The single most important criterion for selecting medical gloves:

Ability to provide very effective barrier performance against blood pathogens and harmful infections.

Studies on Comparative Barrier Performance of Gloves

Author	Failure Rates (%)	
	NATURAL RUBBER	VINYL
Korniewicz 1990	7	63
Korniewicz 2002	2.2	8.2
Klein 1990	<1[a]	22[a]
	<1[b]	56[b]
Olsen 1993	4.2 – 7.9[c]	43
Douglas 1997	1.1[c]	25 – 32[d]
		22 – 27[e]
Rego 1997	0–4	26 – 61[d]
		12 – 20[e]
Kerr (FDA) 2004	4 –10[c]	38[c]
	9 –17[f]	33[f]

KEY:

[a] : No alcohol Pretreatment

[b] : Pretreatment with 70% alcohol

[c] : NR latex powder-free

[d] : Standard vinyl

[e] : Stretch vinyl

[f] : Powdered gloves

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SMG TYPE II

STANDARD MALAYSIAN GLOVE

MADE IN MALAYSIA — ENVIRONMENT FRIENDLY

Certified Quality Glove

Consistent Quality

Excellent Barrier Performance

Minimal Protein Content

Unequaled Comfort, Fit and Feel

Environment Friendly

High Strength and Elasticity

MREPC
Malaysian Rubber Export Promotion Council

SMG - Your Choice for Quality

www.smgonline.biz

MRB CERTIFICATION

This information is assembled and distributed by the Malaysian Rubber Export Promotion Council (USA), which has been registered under the Foreign Agents Registration Act as an agent of the Malaysian Rubber Export Promotion Council (Malaysia). Public information about this registration is available at the U.S. Department of Justice.

SMG® POWDER-FREE

SMG® POWDERED

The Facts About Standard Malaysian Glove (SMG)

High in Barrier Performance and Low in Protein and Powder

The Standard Malaysian Glove (SMG) product quality certification scheme for latex examination gloves has been developed by Malaysia in consultation with various relevant authorities including the U.S. Food and Drug Administration (FDA). Latex gloves with SMG certification, lightly powdered and powder-free, meet stringent requirements for safety and reliability equivalent to international standards and are manufactured at facilities that comply with established quality management system. The SMG scheme 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.

SMG-certified gloves can be identified by a logo, in green for powder-free examination gloves and in orange for lightly powdered examination gloves. The logos may also be in the dominant color of the dispenser box.

SMG®
POWDER-FREE
Green Logo

SMG®
POWDERED
Orange Logo

Environment Friendly Choice

Renewable and Sustainable

SMG gloves are made from natural rubber latex, the sap of the Hevea brasiliensis tree widely grown in Malaysia. Bred to be the most efficient source of rubber latex, rubber trees are a renewable and sustainable resource.

Aid to Atmospheric Renewal

Studies estimate that rubber trees planted worldwide replace as much as 363,000 tonnes of Carbon Dioxide with 264,000 tonnes of oxygen annually through photosynthesis, revitalizing the earth's atmosphere and helping to combat green-house emissions and global warming.

Biodegradable

Natural rubber and its products are biodegradable, unlike synthetic rubber and plastics, such as polyvinyl chloride (PVC).

Ensuring Quality Management

SMG manufacturers are required to implement an established quality management system to ensure continuous compliance with the standard or specification. SMG certification is carried out by the Malaysian Rubber Board (MRB), an internationally recognized organization that has been conducting research on rubber and rubber products for more than 80 years. MRB is accredited to ISO/IEC Guide 65 (general requirement for bodies operating product certification system). An independent Quality Inspectorate of the MRB undertakes regular surveillance testing to ensure quality compliance by SMG manufacturers. The MRB Laboratory is accredited to ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories) and is fully equipped for testing SMG gloves.

Ensuring Barrier Performance

All SMG-labeled gloves must meet the prescribed standard for the water leak test, the internationally recognized testing procedure for barrier performance. The acceptable quality level (AQL) for SMG-certified gloves for this test must not exceed 1.5, or have more than 1.5 percent defectives, compared to the current higher level of 2.5 permitted under ASTM and FDA requirements for examination gloves. SMG gloves are sampled and inspected in accordance with ISO 2589-1 (Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection).

High strength is important to minimize the possibility that gloves will rupture or tear under stress during use. This characteristic is 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	ASTM D3578		EN455
		Type II	Type I	Type II	
1. Water leak test	AQL	1.5	2.5	2.5	1.5
2. Tensile strength before accelerated ageing	MPa	-	18	14	-
3. Elongation-at-break before accelerated ageing	%	650	650	650	-
4. Force-at-break before accelerated ageing	N	6	-	-	6
5. Tensile strength after accelerated ageing	MPa	-	14	14	-
6. Elongation-at-break after accelerated	%	500	500	500	-
7. Force-at-break after accelerated ageing	%	6	-	-	6

Note: Property No.2 to 7: Higher number denotes higher strength
SMG Type II: Conforms to EU requirements
ASTM Type I: Gloves with maximum stress at 500% elongation of 5.5 MPa
ASTM Type II: Gloves with maximum stress at 500% elongation of 2.8 MPa

Ref:
MRB's SMG Technical Requirements for Standard Malaysian Gloves, 3rd Revision Publication 4
ASTM D3578 – 05 (Reapproved 2010): Standard Specification for Rubber Examination Gloves
EN 455-1: 2000 Medical Gloves for Single Use-Requirements and Testing for Freedom from Holes
EN 455-2:2009+A1:2011 Medical Gloves for Single Use-Requirements and Testing for Physical Properties

Minimizing Protein Sensitization

Research shows that latex protein allergies arising from the presence of high levels of residual extractable proteins, especially in highly powdered gloves, can be alleviated through the use of low-protein gloves. The SMG scheme is designed to ensure that natural rubber latex gloves consistently meet the low protein and powder contents as stipulated in the SMG standards.

In the case of SMG powdered gloves, protein and powder contents are kept at very low levels of 200 µg /dm^2 and 150 mg per glove or less respectively. The permitted protein and powder contents of SMG powder-free gloves are even lower at 50 µg /dm^2 and 2 mg per glove. The table below shows the upper limits set for protein and powder under the SMG scheme.

Property	SMG	ASTM D3578	EN455
Powder-free **Upper limit of protein** **Upper limit of powder**	**50 µg/dm^2** **2 mg/glove**	**200 µg/dm^2** **2 mg/glove**	**2 mg/ glove**
Powdered **Upper limit of protein** **Upper limit of powder**	**200 µg/dm^2** **150 mg/glove** **(Approx 14 mg/ dm^2)**	**200 µg/dm^2** **10 mg/glove**	**> 2 mg/ glove**

Ref:
ASTM D6124 - 06(2011) Standard Test Method for Residual Powder on Medical Gloves
EN 455-3:2006 Medical Gloves for Single Use: Requirements and Testing for Biological Evaluation