January 21, 2021

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

Dear William Brodbeck:

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 Coronavirus Disease 2019 (COVID-19).[1] 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.[2]

On May 21, 2020, based on your[3] request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of your product[4] for use in decontaminating compatible N95 respirators[5] for single-user reuse[6] by healthcare personnel (HCP)[7] to prevent exposure to pathogenic biological airborne particulates when there are

[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 7, 2020).
[2] 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).
[3] For ease of reference, this letter will use the term "you" and related terms to refer to STERIS Corporation.
[4] 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.
[5] In the May 21, 2020 EUA, "compatible N95 respirators" were defined as **the 3M 1860, 3M 1860S, and 3M 1804 NIOSH-approved N95 respirators only**. The May 21, 2020 EUA further stated, **"These N95 respirators are labeled with their model numbers,"** and **"Compatibility of other N95 or N95-equivalent respirators with the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers has not yet been demonstrated."**
[6] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination.
[7] For the purposes of this EUA, 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

insufficient supplies of filtering facepiece respirators (FFRs) resulting from the COVID-19 pandemic.

On January 21, 2021, in response to your request to revise the scope of the EUA to include one additional model of compatible N95 respirator, and in response to public health and safety concerns regarding the decontamination of certain respirators, FDA is reissuing the May 21, 2020 letter in order to revise the authorization of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers to include the following aspects:

1. Revision of the definition of "compatible N95 respirators"[8] to additionally include the 3M 8210 model of N95 respirator.
2. Limitation of the maximum number of decontamination cycles to four (4) cycles per compatible N95 respirator with the option to increase the maximum cycles with the submission of, and subject to review and concurrence with, real-world evidence (RWE) for more than 4 cycles.
3. Incorporation of a post-authorization study to collect RWE to verify that compatible N95 respirators are capable of adequate reuse after 4 decontamination cycles.[9]

Your product is no longer authorized to decontaminate compatible N95 respirators up to 10 cycles and is now authorized to perform such decontamination for a maximum of 4 times per respirator. A Condition of Authorization (Section IV.M) has been added in which you must conduct a post-authorization study to verify that compatible N95 respirators are adequate for reuse following 4 decontamination cycles. The maximum number of cycles can be increased following submission and review of RWE for greater than 4 decontamination cycles (see Section IV.N). These revisions are reflected in the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and authorized labeling. Having concluded that revising the May 21, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act, FDA is reissuing the May 21, 2020 letter in its entirety with the revisions incorporated.

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 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.[10] With use of a new steam cycle (STERIS

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).

[8] For the purposes of this revised EUA, "compatible N95 respirators" are **the 3M 8210, 3M 1860, 3M 1860S, and 3M 1805 NIOSH-approved N95 respirators only.** 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.

[9] Other minor corrections and clarifications have also been made during the review and edit process for reissuance of the January 21, 2021 letter.

[10] 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.

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.

In evaluating this EUA, FDA reviewed the totality of scientific evidence available, which includes: 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 and Mycobacterium hassiacum* 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.

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:

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, 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 decontaminating compatible N95 respirators 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.[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 N95 respirators, HCP may need to treat

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 four (4) 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 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 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 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH-approved N95 respirators, previously referenced as "compatible N95 respirators". 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/capacity 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"	9	108

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.

AMSCO 400 36H, 36SL, 36CH, 36CSL		
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 AMSCO Medium Sterilizers’ User Manual(s),[13] as well as 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 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 Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities, and AMSCO Medium Steam Sterilizers User Manuals are collectively referred to as “authorized labeling.” The above described product, when accompanied with the

[13] 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

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 the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers (as described in the Scope of 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) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, 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 Section 520(f)(1) of the Act. 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 request changes to this EUA for the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers[14], including changes to the authorized labeling. Any request for changes to this EUA must be submitted to the Division of Infection Control and Plastic and Reconstructive Surgery (DHT4B)/Office of Health Technology 4: Office of Surgical and Infection Control Devices (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation.

E. STERIS may request and be allowed to add compatible N95 respirator models under Condition D. To support such a request, STERIS must provide to FDA validation data to support new respirator models.

F. STERIS may request and be allowed to increase the maximum capacity of compatible N95 respirators per decontamination cycle under Condition D. To support such a request, STERIS must provide FDA validation data to support the increased decontamination capacity.

G. STERIS may request and be allowed to add additional STERIS STEAM Sterilizer models under Condition D. To support such a request, STERIS must provide to FDA validation data to support additional STERIS STEAM Sterilizer models.

H. 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.

I. STERIS will have a process in place and adequate Medical Device Reporting procedures, in accordance with 21 CFR Part 803, to report to FDA adverse events of which STERIS becomes aware 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,

[14] The following types of revisions may be authorized without reissuing this letter: (1) non-substantive editorial corrections to this letter; (2) new types of authorized labeling, including new fact sheets; (3) new carton/container labels; (4) changes to manufacturing processes, including tests or other authorized components of manufacturing; (5) new conditions of authorization to require data collection or study; (6) new instruments, associated software, components or materials in the authorized product or modifications in the way that the device is used. For changes of the type listed in (5) or (6), review and concurrence is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

compatible N95 respirators"). This includes, but is not limited to, 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.

J. 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.

K. 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.

L. 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.

M. STERIS must collect and submit to FDA real-world use data for FDA review to confirm the continued fit and performance of compatible N95 respirators authorized under this EUA after undergoing four (4) cycles of decontamination. The authorized maximum number of four (4) decontamination cycles per compatible N95 respirator (Scope of Authorization (Section II)) will be maintained or revised based on the real-world use data.

You must complete your study within 60 days of the date of this letter or before 1500 compatible N95 respirators have been decontaminated using your system, whichever is later. You may seek an extension to complete your study where agreed upon by DHT4B/OHT4/OPEQ/CDRH. Your results must be submitted to DHT4B/OHT4/OPEQ/CDRH for review within 15 days of the study completion. Upon completion of FDA's review, you must publish the study results on your website.

At minimum, the study design must include the following testing with acceptance criteria and sampling:

1. Fit Testing (**Required**)
    a. Acceptance Criteria: ≥ 70% of the subjects pass
    b. Sampling: Minimum of 10 representative[15] compatible N95 respirators (minimum of 5 male and 5 female subjects) following 4 decontamination cycles.
    c. Test Design: OSHA guidelines OSHA 1910.134 Appendix A Fit Testing Protocol[16]

[15] Samples must be collected for testing after the 4th decontamination cycle (which is after the 5th use, to confirm through real-world use data that respirators can withstand 4 cycles of decontamination and reuse). Test samples must include a representative variation of respirators that you are receiving for decontamination. Justification must be provided for the sample chosen, including materials, design characteristics, sizes, etc. Records regarding sample type, model, materials, number of decontamination cycles, etc., must be kept for each sample tested.

[16] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA.

2. Filtration Efficiency (**Required**)
    a. Acceptance Criteria: ≥ 95%
    b. Sampling: Minimum of 10 representative[15] compatible N95 respirators following 4 decontamination cycles.
    c. Test Design: CDC guidelines Assessment of Filter Penetration Performance and Fit for Decontaminated N95 Respirators, Section "Particulate Filter Efficiency Testing" on Page 5[17]
3. Indelible Markings (**Required**)
    a. Acceptance Criteria: Markings must be clearly legible.
    b. Sampling: Minimum of 10 representative[15] compatible N95 respirators from Fit Testing following 4 decontamination cycles.
    c. Test Design: Respirators must be visually inspected prior to Fit Testing. An agreement will be met between 2 people evaluating legibility with a form to complete with "yes" or "no" on legibility.

N. Following completion of Condition M, STERIS may request and be allowed to increase the maximum number of decontamination cycles per compatible N95 respirator under Condition D. To support such a request, STERIS must provide to FDA information regarding filtration efficiency and respirator fit testing based on real-world evidence, including, but not limited to, evidence collected in the study design and methods adopted in accordance with Condition M.

Healthcare Facilities

O. 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.

P. 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.

Q. 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, but is not limited to, monitoring healthcare facility 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.

R. Healthcare facilities 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.

[17] https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf.

S. Healthcare facilities must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of 4 decontamination cycles per compatible N95 respirator. Any decontaminated compatible N95 respirator that has exceeded 4 decontamination cycles shall be discarded. Healthcare facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user.

T. Healthcare facilities must maintain documentation for use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers consistent with current healthcare facility protocols. Healthcare facilities must 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

U. All descriptive printed matter, 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 meet the requirements set forth in section 502(a) and (q)(1) and (r) of the Act and FDA implementing regulations.

V. No descriptive printed matter, 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.

W. All descriptive printed matter, 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 by FDA, but has been authorized for emergency use by FDA under an EUA 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 emergency use of 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization 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