The additional funding will not be used to begin new projects, but to expand existing activities under the existing grant. Specifically, supplemental funds will be used to:

1. Increase the number of states that will participate in the upcoming pilot project to field test a competency-based, entry-level respite provider-training curriculum and recruitment campaign. This also includes the option to request additional funding for increased administrative and management oversight; the provision of stipends, if necessary; and increased technical assistance to the pilot states.

2. Enhance documentation and reporting on the pilot project, which could include reports, journal articles, or blogs on pre- and post-pilot work. For example, topics may include, but are not limited to:

a. Detailing the methodology for developing the core competencies being piloted from conception to pilot implementation; and

b. Documenting state successes as a part of the pilot program and/or detailing findings, positive or negative, learned from the one-year pilot.

3. Expand/enhance the respite care tracking (mapping) system that will be available to state program policy personnel to allow them ready access to the findings of the state scans of respite programs and services and build on case studies being developed under this grant program.

4. Expand and enhance the planned communication and information dissemination strategy to reach larger audiences of potential users of the materials developed under this project.

*Program Name:* Lifespan Respite Care Program: Promoting Best Practices, Building State Capacity.

*Recipient:* Center for Health Policy Development.

*Period of Performance:* The supplement award will be issued in the second year of this three-year, fully funded, project scheduled to be completed on September 29, 2023.

*Total Award Amount:* $562,737 in FY 2020.

*Award Type:* Cooperative Agreement Supplement.

*Statutory Authority:* The statutory authority for grants under this program announcement is contained in Title XXIX of the Public Health Service Act (42 U.S.C. 300ii–1: Lifespan Respite Care Grants and Cooperative Agreements), as amended by the Public Health Service Act Public Law 109–442. (Catalog of Federal Domestic Assistance 93.072).

*Basis for Award:* The Lifespan Respite Care Program: Special Projects to Strengthen Program Development, Implementation and Sustainability is currently funded to carry out the objectives of this project for the period of September 30, 2020 through September 29, 2023. Since project implementation began in late 2020, the grantee has accomplished a great deal. The supplement will enable the grantee to carry their work even further, reaching more states with workforce development assistance, information dissemination, direct technical assistance and tracking of state innovations and advancements in respite service design and delivery. The additional funding will not be used to begin new projects or activities.

Dated: August 25, 2021.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

[FR Doc. 2021–18748 Filed 8–30–21; 8:45 am]

**BILLING CODE 4154–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–N–0762]**

### Revocation of Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of 15 Emergency Use Authorizations (EUAs) (the Authorizations), including 12 Authorizations for decontamination systems for personal protective equipment, 1 Authorization for a bioburden reduction system for personal protective equipment, and 2 umbrella Authorizations for certain imported, non-NIOSH (National Institute of Occupational Safety and Health)-approved disposable respirators. FDA revoked the Authorizations for the decontamination and bioburden reduction systems for personal protective equipment on June 30, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by each Authorization holder. FDA revoked the umbrella Authorizations issued to manufacturers and other stakeholders of imported non-NIOSH approved filtering facepiece respirators manufactured in China (China FFR Authorization), and to manufacturers and other stakeholders of imported non-NIOSH approved filtering facepiece respirators (Imports FFR Authorization) on June 30, 2021, under the FD&C Act. The revocations, which each include an explanation of the reasons for the revocation, are reprinted in this document.

**DATES:** The Authorizations for the decontamination and bioburden reduction systems are revoked as of June 30, 2021. The Authorizations for the China FFR Authorization and Imports FFR Authorization are revoked as of July 6, 2021.

**ADDRESSES:** Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

**FOR FURTHER INFORMATION CONTACT:** Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. Notice of the issuance of the Authorizations was published in the **Federal Register** as follows, as required by section 564(h)(1) of the FD&C Act: (1) Published June 5, 2020 (85 FR 34638) for Imports FFR Authorization (Certain Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators) issued March 24, 2020; China FFR Authorization (Certain Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China) issued April 3, 2020; and STERIS Corporation for the STERIS Sterilization Systems (STERIS V–PRO 1 Plus, maX, and maX2 Low Temperature Sterilization Systems) issued April 9, 2020; (2) published July 14, 2020 (85 FR 42407) for Advanced Sterilization Products, Inc. for the ASP STERRAD Decontamination Systems issued April 11, 2020; Stryker

Instruments for the STERIZONE VP4 Sterilizer issued April 14, 2020; Sterilucent, Inc. for the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer issued April 20, 2020; Duke University Health System for the Duke Decontamination System issued May 7, 2020; (3) published November 20, 2020, (85 FR 74346) for STERIS Corporation for the AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle issued May 21, 2020; Stryker Sustainability Solutions (SSS) for the SSS VHP N95 Respirator Decontamination System issued May 27, 2020; Technical Safety Services LLC for the 20–CS Decontamination System issued June 13, 2020; MSU for the MSU Decontamination System issued July 24, 2020; (4) published April 23, 2021, (86 FR 21749) for Roxby Development, LLC for the Zoe-Ann Decontamination System issued October 20, 2020; 3B Medical, Inc. for the Lumin LM3000 Bioburden Reduction UV System issued December 3, 2020; Ecolab Inc. for the Bioquell Technology System issued December 4, 2020; and Yale New Haven Health System for the Yale New Haven Health FILTERING FACEPIECE RESPIRATOR Decontamination System issued January 15, 2021.

Any subsequent reissuances of the Authorizations are listed in the revocation letters reprinted at the end of this document.

The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

## II. EUA Revocation Criteria Met

On June 30, 2021, FDA revoked the China FFR Authorization and Imports FFR Authorization. FDA reviewed the totality of scientific evidence available, including data provided by device manufacturers, distributors, Group Purchasing Organizations, FDA Imports database, healthcare organizations, and Federal/State stockpiles. Based on the change in the Centers for Disease Control and Prevention (CDC) recommendations, the increase in availability of NIOSH-approved respirators, the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) requirements, and information provided by healthcare organizations and others,[1] FDA has concluded that the known and potential benefits of these respirators, when used for such use, no longer outweigh the known and potential risks of continued use, and pursuant to section 564(g)(2)(B), the criteria under section 564(c) of the FD&C Act for issuance of the Authorizations are no longer met. In addition, based on the same information, revocation of the Authorizations is appropriate to protect the public health and safety pursuant to section 564(g)(2)(C) of the FD&C Act.

On June 30, 2021, FDA revoked the Authorizations for decontamination and bioburden reductions systems pursuant to requests from the following entities on the following dates:

- April 9, 2021, from Duke for the Duke Decontamination System;
- April 15, 2021, from Sterilucent, Inc. for the Sterilucent HC 80TT Hydrogen PeroxideSterilizer;
- April 16, 2021, from Yale for the Yale New Haven Health FFR Decontamination System;
- May 13, 2021, from STERIS Corporation for the STERIS Sterilization Systems, as well as the AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle;
- May 25, 2021, from Stryker Sustainability Solutions (SSS) for the SSS VHP N95 Respirator Decontamination System;
- May 27, 2021 from MSU for the MSU Decontamination System;
- June 4, 2021, from Advanced Sterilization Products, Inc. for the ASP STERRAD Decontamination Systems;
- June 7, 2021, from Technical Safety Services LLC for the 20–CS Decontamination System;
- June 7, 2021, from Roxby Development, LLC for the Zoe-Ann Decontamination System;
- June 7, 2021, from 3B Medical, Inc. for the Lumin LM3000 Bioburden Reduction UV System;
- June 7, 2021, from Ecolab Inc. for the Bioquell Technology System; and
- June 8, 2021, from Stryker Instruments for the STERIZONE VP4 Sterilizer.

Because these entities notified FDA that they have ceased operations and associated activities and request withdrawal of their respective Authorizations, and consistent with FDA's belief that the known and potential benefits of these systems, when used for their emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke the Authorizations because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the FD&C Act that other circumstances make revocation appropriate to protect the public health or safety.

