U.S. FOOD & DRUG ADMINISTRATION

April 9, 2020

Mr. Bill Brodbeck
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Dear Mr. Brodbeck:

This letter is in response to your request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of the STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems[1] (hereafter "STERIS Sterilization Systems") for use in decontaminating compatible N95 or N95-equivalent[2] respirators ("compatible N95 respirators")[3] for single-user[4] reuse 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 February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (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.[6] Pursuant to Section 564 of the Act, and on the basis of such determination,

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[1] This EUA includes the emergency use of the STERIS V-PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems in the Non-Lumen Cycle for decontamination of compatible N95 respirators (as defined in footnote 3).

[2] For purposes of this EUA, "N95-equivalent respirators" refers to respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators and in Appendix A of the EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China, which are available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[3] For purposes of this EUA, "compatible N95 respirators" means any N95 or N95-equivalent respirator that does not contain cellulose-based materials. Respirators containing cellulose-based materials are incompatible with the STERIS Sterilization Systems. Please see FDA's website for further information on N95 respirators, available at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks.

[4] Single-user reuse means that the same HCP should use the mask following decontamination.

[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] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that

the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.[7]

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 for decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms during the COVID-19 pandemic 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 preventing exposure to pathogenic airborne particulates when there are insufficient supplies of N95 respirators during the COVID-19 pandemic by decontaminating for a maximum of 10 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, and that the known and potential benefits of the STERIS Sterilization Systems, when used to decontaminate compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic airborne particulates during N95 respirator shortages during the COVID-19 pandemic, outweigh the known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of the STERIS Sterilization Systems for decontaminating compatible N95 respirators for reuse by HCPs during N95 respirator shortages during the COVID-19 pandemic.[8,9]

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) (accessible at https://www.fda.gov/media/135010/download).

[7] 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).

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

[9] There are not sufficient quantities of N95 respirators 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 N95 respirators, 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 N95 respirators is necessary in order to

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 airborne particulates during the COVID-19 pandemic.

Authorized STERIS Sterilization Systems

The STERIS Sterilization Systems, including the V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 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 of the STERIS Sterilization Systems, specifically the V-PRO 1 Plus, V-PRO maX, and V-PRO maX2, the system must be operated in Non-Lumen Cycle to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms so that the respirators can be reused by HCP. N95 or N95-equivalent respirators containing cellulose-based materials are **not** compatible with the STERIS Sterilization Systems. The STERIS 60 Liter chamber units (V-PRO 60 and V-PRO s2) are **not** included in this EUA.

The STERIS Sterilization Systems is 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). 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 can 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 four times during each sterilization cycle (pulse). 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 processed 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 processed for 10 exposures in the Non-Lumen Cycle of the STERIS Sterilization Systems.

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reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

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 should 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 should 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 should not be processed in the STERIS Sterilization Systems and should be immediately discarded.

The STERIS Corporation ("STERIS") must provide the following information pertaining to the emergency use of the STERIS Sterilization Systems before the decontamination process begins (i.e., before a healthcare facility begins preparing and collecting compatible N95 respirators for decontamination for use with STERIS Sterilization Systems—which the healthcare facility already owns, or the healthcare facility has notified STERIS of its intent to purchase—consistent with the use outlined in the Scope of Authorization of this letter (Section II)), which are authorized to be made available to HCP and healthcare facilities:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination Using the STERIS Sterilization Systems ("Instructions for Healthcare Personnel"); and
- Instructions for Healthcare Facilities: Decontamination of Compatible N95 Respirators Using the STERIS Sterilization Systems ("Instructions for Healthcare Facilities").

In addition, following decontamination, compatible N95 respirators decontaminated by the authorized product must be accompanied by the following labeling, developed by STERIS Corporation, upon return of the respirators to the appropriate single-user HCP:

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

The Fact Sheet, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, and Instructions for Use are referred to as "authorized labeling."

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 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 STERIS Sterilization Systems is authorized to be used for decontaminating compatible N95 respirators that are authorized to be used by HCP in healthcare settings under the terms and conditions of this EUA.

