioburden		*TBD*	*TM: ANSI/AAMI/ISO 11737-1*	No

		*At least annual monitoring by factory	
Endotoxin, EU/pair *for sterile glove with low endotoxin claim only*	N/A	*TM: EN 455-3*	N/A

5.6 CHEMICAL PERMEATION EN ISO 374-1	☒ Not applicable		
L - Sulfuric Acid 96%, BTT (minutes)	N/A	*TM: EN 16523-1* *This parameter will be monitored and maintained by Ansell*	N/A
K - Sodium Hydroxide 40%, BTT (minutes)	N/A		N/A
P - Hydrogen Peroxide 30%, BTT (minutes)	N/A		N/A
T – Formaldehyde 37%, BTT (minutes)	N/A		N/A
N - Acetic Acid 99%, BTT (minutes)	N/A		N/A
5.7 CHEMOTHERAPY DRUGS	☐ Not applicable		
Carboplatin 10.0mg/ml	BTT > 240 minutes	*TM: ASTM D6978* *As per US FDA 510(k) approval letter & test report*	No
Carmustine (BCNU) 3.3mg/ml	BTT: 15 minutes		No
Cisplatin 1.0mg/ml	BTT > 240 minutes		No
Cyclophosphamide (Cytoxan) 20.0mg/ml	BTT > 240 minutes		No
Dacarbazine (DTIC) 10.0mg/ml	BTT > 240 minutes		No
Doxorubicin Hydrochloride 2.0mg/ml	BTT > 240 minutes		No
Etoposide (Toposar) 20.0mg/ml	BTT > 240 minutes		No
Fluorouracil 50.0mg/ml	BTT > 240 minutes		No
Ifosfamide 50.0mg/ml	BTT > 240 minutes		No
Methotrexate 25.0mg/ml	BTT > 240 minutes		No
Mitomycin C 0.5mg/ml	BTT > 240 minutes		No
Mitoxantrone 2.0mg/ml	BTT > 240 minutes		No
Paclitaxel (Taxol) 6.0mg/ml	BTT > 240 minutes		No
Thiotepa 10.0mg/ml	BTT: 30.1 minutes		No
Vincristine Sulfate 1.0mg/ml	BTT > 240 minutes		No
Fentanyl citrate	BTT > 240 minutes		No
5.8 FOOD MIGRATION Regulation (EC) 1935/2004	☒ Not applicable		
Distilled Water, mg/dm²	N/A	Test condition in 2 hours 40°C *TM: EN 1186* *This parameter will be monitored and maintained by Ansell*	N/A
Ethanol at 15%, mg/dm²	N/A		N/A
Acetic acid at 3%, mg/dm²	N/A		N/A
Ethanol at 96%, mg/dm²	N/A		N/A
Olive Oil, mg/dm²	N/A		N/A
Ethanol 10%, mg/dm²	N/A	Test condition 10 minutes 40°C *TM: EN 1186* *This parameter will be monitored and maintained by Ansell*	N/A
Acetic acid 3%, mg/dm²	N/A		N/A
Ethanol at 95%, mg/dm²	N/A		N/A
Olive Oil, mg/dm²	N/A		N/A
5.9 CLEANLINESS *for cleanroom gloves only*	☒ Not applicable		
Liquid Particle Count, count/cm² (0.5micron & above)	N/A	N=2 *TM: IEST-RP-CC-005*	N/A
Trace Elements, µg/cm²: Bromide, Br Calcium, Ca Chloride, Cl Fluoride, F Magnesium, Mg Nitrate, NO_3 Phosphate, PO_4 Potassium, K Sodium, Na Sulfate, SO_4 Ammonium, NH_4	N/A		N/A
Silicone Oil, Amide & DOP via FTIR	N/A		N/A
Non-Volatile Residue, mg/g	N/A		N/A
Helmke Drum, total particles>0.3µ	N/A		N/A
Electrostatic Decay (ESD), seconds	N/A	N=2 *TM: FTMS No. 101-C 404*	N/A
Surface Resistivity, ohms/square	N/A	N=2 *TM: ASTM D257*	N/A

5.10 STERILE PRODUCT only	☒ Not applicable		
Dye test	N/A	N=13/size *TM: ASTM F1929-12*	N/A
Seal Strength	N/A	*TM: ISO 11607*	N/A
Sterility	N/A	*TM: ISO 11737-2*	N/A

Product Quality Requirements (continue)

5.11 OTHERS			
White Residue upon IPA rubs*	Max. Level 3	N=4 *TM: OSQA-WI-003*	No
Foaming Test*	Max. Level 3	N=4 *TM: OSQA-WI-004*	No
Odour Test (abnormal odour that deviates from its origin)	Passed	*1 dispenser from each sampled carton* *TM: manual smell test - open the packaging from the side, place the packaging opening near nose and waft the air toward your nose/face, try not to breathe in the air through your nose, but bring in just enough to make sense of the smell.*	Yes
Durability Test*	N/A	N=4 *TM: OSQA-WI-005*	N/A
Grip Test*	N/A	*TM: -*	N/A
Donning Test*	Passed	*TM: -*	No
pH*	N/A	*TM: EN ISO 21420 / EN 1413*	N/A
AZO dyes for colored gloves*	N/A	*TM: EN 14362-1*	N/A
Surface Resistivity*	N/A	*TM: EN 1149-1*	N/A
Charge Decay T_{50} *	N/A	*TM: EN 1149-3*	N/A
Surrogate Mix/Pesticide surrogate, Max. cumulative permeation of disperse yellow in 60 minutes test per ISO 18889 *	N/A	*TM: ISO 19918*	N/A
Formaldehyde*	N/A	MYK 4.1.2111-06 *(Russia only)*	N/A
Moisture Content*	N/A	*TM: -*	N/A
**These parameters are monitored & maintained by Ansell.*			

5.12 SPECIAL MANUFACTURING / MISC REQUIREMENTS	
5.12.1	N/A

6. Packing Configuration and Packaging Specification

Product Name (brand) and Equivalent (s)	Style #	Packing Configuration & Packaging Specification
6.1 Microflex Ultraform	UF-524	Refer to Attachment 1
6.2 Micro-Touch Micro-Thin Nitrile	313014	Refer to Attachment 2

7. Identification and Traceability - Finished Good LOT and BATCH Numbering System

☒ Exam/Life Science	LOT Number	YYMMFF (in 6 digits) Where, YY = year of manufacture/packing MM = month of manufacture/packing FF = the Factory/Origin Code as assigned by Ansell	The LOT # shall be printed/stamped/ink-jetted on each dispenser and carton
	BATCH Number	YYMMXXXXFF (in 10 digits) Where, YY = year of manufacture/packing MM = month of manufacture/packing XXXX = ID as assigned by the manufacturing factory FF = the Factory/Origin Code as assigned by Ansell	The BATCH # shall be printed/stamped/ink-jetted on each dispenser and carton
Note: - The Batch # shall be unique for each product/brand, shipment and/or destination. - Any violation that result in product return and/or recall, the factory shall be responsible for all related cost incurred.			

8. Pre-Shipment QA Controls / Final Release

Certificate of Analysis (COA)	☐ Not applicable
	COA is required for every shipment/lot. For sterile products, Certificate of Irradiation is required for every shipment/lot. EUDR - For product that contain natural rubber latex only and for EMEA only, NRL traceability information for each shipment shall be provided (by uploading to the designated system), and approval shall be obtained prior to ship.
Pre-shipment Samples	☐ Not applicable
	Pre-shipment samples* are required for the first ☒ 1 ☐ 3 ☐ 5 shipments.
NPD/Product Change	☐ Not applicable
	Onsite inspection for the first ☐ 1 ☐ 3 ☒ 5 shipments.
Packaging Change (spec, material, dimension, regulatory)	☐ Not applicable
	Onsite inspection for the first 1 shipment.

Attachment 1: Packing Configuration and Packaging Specification

Product Name	Microflex Ultraform UF-524
Specifics	• Labeling claim/Pictogram: US Ergonomics, Chemo • ASTM D6319

1. Product Identification Numbers

Size	Internal #	External #	Peel Pouch / Unit Pack GTIN #	Dispenser GTIN #	Shipper Case GTIN #
Commercial Pack:					
XS	876246	UF-524-XS	N/A	00769799524103	00769799524004
XS/S	876243	UF-524-XSS	N/A	10076490066052	20076490066059
S	876247	UF-524-S	N/A	00769799524110	00769799524011
S/M	876244	UF-524-SM	N/A	10076490066069	20076490066066
M	876248	UF-524-M	N/A	00769799524127	00769799524028
M/L	876245	UF-524-ML	N/A	10076490066076	20076490066073
L	876249	UF-524-L	N/A	00769799524134	00769799524035
XL	876250	UF-524-XL	N/A	00769799524141	00769799524042
Sample Pack: ☒ Not applicable					
Mix Sizes					
Sample Box: ☒ Not applicable					

Size	Peel Pouch Net Weight, Kg	Peel Pouch Gross Weight, Kg	Dispenser Net Weight, Kg	Dispenser Gross Weight, Kg	Carton Net Weight, Kg	Carton Gross Weight, Kg
Commercial Pack:						
XS	N/A	N/A	0.60	0.69	7.79	8.26
XS/S	N/A	N/A	*TBD*	*TBD*	*TBD*	*TBD*
S	N/A	N/A	0.69	0.78	8.69	9.16
S/M	N/A	N/A	*TBD*	*TBD*	*TBD*	*TBD*
M	N/A	N/A	0.78	0.87	9.59	10.06
M/L	N/A	N/A	*TBD*	*TBD*	*TBD*	*TBD*
L	N/A	N/A	0.87	0.96	10.49	10.96
XL	N/A	N/A	0.81	0.90	9.89	10.36
Sample Pack: ☒ Not applicable						
Sample Box: ☒ Not applicable						

2. Packing Configuration and Labeling Requirements

Packing Configuration and Labeling Requirements	Count Tolerance
Commercial Pack	
☒ **Exam Boxed Gloves** ▪ 300 gloves per dispenser (size XS – L): Layer pack ▪ 250 gloves per dispenser (size XL): Layer pack ▪ 10 dispensers per carton: ☒ Vertical ☐ Horizontal ▪ Dispenser: Print/stamp lot#, batch#, MFG, EXP in the field provided. ▪ 2 labels per carton, to be stickered on the side panel in the field provided.	+/- 2 %
Sample Pack ☒ Not applicable	
▪ N/A	N/A
Sample Box ☒ Not applicable	
▪ N/A	N/A

Attachment 1 (continue)

3. Packaging Components, Material Specification and Artwork

Packaging Components	Packaging Material Specification – Material & Grammage	Packaging Material – Recyclable info & Dimension				
		Unit Weight, g	Surface Finishing	Type of Ink	Recycled Content %	Dimension (mm) L x W x H
Commercial Pack						
☐ Inner wallet	-	-	-	-	-	-
☐ Peel pouch	-	-	-	-	-	-
☒ Dispenser	450gsm recycled paper greyback	*TBD*	*TBD*	*TBD*	> 70	245 x 133 x 82
☒ Carton	Brown corrugated single-wall 275TL/M180/275TL BF	*TBD*	*TBD*	*TBD*	> 90	425 x 275 x 255
☐ Inner polybag	-	-	-	-	-	-
☐ Master polybag	-	-	-	-	-	-
☐ Intermediate liner	-	-	-	-	-	-
☐ Liner bag	-	-	-	-	-	-
☐ Divider	-	-	-	-	-	-
☐ Gamma irradiation indicator	-	-	-	-	-	-
Labels used:						
☐ Dispenser label	-	-	-	-	-	-
☒ Carton label	White adhesive label	*TBD*	*TBD*	*TBD*	*TBD*	152.4 x 101.6
☐ Traceability barcode label	-	-	-	-	-	-
☐ Inner polybag label	-	-	-	-	-	-
☐ Master polybag label	-	-	-	-	-	-
☐ IFU: N/A	-	-	-	-	-	-
☐ Mini IFU: N/A	-	-	-	-	-	-
Sample Pack	☒ Not applicable					
☐ Sample pack	-	-	-	-	-	-
☐ Re-sealable bag	-	-	-	-	-	-
☐ Divider	-	-	-	-	-	-
☐ Carton	-	-	-	-	-	-
☐ Carton label	-	-	-	-	-	-
Sample Box	☒ Not applicable					
☐ Sample box	-	-	-	-	-	-
☐ Carton	-	-	-	-	-	-
☐ Carton label	-	-	-	-	-	-

Packaging artwork: Please refer to Packaging Artwork Master List & Ansell Web Center (AWC) for the latest and approved artwork

4. Lot Number. Manufacture and Expiry Date coding

	Require?	Format	To be printed on:
Lot number	YES	Ansell's 6-digits Lot # and 10-digits Batch # format as described in Clause 7	Dispenser and carton
Manufacture Date	YES	YYYY-MM-DD	Dispenser and carton
Expiry Date	YES	YYYY-MM-DD	Dispenser and carton

5. Glove Marking (if any)

N/A

6. Special Instruction (if any)

Instruction on Manufacture & Expiry Date format:

- The MFG DATE (i.e. YYYY-MM-DD, on the packaging) will always be the 28th day of the previous month.

For example:

Production date /period	MFG Date (YYYY-MM-DD) to be printed on the packaging
From 1/Nov/2020 to 30/Nov/2020	2020-10-28
From 1/Dec/2020 to 31/Dec/2020	2020-11-28
& so on	& so on

MFG Date	Shelf Life	EXP Date (YYYY-MM-DD)			
		Year	Month	Day	Date to be printed on packaging
If MFG date is **2020-10-28**	3 years	Add 3 to the manufacture YEAR i.e. "2020" + 3 = 2023	Same as the manufacture MONTH i.e. "10"	It shall be the last day the full expiration period, so minus 1 from the manufacture DAY i.e. "28" – 1 =27	**2023-10-27**

End of Attachment 1

Attachment 2: Packing Configuration and Packaging Specification

Product Name	Micro-Touch Micro-Thin Nitrile 313014
Specifics	• Labeling claim/Pictogram: Chemo • ASTM D6319

1. Product Identification Numbers

Size	Internal #	External #	Peel Pouch / Unit Pack GTIN #	Dispenser GTIN #	Shipper Case GTIN #
Commercial Pack:					
XS	876251	6034310	N/A	20884792043100	30884792043107
S	876252	6034311	N/A	20884792043117	30884792043114
M	876253	6034312	N/A	20884792043124	30884792043121
L	876254	6034313	N/A	20884792043131	30884792043138
XL	876255	6034314	N/A	20884792043148	30884792043145
Sample Pack: ☒ Not applicable					
Mix Sizes					
Sample Box: ☒ Not applicable					

Size	Peel Pouch Net Weight, Kg	Peel Pouch Gross Weight, Kg	Dispenser Net Weight, Kg	Dispenser Gross Weight, Kg	Carton Net Weight, Kg	Carton Gross Weight, Kg
Commercial Pack:						
XS	N/A	N/A	0.60	0.69	7.79	8.26
S	N/A	N/A	0.69	0.78	8.69	9.16
M	N/A	N/A	0.78	0.87	9.59	10.06
L	N/A	N/A	0.87	0.96	10.49	10.96
XL	N/A	N/A	0.96	1.05	11.39	11.86
Sample Pack: ☒ Not applicable						
Sample Box: ☒ Not applicable						

2. Packing Configuration and Labeling Requirements

Packing Configuration and Labeling Requirements	Count Tolerance
Commercial Pack	
☒ **Exam Boxed Gloves** ▪ 300 gloves per dispenser (all sizes): Layer pack ▪ 10 dispensers per carton: ☒ Vertical ☐ Horizontal ▪ 1 label per dispenser, to be stickered on the side panel in the field provided. ▪ 2 labels per carton, to be stickered on 1 short panel and 1 long panel in the field provided.	+/- 2 %
Sample Pack ☒ Not applicable	
▪ N/A	N/A
Sample Box ☒ Not applicable	
▪ N/A	N/A

Attachment 1 (continue)

3. Packaging Components, Material Specification and Artwork

Packaging Components	Packaging Material Specification – Material & Grammage	Packaging Material – Recyclable info & Dimension				
		Unit Weight, g	Surface Finishing	Type of Ink	Recycled Content %	Dimension (mm) L x W x H
Commercial Pack						
☐ Inner wallet	-	-	-	-	-	-
☐ Peel pouch	-	-	-	-	-	-
☒ Dispenser	450gsm recycled paper greyback	*TBD*	*TBD*	*TBD*	> 70	245 x 133 x 82
☒ Carton	Brown corrugated single-wall 275TL/M180/275TL BF	*TBD*	*TBD*	*TBD*	> 90	425 x 275 x 255
☐ Inner polybag	-	-	-	-	-	-
☐ Master polybag	-	-	-	-	-	-
☐ Intermediate liner	-	-	-	-	-	-
☐ Liner bag	-	-	-	-	-	-
☐ Divider	-	-	-	-	-	-
☐ Gamma irradiation indicator	-	-	-	-	-	-
Labels used:						
☒ Dispenser label	White adhesive label	*TBD*	*TBD*	*TBD*	*TBD*	45 x 95
☒ Carton label	White adhesive label	*TBD*	*TBD*	*TBD*	*TBD*	152.4 x 101.6
☐ Traceability barcode label	-	-	-	-	-	-
☐ Inner polybag label	-	-	-	-	-	-
☐ Master polybag label	-	-	-	-	-	-
☐ IFU: N/A	-	-	-	-	-	-
☐ Mini IFU: N/A	-	-	-	-	-	-
Sample Pack	☒ Not applicable					
☐ Sample pack	-	-	-	-	-	-
☐ Re-sealable bag	-	-	-	-	-	-
☐ Divider	-	-	-	-	-	-
☐ Carton	-	-	-	-	-	-
☐ Carton label	-	-	-	-	-	-
Sample Box	☒ Not applicable					
☐ Sample box	-	-	-	-	-	-
☐ Carton	-	-	-	-	-	-
☐ Carton label	-	-	-	-	-	-

Packaging artwork: Please refer to Packaging Artwork Master List & Ansell Web Center (AWC) for the latest and approved artwork

4. Lot Number. Manufacture and Expiry Date coding

	Require?	Format	To be printed on:
Lot number	YES	Ansell's 6-digits Lot # and 10-digits Batch # format as described in Clause 7	Dispenser and carton
Manufacture Date	YES	YYYY-MM-DD	Dispenser and carton
Expiry Date	YES	YYYY-MM-DD	Dispenser and carton

5. Glove Marking (if any)

N/A

6. Special Instruction (if any)

Instruction on Manufacture & Expiry Date format:

- The MFG DATE (i.e. YYYY-MM-DD, on the packaging) will always be the 28th day of the previous month.

For example:

Production date /period	MFG Date (YYYY-MM-DD) to be printed on the packaging
From 1/Nov/2020 to 30/Nov/2020	2020-10-28
From 1/Dec/2020 to 31/Dec/2020	2020-11-28
& so on	& so on

MFG Date	Shelf Life	EXP Date (YYYY-MM-DD)			
		Year	Month	Day	Date to be printed on packaging
If MFG date is **2020-10-28**	3 years	Add 3 to the manufacture YEAR i.e. "2020" + 3 = 2023	Same as the manufacture MONTH i.e. "10"	It shall be the last day the full expiration period, so minus 1 from the manufacture DAY i.e. "28" – 1 =27	**2023-10-27**

End of Attachment 2

Appendix 1

APPROVAL:

Function	Name	Signature	Date
Product Portfolio Management	Isabelle Degraeve		
Regulatory Affairs (Medical)	Samantha Marshall		
Quality Assurance	Tan Yuin Ru		
Project Management	Victoria Erickson		
R&D (Ansell Design only)	Not applicable	-	-
Operations (in house product only)	Not applicable	-	-

REVISION HISTORY:

Originator/Reviser	Description of Change	Change Control # *(if applicable)*	Revision #	Revision Date
ST Chang	• Product specifications created for new manufacturing source (referenced from PS-313017/DF, Rev 05). • Updated the internal #, dispenser & carton dimension for this source.	CR-02640	00	19 Nov 2024

Appendix 2

Manufacturing Partner Approval

MANUFACTURING CHANGE CONTROL:

Manufacturer/supplier shall ensure that the products are manufactured to the same formulation (component materials), process flow and process control parameters against master sample approved by Ansell and in accordance with "Release/Acceptance" Criteria. No changes of any nature may be made without prior notification to and the written consent /approval of Ansell. A sampling plan and a 60 days buffer period is required before actual implementation of all approved changes unless waived by Ansell.

NOTE: Parameters identified as "Release/Acceptance Criteria" must be measured by the supplier as per the Sampling Plans specified.

PRODUCT VARIATION:

As per basic quality control protocol, it shall be the general understanding that the products are to be manufactured to the target/nominal parameters stipulated. Fluctuation is understood and acknowledged, but not to the extent that the majority, if not all, of the product falls near the limits of the tolerance.

COMPLAINT HANDLING:

All customer complaints referred to the manufacturer/supplier by Ansell shall be treated with the utmost of urgency. Complaint investigations are expected to be completed within required days of notification unless otherwise approved by Ansell. Replies must include root cause analysis, containment action, corrective/preventive action plan and effective date(s). The manufacturer/supplier is also expected to measure and monitor the effectiveness of corrective measures and to take further action as warranted. Ansell shall be so notified in that event.

By signing, the Manufacturing Partner agrees to the above-mentioned conditions

Manufacture Partner	Company Name: **YTY Industry (Manjung) Sdn. Bhd.** Address: **Lot 1422-1424, Batu 10 Lekir, Sitiawan, 32020 Perak Darul Ridzuan, Malaysia.** Factory/Origin code: **DG** Site code: **N/A**
Person Responsible /Management Representative	Name: VENGATESH Title: SENIOR MANAGER, QA Signature:
Date	