May 21, 2020

William Brodbeck
Senior Director, Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Dear William Brodbeck:

This letter is in response to your[1] request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of your product[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 face-filtering respirators (FFRs) 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] For ease of reference, this letter will use the term "you" and related terms to refer to STERIS Corporation.

[2] For ease of reference, this letter will use the term "your product" to refer to AMSCO Medium Steam Sterilizers (a collection of sterilizer products as specified in Section II of this letter) and the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers as the cycle for decontamination of compatible N95 respirators.

[3] For purposes of this EUA, "compatible N95 respirators" means **the 3M 1860, 3M 1860S, and 3M 1804 NIOSH-approved N95 respirators only**. **These N95 respirators are labeled with their model numbers. Compatibility of other N95 or N95-equivalent respirators with the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers has not yet been demonstrated.** 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 respirator is returned for reuse to the same healthcare personnel following its 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*

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.[7]

There are insufficient supplies of compatible N95 respirators to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic, and there are no FDA approved, licensed, or cleared devices for decontaminating compatible N95 respirators. The medical devices that are the subject of this EUA, collectively referred to as "AMSCO Medium Steam Sterilizers" and further identified in Section II of this letter, are FDA-cleared under the premarket notification (510(k)) submissions K010865 and K112055 and are indicated for sterilization of heat and moisture-stable materials used in healthcare facilities.[8] With use of a new steam cycle (STERIS STEAM Decon Cycle) after the installation of a software update on the AMSCO Medium Steam Sterilizers by STERIS service personnel, healthcare facilities can then use the STERIS STEAM Decon Cycle on the AMSCO Medium Steam Sterilizers to decontaminate compatible N95 respirators for single-user reuse by HCP during the COVID-19 pandemic.

FDA has reviewed the following information that you provided: bioburden reduction validation testing using the STERIS STEAM Decon Cycle on 3M N95 respirator test coupons using *Feline calicivirus* as a viral challenge and *Mycobacterium smegmatis* as a mycobacterial challenge; existing performance data on the AMSCO Medium Steam Sterilizers from the 510(k) submissions K010865 and K112055; an analysis of the number of compatible N95 respirators that be accommodated within a given sterilizer; and material compatibility testing, fit testing, and filtration performance testing following repeated decontamination cycles. FDA has concluded that such decontaminated, compatible N95 respirators are fit for single-user reuse for a maximum of 10 decontamination cycles per respirator.

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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers, 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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers, 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:

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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).

[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] The FDA-cleared indications did not include use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers, which is now authorized as described in this letter.

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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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 for a maximum of 10 decontamination cycles per respirator, and that the known and potential benefits of this product, when used as described, 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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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.[9,10]

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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, for a maximum of 10 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic.

Authorized STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers

In this letter, "AMSCO Medium Steam Sterilizers" refers to the AMSCO Century Medium Steam Sterilizers 26" x 37.5" (x 36", 48", or 60") (FDA-cleared under K010865) and the AMSCO 400 Series Medium Steam Sterilizer Models 36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL, 60CSL (FDA-cleared under K112055).

The AMSCO Medium Steam Sterilizers are FDA-cleared as moist heat sterilization systems intended for sterilization of heat and moisture-stable materials used in healthcare facilities and contain pre-programmed sterilization cycles. For this EUA, STERIS Corporation developed a

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

[10] 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 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 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.

new cycle, the STERIS STEAM Decon Cycle, to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms.

The STERIS STEAM Decon Cycle is currently limited to the decontamination of 3M 1860, 3M 1860S, and 3M 1804 NIOSH-approved N95 respirators, previously referenced as "compatible N95 respirators". These N95 respirators are labeled with their model numbers. Compatibility of other N95 or N95-equivalent[11] respirators with the STERIS STEAM Decon Cycle has not yet been demonstrated. Compatible N95 respirators are individually pouched using sterilization pouches that are FDA-cleared for steam sterilization. Visibly soiled, damaged, or wet compatible N95 respirators are not authorized to be decontaminated using the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers and should be immediately discarded.

Depending on the sterilizer, the number of pouched, compatible N95 respirators that can be placed in the sterilizer for one cycle ranges as shown in Table 1 below:

Table 1

Sterilizer Size / Models	**Number of Trays**	**Number of Pouched Respirators**
26" x 37.5" x 36" AMSCO Century 36" AMSCO 400 36H, 36SL, 36CH, 36CSL	9	108
26" x 37.5" x 48" AMSCO Century 48" AMSCO 400 48H, 48SL, 48CH, 48CSL	12	144
26" x 37.5" x 60" AMSCO Century 60" AMSCO 400 60H, 60SL, 60CH, 60CSL	15	180

The STERIS STEAM Decon Cycle operates on the AMSCO Medium Steam Sterilizers as a gravity steam cycle with no preconditioning. The temperature inside the sterilization chamber is increased to 65°C and 21 in mercury (Hg) exposure pressure. Once the temperature and pressure reach the set point, the cycle is held for 30 minutes, followed by a one-minute dry time. Upon cycle completion, to confirm that the cycle completed successfully, the cycle tape should be reviewed to confirm that exposure temperature, pressure, and time specifications were met.

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

[11] For purposes of this EUA, "N95-equivalent respirators" refers to respirators 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.

emergency use, along with the AMSCO Medium Steam Sterilizers' User Manual(s),[12] and is required to be made available to HCP and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination Using the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers; and

- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination using STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers.

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

- Fact Sheet for Healthcare Personnel: STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers for Decontaminating Compatible N95 Respirators.

The AMSCO Medium Steam Sterilizers User Manuals, 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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers, when used and labeled consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such product.

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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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 STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers (as described in the Scope of

[12] STERIS AMSCO Medium Steam Sterilizer User Manuals include instructions for use for all cycles and are not limited to the authorized use under this EUA (i.e., the STERIS STEAM Decon Cycle). The User Manuals include:

- OPERATOR MANUAL - AMSCO 400 Series Medium Steam Sterilizers 26"x 37.5" (660 x 953 mm) – Prevacuum
- OPERATOR MANUAL - AMSCO Century Medium Steam Sterilizers 26"x 37.5" (660 x 953 mm) – Prevacuum – SFPP

Authorization (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers is 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). FDA grants that waiver, including the quality system requirements under 21 CFR 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, 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. STERIS must submit (a) material compatibility data, (b) decontamination validation data, (c) filtration data, and (d) fit data for FDA review in order to revise the scope of this EUA for any of the following:
   i) Inclusion of additional types/models of N95 or N95-equivalent respirators;
   ii) Inclusion of additional STERIS STEAM Sterilizer models that can be updated to use the STERIS STEAM Decon Cycle; or
   iii) Increase in the number of decontamination cycles per compatible N95 respirator.

G. Use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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.

H. STERIS will have a process in place to report adverse events of which they become aware to FDA related to the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers and compatible N95 respirators that have undergone decontamination using the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers ("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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers and users of the decontaminated, compatible N95 respirators.

I. STERIS will have a process in place to collect information on the performance of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers, 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.

J. 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.

K. 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

L. Healthcare facilities shall notify STERIS when they intend to use the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers for the emergency use, consistent with Section II of this letter.

M. 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 are required to be provided by

STERIS.

N. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers and the decontaminated, compatible N95 respirators in accordance with 21 CFR Part 803. This includes monitoring personnel using the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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.

O. 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.

P. 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.

Q. Healthcare facilities shall maintain documentation for use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers consistent with current healthcare facility protocols. Healthcare facilities shall maintain documentation of exposure conditions, including time, temperature, and pressure, as well as confirmation that the specified exposure conditions were met to achieve decontamination of compatible N95 respirators for each cycle run. Healthcare facilities shall maintain this documentation associated with this EUA until otherwise notified by FDA. Such documentation will be made available to FDA upon request.

Conditions Related to Printed Materials, Advertising and Promotion

R. All descriptive printed matter, including advertising and promotional materials, relating to the use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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.

S. No descriptive printed matter, including advertising or promotional materials, relating to the use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers 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.

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

- the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers has 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 STEAM Decon Cycle in AMSCO Medium Steam Sterilizers has been authorized by FDA under an EUA;

- the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, 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: 2020.05.21 17:16:05 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures