June 6, 2020

Bill Brodbeck, Ph.D.
Senior Director, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Dear Dr. Bill Brodbeck:

On April 9, 2020, based on your[1] request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the STERIS Sterilization System[2] for use in decontaminating compatible N95 respirators[3] for single-user reuse[4] by healthcare personnel (HCP)[5] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of N95 respirators resulting from the Coronavirus Disease 2019 (COVID-19) pandemic.

On June 6, 2020, in response to your request and having determined that revising the April 9, 2020 letter is appropriate to protect the public health and safety, FDA is reissuing the April 9, 2020 letter in order to revise the Scope of Authorization (Section II). Specifically, this letter revises the Scope of Authorization to add the STERIS V-PRO 60 and V-PRO s2 Low Temperature Sterilization Systems to your authorized product[6] for use in decontaminating

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to STERIS Corporation.
[2] In the April 9, 2020 letter, the authorized models under the EUA included STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Low Temperature Sterilization Systems.
[3] In the April 9, 2020 letter, "compatible N95 respirators" were defined as any N95 or N95-equivalent respirators that do not contain cellulose-based materials. The April 9, 2020 letter also defined "N95-equivalent respirators" as respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators and identified in Appendix A of the EUA for Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
[4] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination. FDA has made clarifying edits to this definition which was: "single-user reuse means that the same HCP should use the mask following decontamination" in the April 9, 2020 letter. This clarifying edit does not change the Scope of Authorization.
[5] HCP 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 HCP 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).
[6] For ease of reference, this letter will use the term "your product" or "STERIS Sterilization Systems" to refer to the V-PRO 1 Plus, V-PRO maX, V-PRO maX2, V-PRO 60, and V-PRO s2 models of the vaporized hydrogen peroxide

compatible N95 respirators[7] for single-user reuse by HCP as additional authorized products under this EUA. Additionally, FDA is also revising the Scope of Authorization with respect to which respirators may be decontaminated using this decontamination system in order to address public health and safety concerns regarding certain respirators. As set forth in the revised Scope of Authorization, the STERIS Sterilization Systems are no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA nor is the device authorized to decontaminate respirators that have exhalation valves. Having concluded that revising the April 9, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(g)(2)(C)), FDA is reissuing the April 9, 2020 letter in its entirety with the revisions[8] incorporated.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, 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.[9] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[10]

The STERIS Sterilization Systems were previously cleared by FDA as class II devices intended for use in the terminal sterilization of reusable medical devices in healthcare facilities. The STERIS Sterilization Systems are not cleared, approved, or subject to an approved investigational device exemption for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic, and therefore, require an EUA for such use. Additionally, there are no FDA approved or cleared devices for decontaminating the

(VHP) low temperature sterilization systems.

[7] For purposes of this revised EUA, "compatible N95 respirators" are non-cellulose containing respirators that do not have an exhalation valve that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[8] The revisions to the April 9, 2020 letter include the following: (1) the Scope of Authorization has been revised to include the STERIS V-PRO 60 and V-PRO s2 Low Temperature Sterilization Systems for use in decontaminating compatible N95 respirators for single-user reuse by HCP as authorized products under this EUA; (2) the Scope of Authorization is revised such that this decontamination system is no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA and is not authorized to decontaminate respirators that have an exhalation valve; and (3) FDA has made some clarifications to the Conditions of Authorization (Section IV) of this letter.

[9] 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 7, 2020).

[10] U.S. Department of Health and Human Services, *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 17335 (March 27, 2020).

compatible N95 respirators, which are needed for use by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Leveraging performance data submitted within previous applications supporting device clearance of the STERIS Sterilization Systems for use in the terminal sterilization of reusable medical devices in healthcare facilities, FDA has reviewed the totality of scientific evidence available, including the following information that you provided in your request: bioburden reduction validation demonstrating > 3 log reduction of a non-enveloped virus challenge; testing regarding material compatibility, functionality, and filtration performance of compatible N95 respirators after multiple decontamination cycles; and testing regarding hydrogen peroxide residuals after decontamination of compatible N95 respirators.

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 STERIS Sterilization Systems, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the STERIS Sterilization Systems, as described in the Scope of Authorization (Section II) of this letter, 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 STERIS Sterilization Systems may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the STERIS Sterilization Systems for decontamination of compatible N95 respirators to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, during FFR shortages during the COVID-19 pandemic.[11,12]

[11] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[12] There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of FFRs, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be decontaminated for reuse. Providing a method for decontaminating compatible N95 respirators reduces stress on the supply chain and helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with FFRs is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

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 STERIS Sterilization Systems for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of 10 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Authorized STERIS Sterilization Systems

The STERIS Sterilization Systems (i.e., the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2, V-PRO 60, and V-PRO s2 models of the vaporized hydrogen peroxide (VHP) sterilizers), contain a pre-programmed Non-Lumen Cycle, in addition to other cycles, intended for terminal sterilization of properly prepared (cleaned, rinsed, and dried) medical devices in healthcare facilities. For this emergency use, the STERIS Sterilization Systems must be operated in the Non-Lumen Cycle to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms so that the respirators can be decontaminated for single-user reuse by HCP. N95 respirators containing cellulose-based materials and respirators that have exhalation valves are **not** compatible with the STERIS Sterilization Systems. This system is also not authorized to decontaminate respirators authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.

The V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 models are to be used with a maximum of 10 compatible N95 respirators that are individually pouched in STERIS low temperature sterilization pouches (a maximum of 5 per shelf). The V-PRO 60 and V-PRO s2 models are to be used with a maximum of 6 compatible N95 respirators that are individually pouched in STERIS low temperature sterilization pouches (a maximum of 3 per shelf).