Changes to the process, procedures, or labeling for the authorized product may be revised, subject to review and concurrence of the Division of Infection Control and Plastic Surgery Devices/OPEQ/CDRH and OCET/OCS/OC.

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 preventing HCP exposure to pathogenic airborne particulates during N95 respirator shortages during the COVID-19 pandemic by decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, 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 concludes that the STERIS Sterilization Systems, when used to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

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 the following requirements for the STERIS Sterilization Systems during the duration of this EUA:

- applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the authorized STERIS Sterilization Systems used in accordance with this EUA; and
- labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements (see Subpart B of 21 CFR Part 801), except that the STERIS Sterilization Systems must comply with the authorized labeling requirements specified in this EUA (Section II).

IV. Conditions of Authorization

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

<u>STERIS Corporation ("STERIS")</u>

A) STERIS will make available to all existing customers the authorized labeling for the STERIS Sterilization Systems through posting on the STERIS website and notifying their distribution list of healthcare facilities. In this notification, STERIS will instruct healthcare facilities to

notify STERIS if the healthcare facility intends to use the STERIS Sterilization Systems for the emergency use. STERIS will send the appropriate authorized labeling to each healthcare facility that notifies STERIS that the healthcare facility intends to use the STERIS Sterilization Systems for the emergency use, consistent with Section II of this letter.

B) STERIS will make available to all new customers the authorized labeling for the STERIS Sterilization Systems, consistent with Section II of this letter. STERIS will instruct new customers to notify STERIS if the healthcare facility intends to use the STERIS Sterilization Systems for the emergency use.

C) 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.

D) All descriptive printed matter relating to the use of the STERIS Sterilization Systems shall be consistent with the authorized labeling. No descriptive printed matter relating to the use of the STERIS Sterilization Systems may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

E) STERIS will have a process in place for reporting adverse events about the STERIS Sterilization Systems and the decontaminated, compatible N95 respirators of which they become aware and send such reports to FDA, and will establish a process to collect information from healthcare facility customers regarding degradation of decontaminated, compatible N95 respirators and reports of infection or potential infection of users of the decontaminated compatible N95 respirators and send such reports weekly to FDA.

F) STERIS will ensure that any records associated with this EUA, including, but not limited to, records of healthcare facilities that have notified STERIS that the facility is using the STERIS Sterilization Systems consistent with the Section II of this letter, are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

G) 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

H) Healthcare facilities should notify STERIS in advance of use of the STERIS Sterilization Systems for the emergency use, consistent with Section II of this letter.

I) Healthcare facilities using compatible N95 respirators that have undergone decontamination using the STERIS Sterilization Systems ("the decontaminated, compatible N95 respirators") should make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Fact Sheet for Healthcare Personnel and authorized Instructions for

Healthcare Personnel that is required to be provided by STERIS.

J) Healthcare facilities using the decontaminated, compatible N95 respirators should monitor HCP who use such respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to STERIS, so that STERIS can provide a weekly report to FDA consistent with Section IV.F of this EUA. Reports of adverse health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

K) Healthcare Facilities using the decontaminated, compatible N95 respirators must inspect the decontaminated, compatible N95 respirators following the decontamination process using the STERIS Sterilization Systems. Any discoloration or other signs of degradation with a decontaminated respirator should promptly be reported to STERIS, and the healthcare facility should discard the respirator.

L) 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 should maintain documentation for use of the STERIS Sterilization Systems consistent with current healthcare facility protocols.

Conditions Related to Advertising and Promotion

M) All advertising and promotional descriptive printed matter relating to the use of STERIS Sterilization Systems 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.

N) No advertising or promotional descriptive printed matter relating to the use of STERIS Sterilization Systems may represent or suggest that such products are safe or effective for the prevention or treatment of patients who have COVID-19.

O) All advertising and promotional descriptive printed matter relating to the use of STERIS Sterilization Systems clearly and conspicuously shall state that:

- the STERIS Sterilization Systems have neither been cleared or approved for the indication to treat patients with COVID-19 infection;
- 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 the STERIS Sterilization Systems 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 the authorization of the emergency use of the STERIS Sterilization Systems during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures