PRODUCT INFORMATION SHEET

PROFEEL®
NR Latex Powder Free Surgical Gloves

Reorder #		Size: 5½ : P3155-21; 6 : P3160-21; 6½ : P3165-21; 7 : P3170-21; Size: 7½ : P3175-21; 8 : P3180-21; 8½ : P3185-21; 9 : P3190-21
Product Part #		312xx.992021
510K # / MDL #		K972621 / A632620
Design and Feature		Hand Specific, straight fingers, textured surface at palm and fingers area (SBS) and beaded cuff
Type		Powder free, chlorinated and Gamma-sterilized surgical gloves
Material		Natural rubber latex
Color		Natural
Surface Treatment		Chlorination (SBS)
Powder Free Residue (mg/glove)		0.5
Protein Content (µg/dm²)		24
Dimension - Palm Width (mm)		Size: 5½ : 73; 6 : 78; 6½ : 84; 7 : 90; Size: 7½ : 98; 8 : 104; 8½ : 109; 9 : 114
Dimension - Length (mm)		Size: 5½ : 288; 6 : 290; 6½ : 290; 7 : 290; Size: 7½ : 298; 8 : 300; 8½ : 302; 9 : 305
Single-wall Thickness (mm)	Finger Palm Cuff	0.28 0.24 0.18
Physical Properties	Tensile Strength (MPa) Elongation (%) Modulus 500% (MPa) Force at Break (N)	(Before Aging) : 28; : 860; : 3.5; : 20; (After Aging) : 23; : 850; : 3.2; : 19
Packing Mode	Inner Wallet Pouch Dispenser Carton	1 Pair Gloves 1 Inner Wallet 50 Pouches 6 Dispensers
Glove Marking		The cuff of each glove is marked with 'WRP', 'Hand & Size'
Lot # identification on Finished Goods		Lot Number Structure: **YMMPPPPSS** Y = Year of Packing; P = WRP's PWO MM = Month of Packing; SS = Size
Product Shelf Life		3 years upon manufactured date.
Pre-shipment Inspection	Dimension Physical Properties 1000ml Water Leak Protein Content Powder Free Residue Major Visual Inspection Minor Visual Inspection	N=13 (EN455-2); S-2, AQL 4.0 (ASTM D3577) N=13 (EN455-2); S-2, AQL 4.0 (ASTM D3577) G-I, AQL 1.0 N=8 (EN455-3); N=3 (ASTM D3577) N=3 pairs G-I, AQL 1.5 G-I, AQL 4.0
Product Conformance		• EN455 Parts 1, 2 & 3 - In compliance with European Medical Device Directive 93/42/EEC (CE Class IIa) • ASTM D3577
Quality Assurance		• US FDA Quality System Regulation (QSR) • BS EN ISO9001 • BS EN ISO13485 Quality Systems

Note: The above information is a guideline of typical performance values and characteristic of the product; and not to be used as actual product specifications

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SPECIFICATION FOR PROFEEL DHD EXTRA PROTECTION POWDER FREE LATEX SURGICAL GLOVES

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Specification

Tables

1. SCOPE

1.1 This specification describes requirements for single use sterilized gloves made from natural rubber latex and intended for use in surgical work, which are to be worn once and then discarded.

1.2 The gloves conform to ASTM D3577, EN455 (Parts 1, 2 and 3) and FDA's 1000ml water leak test.

2. DESIGNATION

The gloves are designated by type, design and finish as follows:

2.1 Type : natural rubber latex

2.2 Design : The base of the thumb set in front of the index finger (i.e. hand specific) and curved fingers

2.3 Finish : Textured surface at the palm and fingers of glove

3. MATERIALS

3.1 Gloves shall be manufactured from natural rubber latex. The gloves may be coated with a surface material to assist the user putting them on.

3.2 The chemical formulation of the gloves and surface lubricating materials should be such that they do not contain any substances normally known to be harmful to the wearer or to any person with whom the glove comes into contact.

4. DIMENSIONS

4.1 Test method as described in QCTM2018. The dimensions of the gloves shall be specified in Table 1.

Table 1: GLOVE DIMENSION

Size	Palm Width (mm)	Length (mm)
5½	72 ± 4	min. 270
6	77 ± 5	min. 275
6½	83 ± 5	min. 275
7	89 ± 5	min. 280
7½	95 ± 5	min. 285
8	102 ± 6	min. 285
8½	108 ± 6	min. 285
9	114 ± 6	min. 285

4.2 The length in mm shall be measured from the tip of the second finger to the outside edge of the cuff.

4.3 Palm width in mm shall be measured at a level between the base of the index finger and the crotch of the thumb.

5. THICKNESS

Test method as described in QCTM2018. The thickness of the gloves shall be as specified in Table 2 at the following locations:

5.1 13 ± 3mm from the extreme tip of the central digit.

5.2 Approximately the center of the palm opposite the thumb crotch.

5.3 25 ± 5mm from the cuff end

Table 2: THICKNESS OF GLOVE

Location	Single-wall Thickness (mm)
Finger	min. 0.26
Palm	min. 0.22
Cuff	min. 0.17

6. PHYSICAL PROPERTIES

6.1 The tensile strength, elongation and force at break of the glove shall be determined as described in QCTM2017 and QCTM0135.

6.2 Before and after accelerated aging, the glove shall conform to the physical properties requirements as specified in Table 3.

Table 3: PHYSICAL PROPERTIES

Parameters		Requirements
Before aging		
Tensile strength	(MPa)	min. 24
Elongation at break	(%)	min. 750
Modulus 500%	(MPa)	max. 5.5
Force at break	(N)	min. 12
After aging		
Tensile strength	(MPa)	min. 18
Elongation at break	(%)	min. 560
Modulus 500%	(MPa)	not applicable
Force at break	(N)	min. 9

7. VISUAL INSPECTION

7.1 Visual inspection is undertaken to detect major and minor defects on the glove using air inflation.

7.2 Inflate the glove with air to give an approximately circular cross section of the palm. Immediately examine the glove for visual defects and manipulating the glove as necessary to ensure that any air leakage can be detected by sensory means.

7.3 Any area of the cuff which does not become inflated as described in 7.2 shall be examined visually for holes.

7.4 The classification of major and minor defects of the gloves is specified in Table 4.

7.5 Visual inspection on every glove is carried out by Production personnel in cleanroom which is part of the manufacturing quality plan.

Table 4: CRITERIA FOR VISUAL INSPECTION

Major Defects	Minor Defects
1. Wrong size	1. Thin spots
2. Wrong type	2. Lump 0.6 to 2.4mm^2
3. Pin hole /visible hole	3. Stain 0.6 to 2.4mm^2
4. Lump $\geq$ 2.5mm^2	4. Dirt 0.6 to 2.4mm^2
5. Stain $\geq$ 2.5mm^2	5. Discoloration
6. Dirt $\geq$ 2.5mm^2	6. Poor beading
7. Sticky pleat $\geq$ 5mm	
8. Tear / crack	
9. Stickiness	
10. Foreign matter	

8. 1000ML WATER LEAK TEST

Test method as described in QCTM0053, conforms to FDA's 1000ml water leak test, ASTMD5151 and EN455 (Part 1).

9. POWDER FREE RESIDUE

The powder free residue of a glove shall be less than 2mg per glove. Test method as described in QCTM0027.

10. PROTEIN CONTENT

The glove shall conform to the recommended aqueous soluble protein content limit of 200µg/dm². An allowance of 50% is given for test results in excess of the recommended limit until greater precision of the method can be attained.

Protein test method as described in QCTM0139.

For gloves packaged with protein claim labeling, the protein content of a glove shall be less than 50µg/g.

11. STERILITY

Test method as described in ANSI/AAMI/ISO11137 and USP (United States Pharmacopoeia) and the sterilization requirements are:

11.1 Gamma irradiation

11.2 Irradiation dose : 25kGy to 45kGy

11.3 A Gamma sterilization indicator shall be pasted onto each dispenser and shipping case.

Note: The indicator shall turn into RED upon sterilization.

12. PACKAGING

12.1 The gloves shall be double wrapped. The peel pack must be sealed before sterilization. The unit pack shall facilitate the aseptic extraction of the contents and shall not be capable of easy re-closure.

