WRP
Your Partner In Protection™

DERMAGRIP®

Nitrile Examination Gloves

Powder Free

Nitrile

Ambidextrous

Finger Textured Surface

Key Features

No unpleasant odor

Chemotherapy tested

Beaded Cuff

Product Information

Reorder No.	D15xx-17
Material	Nitrile
Sizes	XS - XL
Length (mm)	240
Finger Thickness (mm)	0.16
Colour	Blue
Packing Mode	100pc/bx, 10 bx/cs

PRODUCT CONFORMANCE

- ASTM D6319
- Meets ASTM D6978 for Chemotherapy testing
- Medical Device: in compliance with MDR (EU)2017/745 (CE Class I)
- UK Medical Device Regulations 2002 Part II (UKCA Class IIa)
- EN 455: Part 1/2/3/4
- EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018, IS0 16604:2004
- Food Contact Compliance FDA 21 CFR 177.2600 & EU No. 10/2011

QUALITY ASSURANCE

- MDSAP-ISO 13485:2016 Quality Management System
- ISO 9001:2015 Quality Management System
- EN ISO 13485:2016
- ISO 14001:2015 Environmental Management System

MD MEDICAL DEVICE · MDR REGULATION (EU) 2017/745 · PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425 · CE 2797 · UK CA 0086 · ISO 374-1/ TYPE B KPT · USER INFORMATION · ISO 374-5:2016 VIRUS · USER INFORMATION

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SPECIFICATION SHEET

Product Name			Dermagrip Nitrile Powder Free Exam Gloves		
Reorder Number			D15xx-17		
Product Part Number			142xx.10231043		
Product Description					
Design and Feature			Ambidextrous, textured surface at fingers and beaded cuff		
Type			Powder free and non-sterile examination glove		
Material			Nitrile		
Colour			Blue (PMS 285)		
Surface Treatment			Chlorination on donning side		
Product Quality Requirement					
Dimension		Size	Target weight (g/pc)	Palm Width (mm)	Length (mm)
		XS	4.1 ± 0.3	≤ 80	Min. 240
		S	4.8 ± 0.3	80 ± 10	Min. 240
		M	5.5 ± 0.3	95 ± 10	Min. 240
		L	6.2 ± 0.3	110 ± 10	Min. 240
		XL	6.9 ± 0.3	≥ 110	Min. 240
			*Non-release criteria		
Single-wall Thickness (mm) *All sizes		Finger	Min. 0.14		
		Palm	Min. 0.10		
		Cuff	Min. 0.08		
Powder Residue (mg/glove)			≤ 2		
Physical Properties	Standard	Parameters	Before Aging	After Aging	
	EN 455 Part 2	Force at break (N)	≥ 9	≥ 6	
	ASTM D6319	Tensile Strength (MPa)	Min. 14	Min. 14	
		Ultimate Elongation (%)	Min. 500	Min. 400	
Shelf life (upon manufacturing date)			5 years		
Glove Cuff Printing			No marking		
Packing configuration			100 gloves by weight and 10 dispensers per carton		
Pre-shipment Inspection *Single-Normal Sampling Plan	Standard/Parameters		EN 455 Part 1,2,3	ASTM D6319	
	Dimension		N=13, Median	S-2, AQL 4.0	
	Physical Properties		N=13, Median	S-2, AQL 4.0	
	1000ml Water Leak		G-I, AQL 1.5	G-I, AQL 1.5	
	Powder Residue		N=5	N=5	
	Visual Inspection (Major Defects)		G-I, AQL 2.5	G-I, AQL 2.5	
	Visual Inspection (Minor Defects)		G-I, AQL 4.0	G-I, AQL 4.0	
Product Conformance					
Medical Device			EU Compliance: MDR (EU) 2017/745 (CE Class I)	EN 455 Part 1,2,3,4	
			UK Compliance: UK Medical Device Regulations 2002 Part II (UKCA Class I)		
			US FDA: 510(k): K161422 MDL: D278303	ASTM D6319 ASTM D6978 – Tested for use with Chemotherapy Drugs	
Personal Protective Equipment			EU Compliance: PPE Regulation EU 2016/425 (PPE Cat.III)	EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016 & ISO 16604:2004	
			UK Compliance: Regulation 2016/425 on personal protective equipment, as amended to apply in GB		
Glove Marking			Medical Device: CE Class I PPE: CE 2797 & UKCA 0086		
Food Contact			FDA 21 CFR 177.2600 EU No. 10/2011		
Others			Health Canada Compliance		
Quality Assurance & Environment Management System					
• MDSAP ISO 13485:2016 Quality Management System • ISO 9001:2015 Quality Management System • EN ISO 13485:2016 Quality Management System – Regulatory Purpose • ISO 14001:2015 Environmental Management System					

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