U.S. FOOD & DRUG ADMINISTRATION

January 21, 2021

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

Dear Mr. Brent Hart:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[2]

On June 13, 2020, based on your[3] request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of your product[4] for use in decontaminating compatible N95 respirators[5] for multiple-user[6] reuse by healthcare personnel (HCP)[7] to prevent exposure to pathogenic biological airborne particulates when there are

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).
[3] For ease of reference, this letter will use the term "you"' and related terms to refer to Technical Safety Services LLC (TSS).
[4] For ease of reference, this letter will use the term "your product" to refer to the 20-CS Decontamination System.
[5] In the June 13, 2020 letter, "compatible N95 respirators" were defined as any non-cellulose containing NIOSH-approved N95 respirator that does not have an exhalation valve that are authorized in the NIOSH-Approved Air Purifying Respirators EUA (available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization). Please see FDA's website for further information on N95 respirators, available at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks.
[6] Multiple-user reuse means that healthcare personnel may receive a different respirator following decontamination than the one they had previously used.
[7] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or

insufficient supplies of filtering facepiece respirators (FFRs) resulting from the COVID-19 pandemic.

On January 21, 2021, in response to public health and safety concerns regarding the decontamination of certain respirators, FDA is reissuing the June 13, 2020 letter in order to revise the authorization of the 20-CS Decontamination System to include the following aspects:

1. Limitation of the respirator features that are considered to be compatible N95 respirators[8] in which this decontamination system is authorized to decontaminate.
2. Limitation of the maximum number of decontamination cycles to four (4) cycles per compatible N95 respirator with the option to increase the maximum cycles with the submission of, and subject to review and concurrence with, real-world evidence (RWE) for more than 4 cycles.
3. Incorporation of a post-authorization study to collect RWE to verify that compatible N95 respirators are capable of adequate reuse after 4 decontamination cycles.
4. Incorporation of a Condition of Authorization that requires healthcare facilities to ensure that HCP receive the same model of decontaminated compatible N95 respirator for which they have been fit tested. If such model of respirator is unavailable, then healthcare facilities must provide HCP with fit testing prior to using an alternative model of decontaminated compatible N95 respirator.[9]

Your product is no longer authorized to decontaminate compatible N95 respirators with antimicrobial agents or a duck-billed design. Additionally, your product is no longer authorized to decontaminate compatible N95 respirators up to 20 cycles and is now authorized to perform such decontamination for a maximum of 4 times per respirator. A Condition of Authorization (Section IV.S) has been added in which you must conduct a post-authorization study to verify that compatible N95 respirators are adequate for reuse following 4 decontamination cycles. The maximum number of cycles can be increased following submission and review of RWE for greater than 4 decontamination cycles (see Section IV.T). These revisions are reflected in the Scope of Authorization (Section II), Conditions of Authorization (Section IV), and authorized labeling. Having concluded that revising the June 13, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act (21 U.S.C. §360bbb-3(g)(2)(C)), FDA is reissuing the June 13, 2020 letter in its entirety with the revisions incorporated.

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contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

[8] For purposes of this revised EUA, "compatible N95 respirators" are defined as any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design, and that are authorized in the NIOSH-Approved Air Purifying Respirators EUA, which is available at https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization. Please see FDA's website for further information on N95 respirators, available at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks.

[9] Other minor corrections and clarifications have also been made during the review and edit process for reissuance of the January 21, 2021 letter.

Your product has not been previously cleared or approved by FDA for any indication. In addition, 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. In evaluating this EUA, FDA reviewed the totality of scientific evidence available, which includes: scientific literature characterizing the effect of vaporous hydrogen peroxide (VHP) on compatible N95 respirators; validation testing of VHP bioburden reduction of compatible N95 respirators with the most difficult to kill bacterial spores; historical biological indicator inactivation data for your product; filtration efficiency, fit testing and breathability testing following multiple decontamination cycles; and testing regarding hydrogen peroxide residuals after decontamination.

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 20-CS Decontamination System, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the 20-CS Decontamination System, as described in the Scope of Authorization (Section II) of this letter, meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

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

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the 20-CS Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCPs to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks of the use of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the 20-CS Decontamination System for decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic.[10,11]

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

[11] There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of 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.

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 20-CS Decontamination System, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of four (4) decontamination cycles per respirator, for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

The 20-CS Decontamination Cycle is not authorized for use in decontaminating incompatible N95 respirators. N95 respirators containing cellulose-based materials, exhalation valves, antimicrobial agents, and duck-billed design are incompatible with the 20-CS Decontamination System. This system is also not authorized to decontaminate respirators authorized by the non-NIOSH-approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.

Authorized 20-CS Decontamination System

The 20-CS Decontamination System is a mobile enclosure designed to use vaporized hydrogen peroxide (VHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms. The system is designed to allow for flexibility in decontamination location, in that the 20-CS Decontamination System may be utilized at any location where space and safety requirements permit.

The 20-CS Decontamination System requires an overall footprint of 26 feet (ft) by 13 ft and can accommodate a maximum capacity of approximately 5,000 compatible N95 respirators per decontamination cycle, with a maximum of two (2) runs per day. The 20-CS Decontamination System includes an anteroom that allows for the ability of personnel operating the system to don PPE as required, as well as pass-through of materials. The 20-CS Decontamination system is to be operated only by Technical Safety Services personnel.

The 20-CS Decontamination System will be operated in accordance with the H_2O_2.20CS.LSD protocol reviewed by FDA. An overview of the critical activities is outlined below:

1. Place the 20-CS Decontamination System in a location approved by Technical Safety Services and the healthcare facility owner as appropriate for use, with a minimum clearance of 20 ft from any access/egress doors and any/all air intakes or potential breathing zones. Ensure appropriate utilities are provided. The 20-CS will require an overall footprint of 26 ft by 13 ft.
2. Collect and receive compatible N95 respirators per *Instructions for Healthcare Personnel: Requirements for Compatible N95 Respirators Decontaminated by TSS*. Respirators as received will be labeled with a unique ID and corresponding QR code labels will be provided to the customer. Compatible N95 respirators that are soiled or damaged will be discarded.
3. Wearing appropriate PPE, Technical Safety Services personnel will load compatible N95 respirators into the 20-CS Decontamination System's containment system such that they do not overlap with the outside of the respirator facing upward.

4. Chemical indicators will be placed throughout the containment system to cover representative zones of shelves to ensure that compatible N95 respirators placed in the most difficult to reach zones are successfully decontaminated.
5. The containment system will be conditioned such that humidity is at or below 40% and temperature is at or above 30°C.
6. VHP is injected into the containment system to an effective concentration.
7. VHP concentrations are maintained at the target concentration level for 120 minutes to kill microorganisms.
8. Technical Safety Services personnel will confirm that H_2O_2 parts per million (ppm) and chemical indicator (CI) results meet protocol ("the Technical Safety Services H_2O_2.20CS.LSD protocol") acceptance criteria for release of compatible N95 respirators. Any run that has a CI result that is not a complete, reflected by a full color change, will be considered ineffective and respirators will not be released.
    a. Note: In the event of a run that does not meet protocol acceptance criteria, the decontamination cycle count will be increased, compatible N95 respirators that have exceeded 4 decontamination cycles will be discarded, and the decontamination cycle will be re-run.
9. The containment system is vented until the concentration of hydrogen peroxide is < 1 ppm. The containment system is then aerated until hydrogen peroxide is reduced to an acceptable level and decontaminated, compatible N95 respirators are ready for use.
10. Technical Safety Services personnel will remove decontaminated, compatible N95 respirators from the containment system, scanning the QR code for each respirator, which indicates the addition of a decontamination cycle to the total decontamination cycle count of the respirator, and place the respirator into the designated clean respirator bins that will be staged in the anteroom. Any respirator that has reached 4 decontamination cycles will be tagged with indelible ink so the user and Technical Safety Services personnel will know that these respirators will need to be discarded after the next use. Any respirators found to be visibly degraded will be discarded.
11. Technical Safety Services personnel will return decontaminated, compatible N95 respirators and appropriate chain of custody and labeling documentation to healthcare facilities' dedicated point of contact.

The above described product is authorized to be accompanied with the following product-specific information (that will be made available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) pertaining to emergency use, and is required to be made available to healthcare personnel and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Requirements for Compatible N95 Respirators Decontaminated by TSS; and

- Instructions for Healthcare Facilities: Requirements for Compatible N95 Respirators Decontaminated by TSS.

In addition, following decontamination, compatible N95 respirators decontaminated by the 20-CS Decontamination System must be accompanied by the following labeling, developed by

Technical Safety Services, upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: 20-CS Decontamination System for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, and/or Instructions for Healthcare Facilities are collectively referred to as "authorized labeling." The above described product, when accompanied with the described labeling is authorized to be distributed to and administered under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the 20-CS Decontamination System, when used and labeled consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the 20-CS Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic, when used consistently with the Scope of Authorization (Section II) of this letter, pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of this letter, and concludes that the 20-CS Decontamination System (as described in the Scope of Authorization (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the 20-CS Decontamination System must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, the 20-CS Decontamination System is authorized for emergency use, as described in the Scope of Authorization (Section II).

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practices otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under Section 520(f)(1) of the Act. FDA grants that waiver, including the quality system requirements under 21 CFR 820.