## III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/* and *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#covid19*.

## IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(B) and 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the following Authorizations:

- China FFR Authorization;
- Imports FFR Authorization;
- Duke's Duke Decontamination System;
- Sterilucent, Inc.'s Sterilucent HC 80TT Hydrogen Peroxide Sterilizer;
- Yale's Yale New Haven Health FFR Decontamination System;
- STERIS Corporation's STERIS Sterilization Systems, as well as the AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle;
- Stryker Sustainability Solutions's SSS VHP N95 Respirator Decontamination System;
- MSU's MSU Decontamination System;
- Advanced Sterilization Products, Inc.'s ASP STERRAD Decontamination Systems;

[1] Non-NIOSH approved FFRs were previously recommended by CDC as a crisis capacity strategy when there was a severe shortage of NIOSH-approved FFRs available for healthcare personnel (HCP). Available information now shows an increase in the current and projected U.S. supply of NIOSH-approved respirators, including N95s (*https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1.html*). As such, on April 9 and May 27, 2021, CDC updated their recommendations to reflect that healthcare facilities should return to conventional capacity strategies and thus CDC no longer recommends the use of non-NIOSH-approved FFRs. On May 27, 2021, FDA also recommended that healthcare facilities and HCP ''transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s'' (*https://www.fda.gov/medical-devices/letters-health-care-providers/update-fda-recommends-transition-use-non-niosh-approved-and-decontaminated-disposable-respirators*). In addition, on June 21, 2021 (86 FR 32376), OSHA issued an Emergency Temporary Standard (ETS) to adequately address the hazard of COVID–19 for HCP. The ETS requires, among other things, healthcare employers to provide NIOSH-approved or FDA-authorized respirators for healthcare workers potentially exposed to COVID–19.

- Technical Safety Services LLC's 20–CS Decontamination System;
- Roxby Development, LLC's Zoe-Ann Decontamination System;
- 3B Medical, Inc.'s Lumin LM3000 Bioburden Reduction UV System;
- Ecolab Inc.'s Bioquell Technology System; and
- Stryker Instruments's STERIZONE VP4 Sterilizer.

The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

June 30, 2021

To: Manufacturers of Non-NIOSH Approved Filtering Facepiece Respirators Manufactured in China;
Health Care Personnel;
Hospital Purchasing Departments and Distributors;
Importers and Commercial Wholesalers; and
Any Other Stakeholders

This letter is to revoke the Emergency Use Authorization (EUA) issued April 3, 2020 and revised and reissued on May 7, 2020, June 6, 2020, and October 15, 2020, for emergency use of non-National Institute for Occupational Safety and Health (NIOSH) approved respirators manufactured in China[1] in healthcare settings by healthcare personnel (HCP)[2], when used in accordance with Centers for Disease Control and Prevention (CDC) recommendations to prevent HCP exposure to pathogenic biological airborne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak. The revocation is effective July 6, 2021.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act).

FDA has reviewed the totality of scientific evidence available, including data provided by device manufacturers, distributors, Group Purchasing Organizations (GPOs), FDA Imports database, healthcare organizations, and federal/state stockpiles. Based on the change in CDC recommendations, the increase in availability of NIOSH-approved respirators, the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) requirements, and information provided by healthcare organizations and others,[3] FDA has concluded that the

[1] Umbrella EUA: Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China

[2] Healthcare personnel 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 healthcare personnel 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).

[3] Non-NIOSH approved FFRs were previously recommended by CDC as a crisis capacity strategy when there was a severe shortage of NIOSH-approved FFRs available for HCP. Available information now shows an increase in the current and projected U.S. supply of NIOSH-approved respirators, including N95s. As such, on April 9 and May 27, 2021, CDC updated their recommendations to reflect that healthcare facilities should return to conventional capacity strategies and thus CDC no longer recommends the use of non-NIOSH-approved FFRs. On May 27, 2021, FDA also recommended that healthcare facilities and HCP "transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s." In addition, on June 21, 2021, OSHA issued an

known and potential benefits of these respirators, when used for such use, no longer outweigh the known and potential risks of continued use, and pursuant to section 564(g)(2)(B), the criteria under section 564(c) of the Act for issuance of the EUA are no longer met. In addition, based on the same information, revocation of the EUA is appropriate to protect the public health and safety pursuant to section 564(g)(2)(C) of the Act.

