



CONTACT PERSON : MR. Y.W. CHOW  
**WEMBLEY RUBBER PRODUCTS**  
**(M) SDN BHD**

K962188

Lot 1, Jalan 3  
 Kawasan Perusahaan Bandar Baru  
 Salak Tinggi, 43900 Sepang,  
 Selangor, Malaysia.  
 Corporate Office Tel: 8461486  
 8461867  
 Fax: 8461485  
 8461557  
 Factory Office: 8461495  
 8461496  
 Fax: 8461488  
 8461608

**JUL 26 1996**

**510 (K) SUMMARY**

1. **Trade Name** : COMFIT POWDER FREE BLUE EXAMINATION GLOVES (HYPOALLERGENIC, LOW PROTEIN)

2. **Common Name** : Examination Gloves

3. **Classification Name** : Patient Examination Glove

4. **Substantial Equivalence** :

Class I latex patient examination glove 80 LYY, powder free, hypoallergenic, low protein, that meets all of the requirements of ASTM standard D3578-91.

5. **Description of device** :

Class I latex patient examination glove 80 LYY, powder free, hypoallergenic, low protein, that meets all of the requirements of ASTM standard D3578-91.

6. **Intended use of device** :

The gloves are intended to be worn on the hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.



BS EN ISO 9002 : 1994  
 BRITISH STANDARDS INSTITUTION  
 REGISTRATION NO: FM 13934



GOOD MANUFACTURING PRACTICE  
 UK DEPARTMENT OF HEALTH  
 REGISTRATION NO: R0589/SP



MALAYSIA  
 QUALITY SYSTEM MS ISO 9002 : 1991  
 REGISTRATION NO: AR 0027

TEST	ASTM D 3578-91	COMFIT Powder Free Blue Examination Gloves (Hypoallergenic, Low Protein)
1. Watertight (1000 ml)	S-4, AQL 4.0	Pass based on AQL of 2.5
2. Length (mm)		
Size XS	-	-
S	min 230	297
M	min 230	303
L	min 230	300
XL	-	293
3. Palm width (mm)		
Size XS	-	-
S	80 ± 10	84
M	95 ± 10	95
L	111 ± 10	105
XL	-	118
4. Thickness (mm)		
Finger	min 0.08	0.40
Palm	min 0.08	0.30
5. Physical Properties		
<u>Before Ageing :</u>		
Tensile Strength (MPa)	min 21	31.23
Ultimate Elongation (%)	min 700	895
<u>After Ageing :</u>		
Tensile Strength (MPa)	min 16	26.64
Ultimate Elongation (%)	min 500	946
6. Powder Content	-	below 2 mg / glove
7. Protein Content	-	below 50 microgram / gram

8. **Substantial Equivalence based on assessment of Non-Clinical performance data**

The performance test data of device as shown above indicate that this glove meets requirements of ASTM D 3578-91.

Protein content tested on recently manufactured and accelerated ageing gloves using ASTM D5712 is below 50 microgram / gram.

9. **Assessment of Clinical Performance data**

Clinical data of 200 Human subjects on Modified Draize test done on this glove demonstrated no potential for eliciting either dermal irritation or sensitization and support the labeling claim for "hypoallergenic".

10. **Conclusion**

This glove exceed the ASTM D 3578-91 requirements, meet pinhole FDA requirements, meet Hypoallergenic labeling claim and below 50 microgram / gram protein content labeling claim.

Date Summary Prepared : May 27, 1996