IV. Conditions of Authorization

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

Technical Safety Services LLC

A. Technical Safety Services 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, Scope of Authorization.

B. Technical Safety Services must provide to all healthcare facility customers the authorized labeling, before the decontamination process begins.

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

D. Technical Safety Services may request changes to this EUA for the 20-CS Decontamination System[12], including changes to the authorized labeling. Any request for changes to this EUA must be submitted to the Division of Infection Control and Plastic and Reconstructive Surgery (DHT4B)/Office of Health Technology 4: Office of Surgical and Infection Control Devices (OHT4)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Such changes require appropriate authorization from FDA prior to implementation.

E. Technical Safety Services may request and be allowed to add compatible N95 respirator models under Condition D. To support such a request, Technical Safety Services must provide to FDA validation data to support new respirator models.

F. Technical Safety Services may request and be allowed to increase the maximum capacity of compatible N95 respirators per decontamination cycle under Condition D. To support such a request, Technical Safety Services must provide FDA validation data to support the increased decontamination capacity.

G. Use of the 20-CS Decontamination System on other types of personal protective equipment is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.

[12] The following types of revisions may be authorized without reissuing this letter: (1) non-substantive editorial corrections to this letter; (2) new types of authorized labeling, including new fact sheets; (3) new carton/container labels; (4) changes to manufacturing processes, including tests or other authorized components of manufacturing; (5) new conditions of authorization to require data collection or study; (6) new instruments, associated software, components or materials in the authorized product or modifications in the way that the device is used. For changes of the type listed in (5) or (6), review and concurrence is required from the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

H. Technical Safety Services will have a process in place and adequate Medical Device Reporting procedures, in accordance with 21 CFR Part 803, to report to FDA adverse events of which Technical Safety Services becomes aware related to the 20-CS Decontamination System and compatible N95 respirators that have undergone decontamination using the 20-CS Decontamination System ("the decontaminated, compatible N95 respirators"). This includes, but is not limited to, reports from healthcare facilities concerning infection or potential infection of the healthcare facility personnel involved in the use of the 20-CS Decontamination System and users of the decontaminated, compatible N95 respirators. Other examples of reportable events that may be relevant to the authorized product include, but are not limited to: allergic reactions or eye, mouth, or nose irritation, evidence that a decontaminated, compatible N95 respirator is unable to perform its essential function, events related to residuals or user contact with residuals (if applicable), infection in decontaminated, compatible N95 respirator wearers, or concerns with the process control or malfunctions of the authorized product used to decontaminate the compatible N95 respirators.

I. Technical Safety Services will have a process in place to collect information on the performance of the 20-CS Decontamination System, including information regarding degradation of decontaminated, compatible N95 respirators, and evaluate this information to determine if adverse event reporting in accordance with 21 CFR Part 803 is warranted.

J. Technical Safety Services will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

K. Technical Safety Services is authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

L. The 20-CS Decontamination System shall only be operated by Technical Safety Services personnel and shall not be distributed to third parties.

M. Technical Safety Services is authorized to decontaminate up to 5,000 compatible N95 respirators per cycle, consistent with the data provided to FDA.

N. Technical Safety Services shall maintain records, including, but not limited to, data from chemical indicators and periodic use of biological indicators used to monitor the decontamination of compatible N95 respirators, and any reductions in decontamination ability. If Technical Safety Services demonstrates any reduction in decontamination ability for a given system, Technical Safety Services shall immediately notify FDA. Technical Safety Services will implement the following process controls for chemical and biological indicators for the 20-CS Decontamination System:

- Technical Safety Services will use biological indicators (BIs) at every CI location on the first decontamination cycle for every 20-CS Decontamination System.

- Technical Safety Services will use BIs at the same CI locations once per day for the first week of use for each 20-CS Decontamination System. Every day for the first week of use, if BI results demonstrate no growth, Technical Safety Services can transition to using BIs once per week.

- Technical Safety Services will use CIs for every decontamination cycle in every 20-CS Decontamination System as described in Section II of this letter, Scope of Authorization.

O. Technical Safety Services will maintain records of the chain of custody of the compatible N95 respirators sent to Technical Safety Services for decontamination through use of a barcode system and tracking database.

P. The 20-CS Decontamination System will be used to decontaminate compatible N95 respirators in accordance with the H_2O_2.20CS.LSD protocol, including completion of all deliverables as required of the Technical Safety Services H_2O_2.20CS.LSD protocol, such as Technical Safety Services eData decontamination report.

Q. Technical Safety Services shall provide FDA, in advance of establishing additional facilities where Technical Safety Services will perform decontamination using the 20-CS Decontamination System, confirmation that all units, critical parameters, logistics, processes, containment systems, and labeling are identical and in place at all additional facilities. After implementation, at the current and all additional facilities, if Technical Safety Services demonstrates any reduction in decontamination ability for a given site, Technical Safety Services shall immediately notify FDA.

R. Technical Safety Services must inspect the compatible N95 respirators upon receipt from the healthcare facilities for visible evidence of soil or damage. If there is any discoloration, any signs of soiling, or other signs of degradation, the compatible N95 respirator will not be decontaminated, and Technical Safety Services must discard the respirator.

S. Technical Safety Services must collect and submit to FDA real-world use data for FDA review to confirm the continued fit and performance of compatible N95 respirators authorized under this EUA after undergoing four (4) cycles of decontamination. The authorized maximum number of four (4) decontamination cycles per compatible N95 respirator (Scope of Authorization (Section II)) will be maintained or revised based on the real-world use data.

   You must complete your study within 60 days of the date of this letter or before 1500 compatible N95 respirators have been decontaminated using your system, whichever is later. You may seek an extension to complete your study where agreed upon by DHT4B/OHT4/OPEQ/CDRH. Your results must be submitted to DHT4B/OHT4/OPEQ/CDRH for review within 15 days of the study completion. Upon completion of FDA's review, you must publish the study results on your website.

   At minimum, the study design must include the following testing with acceptance criteria and sampling:

   1. Fit Testing (**Required**)

a. Acceptance Criteria: ≥ 70% of the subjects pass
b. Sampling: Minimum of 10 representative[13] compatible N95 respirators (minimum of 5 male and 5 female subjects) following 4 decontamination cycles.
c. Test Design: OSHA guidelines OSHA 1910.134 Appendix A Fit Testing Protocol[14]

2. Filtration Efficiency (**Required**)
   a. Acceptance Criteria: ≥ 95%
   b. Sampling: Minimum of 10 representative[13] compatible N95 respirators following 4 decontamination cycles.
   c. Test Design: CDC guidelines Assessment of Filter Penetration Performance and Fit for Decontaminated N95 Respirators, Section "Particulate Filter Efficiency Testing" on Page 5.[15]
3. Indelible Markings (**Required**)
   a. Acceptance Criteria: Markings must be clearly legible.
   b. Sampling: Minimum of 10 representative[13] compatible N95 respirators from Fit Testing following 4 decontamination cycles.
   c. Test Design: Respirators should be visually inspected prior to Fit Testing. An agreement should be met between 2 people evaluating legibility with a form to complete with "yes" or "no" on legibility.

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

Healthcare Facilities

U. 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 Technical Safety Services.

V. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the 20 CS Decontamination System and the decontaminated, compatible N95 respirators in accordance with 21 CFR 803. This includes, but is not limited to, monitoring HCPs using the decontaminated, compatible N95 respirators for signs and

[13] Samples must be collected for testing after the 4th decontamination cycle (which is after the 5th use, to confirm through real-world use data that respirators can withstand 4 cycles of decontamination and reuse). Test samples must include a representative variation of respirators that you are receiving for decontamination. Justification must be provided for the sample chosen, including materials, design characteristics, sizes, etc. Records regarding sample type, model, materials, number of decontamination cycles, etc., must be kept for each sample tested.
[14] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA
[15] https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf

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

W. Healthcare facilities must inspect the decontaminated, compatible N95 respirators. Any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator shall promptly be reported to Technical Safety Services, and the healthcare facility must discard the respirator.

X. Healthcare facilities must ensure that HCP receive the same model of decontaminated, compatible N95 respirator for which they have been fit tested. If such model of respirator is unavailable, then healthcare facilities must provide HCP with fit testing[16] prior to using an alternative model of decontaminated, compatible N95 respirator.

Conditions Related to Printed Materials, Advertising and Promotion

Y. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (q)(1) and (r) of the Act and FDA implementing regulations.

Z. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that such products are safe or effective for the decontamination of compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

AA. All descriptive printed matter, advertising, and promotional materials relating to the use of your product clearly and conspicuously shall state that:

- the 20-CS Decontamination System has neither been cleared or approved by FDA, but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;

[16] Under OSHA regulations, fit test means "the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual" (29 CFR 1910.134(b)). In addition, "an employee using a tight-fitting facepiece respirator [must be] fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter" (29 CFR 1910.134(f)(2)). Fit test differs from a user performing a self-seal check in that the latter refers to an action conducted by the respirator user to determine if the respirator is properly seated to the face. In practice, fit testing serves as an additional safeguard to performing a self-seal check when the end user receives a model for which they have not been previously fit tested.

- the emergency use of the 20-CS Decontamination System 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures