BỘ KHOA HỌC VÀ CÔNG NGHỆ
TỔNG CỤC TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG

Số: 1790 /TĐC-TBT
V/v thông tin về xuất khẩu khẩu trang sang Hoa Kỳ

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Hà Nội, ngày 12 tháng 6 năm 2020

Kính gửi:
- Bộ Công Thương;
- Bộ Y tế;
- Phòng Thương mại và Công nghiệp Việt Nam (VCCI);
- Hiệp hội Dệt May Việt Nam.

Trên cơ sở yêu cầu của Tổng cục Tiêu chuẩn Đo lường Chất lượng (Văn phòng TBT Việt Nam), Cơ quan thông báo và hỏi đáp quốc gia về TBT của Hoa Kỳ đã gửi các thông tin liên quan đến các quy định bắt buộc khi xuất khẩu khẩu trang y tế sang thị trường Hoa Kỳ, bao gồm cả quy định về chứng nhận FDA. Tổng cục Tiêu chuẩn Đo lường Chất lượng (Tổng cục TCĐLCL) xin gửi đến Quý Cơ quan, Đơn vị các thông tin này, cụ thể như sau:

1. Thông tin về các thiết bị bảo vệ cá nhân (Personal Protective Equipment (PPE)) nhằm kiểm soát dịch bệnh:

- Khẩu trang phẫu thuật là loại khẩu trang dùng một lần, được thiết kế để miệng và mũi của người đeo không tiếp xúc với các chất gây ô nhiễm trong môi trường, quy định tại Quy định số 21 CFR 878.4040. Khẩu trang phẫu thuật có thể được dán nhãn là khẩu trang phẫu thuật, khẩu trang cách ly, khẩu trang nha khoa hoặc khẩu trang y tế. Khẩu trang phẫu thuật bao gồm cả khẩu trang có kính chắn mặt hoặc không.

- Khẩu trang N95 là một loại thiết bị bảo vệ hô hấp được thiết kế để phù hợp với khuôn mặt và lọc các hạt hiệu quả trong không khí.

Chỉ định 'N95' có nghĩa là khi được kiểm tra nghiêm ngặt, khẩu trang đạt chuẩn N95 có thể ngăn chặn ít nhất 95 phần trăm các hạt thử nghiệm rất nhỏ (0,3 micron). Nếu sử dụng đúng cách, khả năng lọc của khẩu trang N95 tốt hơn nhiều so với khẩu trang thông thường. Tuy nhiên, ngay cả khi được trang bị đúng cách, khẩu trang N95 cũng không hoàn toàn loại bỏ được các nguy cơ mắc bệnh hoặc tử vong.

Một số khẩu trang N95 được dùng để sử dụng trong cơ sở chăm sóc y tế. Đặc biệt, các thiết bị bảo vệ sử dụng một lần này được các nhân viên y tế dùng để bảo vệ chính họ và bệnh nhân khỏi việc lây nhiễm qua các hạt và dịch trong quá trình tiếp xúc với bệnh nhân. Các khẩu trang phẫu thuật N95 này là các thiết bị loại II được quy định theo Quy định 21 CFR 878.4040 bởi Cục quản lý Thực phẩm và Dược phẩm Hoa Kỳ (FDA) và theo Quy định 42 CFR Phần 84 bởi

Trung tâm kiểm soát và phòng ngừa dịch bệnh - Viện Sức khỏe và An toàn Lao động Quốc gia Hoa Kỳ (CDC NIOSH).

Thông tin cụ thể, đề nghị xem tại trang web của Cục quản lý Thực phẩm và Dược phẩm Hoa Kỳ (FDA): https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks.

2. Liên quan đến tình trạng khẩn cấp về y tế do dịch bệnh Covid 19, ngày 28/3/2020, cơ quan FDA của Hoa Kỳ đã cung cấp thông tin liên quan tới các nhà sản xuất, sản phẩm khẩu trang dùng một lần nhập khẩu và khẩu trang dùng một lần không được NIOSH phê chuẩn (Non-NIOSH- Approved Disposable Filtering Facepiece Respirators), nhân viên chăm sóc sức khỏe, các đơn vị thu mua và phân phối sản phẩm y tế; nhà nhập khẩu, bán buôn và các bên liên quan khác (xem phụ lục gửi kèm).

3. Ngoài ra, khi có khó khăn trong việc xuất khẩu các sản phẩm nêu trên doanh nghiệp có thể tìm hiểu thêm các nội dung liên quan tại đường dây nóng do Hoa Kỳ cung cấp. Địa chỉ liên hệ với đường dây nóng FDA COVID:

1-888-INFO-FDA(https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#,), bấm * để chọn các thông tin khác nhau.

- Địa chỉ email: Đối với khẩu trang:

CDRH-COVID19-SurgicalMasks@fda.hhs.gov

- Đối với thiết bị xét nghiệm, chẩn đoán:

COVID19DX@FDA.HHS.GOV

Thời gian: Thứ Hai-Thứ Sáu: 8h00 - 24h00. Ngày lễ: 8h00- 20h00.

Tổng cục TCĐLCL xin gửi Quý Cơ quan, Đơn vị các thông tin trên và kính đề nghị phổ biến, cung cấp đến các doanh nghiệp xuất khẩu liên quan và phản hồi thông tin cho Tổng cục TCĐLCL thông qua Văn phòng TBT Việt Nam, địa chỉ số 08 Hoàng Quốc Việt, Cầu Giấy, Hà Nội, điện thoại 0243.7912.145, email tbtvn@tcvn.gov.vn trong trường hợp doanh nghiệp gặp khó khăn khi đáp ứng các quy định nêu trên của Hoa Kỳ.

Trân trọng cảm ơn sự hợp tác của Quý Cơ quan, Đơn vị./.

Nơi nhận:
- Như trên;
- Lưu: VT, TBT.

KT. TỔNG CỤC TRƯỞNG
PHÓ TỔNG CỤC TRƯỞNG

Nguyễn Hoàng Linh

Phụ lục

THÔNG ĐIỆP CỦA FDA VỀ CẤP PHÉP DO TÌNH TRẠNG DỊCH BỆNH COVID 19

(Kèm theo Công văn số 1790 /TĐC-TBT ngày 12 tháng 6 năm 2020 của Tổng cục Tiêu chuẩn Đo lường Chất lượng)

U.S. FOOD & DRUG ADMINISTRATION

March 28, 2020

To: Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators;
Health Care Personnel;
Hospital Purchasing Departments and Distributors;
Importers and Commercial Wholesalers; and
Any Other Applicable Stakeholders.

Dear Stakeholder:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the Coronavirus Disease 2019 (COVID-19) outbreak, subject to the terms of any authorization issued under that Section.[1]

On March 24, 2020, in response to this evolving public health emergency and continued filtering facepiece respirator (FFR or respirator) shortages, FDA concluded based on the totality of scientific evidence available that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety (as described under section II Scope of Authorization) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3).

On March 28, 2020, to further address the shortage of disposable FFRs, FDA determined it was necessary to reissue the March 24, 2020 letter in order to amend the Scope of Authorization (Section II) to additionally authorize the use of authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.[2]

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[1] U.S. Department of Health and Human Services. *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 4, 2020). U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. March 2, 2020.

[2] For purposes of this EUA, an "authorized decontamination system" means any decontamination system that has been issued an EUA. Authorized decontamination systems can be found on FDA's Emergency Use Authorization webpage, available at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Having concluded that revising the EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the March 24, 2020 letter in its entirety with the amendment[3] incorporated to authorize the emergency use of:

1) Authorized respirators listed in Exhibit 1 for use in healthcare settings by healthcare personnel (HCP)[4] when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak; and,
2) Authorized respirators listed in Exhibit 1 that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

This EUA does not affect the previous March 2, 2020, EUA (reissued on March 27, 2020, and again on March 28, 2020), which authorizes, in part, the emergency use of certain respirators approved by NIOSH, in accordance with 42 CFR Part 84, as non-powered air-purifying particulate FFRs for use in healthcare settings by HCP to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, pursuant to Section 564 of the Act.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the authorized respirators, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter for use in healthcare settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators. This EUA does not permit use of authorized respirators by the general public.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized respirators as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP to prevent wearer

[3] The March 28, 2020 amendment to the March 24, 2020 letter revises the scope of authorized respirators to include authorized respirators listed in Exhibit 1 that are decontaminated using an authorized decontamination system.

[4] Healthcare personnel refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel.

exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID-19, outweigh the known and potential risks of such products; and

3. There is no adequate, approved, and available alternative to the emergency use of the certain respirators for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.[5,6]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized respirators listed in Exhibit 1, and to authorized respirators listed in Exhibit 1 that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system, for use in healthcare settings by HCP as recommended by CDC to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

Respirators Eligible for Authorization under this EUA

Respirators meeting the criteria in the following two categories are eligible for authorization under this EUA as described in this section (Scope of Authorization (Section II)). Respirators that satisfy the eligibility criteria in numerals 1 and/or 2, and that meet the terms and conditions (Conditions of Authorization (Section IV)) of this EUA will be listed in Exhibit 1 pursuant to the procedure outlined below. The categories of eligibility are as follows:

1. **Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications, as follows:**

[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[6] There are not sufficient quantities of FFRs that are both NIOSH-approved and meet FDA regulatory requirements to meet the needs of the U.S. healthcare system. These disposable respirators are an integral part of routine patient care. Providing HCP who are on the forefront of the COVID-19 response with FFRs consistent with the CDC's guidance and recommendations is necessary in order to reduce the risk of illness in HCPs and increase their willingness to provide care to affected patients or those suspected of having COVID-19.

Table 1:

Jurisdiction[7]	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

2. **Disposable FFRs which have a marketing authorization in one of the following regulatory jurisdictions:**

    - European CE Mark
    - Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion
    - Health Canada Licence
    - Japan Pharmaceuticals and Medical Device (PMDA)/Ministry of Health Labour and Welfare (MHLW)

In order to be added to Exhibit 1 as an authorized respirator under this EUA, manufacturers and/or importers must send a request to FDA by email of their intent to import non-NIOSH approved disposable respirators that are eligible for authorization under 1 and/or 2 above. The manufacturer or importer should send a request to be authorized under this EUA by email to FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the following information, which will allow FDA to determine whether the disposable respirator meets the criteria to be added to Exhibit 1 as an authorized respirator under this EUA:

- Specify the manufacturer, model number(s), marketing authorization/certificate from another regulatory authority or conformity assessment body acting on their behalf (including the authorization number (if any)), certificate of conformity (if available),

[7] Canada is not listed because it allows self-declaration to NIOSH or equivalent standards.

applicable performance standards that their product meets, and any applicable guidance documents.

- An estimate of the number of respirators you are planning to import during the public health emergency,
- A copy of the product labeling. Respirators must comply, at a minimum, with the labeling requirements in conditions A and B under the Conditions of Authorization (Section IV) of this letter.

Once FDA receives the above information, and any additional information it needs to confirm applicability of the imported disposable respiratory with eligibility under the categories outlined above, FDA will notify the manufacturer of the inclusion of their authorized respirator(s) in Exhibit 1 under this EUA by replying to the manufacturer's or importer's email.

Authorized Respirators

The above described authorized respirators listed in Exhibit 1, when labeled as described in this letter, are authorized to be distributed to and used in healthcare settings by HCPs when used in accordance with CDC's recommendations under this EUA, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

Additionally, authorized respirators listed in Exhibit 1 that have been decontaminated using an authorized decontamination system remain authorized under this EUA to be used in healthcare settings by HCP when used in accordance with the terms and conditions of the authorized decontamination system without the need for any action by the respirators' manufacturer, despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized respirators when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized respirators may be effective at preventing HCP exposure to certain particulates to prevent disease spread, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and conclude that the authorized respirators, when used in healthcare settings to prevent HCP exposure to certain particulates to prevent disease spread (as described in the Scope of Authorization of this letter (Section II)), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized respirators under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the

Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the authorized respirators are authorized to be used in healthcare settings by HCP under the terms and conditions of this EUA. EUA amendments may be undertaken as needed with concurrence of: OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized respirators that are used in accordance with this EUA.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Manufacturers of Authorized Respirators

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

C. Manufacturers of authorized respirators will notify the importer (if applicable) of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

D. Manufacturers of authorized respirators will have a process in place for reporting adverse events of which they become aware and send such reports to FDA.

E. All descriptive printed material relating to the use of the authorized respirators in the United States shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

F. No descriptive printed matter relating to the use of the authorized respirators in the United States may represent or suggest that the product is safe or effective for the prevention of COVID-19.

G. Manufacturers of authorized respirators will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

H. Manufacturers of authorized respirators that are decontaminated by an authorized decontamination system are not responsible for any additional conditions that may apply to the manufacturer and/or operator of the decontamination system, unless they are the same manufacturer.

Importers

I. All descriptive printed material relating to the use of the authorized respirators shall be consistent with applicable CDC recommendations for use during the COVID-19 outbreak, as well as the terms set forth in this EUA.

J. No descriptive printed material relating to the use of the authorized respirators may represent or suggest that the product is safe or effective for the prevention of COVID-19.

K. Importers of authorized respirators will notify manufacturers of the terms and conditions of this EUA and ensure that the end user facility (e.g., each hospital, etc.) that receives the authorized respirators also receives the information required under Condition B.

L. Importers of authorized respirators will ensure that any records associated with this EUA are maintained until the end of this public health emergency.

Manufacturers and/or Operators of Authorized Decontamination Systems

M. Each manufacturer and/or operator of an authorized decontamination system for decontamination of authorized respirators must comply with the Conditions of Authorization and authorized labeling as set forth in the Letter of Authorization for the authorized decontamination system.

The emergency use of the authorized respirators as described in this letter of authorization must comply with the conditions and all other terms of this authorization.