DERMAGRIP

NR LATEX HIGH RISK EXAMINATION GLOVES, POWDER FREE, NON-STERILE

PRODUCT INFORMATION

Type : Powder free, extra-thick, extra-long and non-sterile examination gloves

Material : Natural rubber latex, in compliance with ISO2004

Dimension :

Glove Size	Palm Width (mm)	Length (mm)
Extra-small	79	292
Small	84	292
Medium	96	295
Large	105	295
Extra-large	117	295

Thickness :

Location of Thickness Measurement	Double-wall (mm)
Finger (at 15mm from the extreme tip)	0.80
Palm (at center of palm)	0.60

Physical Properties :

Parameters	Before Aging	After Aging
Tensile Strength (MPa)	29	26
Elongation (%)	900	860
Force At Break (N)	28	23

Protein Content : Contains less than 50µg/g extractable latex protein

Powder Residue : Contains less than 2mg/glove

Color : Blue

Design and feature : Ambidextrous, straight fingers, textured surface all over fingers area (E4) and beaded cuff

Packing : 50 gloves per dispenser and 10 dispensers per carton

Pre-shipment

Inspection Criteria	Insp.Level	AQL
Dimension	S-2	4.0
Physical Properties	S-2	4.0
1000ml Water Leak Test	G-I	1.5
Visual Inspection for Major Defects	G-I	2.5
Visual Inspection for Minor Defects	G-I	4.0

Product Conformance :

- Conform to ASTM D3578 and BS EN455 Parts 1, 2 & 3
- In compliance with European Medical Device Directive 93/42/EEC (CE Class I)
- In compliance with Personal Equipment Directive 89/686/EEC (Complex Design Category and type tested to EN420, EN374-2 and EN374-3)

Quality Assurance : Manufacturing process is in compliance with US FDA Quality System Regulation (QSR) and BS EN ISO9001 Quality System

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.

SPECIFICATION FOR DERMAGRIP NR LATEX HIGH RISK EXAMINATION GLOVES, POWDER FREE, NON-STERILE

CONTENTS PAGE

Specification

Tables

1. SCOPE

1.1 This specification describes requirements for single use gloves made from natural rubber latex and intended for use when conducting medical examination, emergency medical services, diagnostic procedures, therapeutic procedures, handling contaminated medical material and for chemical splash protection, which are to be worn once and then discarded.
Note : The gloves are not intended for surgical work i.e. as a substitute for surgeon's gloves.

1.2 The gloves conform to ASTM D3578, EN455 (Parts 1, 2 and 3) and FDA's 1000ml water leak test.

1.3 In compliance with European Medical Device Directive 93/42/EEC (CE Class I).

1.4 In compliance with Personal Equipment Directive 89/686/EEC (Complex Design Category and type tested to EN420, EN374-2 and EN374-3).

2. DESIGNATION

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

2.1 Type : natural rubber latex

2.2 Design : ambidextrous (i.e. fit either hand) and straight fingers

2.3 Finish : textured surface finish over the fingers

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 QCTM1022. The dimensions of the gloves shall be specified in Table 1.

Table 1 : GLOVE DIMENSION

Size	Palm Width (mm)	Length (mm)
Extra-Small	75±10	290, min
Small	80±10	290, min
Medium	95±10	290, min
Large	110±10	290, min
Extra-Large	115±10	290, min

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 QCTM1022. The double-wall thickness of the gloves shall be as specified in Table 2 at both of 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.

Table 2 : THICKNESS OF GLOVE

Location	Single-wall Thickness (mm)	Double-wall Thickness (mm)
Finger	0.38, min	0.76, min
Palm	0.23, min	0.46, min

6. PHYSICAL PROPERTIES

6.1 The tensile strength, elongation and force at break of the glove shall be determined as described in QCTM1021 and QCTM0135.

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

Parameters		Requirements
Before aging		
Tensile strength	(MPa)	18, min
Elongation at break	(%)	650, min
Stress @ 500%	(MPa)	5.5, max.
Force at break	(N)	9, min
After aging		
Tensile strength	(MPa)	14, min
Elongation at break	(%)	500, min
Force at break	(N)	6, min

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 is carried out as a routine testing procedure which is part of the manufacturing quality plan.

Table 4 : CRITERIA FOR VISUAL INSPECTION

Major Defects	Minor Defects
1. Wrong size 2. Wrong type 3. Pin hole /visible hole 4. Lump $\geq$ 2.5mm² 5. Stain $\geq$ 2.5mm² 6. Dirt $\geq$ 2.5mm² 7. Sticky pleat $\geq$ 5mm 8. Tear / crack 9. Stickiness 10. Foreign matter	1. Thin spots 2. Lump 0.6 to 2.4mm² 3. Stain 0.6 to 2.4mm² 4. Dirt 0.6 to 2.4mm² 5. Discoloration 6. Poor beading

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. MOISTURE CONTENT

The moisture content of a glove shall not exceed 0.80%. Test method as described in QCTM0082.

12. IODINE TEST

The glove shall give negative result in the Iodine test. Test method as described in QCTM0145.

13. PACKAGING

13.1 The unit packaging shall be 50 gloves in a inner dispenser, 10 inner dispensers in a outer carton and taped.

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

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

14. LABELING AND MARKING REQUIREMENTS

The inner dispenser and outer carton of gloves shall be legibly marked with the following information :

14.1 Description of the content, e.g. examination gloves
14.2 Name and country of origin
14.3 Size of glove, e.g. Size XS, S, M, L or XL
14.4 Quantity of gloves, e.g. 50 gloves by weight
14.5 Month and year of manufacture, e.g. 2002-07
14.6 Month and year of expiry or 'use by', e.g. 2005-06
14.7 The words 'For single use only' or equivalent, and/or the symbol for 'do not reuse' specified in EN 980:1996;
14.8 The manufacturer's identifying lot number
14.9 Any necessary instruction for storage and handling

LOT NUMBER STRUCTURE : **YMMPPPPSXX** (10 digits)

Table 5 : LOT NUMBER STRUCTURE

No.	Denote
Y	Year of packing i.e. 4 for 2004, 5 for 2005, 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.
S	Glove size i.e. 0 for size XS 1 for size S 2 for size M 3 for size L 4 for size XL
XX	Denote the sequential no. for every 100,000 gloves of the same size same PWO

15. SAMPLING FOR PRE-SHIPMENT QUALITY INSPECTION

15.1 Gloves shall be sampled and inspected in accordance to ANSI/ASQC Z1.4:1993 / ISO2859. The sampling plan shall be as specified in Table 5.

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

Table 6 : SAMPLING PLAN FOR PRE-SHIPMENT INSPECTION

Inspection criteria	Related Defects	Sampling plan	
		Insp. Level	AQL
Dimension	Palm width Length Thickness	S-2 S-2 S-2	4.0 4.0 4.0
Physical properties	Before aging After aging	S-2 S-2	4.0 4.0
Visual inspection	Major defects Minor defects	G-I G-I	2.5 4.0
1000ml water leak test	Hole /leak	G-I	1.5
Powder free residue	Powder residue	N=5	Not applicable
Protein content	Protein level	N=3	Not applicable
Moisture content	Moisture level	S-2	1.5
Iodine test	No cornstarch	S-2	1.5