Accordingly, pursuant to section 564(g)(2)(B) and 564(g)(2)(C) of the Act, FDA revokes the EUA.

Effective on July 6, 2021, which is 15 days after the effective date of the OSHA ETS, and the date by which compliance by healthcare facilities is required, the devices listed in Appendix A as covered by the October 15, 2020 EUA are not authorized by FDA for use as respirators in healthcare settings by HCP to prevent HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, and therefore cannot be legally introduced into interstate commerce with that intended use.

FDA encourages manufacturers and other stakeholders to inform their customers and HCP, as applicable, of this revocation. Manufacturers, HCP, hospital purchasing departments, distributors, importers, commercial wholesalers, states, and any other stakeholders who have questions about options to redistribute or recondition their supply of non-NIOSH-approved respirators that will not be authorized effective July 6, 2021, may reference the publicly posted frequently asked questions (FAQ) regarding this revocation letter or contact FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Emergency Temporary Standard (ETS) to adequately address the hazard of COVID-19 for HCP. The ETS requires, among other things, healthcare employers to provide NIOSH-approved or FDA-authorized respirators for healthcare workers potentially exposed to COVID-19.

June 30, 2021

To: Manufacturers of Imported, Non-NIOSH Approved Filtering Facepiece Respirators;
Health Care Personnel;
Hospital Purchasing Departments and Distributors;
Importers and Commercial Wholesalers; and
Any Other Stakeholders

This letter is to revoke the Emergency Use Authorization (EUA) issued March 24, 2020 and revised and reissued on March 28, 2020, June 6, 2020, and March 24, 2021, for emergency use of imported non-National Institute for Occupational Safety and Health (NIOSH) approved respirators[1] in healthcare settings by healthcare personnel (HCP)[2], when used in accordance with Centers for Disease Control and Prevention (CDC) recommendations to prevent HCP exposure to pathogenic biological airborne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak. The revocation is effective July 6, 2021.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act).

FDA has reviewed the totality of scientific evidence available, including data provided by device manufacturers, distributors, Group Purchasing Organizations (GPOs), FDA Imports database, healthcare organizations, and federal/state stockpiles. Based on the change in CDC recommendations, the increase in availability of NIOSH-approved respirators, the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard (ETS) requirements, and information provided by healthcare organizations and others,[3] FDA has concluded that the

[1] Umbrella EUA: Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators

[2] Healthcare personnel 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 healthcare personnel 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).

[3] Non-NIOSH approved FFRs were previously recommended by CDC as a crisis capacity strategy when there was a severe shortage of NIOSH-approved FFRs available for HCP. Available information now shows an increase in the current and projected U.S. supply of NIOSH-approved respirators, including N95s. As such, on April 9 and May 27, 2021, CDC updated their recommendations to reflect that healthcare facilities should return to conventional capacity strategies and thus CDC no longer recommends the use of non-NIOSH-approved FFRs. On May 27, 2021, FDA also recommended that healthcare facilities and HCP "transition away from crisis capacity conservation strategies, such as using non-NIOSH-approved disposable respirators, including imported respirators such as KN95s." In addition, on June 21, 2021, OSHA issued an Emergency Temporary Standard (ETS) to adequately address the hazard of COVID-19 for HCP. The ETS requires, among other things, healthcare employers to provide NIOSH-approved or FDA-authorized respirators for healthcare workers potentially exposed to COVID-19.

known and potential benefits of these respirators, when used for such use, no longer outweigh the known and potential risks of continued use, and pursuant to section 564(g)(2)(B), the criteria under section 564(c) of the Act for issuance of the EUA are no longer met. In addition, based on the same information, revocation of the EUA is appropriate to protect the public health and safety pursuant to section 564(g)(2)(C) of the Act.

Accordingly, pursuant to section 564(g)(2)(B) and 564(g)(2)(C) of the Act, FDA revokes the EUA.

Effective on July 6, 2021, which is 15 days after the effective date of the OSHA ETS, and the date by which compliance by healthcare facilities is required, the devices listed in Exhibit 1 as covered by the March 24, 2021 EUA are not authorized by FDA for use as respirators in healthcare settings by HCP to prevent HCP exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak, and therefore cannot be legally introduced into interstate commerce with that intended use.

FDA encourages manufacturers and other stakeholders to inform their customers and HCP, as applicable, of this revocation. Manufacturers, HCP, hospital purchasing departments, distributors, importers, commercial wholesalers, states, and any other stakeholders who have questions about options to redistribute or recondition their supply of non-NIOSH-approved respirators that will not be authorized effective July 6, 2021, may reference the publicly posted frequently asked questions (FAQ) regarding this revocation letter or contact FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

Monte Brown, MD
Vice President of Administration and Secretary
Duke University Health System
107B Davison Building
Durham, NC 27710

**Re: Revocation of EUA**

Dear Dr. Brown:

This letter is in response to Duke University Health System's (Duke's) request dated April 9, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Duke Decontamination System for Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor (hereafter referred to as "Duke Decontamination System") issued on May 7, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Duke will no longer make the Duke Decontamination System available for the authorized emergency use. In its request, Duke confirmed that it has ceased operation of all Duke Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Duke has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Duke's EUA for the Duke Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Duke Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Duke to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

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

**Re: Revocation of EUA**

Dear Mr. Kalkbrenner:

This letter is in response to Sterilucent, Inc.'s (Sterilucent's) request dated April 15, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (hereafter referred to as "Sterilucent Decontamination System") issued on April 20, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Sterilucent will no longer make the Sterilucent Decontamination System available for the authorized emergency use. In its request, Sterilucent confirmed that it has ceased operation of all Sterilucent Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Sterilucent has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Sterilucent's EUA for the Sterilucent Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Sterilucent Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Sterilucent to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

Ms. Nancy Havill
Manager, Infection Prevention Ambulatory Services
Yale New Haven Health System
20 York Street
New Haven, CT 06504

**Re: Revocation of EUA**

Dear Ms. Havill:

This letter is in response to Yale New Haven Health System's (Yale's) request dated April 16, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Yale New Haven Health FFR Decontamination System (hereafter referred to as "Yale Decontamination System") issued on January 15, 2021. Yale will no longer make the Yale Decontamination System available for the authorized emergency use. In its request, Yale confirmed that it has ceased operation of all Yale Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Yale has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Yale's EUA for the Yale Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Yale Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Yale to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

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

**Re: Revocation of EUA**

Dear Dr. Brodbeck:

This letter is in response to STERIS Corporation's (STERIS's) request dated May 13, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for 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 (hereafter referred to as "STERIS Decontamination Systems") issued on April 9, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. STERIS will no longer make the STERIS Decontamination Systems available for the authorized emergency use. In its request, STERIS confirmed that it has ceased operation of all STERIS Decontamination Systems sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because STERIS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of these systems, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes STERIS's EUA for the STERIS Decontamination Systems, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the STERIS Decontamination Systems are no longer authorized for emergency use by FDA.

FDA encourages STERIS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

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

**Re: Revocation of EUA**

Dear Dr. Brodbeck:

This letter is in response to STERIS Corporation's (STERIS's) request dated May 13, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the AMSCO Medium Steam Sterilizers and the STERIS STEAM Decontamination Cycle in AMSCO Medium Steam Sterilizers as the cycle for decontamination of compatible N95 respirators (hereafter referred to as "STERIS Steam Decontamination System") issued on May 21, 2020, and revised and reissued on January 21, 2021. STERIS will no longer make the STERIS Steam Decontamination System available for the authorized emergency use. In its request, STERIS confirmed that it has ceased operation of all STERIS Steam Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because STERIS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes STERIS's EUA for the STERIS Steam Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the STERIS Steam Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages STERIS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

June 30, 2021

Moira Barton-Varty, RAC
Senior Principal Regulatory Affairs
Stryker Sustainability Solutions
1810 West Drake Drive
Tempe, AZ 8528

**Re: Revocation of EUA**

Dear Ms. Barton-Varty:

This letter is in response to Stryker Sustainability Solution's (SSS's) request dated May 25, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Stryker Sustainability Solutions VHP N95 Respirator Decontamination System (hereafter referred to as "SSS Decontamination System") issued on May 27, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. SSS will no longer make the SSS Decontamination System available for the authorized emergency use. In its request, SSS confirmed that it has ceased operation of all SSS Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because SSS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes SSS EUA for the SSS Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the SSS Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages SSS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

June 30, 2021

Joseph R. Haywood
Assistant Vice President of Regulatory Affairs
o/b/o F. Claire Hankenson, DVM, MS, Director
Campus Animal Resources and University Veterinarian
Michigan State University Animal Care Program
4000 Collins, Suite 120
Lansing, MI 48910

**Re: Revocation of EUA**

Dear Mr. Haywood:

This letter is in response to Michigan State University Animal Care Program's (MSU's) request dated May 27, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the MSU System for Decontaminating Compatible N95 Respirators (hereafter referred to as "MSU Decontamination System") issued on July 24, 2020, and revised and reissued on January 21, 2021. MSU will no longer make the MSU Decontamination System available for the authorized emergency use. In its request, MSU confirmed that it has ceased operation of all MSU Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because MSU has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes MSU's EUA for the MSU Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the MSU Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages MSU to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

Ms. Carolyn Shelton
VP, Global Regulatory & Medical Affairs, Product Stewardship
Advanced Sterilization Products, Inc.
6920 Seaway Blvd.
Everett, WA 98203

**Re: Revocation of EUA**

Dear Ms. Shelton:

This letter is in response to Advanced Sterilization Products, Inc. (ASP) STERRAD's request dated June 4, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the ASP STERRAD 100S, NX, and 100NX Sterilization Systems (hereafter referred to as "ASP STERRAD Decontamination Systems") issued on April 11, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. ASP STERRAD will no longer make the ASP STERRAD Decontamination Systems available for the authorized emergency use. In its request, ASP STERRAD confirmed that it has ceased operation of all ASP STERRAD Decontamination Systems sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because ASP STERRAD has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of these systems, when used for their emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes ASP STERRAD's EUA for the ASP STERRAD Decontamination Systems, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the ASP STERRAD Decontamination Systems are no longer authorized for emergency use by FDA.

FDA encourages ASP STERRAD to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

Mr. Brent Hart
Technical Safety Services LLC
620 Hearst Avenue
Berkeley, CA 94710

**Re: Revocation of EUA**

Dear Mr. Hart:

This letter is in response to Technical Safety Services LLC's (TSS's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the 20-CS Decontamination System (hereafter referred to as "TSS Decontamination System") issued on June 13, 2020, and revised and reissued on January 21, 2021. TSS will no longer make the TSS Decontamination System available for the authorized emergency use. In its request, TSS confirmed that it has ceased operation of all TSS Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because TSS has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes TSS's EUA for the TSS Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the TSS Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages TSS to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

June 30, 2021

Mr. Jeffrey J. Morris
President
Roxby Development, LLC
102 Carmel Road
Wheeling, WV 26003

**Re: Revocation of EUA**

Dear Mr. Morris:

This letter is in response to Roxby Development, LLC's (Roxby's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Zoe-Ann Decontamination System (hereafter referred to as "Roxby Decontamination System") issued on October 20, 2020. Roxby will no longer make the Roxby Decontamination System available for the authorized emergency use. In its request, Roxby confirmed that it has ceased operation of all Roxby Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Roxby has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Roxby's EUA for the Roxby Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Roxby Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Roxby to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

Mr. Yasser Estafanous
Director for Regulatory Affairs and Quality Assurance
3B Medical, Inc.
203 Avenue A NW, Suite 300
Winter Haven, FL 33881

