January 21, 2021

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

Dear Dr. Bill 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 April 9, 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 the STERIS Sterilization System[4] for use in decontaminating compatible N95 respirators[5] for single-user reuse[6] by

[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" 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 (VHP) low temperature sterilization systems. As originally issued on April 9, 2020, the EUA authorized the emergency use of the STERIS V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 Low Temperature Sterilization Systems. On June 6, 2020, FDA revised the Scope of Authorization to add the STERIS V-PRO 60 and V-PRO s2 Low Temperature Sterilization Systems as additional authorized products.
[5] In the June 6, 2020 letter, "compatible N95 respirators" were defined as any N95 or N95-equivalent respirators that do not contain cellulose-based materials or exhalation valves. The June 6, 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, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
[6] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination. In the April 9, 2020 letter, FDA made clarifying edits to this definition which was: "single-user reuse means that the same HCP should use the mask following decontamination". This clarifying edit did not change the Scope of Authorization.

healthcare personnel (HCP)[7] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators (FFRs) resulting from the COVID-19 pandemic.

On June 6, 2020, in response to your request, FDA reissued the April 9, 2020 letter in order to revise the Scope of Authorization to add the STERIS V-PRO 60 and V-PRO s2 Low Temperature Sterilization Systems to the authorized product. Additionally, FDA revised 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 were no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA nor was the device authorized to decontaminate respirators that have exhalation valves.

On January 21, 2021, in response to public health and safety concerns regarding the decontamination of certain respirators, FDA is reissuing the June 6, 2020 letter in order to revise the authorization of the STERIS Sterilization Systems to include the following aspects:

1. Limitation of the respirator features that are considered to be compatible N95 respirators[8] in which this decontamination system is authorized to decontaminate.
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 with antimicrobial agents or a duck-billed design. Additionally, your product is no longer authorized to decontaminate compatible N95 respirators up to 10 cycles and is now authorized to perform decontamination for a maximum of 4 times per respirator. A Condition of Authorization (Section

[7] 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).

[8] For purposes of this revised EUA, "compatible N95 respirators" are defined as any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design, and 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/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization. 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.

IV.L) 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.M). These revisions are reflected in the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and authorized labeling. Having concluded that revising the June 6, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act, FDA is reissuing the June 6, 2020 letter in its entirety with the revisions incorporated.

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 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 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.[10,11]

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 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.

The STERIS Sterilization Systems are not authorized for use in decontaminating incompatible N95 respirators. N95 respirators containing cellulose-based materials, and respirators that have exhalation valves, antimicrobial agents, or a duck-billed design are incompatible with the STERIS Sterilization System. This system is also not authorized to decontaminate respirators authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.

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.

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

[11] 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.

The V-PRO 1 Plus, V-PRO maX, and V-PRO maX2 models are to be used with a maximum capacity 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 capacity 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 4 times. The respirator reuse limit is based upon the filtration performance evaluations of respirators that were decontaminated 4 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) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, 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

Section 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 request changes to this EUA for the STERIS Sterilization Systems[12], 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. 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.

[12] 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.

H. 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 Sterilization Systems and compatible N95 respirators that have undergone decontamination using the STERIS Sterilization Systems ("the decontaminated, compatible N95 respirators"). This includes, but is not limited to, reports from healthcare facilities concerning infection or potential infection of the healthcare facility personnel involved in the use of the STERIS Sterilization Systems and users of the decontaminated, compatible N95 respirators. Other examples of reportable events that may be relevant to the authorized product include, but are not limited to: allergic reactions or eye, mouth, or nose irritation, evidence that a decontaminated, compatible N95 respirator is unable to perform its essential function, events related to residuals or user contact with residuals (if applicable), infection in decontaminated, compatible N95 respirator wearers, or concerns with the process control or malfunctions of the authorized product used to decontaminate the compatible N95 respirators.

I. 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.

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.

L. 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[13] 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[14]

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.[15]
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 should be visually inspected prior to Fit Testing. An agreement should be met between 2 people evaluating legibility with a form to complete with "yes" or "no" on legibility.

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

Healthcare Facilities

N. 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.

O. 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.

P. 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, but is not limited to, monitoring HCPs using the STERIS Sterilization Systems and HCPs using the

[13] 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.
[14] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA
[15] https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf

decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. Other examples of reportable events that may be relevant to the authorized product include, but are not limited to: allergic reactions or eye, mouth, or nose irritation, evidence that a decontaminated, compatible N95 respirator is unable to perform its essential function, events related to residuals or user contact with residuals (if applicable), infection in decontaminated, compatible N95 respirator wearers, or concerns with the process control or malfunctions of the authorized product used to decontaminate the compatible N95 respirators.

Q. 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.

R. 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. 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

S. 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.

T. No descriptive printed matter, 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.

U. All descriptive printed matter, 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 by FDA, but have 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 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 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