STERIS recommends only the use of Tyvek pouches that have been cleared for use in sterilization by vaporized hydrogen peroxide. Cellulose-based pouches are **not** compatible with the STERIS Sterilization Systems. A chemical indicator or chemical indicator tape identified for the STERIS Sterilization Systems must be placed in the chamber to verify sterilant exposure.

When the Non-Lumen Cycle starts, the load is processed by automatic moisture checks in order to ensure the removal of the moisture from the load. VHP is injected during four sterilization pulses per sterilization cycle. The load is automatically aerated after the last segment and the chamber is exhausted through a catalytic converter that decomposes VHP into water and oxygen.

Validation studies conducted by the firm indicate that compatible N95 respirators can be decontaminated through the Non-Lumen Cycle of the STERIS Sterilization Systems a maximum of 10 times. The respirator reuse limit is based upon the filtration performance evaluations of respirators that were decontaminated 10 times using the Non-Lumen Cycle of the STERIS Sterilization Systems.

At completion of the sterilization cycle, the load is removed and can be immediately used or stored prior to use. Following completion of the cycle, the chemical indicator's color will be compared to the "PASS" reference color. If the colors matched or the color present is lighter, the respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirators will not be considered decontaminated and either re-run through the Non-Lumen Cycle of the STERIS Sterilization Systems or discarded. Any visibly soiled (e.g., contaminated with mucous, blood, or other extraneous soil) or damaged respirators will not be decontaminated in the STERIS Sterilization Systems and will be immediately discarded.

The above described product is authorized to be accompanied with the following product-specific information (that will be made available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) pertaining to emergency use, and is required to be made available to healthcare personnel and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination Using the STERIS Sterilization Systems; and

- Instructions for Healthcare Facilities: Decontamination of Compatible N95 Respirators Using the STERIS Sterilization Systems.

In addition, following decontamination, compatible N95 respirators decontaminated by the STERIS Sterilization Systems must be accompanied by the following labeling, developed by STERIS Corporation, upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: STERIS Sterilization Systems for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities are collectively referred to as "authorized labeling." The above described product, when accompanied with the described labeling is authorized to be distributed to and administered under this EUA, despite the fact that it does 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 STERIS Sterilization Systems, when used and labeled 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 STERIS Sterilization Systems may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic, when used consistently with the Scope of Authorization (Section II) of this letter, 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 of this letter, and concludes that the STERIS Sterilization Systems (as described in the Scope of Authorization (Section II)), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the STERIS Sterilization Systems 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 and conditions 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 STERIS Sterilization Systems are authorized for emergency use, as described in the Scope of Authorization (Section II).

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practices otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under sections 520(f)(1) of the Act. FDA grants that waiver, including the quality system requirements under 21 CFR Part 820.

IV. Conditions of Authorization

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

STERIS Corporation ("STERIS")

A. STERIS must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions), as well as those described in Section II of this letter, the Scope of Authorization.

B. STERIS must provide to all healthcare facility customers the authorized labeling before the decontamination process begins.

C. STERIS must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities before the decontamination process begins.

D. STERIS may make changes to the process, procedures, and/or labeling for the authorized product, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

E. STERIS may make changes to the scope of this EUA, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of Chief Scientist (OCS)/Office of the Commissioner (OC).

F. Use of the STERIS Sterilization Systems on other types of personal protective equipment is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.

G. STERIS will have a process in place to report adverse events of which they become aware to FDA related to the STERIS Sterilization Systems and compatible N95 respirators that have undergone decontamination using the STERIS Sterilization Systems ("the decontaminated, compatible N95 respirators") in accordance with 21 CFR Part 803. This includes reports from healthcare facilities concerning infection or potential infection of personnel involved in the use of the STERIS Sterilization Systems and users of the decontaminated, compatible N95 respirators.

H. STERIS will have a process in place to collect information on the performance of the STERIS Sterilization Systems, including information regarding degradation of decontaminated, compatible N95 respirators, and evaluate this information to determine if adverse event reporting in accordance with 21 CFR Part 803 is warranted.

I. STERIS 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.

J. STERIS is authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Healthcare Facilities

K. Healthcare facilities shall notify STERIS when they intend to use the STERIS Sterilization Systems for the emergency use, consistent with Section II of this letter.

L. Healthcare facilities shall make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Fact Sheet for Healthcare Personnel and Instructions for Healthcare Personnel that is required to be provided by STERIS.

M. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the STERIS Sterilization Systems and the decontaminated, compatible N95 respirators in accordance with 21 CFR Part 803. This includes monitoring personnel using the STERIS Sterilization Systems and HCPs using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections.

N. Healthcare facilities using the decontaminated, compatible N95 respirators must inspect the decontaminated, compatible N95 respirators. Any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator shall promptly be reported to STERIS, and the healthcare facility must discard the respirator.

O. Healthcare facilities must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of 10 decontamination cycles per compatible N95 respirator. Healthcare facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user. Healthcare facilities shall maintain documentation for use of the STERIS Sterilization Systems consistent with current healthcare facility protocols.

Conditions Related to Printed Materials, Advertising and Promotion

P. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Q. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product may represent or suggest that such products are safe or effective for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

R. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product clearly and conspicuously shall state that:

- the STERIS Sterilization Systems have neither been cleared or approved for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;
- the STERIS Sterilization Systems have been authorized by FDA under an EUA;
- the STERIS Sterilization Systems are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton -S3

Digitally signed by Denise M. Hinton -S3
Date: 2020.06.06 22:55:47 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures