April 11, 2020

Ms. Laurie Cartwright
Director, Worldwide Regulatory Affairs
Advanced Sterilization Products, Inc.
33 Technology
Irvine, California 92618

Dear Ms. Cartwright:

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 Advanced Sterilization Products, Inc. (ASP) STERRAD 100S, NX, and 100NX Sterilization Systems[1] (hereafter "ASP STERRAD Sterilization Systems") for use in decontaminating compatible N95 or N95-equivalent[2] respirators ("compatible N95 respirators")[3] for single-user[4] reuse by healthcare personnel (HCP)[5] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of N95 respirators resulting from the Coronavirus Disease 2019 (COVID-19) pandemic.[6]

[1] This EUA includes the emergency use of the ASP STERRAD 100S, NX, and 100NX Sterilization Systems in the STERRAD 100S, NX Standard, and 100NX Express Cycles, respectively, for decontamination of compatible N95 respirators (as defined in footnote 3). Use of the ASP STERRAD 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.

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

[3] For purposes of this EUA, "compatible N95 respirators" means any N95 or N95-equivalent respirator that does not contain cellulose-based materials. Respirators containing cellulose-based materials are incompatible with the ASP STERRAD Sterilization Systems.

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

[5] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

[6] The ASP STERRAD Sterilization Systems are FDA cleared for use in the sterilization of certain metal and non-metal medical devices, which do not include N95 respirators (see K023290, K162007, and K160903 for the most recent clearances).

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.[7] 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 medical devices, due to shortages during the COVID-19 outbreak, pursuant to Section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.[8]

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 ASP STERRAD 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 ASP STERRAD Sterilization Systems for decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ASP STERRAD Sterilization Systems may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of N95 respirators during the COVID-19 pandemic by decontaminating, for a maximum of 2 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, and that the known and potential benefits of the ASP STERRAD Sterilization Systems, when used to decontaminate compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic airborne particulates during N95 respirator shortages during the COVID-19 pandemic, outweigh the known and potential risks; and

[7] 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).
[8] 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. There is no adequate, approved, and available alternative to the emergency use of the ASP STERRAD Sterilization Systems for decontaminating compatible N95 respirators for single-user reuse by HCP during N95 respirator 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 ASP STERRAD Sterilization Systems for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for no more than 2 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to pathogenic airborne particulates during the COVID-19 pandemic.

Authorized ASP STERRAD Sterilization Systems

The ASP STERRAD Sterilization Systems, specifically the STERRAD 100S, NX, and 100NX Sterilization Systems, must be operated in the STERRAD 100S, NX Standard, and 100 NX Express Cycles (hereafter "STERRAD decontamination cycles"), respectively, to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms so that the respirators can be reused by HCP. N95 respirators containing cellulose-based materials are not compatible with the ASP STERRAD Sterilization Systems. Any visibly soiled or damaged masks should not be processed in the ASP STERRAD Sterilization Systems and should be immediately discarded.

The ASP STERRAD Sterilization Systems are to be used with the cleared and commercially available STERRAD Cassettes, compatible sterilization pouches, such as Tyvek pouches with STERRAD Chemical Indicators, STERRAD Chemical Indicator Strips, SEALSURE Chemical Indicator Tape, and VELOCITY Biological Indicator/Process Challenge Devices. The ASP STERRAD Sterilization Systems are to be loaded with compatible N95 respirators that are individually pouched in Tyvek Pouches with STERRAD Chemical Indicator. The sterilizer may contain ten pouches per sterilizer load. A Chemical Indicator or chemical indicator tape identified for the ASP STERRAD Sterilization Systems may be placed in the chamber to verify sterilant exposure.

The STERRAD decontamination cycles decontaminate utilizing hydrogen peroxide vapor. Hydrogen peroxide vapor is generated by injecting aqueous hydrogen peroxide solution into the vaporizer subassembly where the solution is then concentrated and vaporized at relatively low temperatures through a process that utilizes a combination of heating and sub-ambient pressures

[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 N95 respirators to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of N95 respirators, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be decontaminated for reuse. Providing a method for decontaminating compatible N95 respirators reduces stress on the supply chain and helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with N95 respirators is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

created by an on-board vacuum pump. The vaporized hydrogen peroxide is then introduced into the chamber under sub-ambient pressure to allow perfusion of the hydrogen peroxide throughout the chamber and, facilitating hydrogen peroxide contact with the surfaces to be sterilized. The vapor in the chamber is transformed into gas plasma using electrical energy. The chamber is then vented to allow the sterilization chamber to return to atmospheric pressure. This process is repeated an additional time to complete a full STERRAD decontamination cycle (i.e., the full sterilization cycle is composed of two identical half-cycles). The ASP STERRAD Sterilization Systems use a disposable sterilant cassette that contains a 59% nominal hydrogen peroxide solution in a plastic cell pack and cassette shells. Following completion of the cycle, the chemical indicator's color should be compared to the "PASS" reference color. If the colors matched or the color present is lighter, the compatible N95 respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirators should not be considered decontaminated and either re-run through the STERRAD decontamination cycle or discarded.

Validation and performance studies conducted by the firm indicate compatible N95 respirators can be processed through the STERRAD decontamination cycle of the ASP STERRAD Sterilization Systems a maximum of 2 times. The respirator reuse limit is based upon the filtration performance evaluation of the respirators processed for 2 exposures in the STERRAD decontamination cycles of the ASP STERRAD Sterilization Systems.

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

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

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

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

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

The emergency use of the ASP STERRAD Sterilization Systems must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the

circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the authorized ASP STERRAD Sterilization Systems are authorized to be used for decontaminating compatible N95 respirators that are authorized to be used by HCP in healthcare settings under the terms and conditions of this EUA.

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

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the ASP STERRAD 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 ASP STERRAD Sterilization Systems may be effective at preventing HCP exposure to pathogenic airborne particulates during N95 respirator shortages during the COVID-19 pandemic by decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that ASP STERRAD Sterilization Systems, when used to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain FDA Requirements

I am waiving the following requirements for the ASP STERRAD Sterilization Systems during the duration of this EUA:

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

IV. Conditions of Authorization

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

Advanced Sterilization Products, Inc. ("ASP")

A) ASP will make available to all existing customers the authorized labeling for the ASP STERRAD Sterilization Systems through posting on the ASP website and notifying their distribution list of healthcare facilities. In this notification, ASP will instruct healthcare facilities to notify ASP if the healthcare facility intends to use the ASP STERRAD Sterilization Systems for the emergency use. ASP will send the appropriate authorized labeling to each healthcare facility who notifies ASP that the healthcare facility intends to use the ASP STERRAD Sterilization Systems for the emergency use, consistent with Section II of this letter.

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

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

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

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

F) ASP 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

G) Healthcare facilities must notify ASP when they intend to use ASP STERRAD Sterilization Systems for the emergency use, consistent with Section II of this letter.

H) Healthcare facilities using compatible N95 respirators that have undergone decontamination using the ASP STERRAD Sterilization Systems ("the decontaminated, compatible N95 respirators") must make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Fact Sheet for Healthcare Personnel and authorized Instructions for Healthcare Personnel that is required to be provided by ASP.

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

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

K) Healthcare facilities must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of 2 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 ASP STERRAD Sterilization Systems consistent with current healthcare facility protocols.

Conditions Related to Advertising and Promotion

L) All advertising and promotional descriptive printed matter relating to the use of the ASP STERRAD Sterilization Systems shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

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

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

- the ASP STERRAD Sterilization Systems have neither been cleared or approved for the prevention of the COVID-19 infection;
- the ASP STERRAD Sterilization Systems have been authorized by FDA under an EUA;

- the ASP STERRAD Sterilization Systems are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the ASP STERRAD Sterilization Systems under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

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

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures