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510 (K) SUMMARY

1. **Trade Name** : COMFIT POWDER FREE GREEN 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 Green 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 M L XL	- min 230 min 230 min 230 -	249 249 249 249 251
3. Palm width (mm) Size XS S M L XL	- 80 ± 10 95 ± 10 111 ± 10 -	79 85 96 105 110
4. Thickness (mm) Finger Palm	min 0.08 min 0.08	0.22 0.16
5. Physical Properties <u>Before Ageing :</u> Tensile Strength (MPa) Ultimate Elongation (%) <u>After Ageing :</u> Tensile Strength (MPa) Ultimate Elongation (%)	min 21 min 700 min 16 min 500	35.03 868 29.85 826
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