June 6, 2020

Ms. Susanne Galin
Stryker Instruments
2505 Avenue Dalton
Quebec, QC G1P3S5
Canada

Dear Ms. Galin:

On April 14, 2020, based on your request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of Stryker Instrument's Sterizone VP4 Sterilizer[1] (hereafter "STERIZONE VP4 Sterilizer") N95 Respirator Decontamination Cycle ("STERIZONE VP4 N95 Respirator Decontamination Cycle") for use in decontaminating compatible N95 respirators[2] for single-user reuse[3] by healthcare personnel (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.

[1] This EUA, as originally issued on April 14, 2020, authorized the emergency use of the Sterizone VP4 Sterilizer for the otherwise unapproved use to decontaminate compatible N95 or N95-equivalent respirators for single-user reuse using the STERIZONE VP4 N95 Respirator Decontamination Cycle. The Sterizone VP4 Sterilizer is 510(k)-cleared (K172191, K173694, and K153392) for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in healthcare facilities.

[2] In the April 14, 2020 letter, "compatible N95 respirators" were defined as any N95 or N95-equivalent respirators that do not contain cellulose-based materials. The April 14, 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 and identified 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.

[3] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following decontamination. FDA has revised this to be clearer and notes that this clarifying edit does not change the Scope of Authorization. This previously read: "single-user reuse means that the same Healthcare Personnel 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).

On June 6, 2020, FDA is reissuing the April 14, 2020 letter in order to revise which compatible N95 respirators[5] this decontamination system is authorized to decontaminate in order to address public health and safety concerns regarding certain respirators. As described in the Scope of Authorization (Section II), the STERIZONE VP4 N95 Respirator Decontamination Cycle is no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA or authorized respirators that have exhalation valves. Having concluded that revising the April 14, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(g)(2)(C)), FDA is reissuing the April 14, 2020 letter in its entirety with the revisions[6] incorporated.

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 during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[8]

The Sterizone VP4 Sterilizer is 510(k)-cleared (K172191, K173694, and K153392) for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in healthcare facilities. The Sterizone VP4 Sterilizer is not cleared, approved, or subject to an approved investigational device exemption for use in decontaminating compatible N95 respirators, and therefore, requires authorization for such use. Additionally, there are no FDA approved or cleared devices for decontaminating compatible N95 respirators, which are needed for use by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. FDA has reviewed the totality of scientific evidence available, including testing that was submitted within previous applications supporting device clearance for other uses that spanned more than 21 different types of polymer materials, including materials consistent with those found in compatible N95 respirators. FDA has leveraged the performance data (e.g., half cycle test, sporicidal test, compatibility, residual analysis, functionality) from the

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[5] For purposes of this revised EUA, "compatible N95 respirators" are non-cellulose containing respirators that do not have an exhalation valve 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/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[6] The revisions to the April 14, 2020 letter include the following: (1) the Scope of Authorization has been revised such that this decontamination system is no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA or authorized respirators that have an exhalation valve; and (2) FDA has made some clarifications to the Conditions of Authorization (Section IV) of this letter.

[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).

previous submissions to support that the emergency use, which repurposes the Stryker STERIZONE VP4 Sterilizer to be used for compatible N95 respirators, may be effective.

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 STERIZONE VP4 N95 Respirator Decontamination Cycle, 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 STERIZONE VP4 N95 Respirator Decontamination Cycle, as described in the Scope of Authorization (Section II) of this letter, 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 STERIZONE VP4 N95 Respirator Decontamination Cycle may be effective at preventing exposure to pathogenic biological airborne particulates 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 this device, when used for such use, outweigh the known and potential risks; and

3. There is no adequate, approved, and available alternative to the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle for decontaminating compatible N95 respirators for single-user reuse by HCP during FFR shortages during the COVID-19 pandemic.[9,10]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the STERIZONE VP4 N95 Respirator Decontamination Cycle, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated

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

[10] There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of N95 respirators, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be decontaminated for reuse. Providing a method for decontaminating compatible N95 respirators reduces stress on the supply chain and helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with FFRs is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of 2 decontamination cycles per respirator, for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Authorized Product

The STERIZONE VP4 Sterilizer is a self-contained stand-alone device, using vaporized hydrogen peroxide and ozone in a multiphase process. The STERIZONE VP4 N95 Respirator Decontamination Cycle offers a single sterilization cycle that is FDA-cleared for general instruments, flexible endoscopes, and rigid-channel devices. Under this emergency use authorization, the authorized product's single pre-programmed cycle is authorized for use to decontaminate up to twenty (20) 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 the original HCP (i.e., single-user). N95 respirators that have exhalation valves and respirators containing cellulose-based or paper materials, natural rubber, or latex are **not** compatible with the STERIZONE VP4 N95 Respirator Decontamination Cycle. This system is also not authorized to decontaminate respirators authorized by the non-NIOSH-approved Filtering Facepiece Respirator manufactured in China EUA.

The STERIZONE VP4 N95 Respirator Decontamination Cycle uses any Tyvek pouch that has been FDA-cleared for use in hydrogen peroxide applications. Cellulose-based pouches cannot be used.

The Sterizone Chemical Indicator (cleared in K141698) for the Sterizone VP4 Sterilizer must be placed in the chamber to verify sterilant exposure. Following completion of the cycle, the chemical indicator's color is 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. The respirators should be used immediately; no additional aeration is required. If the indicator does not match the "PASS" criteria, the compatible N95 respirators will not be considered decontaminated and either rerun through the STERIZONE VP4 N95 Respirator Decontamination Cycle or discarded. Any visibly soiled or damaged respirators will not be decontaminated in the STERIZONE VP4 N95 Respirator Decontamination Cycle and shall be immediately discarded.

Available scientific information indicates that compatible N95 respirators can be decontaminated two times using the STERIZONE VP4 N95 Respirator Decontamination Cycle. Compatible N95 respirators can be decontaminated a maximum of two times by this process. The pouches may be decontaminated one time. The number of decontamination cycles is recorded on the respirator. If at any time, this identification becomes illegible for any reason, the respirator shall be discarded.

The Stryker Instruments ("Stryker") must provide the following information pertaining to the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle before the decontamination process begins (i.e., before a healthcare facility begins preparing and collecting compatible N95 respirators for decontamination using the STERIZONE VP4 N95 Respirator Decontamination Cycle —which the healthcare facility already owns, or the healthcare facility

has notified Stryker 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 by the STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle;
- Instructions for Healthcare Facilities: Emergency Use Decontamination of Compatible N95 Respirators in Stryker's STERIZONE VP4 Sterilizer Using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle.

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

- Fact Sheet for Healthcare Personnel: STRYKER Decontamination Cycle for Decontaminating Compatible N95 Respirators.

The Fact Sheet, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, the following previously cleared labeling are referred to as "authorized labeling":

- STERIZONE VP4 Sterilizer User Manual;
- STERIZONE VP4 Test Pack Instructions for Use (MA-900-066);
- STERIZONE BI+ Indicator Instructions for Use (MA-900-043); and
- STERIZONE CI+ instructions for use (MA-900-044).

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 STERIZONE VP4 N95 Respirator Decontamination Cycle, 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 STERIZONE VP4 N95 Respirator Decontamination Cycle 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 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 the STERIZONE VP4 N95 Respirator Decontamination Cycle, 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.

The emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle 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 STERIZONE VP4 N95 Respirator Decontamination Cycle 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 Part 820.

IV. Conditions of Authorization

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

Stryker Instruments (Stryker)

A. Stryker 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. Stryker must provide to all healthcare facility customers the authorized labeling before the decontamination process begins.

C. Stryker must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities before the decontamination process begins.

D. Stryker may make changes to the process, procedures, and/or labeling for the authorized product, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

E. Stryker may make changes to the scope of this EUA, upon request and subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive

Surgery/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of Chief Scientist (OCS)/Office of the Commissioner (OC).

F. Use of the STERIZONE VP4 N95 Respirator Decontamination Cycle 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.

G. Stryker will have a process in place to report adverse events of which they become aware to FDA related to the STERIZONE VP4 N95 Respirator Decontamination Cycle and compatible N95 respirators that have undergone decontamination using the STERIZONE VP4 N95 Respirator Decontamination Cycle ("the decontaminated, compatible N95 respirators") in accordance with 21 CFR Part 803. This includes reports from healthcare facilities concerning infection or potential infection of personnel involved in the use of STERIZONE VP4 N95 Respirator Decontamination Cycle and users of the decontaminated, compatible N95 respirators.

H. Stryker will have a process in place to collect information on the performance of STERIZONE VP4 N95 Respirator Decontamination Cycle, 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.

I. Stryker 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.

J. Stryker 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

K. Healthcare facilities shall notify Stryker when they intend to use the STERIZONE VP4 N95 Respirator Decontamination Cycle for the emergency use, consistent with Section II of this letter.

L. 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 Stryker.

M. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the STERIZONE VP4 N95 Respirator Decontamination Cycle and the decontaminated, compatible N95 respirators in accordance with 21 CFR Part 803. This includes monitoring personnel using the STERIZONE VP4 N95 Respirator Decontamination Cycle and HCP 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.

N. Healthcare Facilities using the decontaminated, compatible N95 respirators must inspect the decontaminated, compatible N95 respirators following the decontamination process using the STERIZONE VP4 N95 Respirator Decontamination Cycle. Any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator shall promptly be reported to Stryker, and the healthcare facility must discard the respirator.

O. 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 N95 respirator is returned to its previous user. Healthcare facilities shall maintain documentation for use of the STERIZONE VP4 N95 Respirator Decontamination Cycle consistent with current healthcare facility protocols.

Conditions Related to Advertising and Promotion

P. All descriptive printed matter, including advertising and promotional materials, relating to the use of STERIZONE VP4 N95 Respirator Decontamination Cycle 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.

Q. No descriptive printed matter, including advertising or promotional materials, relating to the use of STERIZONE VP4 N95 Respirator Decontamination Cycle 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.

R. Except for the authorized labeling described in Section II, all descriptive printed matter, including advertising and promotional materials, relating to the use of STERIZONE VP4 N95 Respirator Decontamination Cycle clearly and conspicuously shall state that:

- the STERIZONE VP4 N95 Respirator Decontamination Cycle has neither been cleared or approved for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;

- the STERIZONE VP4 N95 Respirator Decontamination Cycle has been authorized by FDA under an EUA;

- the STERIZONE VP4 N95 Respirator Decontamination Cycle is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

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