April 20, 2020

Peter Kalkbrenner
Sterilucent, Inc.
1400 Marshall Street NE
Minneapolis, MN 55413

Dear Mr. Kalkbrenner:

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 Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (hereafter "Sterilucent Sterilizer System") for use in decontaminating compatible N95 or N95-equivalent[1] respirators ("compatible N95 respirators")[2] for single-user reuse[3] by healthcare providers (HCP)[4] 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.[5] 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, including alternative products used as

[1] 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, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[2] For purposes of this EUA, "compatible N95 respirators" means any N95 or N95-equivalent respirator that does not contain cellulose. 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

[3] Single-user reuse means that the same healthcare provider should use the respirator following decontamination.

[4] 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).

[5] 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).

medical devices, during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[6]

The Sterilucent Sterilizer System is an FDA-cleared sterilization system for terminal sterilization of certain types of medical devices. This EUA would authorize expansion of the indication to decontamination of compatible N95 respirators as described in the Scope of Authorization, Section II of this letter.

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. Use of the Sterilucent Sterilization System would allow for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for up to 10 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to pathogenic airborne particulates during the COVID-19 pandemic. In support of the issuance of this EUA, sterility, residual sterilant, and performance testing has been completed, as well as N95 respirator functionality testing, including filtration performance and fit-test data, to show no deterioration in performance after 10 decontamination cycles. Half-cycle sterility testing showed complete kill when $\geq 10^6$ *Geobacillus stearothermophilus* spores were inoculated on compatible N95 respirators using end-of-shelf-life hydrogen peroxide. Dissipation studies confirmed that residual hydrogen peroxide on the compatible N95 respirators was reduced to safe levels (< 1ppm) after six-hours aeration. No evidence of material incompatibility was identified when decontaminating non-cellulose based compatible N95 respirators using the Sterilucent Sterilizer System.

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 Sterilucent Sterilization System, 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 Sterilucent Sterilization System, 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 Sterilucent Sterilization System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to pathogenic

[6] 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).

biological airborne particulates, and that the known and potential benefits of this device, 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 Sterilucent Sterilization System for decontamination of compatible respirators for single-user reuse by HCP during FFR shortages during the COVID-19 pandemic.[7,8]

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

Authorized Sterilucent Sterilization System

The Sterilucent Sterilization System must be used in the Flexible 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 reused by HCP. N95 respirators containing cellulose-based materials are not compatible with the Sterilucent Sterilization System. Any visibly soiled or damaged respirators should not be processed in the Sterilucent Sterilization System and should be immediately discarded. Use of the Sterilucent Sterilization System 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.

The Sterilucent Sterilization System is to be used with the cleared and commercially available Sterilucent Sterilant, Sterilucent Chemical Indicators, Sterilucent Biological Indicator and Cycle-Specific Process Challenge Device, and Tyvek sterilization pouches. The Sterilucent Sterilization System is to be loaded with compatible N95 respirators that are individually pouched in Tyvek (or equivalent) pouches with a Sterilucent Chemical Indicator inside of a single sterilization basket. The sterilizer may contain up to a maximum of 12 pouches per sterilizer load. The Sterilucent Chemical Indicator or chemical indicator tape identified for the Sterilucent Sterilization System may be placed in the chamber to verify sterilant exposure.

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

[8] 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.

The Sterilucent Sterilization System, using the Flexible Cycle for approximately 35 minutes, decontaminates utilizing hydrogen peroxide vapor. After the initial injection of sterilant into the chamber, a real-time hydrogen-peroxide UV monitor measures the actual vapor concentration of H_2O_2. This data is used to establish the amount of sterilant injected in a series of 3 maintenance injections, the first being initiated 10 seconds after the initial injection. The second and third maintenance injections occur at subsequent 60-second intervals unless the measured gas concentration is below pre-set levels, which would prompt a faster injection sequence. After completion of all required sterilant exposures, the Aeration step is initiated, which requires a series of pressure changes designed to remove residual sterilant from both the chamber and exposed devices. At the end of the Aeration step, the chamber is returned to atmospheric pressure, and the chamber door may be opened. Following completion of the Flexible Cycle, the chemical indicator's color should be compared to the "PASS" reference color (blue). If the indicator does not match the "PASS" criteria, the compatible N95 respirators should not be considered decontaminated and either re-run through the Sterilucent Sterilization System Flexible Cycle or discarded.