12.2 The peel pack should serve as a microbiological barrier and should be sufficiently robust to maintain the sterility of its contents under condition of handling and storage normally encountered in hospitals an in medical practice for at least the period of the shelf life.

12.3 The packaging material (inner dispenser and outer carton) shall not contain any material likely to impair the quality and use of the gloves.

12.4 The outer carton shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.

12.5 1 pair (1 left hand and 1 right hand) of gloves in a peel pack, 50 peel packs in a dispenser and 6 dispensers in a shipping case or alternatively as agreed between buyer and supplier.

13. LABELING AND MARKING

13.1 INNER WRAPPER

The inner wrapper for each pair of gloves shall be legibly marked with the size and specific hand (Left and Right) of glove.

13.2 PEEL PACK

The peel pack for each pair of gloves shall be legibly marked with the following information:

a. Description of the content, e.g. surgical gloves
b. Name and country of origin
c. Size of glove, e.g. Size 5½, 6, 6½ and etc.
d. Quantity of gloves, e.g. 1 pair and etc..
e. Month and year of manufacture /sterilization, e.g. 2009-11
f. Month and year of expiry or 'use by', e.g. 2014-10
g. The words 'for single use only' or equivalent, and/or the symbol for 'do not reuse' specified in EN 980:1996
h. The manufacturer's identifying lot number
i. The word 'sterile'

Note: Marking the peel pack with the word 'STERILE' means the pack and contents have been subjected to sterilization process

13.3 DISPENSER AND OUTER CARTON

The dispenser and outer carton shall be legibly marked with items as specified in clause 12.2 and instructions for storage.

LOT NUMBER STRUCTURE: **YMMPPPPSS** (9 digits)

Table 5: LOT NUMBER STRUCTURE

No.	Denote
Y	Year of packing i.e. 9 for 2009, 0 for 2010, etc.
MM	Month of packing i.e. 01 for January, 02 for February, etc.
PPPP	Last 4 digits of WRP's Packing Work Order no.
SS	Glove size i.e. • 55 for size 5½ • 60 for size 6 • 65 for size 6½ • 70 for size 7 • 75 for size 7½ • 80 for size 8 • 85 for size 8½ • 90 for size 9

BARCODE NUMBERS FOR DISPENSER AND CARTON

Table 6: BARCODE NUMBERING

Size	Peel Pouch	Dispenser	Carton
5½	-	955 7955 00255 8	(01) 0 955 7955 00233 3
6	-	955 7955 00226 5	(01) 0 955 7955 00234 0
6½	-	955 7955 00227 2	(01) 0 955 7955 00235 7
7	-	955 7955 00228 9	(01) 0 955 7955 00236 4
7½	-	955 7955 00229 6	(01) 0 955 7955 00237 1
8	-	955 7955 00230 2	(01) 0 955 7955 00238 8
8½	-	955 7955 00231 9	(01) 0 955 7955 00239 5
9	-	955 7955 00232 6	(01) 0 955 7955 00240 1

14. SAMPLING FOR PRE-SHIPMENT QUALITY INSPECTION

14.1 Gloves shall be sampled and inspected in accordance to ANSI/ASQC Z1.4:1993 / ISO2859. The sampling plan shall be as specified in Table 7.

14.2 This sampling plan pertain to pre-shipment inspection undertake by QA personnel.

Table 7: SAMPLING PLAN FOR PRE-SHIPMENT INSPECTION

Inspection Criteria	Related Defects	Sampling plan	
		Insp. Level	AQL
Dimension	Palm width	N=13	Median
	Length	N=13	Median
	Thickness	N=13	Median
Physical properties	Before aging	N=13	Median
	After aging	N=13	Median
1000ml water leak test	Hole /leak	G-I	1.0
Powder free residue	Powder residue	N=3 pairs	Not applicable
Powder content	Powder level	Not applicable	Not applicable
Protein content	Protein level	N=8	Not applicable
Sterility	Fails sterility	*A*	Not applicable
Visual inspection	Major defects	G-I	1.5
	Minor defects	G-I	4.0