

## **Public Comment Submission to the U.S. Department of Commerce Bureau of Industry and Security**

**Notice Title:** Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices

**Submitted By:** Malaysian Rubber Council (MRC)

**Date:** October 9, 2025

**Affected Malaysian Sectors:** Medical Rubber Gloves, Male and Female Condoms, and Rubber Catheters

### **Introduction: Malaysia as the Trusted and Reliable Partner of U.S. Public Health Safety**

The Malaysian Rubber Council (MRC) submits this comment on behalf of Malaysian manufacturers of critical medical consumables—specifically medical rubber gloves, condoms, and rubber catheters—in response to the Section 232 National Security Investigation. These products are foundational to daily patient care, surgical procedures, and public health initiatives across the United States. For decades, the U.S. has relied upon Malaysia as a **trusted, transparent, and high-quality source** for these essential rubber-based medical goods.

This submission provides substantive data and analysis demonstrating that imports from Malaysia do not pose a threat to U.S. national security but, conversely, are **indispensable to its resilience, security, and medical infrastructure**. We address, point by point, the issues of particular interest to the Department.

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### **I. U.S. Demand, Capacity, and the Complementary Role of Malaysian Imports**

We fully recognize the Department's interest in securing reliable supply (BIS i, ii, viii). However, the investigation must be grounded in the reality of **U.S. production capabilities, particularly concerning rubber products**.

**(i) Current and Projected U.S. Demand:** Substantive verified data (Appendix A) shows that U.S. demand for medical gloves alone exceeded **4.35 billion dozen pair (DPR) annually** in 2024, representing the total U.S. import quantity, with similar requirements of importance for condoms and rubber catheters. This demand is consistent and is projected to increase

by **10% (CAGR)** over the next several years due to aging populations and continued public health awareness.

**(ii) Domestic Capacity vs. Demand:** The U.S. lacks the domestic capacity to meet this massive demand as the U.S. is not a major producer of rubber or rubber products. Current U.S. domestic production for **rubber gloves** meets less than **10%** of clinical demand. Malaysia alone accounted for approximately **49% of the total U.S. medical glove import quantity** in 2024 (2.126 billion DPR), unequivocally demonstrating the critical U.S. partnership has with Malaysia as a trusted foreign supply partner. The case for domestic glove production faces the **economic reality** of significantly higher costs compared to imports from Southeast Asia.

**(viii) Feasibility of Increasing Domestic Capacity:** While increasing domestic synthetic (nitrile) capacity is plausible, the highly specialized machinery, engineering expertise, and access to raw materials (particularly natural rubber latex) necessary for high-quality glove, condom, and rubber catheter production render **full self-sufficiency for these specific items infeasible**.

- Recent attempts by the U.S. government to pour hundreds of millions (USD) into domestic glove factories in cities such as **Baltimore** and **Louisiana** have faced major challenges, resulting in one facility never producing a single glove and another shutting its doors after barely three years.
- The raw materials, both **natural latex and synthetic nitrile**, are sourced locally in Malaysia, which cuts costs significantly compared to U.S. production. Malaysian plants benefit from **vast scale**, with some having the capacity to produce billions of gloves annually catering to markets worldwide, an advantage built over three decades.
- An analysis of the significant federal investment into domestic manufacturing, if redirected to imports, could have purchased roughly **7 billion pieces of Malaysian gloves** at 2024 prices, a quantity nearly five times the current U.S. Strategic National Stockpile (SNS). This stark comparison highlights the **magnitude of opportunity cost** and the economic case for strategic imports over costly domestic manufacturing strategies.

Furthermore, Malaysia's specialized exports of catheters and related medical equipment (HS 901839) to the U.S., valued at over **USD 109 million** in 2024, highlight our deep integration into complex medical device supply chains. This integration is so fundamental that a number of major **U.S. medical device manufacturers, including Becton Dickinson, Teleflex, and Medtronic (which acquired Covidien), operate their own manufacturing**

**facilities in Malaysia** to produce high-quality rubber catheters and other specialized medical products for the global and U.S. markets. This strategic investment by American companies demonstrates commercial trust in Malaysia's operational stability, skilled workforce, and high-quality standards. Malaysia's complementary supply therefore supports, rather than compromises, U.S. healthcare stability.

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## II. Dispelling Unfair Trade Allegations and National Security Risks

Malaysia's long-term market dominance is a function of competitive excellence, not illicit practices. We offer a direct response to allegations concerning trade fairness and supply chain vulnerability (BIS v, vi, iii, iv, x, xi).

**(v) and (vi) Foreign Subsidies and Predatory Trade Practices & Upholding Integrity:** The Malaysian rubber industry conducts its business in **good faith, underpinned by a commitment to fair and transparent trade practices**. Our competitive pricing is **not artificially suppressed**; rather, it is the direct result of decades of strategic investment in **R&D and advanced manufacturing**, leading to unparalleled efficiency and scale. Malaysia's industry has pioneered innovations in tactile sensitivity, allergen reduction, and enhanced barrier protection. Our manufacturing efficiency is market-driven.

- This efficiency is rooted in structural advantages, including significantly lower factory wages of **USD 3–5** (MYR 13 – 21.5) **an hour** compared with USD 25–30 on average in the U.S.
- **Automated inspection systems** keep the defect rates on Malaysian gloves within the international standard's Acceptable Quality Level (AQL), ensuring high-quality and market leadership.

We are confident that a review will confirm our strict adherence to international trade norms. To further safeguard this integrity and ensure fair competition, the Malaysian Government through its agency, the Malaysian Rubber Board (MRB) has implemented new, strict regulations to curb the **transshipment** of rubber gloves. As of 6 May 2025, licensed exporters in Malaysia must only export gloves produced by local manufacturers, and only companies that complete the entire manufacturing process in Malaysia are eligible to receive a **Non-Preferential Certificate of Origin (NPCO)** issued by the Ministry of Investment, Trade, and Industry (MITI). This enhanced oversight development as acknowledged by U.S Trade Representative Jamieson Greer is a proactive measure to prevent foreign parties from using Malaysia to evade tariffs imposed by U.S trade regulations and protects the integrity of the

"Made in Malaysia" brand, ensuring adherence to high environmental, social, and governance (ESG) standards, including addressing past scrutiny over labor. This includes a commitment made stronger through the recently launched **Malaysia's National Action Plan on Forced Labor (NAPFL)** to eliminate forced labor by 2030.

**(iii) and (iv) Role of Foreign Supply Chains and Concentration Risk:** The Malaysian supply chain serves as a stabilizing force. Our specialization in both natural and synthetic rubber-based products ensures the U.S. has access to essential, high-quality items. Any perceived "concentration" is simply the result of Malaysia's decades-long history of being the **global technological leader** in these specific categories. This specialization is a **critical asset**, not a risk, as it diversifies the U.S. away from regions that may be politically less stable or have lower quality controls. Furthermore, Malaysia's **well-developed ports and shipping links** ensure deliveries arrive on time, adding to its logistical strength.

**(x) and (xi) Foreign Control/Exploitation and Weaponization:** Malaysia is a decades-old, dependable U.S. trading partner. There is **no evidence and no plausible scenario** wherein Malaysian-built medical products would be "weaponized" or used to "exploit" the U.S. supply chain. Our manufacturing operations are subject to rigorous international scrutiny and quality audits (e.g., FDA requirements), ensuring our products maintain superior quality that consistently meets or exceeds American regulatory standards. Malaysia is increasingly seen as a **strategic partner** for the U.S., having a tested and trusted track record built over the years.

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### III. Protecting U.S. National Security Through Free Trade

We caution against measures that would ultimately weaken U.S. national security by making essential medical supplies scarce and expensive (BIS vii, ix).

**(vii) Potential for Export Restrictions:** The Malaysian Government has an established track record of **prioritizing export consistency, especially for humanitarian and medical purposes**, even during severe global crises (like the COVID-19 pandemic). Our commitment to free trade and global supply chain stability minimizes this risk.

**(ix) Impact of Current Trade Policies and Necessity of New Measures:** Imposing new measures, such as additional tariffs or quotas, would constitute a direct threat to U.S. public health security. Such measures would **artificially inflate prices, restrict access, and strain the budgets** of U.S. healthcare providers and government agencies. This would force them to compromise on quality or volume, directly undermining the national security goal of

protecting the health of the American public. A more resilient strategy for the U.S. would be to adopt a **hybrid approach** that combines imports anchored by Malaysia's unrivalled industry with safeguards at home.

- This hybrid strategy could include **import diversification** (sourcing from Malaysia, and other allies from the Southeast Asia region based on competitive trade), maintaining a robust and strategic **stockpile** rotated regularly to avoid expiry, and a **reasonable level of U.S. production**, if deemed necessary, as a vital fallback during an emergency.

**(xii) Any Other Relevant Factors (Quality and Partnership):** Malaysian quality medical rubber gloves, condoms, and rubber catheters have kept the American public safe for decades. Our products meet the stringent quality requirements and standards of U.S. hospitals and consumers, consistently demonstrating superior strength, durability, and reliability.

**Malaysian manufacturers consistently secure FDA clearances and ISO certifications.**

We view our role as a long-term, trusted partner committed to sustaining this relationship for future generations. Our approximately **USD 1.3 billion in rubber glove exports, mostly medical gloves** to the U.S. in 2024 is proof of this robust and mutually beneficial partnership. Malaysia is America's **most strategic and dependable partner** in glove supply.

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## Conclusion

The Malaysian Rubber Council urges the Department of Commerce to conclude that the import of high-quality Malaysian medical rubber gloves, condoms, and rubber catheters does not impair U.S. national security. Our manufacturers provide a vital, complementary supply that U.S. domestic capacity cannot replace, maintaining high safety standards and contributing to the stability of the U.S. healthcare system. The struggles of costly domestic manufacturing initiatives show what happens when good intentions collide with **economic reality**. In the next crisis, America's preparedness will depend not on factories built in haste, but on the **partnerships and strategies** it chooses now.

We stand ready to provide any additional data, transparency, and assurance needed to reinforce our role as a reliable and essential global partner.

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Additional information is available at the Department of Justice, Washington, D.C.