檔　　號：
保存年限：

經濟部國際貿易署　函

承辦單位：雙邊貿易二組
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受文者：臺灣橡膠暨彈性體工業同業公會
發文日期：中華民國114年9月30日
發文字號：貿雙二字第1147035948號
速別：普通件
密等及解密條件或保密期限：
附件：如文

主旨：有關美國商務部啟動對個人防護裝備、醫療耗材及設備之232條款調查，並將徵詢公眾評論事，請查照並惠轉知會員廠商。

說明：

一、依據駐美國代表處經濟組本(114)年9月25日經美字第1140000974號函辦理。

二、美國商務部於本年9月24日發布預公告，已於本年9月2日依據《1962年貿易擴張法》第232條規定啟動對個人防護裝備、醫療耗材及設備（Personal Protective Equipment, Medical Consumables, and Medical Equipment）及其零組件之國家安全調查，並將徵求公眾評論至10月17日止（預定9月26日正式公告後21天內）。

三、本案調查範圍不包括已另案調查之藥品，涵蓋產品清單如下：

(一)個人防護裝備：係指醫療環境中所使用之防護裝備，包括外科口罩、N95 口罩、手套、防護衣及相關醫療零組件。

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(二)醫療耗材：係指用於診斷、治療及預防疾病之一次性或短期使用物品及相關零組件，包括：

1、醫療/手術器械，如注射器、針頭、輸液幫浦、鑷子及手術刀。

2、醫療/手術用品，如：靜脈輸液袋、導管、氣管切開術導管、麻醉設備、紗布/繃帶、縫線、診斷及實驗室試劑。

(三)醫療設備：

1、醫療環境中所使用支持照顧病患之耐久設備、工具及機械，包括推車、輪椅、拐杖及病床。

2、另包括醫療器材（medical device）：用於診斷、監測或治療之任何儀器、設備或機械，如植入式裝置（心律調節器、胰島素幫浦、冠狀動脈支架、心臟瓣膜）、輔助裝置（助聽器、義肢、血糖監測、骨科器具）、電子醫療設備（電腦斷層掃描儀、核磁共振儀、X光儀器）、呼吸及支持生命設備（呼吸器、氧氣設備）。

四、具關係人士提交之書面評論，包括協助商務部判斷影響國家安全之資訊如下：

(一)供需情形：美國國內需求現況、預測及其最適情況、國內生產滿足此類需求之程度，及主要出口國在相關供應鏈之角色。

(二)競爭議題：進口來源是否過度集中在少數供應商、外國政府補貼、不公平貿易行為、過度生產等之影響。

(三)國家安全：外國實施出口限制，並透過控制本案產品之供應，將該等供應鏈武器化之可能性；外國人將外國製造本案產品的功能或屬性武器化之可能性；外國控制或利用相關供應鏈之可能性。

(四)解決方案：提高國產化製造、減少出口依賴之可行性，

及是否需要實施額外措施（關稅或配額），以保護國家安全。

五、檢送前述聯邦公報如附件，併請卓參。

正本：中華民國全國工業總會、台灣醫療暨生技器材工業同業公會、台灣醫療照護輔具協會、中華民國醫療器材商業同業公會全國聯合會、中華民國儀器商業同業公會全國聯合會、臺灣橡膠暨彈性體工業同業公會、財團法人中華民國紡織業拓展會、台北市進出口商業同業公會、中華民國進出口商業同業公會全國聯合會、社團法人中華民國助聽器同業聯合協進會、中華民國助聽器商業同業公會全國聯合會

副本：駐美國代表處經濟組、本署貿易管理組

署長劉盛麟

3510-33-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 250924-0160]

XRIN 0694-XC134

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

AGENCY: Bureau of Industry and Security, Office of Strategic Industries and Economic Security, U.S. Department of Commerce.

ACTION: Notice of request for public comments.

SUMMARY: On September 2, 2025, the Secretary of Commerce initiated an investigation to determine the effects on the national security of imports of personal protective equipment (PPE), medical consumables, and medical equipment including devices. This investigation has been initiated under section 232 of the Trade Expansion Act of 1962, as amended (Section 232). Interested parties are invited to submit written comments, data, analyses, or other information pertinent to the investigation to the Department of Commerce's (Department) Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security. This notice identifies issues on which the Department is especially interested in obtaining the public's views.

DATES: Comments may be submitted at any time but must be received by [INSERT DATE 21 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments on this notice may be submitted to the Federal rulemaking portal at: *www.regulations.gov*. The *regulations.gov* ID for this notice is BIS-2025-0258. Please refer to XRIN 0694-XC134 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone

submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission. For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC." Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. The required corresponding non-confidential version of those comments must be clearly marked "PUBLIC." The file name of the non-confidential version should begin with the character "P." Any submissions with file names that do not begin with either a "BC" or a "P" will be assumed to be public and will be made publicly available at: *https://www.regulations.gov*. Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: Stephen Astle, Director, Defense Industrial Base Division, Office of Strategic Industries and Economic Security, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482-4506, medicalequipment232@bis.doc.gov. For more information about the Section 232 program, including the regulations and the text of previous investigations, see *www.bis.doc.gov/232*.

SUPPLEMENTARY INFORMATION:

Background

On September 2, 2025, the Secretary of Commerce initiated an investigation under Section 232 (19 U.S.C. 1862) to determine the effects on national security of imports of personal protective equipment (PPE), medical consumables, and medical equipment, including devices.

Request for Public Comments

This investigation is being undertaken in accordance with part 705 of the National Security Industrial Base Regulations (15 CFR parts 700 to 709) (NSIBR). Interested parties are invited to submit written comments, data, analyses, or information pertinent to this investigation to BIS's Office of Strategic Industries and Economic Security no later than [INSERT DATE 21 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. For purposes of this investigation:

Personal protective equipment (PPE) refers to PPE used in health care settings. PPE includes, but is not limited to, surgical masks, N95 respirators, gloves, gowns, and related medical parts and components.

Medical consumables refers to single-use or short-term-use items used for patient diagnosis, treatment, and prevention of conditions. Medical consumables include but are not limited to: medical/surgical instruments (*e.g.*, syringes, needles, infusion (IV) pumps, forceps, scalpels); medical/surgical supplies (*e.g.*, intravenous (IV) bags, catheters, tracheostomy tubes, anesthesia equipment, gauze/bandages, sutures, diagnostic and laboratory reagents); and related medical parts and components. Pharmaceuticals, such as prescription drugs, over-the-counter drugs, biologics, and specialty drugs, will not be covered under this investigation as those imports are being examined in a separate Section 232 investigation.

Medical equipment refers broadly as durable equipment, tools, and machines used in healthcare to support patient care. Examples include but are not limited to: carriages and wheelchairs; crutches; and hospital beds.

A medical device is any instrument, apparatus, or machine used in the diagnosis, monitoring, or treatment of medical conditions. Examples include but are not limited to: pacemakers; insulin pumps; coronary stents; heart valves; hearing aids; robotic and non-robotic prosthetics; blood glucose monitors; orthopedic appliances; electromedical apparatus (*e.g.*, computed tomography scanners, magnetic resonance imaging machines); electrosurgical

apparatus; x-ray apparatus/other radiation equipment; respiratory machines (*e.g.*, ventilators, respirators, oxygen apparatus); and MRI machines.

The Department is particularly interested in comments and information directed at the criteria listed in § 705.4 of the regulations as they affect national security, including the following:

(i) The current and projected demand for PPE, medical consumables, and medical equipment, including devices, in the United States;

(ii) the extent to which domestic production of PPE, medical consumables, and medical equipment, including devices, can meet domestic demand;

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for PPE, medical consumables, and medical equipment, including devices;

(iv) the concentration of U.S. imports of PPE, medical consumables, and medical equipment, including devices, from a small number of suppliers or foreign nations and the associated risks;

(v) the impact of foreign government subsidies and predatory trade practices on the competitiveness of PPE, medical consumables, and medical equipment, including devices, manufacturers, in the United States;

(vi) the economic impact of artificially suppressed prices of PPE, medical consumables, and medical equipment, including devices, due to foreign unfair trade practices and state-sponsored overproduction;

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over supplies of PPE, medical consumables, and medical equipment (including devices);

(viii) the feasibility of increasing domestic capacity for PPE, medical consumables, and medical equipment, including devices, to reduce import reliance;

(ix) the impact of current trade policies on domestic production of PPE, medical consumables, and medical equipment, including devices, and whether additional measures, including tariffs or quotas, are necessary to protect national security;

(x) the potential for foreign control or exploitation of supply chains for PPE, medical consumables, and medical equipment, including devices, supply chain;

(xi) the ability of foreign persons to weaponize the capabilities or attributes of foreign-built PPE, medical consumables, and medical equipment, including devices; and

(xii) any other relevant factors.

Material submitted by members of the public that is business confidential information will be exempted from public disclosure as provided for by § 705.6 of the regulations (see the **ADDRESSES** section of this notice). Communications from agencies of the United States Government will not be made available for public inspection. BIS does not maintain a separate public inspection facility. Requesters should first view the Bureau's webpage, which can be found at: *https://efoia.bis.doc.gov/* (see "Electronic FOIA" heading). If requesters cannot access the website, they may call (202) 482-0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published at 15 CFR 4.1, *et seq.*

Julia A. Khersonsky,

Deputy Assistant Secretary for Strategic Trade.

[FR Doc. 2025-18729 Filed: 9/24/2025 4:15 pm; Publication Date: 9/26/2025]