

THE FACTS ABOUT STANDARD MALAYSIAN GLOVE (SMG)

High in Barrier Protection and Low in Protein

As the world's leader in medical gloves, Malaysia is committed to supplying gloves of an internationally high standard for safety and reliability. We take pride in introducing the Standard Malaysian Glove (SMG) Program, a joint effort by the Rubber Research Institute of Malaysia and Malaysian glove manufacturers. The SMG program was developed in consultation with regulatory and standard setting bodies such as the U.S. Food and Drug Administration (FDA) and other relevant authorities. The SMG program establishes standards not only for barrier performance, the single most important function of medical gloves, but also for protein and powder content, elements believed to cause allergic reactions in individuals sensitive to latex proteins. The program applies initially to medical examination gloves, powdered and powder-free, which are identified by the following logos:



However, SMG certified gloves can also be identified by any dominant colour of the dispenser box.

ENSURING QUALITY MANAGEMENT

All SMG manufacturers must have a quality management system in accordance with ISO 9001 or its equivalent. SMG certification is carried out by the Rubber Research Institute of Malaysia, a world renowned organization that has been conducting research on natural rubber products for more than 75

years. An independent Quality Inspectorate of the Malaysian Rubber Board undertakes regular surveillance testing to provide oversight and to ensure quality compliance by SMG producers. The MRB Testing Laboratory is accredited to ISO/IEC Guide 17025 and is fully equipped for testing SMG gloves.

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ENSURING BARRIER PROTECTION

All SMG labeled gloves must meet the prescribed standard for the water leak test, the internationally recognized testing procedure for barrier performance. Gloves are sampled and inspected in accordance with ISO 2859-1. Under the SMG program, the Acceptable Quality Level (AQL) of 1.5 at inspection level of G1 compares favorably with ASTM (AQL of 2.5) and FDA

requirements for examination gloves. High strength and elasticity are important to minimize the possibility that gloves will rupture or tear under in-use stress conditions. These characteristics are measured on the basis of tensile strength and elongation at break. The requirements under the SMG program are as shown below:

PROPERTY	UNIT	MINIMUM REQUIREMENTS*		
		SMG Publication #3	ASTM D 3578	
			Type I**	Type II***
Tensile strength (before ageing)	MPa	18	18	14
Elongation-at-break (before ageing)	%	550	550	550
Tensile strength (after ageing)	MPa	14	14	14
Elongation-at-break (after ageing)	%	500	500	500

* High numbers denote higher strength and elasticity.

** Gloves with maximum stress of 5.5 MPa at 500% elongation are classified as Type I.

*** Gloves with maximum stress of 2.8 MPa at 500% elongation are classified as Type II.

MINIMIZING PROTEIN SENSITIZATION

The older generation of natural rubber latex gloves could have extractable proteins of more than 1,000 micrograms/dm². However, the new generation of natural rubber latex gloves, with proper leaching process, can have extractable proteins markedly lower than that of the older generation of gloves. The SMG is designed to ensure that natural rubber latex gloves can consistently meet low protein and powder content as stipulated by the program. In the case of SMG

powdered gloves, protein and powder contents are kept at very low level of 200 micrograms/dm² and 150 milligrams/glove or less, respectively. The protein and powder contents of SMG powder-free gloves are even much lower at 50 micrograms/dm² and 2 milligrams/glove or less, respectively. The table shows the upper limits set for protein and powder under the SMG program.

PROPERTY	SMG Publication #3	ASTM D 3578
POWDER-FREE : Upper limit of protein Upper limit of powder	50 micrograms/dm ² 2 milligrams/glove	200 micrograms/dm ² 2 milligrams/glove
POWDERED Upper limit of protein Upper limit of powder	200 micrograms/dm ² 150 milligrams/glove (Approx. 15 milligrams/dm ²)	200 micrograms/dm ² 10 milligrams/dm ²

Additional information about the SMG program and where to purchase SMG gloves can be found on our [website www.smg-online.biz](http://www.smg-online.biz).



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