Validation and performance studies conducted by the firm indicate compatible N95 respirators can be processed through the Sterilucent Sterilization System, in the Flexible Cycle, up to 10 times. The respirator reuse limit is based upon the filtration performance and fit-test data in evaluation of the respirators after 10 decontamination cycles in the Sterilucent Sterilization System. Users must allow the decontaminated respirators to aerate for 6 hours prior to reuse.

The above described product is authorized to be accompanied with Sterilucent's User Manual for the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer,[9] together with the following product-specific information pertaining to emergency use, and is required to be made available to healthcare providers and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Emergency Use of Sterilucent Sterilization System to Decontaminate Compatible N95 Respirators;
- Instructions for Healthcare Facilities: Emergency Use of Sterilucent Sterilization System to Decontaminate Compatible N95 Respirators.

In addition, following decontamination, compatible N95 respirators decontaminated by the Sterilucent Sterilization System must be accompanied by the following labeling, developed by Sterilucent, Inc, upon return of the respirators to the single-user HCP:

- Fact Sheet for Healthcare Personnel: Sterilucent Sterilization System for Decontaminating Compatible N95 Respirators

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities, and Sterilucent's "User Manual for the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer" are referred to as "authorized labeling." The above described product, when accompanied with the described labeling is authorized to be distributed to and administered

[9] Sterilucent HC 80TT Hydrogen Peroxide Sterilizer's product information is as follows and can be found at:

- 510(k) K190005 is available at the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190005.pdf Sterilucent's User Manual for the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer is available at: http://www.sterilucent.com/literature/490034-001_A_User%20Manual%20HC%2080TT_Art.pdf

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 Sterilucent Sterilization System, 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 Sterilucent Sterilization System may be effective at preventing HCP exposure to pathogenic airborne particulates during FFR shortages during the COVID-19 pandemic, when used consistently with this section (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 Sterilucent Sterilization System (as described the 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 Sterilucent Sterilization System 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 Sterilucent Sterilization System 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 practice 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:

<u>Sterilucent, Inc.</u>

A. Sterilucent, Inc. must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and labeling requirements specified in this EUA, as well as those

described in Section II of this letter, Scope of Authorization. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

B. Sterilucent, Inc. must provide to all healthcare facility customers the authorized labeling before the decontamination process begins (i.e., before a healthcare facility begins preparing and collecting compatible N95 respirators for decontamination using the Sterilucent Sterilization System—which the healthcare facility already owns, or the healthcare facility has notified Sterilucent, Inc. of its intent to purchase).

C. Sterilucent, Inc. must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities, before the decontamination process begins as described in Condition B of this letter.

D. Sterilucent, Inc. 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 Surgery Devices/OPEQ/CDRH.

E. Sterilucent, Inc. 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 Surgery Devices/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of Chief Scientist.

F. Sterilucent, Inc. will have a process in place for reporting adverse events related to the respirators that have undergone decontamination using the Sterilucent Sterilization System ("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.

G. Sterilucent, Inc. will ensure that any records associated with this EUA, including, but not limited to, records of healthcare facilities that have notified Sterilucent, Inc. that the facility is using the Sterilucent Sterilization System 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.

H. Sterilucent, Inc. 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

I. Healthcare facilities should notify Sterilucent, Inc. when they intend to use the Sterilucent Sterilization System for the emergency use, consistent with Section II of this letter.

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

K. 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 Sterilucent, Inc., so that Sterilucent, Inc. can provide a weekly report to FDA consistent with Section IV.F of this letter. Reports of adverse events should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

L. Healthcare facilities using the decontaminated, compatible N95 respirators must inspect the decontaminated, compatible N95 respirators following the decontamination process using the Sterilucent Sterilization System. Any discoloration or other signs of degradation with a decontaminated respirator should promptly be reported to Sterilucent, Inc., and the healthcare facility should discard the respirator.

M. 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 Sterilucent Sterilization System consistent with current healthcare facility protocols.

Conditions Related to Advertising and Promotion

N. All descriptive printed matter, including advertising and promotional materials, relating to the use of the Sterilucent Sterilization System 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.

O. No descriptive printed matter, including advertising or promotional materials, relating to the use of the Sterilucent Sterilization System 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.

P. All descriptive printed matter, including advertising and promotional materials, relating to the use of the Sterilucent Sterilization System clearly and conspicuously shall state that:

- the Sterilucent Sterilization System has neither been cleared or approved for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates;

- the Sterilucent Sterilization System has been authorized by FDA under an EUA;

- the Sterilucent Sterilization System is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical of medical devices, including alternative products used as 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures