

K964321

石家莊鴻銳塑料製品有限公司  
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### Shijiazhuang HongRay Plastic Products Co., Ltd.

HEAD OFFICE NO. 135 XIN HUA WEST ROAD, SHIJIAZHUANG CITY,  
& FACTORY HEBEI PROVINCE, CHINA

P.O. BOX, 050081

TEL. 86 311-334449 334221

BRANCH OFFICE, RM3, 5TH FL., NO. 76 FUSHING SOUTH ROAD,

SECTION 1, TAIPEI, TAIWAN

P.O. BOX, 53-186, TAIPEI

TEL. 886-2-7720306-7 7110338 7217339

FAX, 886-2-7712601 TELEEX, 22602 KENAN



OUR REF.

YOUR REF.

JAN - 9 1997

510(K) SUMMARY - K964321

1.0 APPLICANT:

MR. LIN CHIN YU  
SHIJIAZHUANG HONGRAY PLASTIC PRODUCTS CO., LTD.  
NO. 135 XIN-HUA WEST RD.  
SHIJIAZHUANG, CHINA  
TEL. 886 2 772-0306-7  
FAX. 886 2 771-2601

2.0 CONTACT PERSON

MR. LIN CHIN YU  
SHIJIAZHUANG HONGRAY PLASTIC PRODUCTS  
NO. 135 XIN-HUA WEST RD.  
SHIJIAZHUANG, CHINA  
TEL. 886 2 772-0306-7  
FAX. 886 2 771-2601

AGENT:

MR. DON MORRIS  
14 LEEWARD ISLAND  
CLEARWATER, FL. 34630  
USA  
TEL. 800-366-9545  
FAX. 813-443-3482

3.0 Device Class: 1

Product Code: 80LYZ

4.0 Specification: Glove, Patient Examination, Vinyl (Powdered)  
meets all of the requirements of ASTM Standard D5250

5.0 Device Description: Glove, Patient Examination, Vinyl (Powdered)

6.0 Intended Use: A glove is worn on the hand of healthcare and similar  
personnel to prevent contamination between healthcare personnel and  
the patient's body, fluids, waste or environment.

7.0 Inner Surface: Prepowdered

8.0 Biocompatibility Testing: Primary Dermal Irritation in Rabbits  
and Guinea Pig Sensitization (Buehler) by Consumer Products  
Testing Co., USA.

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## 9.0 Quality Characteristics

### SPECIFICATION OF VINYL GLOVES (AMBIDEXTROUS) POWDER 10"

SIZE SPEC	SMALL	MEDIUM	LARGE	X-LARGE	TEST CODE
CIRCUMPERENCE OF PALM (M/M) (INCH)	178 6-3/4	210 7-3/4	218 8-1/2	230 9	JIS-S-2045.5.9
TOTAL LEENGTH (± 5M/M)	240	245	245	245	JIS-S-2045.5.9
LNGTH OF FINGERS (M/M) THUMBS INDEX FINGER MIDDLE FINGER RING FINGER LITTLE FINGER	55 66 74 69 54	57 70 81 74 55	61 75 88 79 60	63 78 92 82 62	JIS-2045.5.9
CIRCUMFERENCE FINGERS THUMB INDEX FINGER MIDDLE FINGER RING FINGER LITTLE FINGER	63 58 59 56 50	71 64 66 63 57	78 70 72 69 62	83 74 76 73 66	JIS-S-2045.5.9
TENSILE STRENGTH (Mpa)	Min. 10.0	Min. 10.00	Min. 10.00	Min. 10.00	JIS-2045.5.2
ELONGATION (Min.)	350%	350%	350%	350%	JIS-2045.5.2
WEIGHT (g/pc)	7.0	8.0	9.0	9.5	± 0.2g
THICKNESS	Finger Tip 0.08mm ± 0.02mm Cuff 0.09mm ± 0.02mm Palm 0.15mm ± 0.02mm				
QUALITY ASSURANCE	UNDER 4% PINHOLE RATE				FDA GLOVE 1000 ML WATER LEAK TEST

10.0 Conclusion: Shinjiazhuang Hongray Plastic Products Co., Ltd. Vinyl Patient Examination Gloves meet ASTM Standards - meets pinhole requirements and labeling claims.