**Re: Revocation of EUA**

Dear Mr. Estafanous:

This letter is in response to 3B Medical, Inc.'s (3B Medical's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Lumin LM3000 Bioburden Reduction UV System (hereafter referred to as "3B Medical Bioburden Reduction System") issued on December 3, 2020. 3B Medical will no longer make the 3B Medical Bioburden Reduction System available for the authorized emergency use. In its request, 3B Medical confirmed that it has ceased operation of all 3B Medical Bioburden Reduction System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because 3B Medical has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes 3B Medical's EUA for the 3B Medical Bioburden Reduction System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the 3B Medical Bioburden Reduction System is no longer authorized for emergency use by FDA.

FDA encourages 3B Medical to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

Mr. Raghu Jainapur
Vice President, Regulatory Affairs, Global Healthcare
Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102

**Re: Revocation of EUA**

Dear Mr. Jainapur:

This letter is in response to Ecolab Inc's (Ecolab's) request dated June 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Bioquell Technology System (hereafter referred to as "Ecolab Decontamination System") issued on December 4, 2020. Ecolab will no longer make the Ecolab Decontamination System available for the authorized emergency use. In its request, Ecolab confirmed that it has ceased operation of all Ecolab Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Ecolab has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Ecolab's EUA for the Ecolab Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Ecolab Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Ecolab to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

June 30, 2021

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

**Re: Revocation of EUA**

Dear Ms. Galin:

This letter is in response to Stryker Instruments' (Stryker's) request dated June 8, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA) for the Stryker Instrument's Sterizone VP4 Sterilizer N95 Respirator Decontamination Cycle (hereafter referred to as "Stryker Decontamination System") issued on April 14, 2020, and revised and reissued on June 6, 2020, and January 21, 2021. Stryker will no longer make the Stryker Decontamination System available for the authorized emergency use. In its request, Stryker confirmed that it has ceased operation of all Stryker Decontamination System sites as well as associated activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may be revoked when the circumstances described under section 564(b)(1) of the Act no longer exist (section 564(g)(2)(A) of the Act), the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Stryker has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, and consistent with FDA's belief that the known and potential benefits of this system, when used for its emergency use, no longer outweigh the known and potential risks of such use, FDA has determined that it is appropriate to revoke this authorization because the criteria for issuance of an EUA under section 564(c)(2)(B) of the Act are no longer met. Moreover, based on the same information, FDA has concluded under section 564(g)(2)(C) of the Act that other circumstances make revocation of this EUA appropriate to protect the public health or safety.

Accordingly, FDA hereby revokes Stryker's EUA for the Stryker Decontamination System, pursuant to sections 564(g)(2)(B) and 564(g)(2)(C) of the Act. As of the date of this letter, the Stryker Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Stryker to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.



Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

BILLING CODE 4164–01–C

Dated: August 26, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–18777 Filed 8–30–21; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

**[Docket No. FDA–2021–N–0412]**

## Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Curative Inc. for the Curative SARS–Cov–2 Assay. FDA revoked the Authorization on July 15, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by Curative Inc. on June 16, 2021. The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

**DATES:** The Authorization for the Curative SARS–Cov–2 Assay is revoked as of July 15, 2021.

**ADDRESSES:** Submit written requests for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On April 16, 2020, FDA issued the Authorization to Curative Inc. (original issuance to KorvaLabs, Inc. under the name Curative-Korva SARS–Cov–2 Assay). Notice of the issuance of the Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2)(C) of the FD&C Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety.

### II. EUA Revocation Request of an In Vitro Diagnostic Device

On June 16, 2021, Curative Inc. requested the revocation of, and on July 15, 2021, FDA revoked, the Authorization for the Curative SARS–Cov–2 Assay. Because Curative Inc. notified FDA that it will no longer be using the Curative SARS–Cov–2 Assay as of July 15, 2021, and requested FDA revoke the authorization effective that day, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

### III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/* and *https://www.fda.gov/media/150773/download.*

### IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for the Curative SARS–Cov–2 Assay. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P