January 21, 2021

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

Dear Dr. Monte Brown:

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 May 7, 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 reuse[6] by healthcare personnel

[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 Duke University Health System.
[4] For ease of reference, this letter will use the term "your product" or "Duke Decontamination System" to refer to the Duke Decontamination System for Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor.
[5] In the May 7, 2020 letter, "compatible N95 respirators" were defined as any N95 or N95-equivalent respirators that do not contain cellulose-based materials. The May 7, 2020 letter also defined "N95-equivalent respirators" as respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators and identified in Appendix A of the EUA for Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
[6] Multiple-user reuse means that healthcare personnel may receive a different respirator following decontamination than the one they had previously used. In the May 7, 2020 letter, this was not explicitly stated as "multiple-user" reuse. FDA has revised this to be clearer in the letter and notes that this clarifying edit does not change the Scope of

(HCP)[7] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators (FFRs) resulting from COVID-19 pandemic.

On June 6, 2020, in response to public health and safety concerns about the appropriateness of decontaminating certain respirators, FDA reissued the May 7, 2020 letter in order to revise which compatible N95 respirators[8] this decontamination system is authorized to decontaminate.

On January 21, 2021, in response to public health and safety concerns regarding the decontamination of certain respirators, FDA is reissuing the June 6, 2020 letter in order to revise the authorization of the Duke Decontamination System to include the following aspects:

1. Limitation of the respirator features that are considered to be compatible N95 respirators[9] 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 Duke must

Authorization.

[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 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] In the June 6, 2020 letter, "compatible N95 respirators" were defined as non-cellulose containing respirators that do not have an exhalation valve that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. As described in the revised Scope of Authorization (Section II), the Duke Decontamination System was no longer authorized to decontaminate respirators that are authorized under the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA or authorized respirators that have exhalation valves.

[9] For purposes of this 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 either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at https://www.fda.gov/emergency-preparedness-and-response/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.

provide HCP with fit testing prior to using an alternative model of decontaminated compatible N95 respirator.[10]

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 to support 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 6, 2020 letter is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act, FDA is reissuing the June 6, 2020 letter in its entirety with the revisions incorporated.

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 contaminated with viruses and the most difficult to inactivate bacterial spores; the effect of VHP on multiple types of viruses and the most difficult to inactivate bacterial spores; filtration efficiency and breathability testing following multiple decontamination cycles; historical biological indicator inactivation data for your product; testing regarding hydrogen peroxide residuals after decontamination; and fit testing for decontaminated, compatible N95 respirators.

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 Duke 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 Duke 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;

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

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Duke Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP 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 for such use, 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 Duke 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.[11,12]

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 Duke 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 Duke Decontamination System is not authorized for use in decontaminating incompatible N95 respirators. N95 respirators containing cellulose-based materials, and respirators that have exhalation valves, antimicrobial agents, or a duck-billed design are incompatible with the Duke Decontamination System. This system is also not authorized to decontaminate respirators authorized by the non-NIOSH-approved Filtering Facepiece Respirator manufactured in China EUA.

Authorized Duke Decontamination System

The Duke Decontamination System is a self-contained decontamination product that uses vapor phase hydrogen peroxide (VHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic organisms.

The Duke Decontamination System is a combination of Bioquell VHP systems, Drager X-am 5100, and PortaSens II/PortaSens III hydrogen peroxide monitoring equipment, and five rooms within the Duke University Health System, that are specifically designated for use with each Bioquell VHP system.

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

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

- The Duke Regional Biocontainment Lab (RBL) is used in conjunction with the Bioquell Clarus C system; the RBL contains its own exhaust system to remove residual hydrogen peroxide from the room.
- The other four rooms are used in conjunction with Bioquell Z-2 and ProteQ systems, which have integrated aeration units to process room air to remove hydrogen peroxide. Each room contains a number of 18" x 36" shelves, dependent on the size of the room, for placing individual compatible N95 respirators for subsequent decontamination.
- Drager X-am 5100 H_2O_2 global sensors are used to monitor hydrogen peroxide concentrations inside the room; PortaSens II and III gas leak detectors are also used to confirm H_2O_2 levels.

Depending on the room, with larger rooms generally accommodating more shelves, the capacity of compatible N95 respirators that can be placed in this manner ranges as shown in Table 1:

Table 1

Decontamination chamber name	**VHP generator(s)**	**Capacity of Compatible N95 Respirators per cycle**
RBL	Bioquell Clarus C, Bioquell Z-2	1,260
Duke University Hospital (DUH) 1	Bioquell ProteQ, Bioquell Z-2	1,323
DUH 2	Bioquell ProteQ, Bioquell Z-2	1,764
Duke Regional Hospital (DRH)	Bioquell ProteQ, Bioquell Z-2	1,470
Duke Raleigh Hospital (DRaH)	Bioquell ProteQ, Bioquell Z-2	882

Each decontamination cycle in the Duke Decontamination System consists of injecting VHP into the decontamination room until achieving a saturated atmosphere indicated by micro condensation; maintaining the VHP exposure for a 20-minute dwell time; and allowing the VHP to off gas to a level below 1 ppm prior to post decontamination processing. A minimum of one biological indicator is dispersed throughout the system to indicate a successful decontamination cycle. This decontamination system enables the multiple-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or decontaminated.

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 providers and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by Duke Health Using the Duke Decontamination System with Hydrogen Peroxide Vapor;

- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by Duke Health Using the Duke Decontamination System with Hydrogen Peroxide Vapor; and
- Instructions for Duke Decontamination Facility: Decontamination of Compatible N95 Respirators with Hydrogen Peroxide Vapor.

In addition, following decontamination, compatible N95 respirators decontaminated by the Duke Decontamination System must be accompanied by the following labeling, developed by Duke University Health System, upon return of the decontaminated compatible N95 respirators to HCP:

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

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, and Instructions for Duke Decontamination Facility 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 Duke 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 Duke 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 Duke 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 Duke 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 Duke 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 Part 820.

IV. Conditions of Authorization

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

Duke University Health System ("Duke")

A. Duke must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions), as well as those described in Section II of this letter, the Scope of Authorization.

B. Duke may request changes to this EUA for the Duke Decontamination System[13], 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 Devices (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.

C. Duke may request and be allowed to add compatible N95 respirator models under Condition B. To support such a request, Duke must provide to FDA validation data to support new respirator models.

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

E. Use of the Duke 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.

[13] 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.

F. Duke 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 Duke becomes aware related to the Duke Decontamination System and compatible N95 respirators that have undergone decontamination using the Duke 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 Duke 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.

G. Duke will have a process in place to collect information on the performance of the Duke 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.

H. Duke 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.

I. Duke 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.

J. Duke shall make available to HCP who are or may be using the decontaminated, compatible N95 respirators the authorized Face Sheet for Healthcare Personnel and Instructions for Healthcare Personnel that are required to be provided by Duke.

K. Duke personnel using the decontaminated, compatible N95 respirators must inspect the decontaminated, compatible N95 respirators following the decontamination process using the Duke Decontamination System. Duke shall maintain records regarding discoloration or other signs of degradation of a decontaminated, compatible N95 respirator, and the healthcare facility must discard the respirator.

L. Duke must track the number of times a compatible N95 respirator is decontaminated, up to a maximum of four (4) decontamination cycles per compatible N95 respirator. Any decontaminated compatible N95 respirator that has exceeded 4 decontamination cycles shall be discarded.

M. Duke shall maintain documentation for use of the Duke Decontamination System consistent with current healthcare facility protocols. Duke must maintain documentation that critical process parameters were met to achieve decontamination of compatible N95 respirators for

each cycle. Duke shall maintain this documentation associated with this EUA until otherwise notified by FDA. Such documentation will be made available to FDA upon request.

N. The Duke Decontamination System shall only be operated by Duke University Health System in the Duke RBL, DUH 1, DUH 2, DRH, and DRaH decontamination chambers, and shall not be distributed to third parties.

O. Duke shall not distribute decontaminated, compatible N95 respirators to any other healthcare facility.

P. Duke is authorized to decontaminate up to 1,260, 1,323, 1,764, 1,470, and 882 compatible N95 respirators per chamber load in the Duke RBL, DUH 1, DUH 2, DRH, and DRaH decontamination chambers, respectively, based on chamber dimensions and geometry for supporting shelving units, consistent with data provided to FDA. Duke 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.

Q. Duke is authorized to add additional decontamination chambers on the condition that Duke shall provide in advance to FDA information on validation data to demonstrate that additional chambers have met the following critical parameters: 1) minimum concentration of 480 ppm and minimum gas dwell time of 20 minutes, 2) 6-log reduction in biological indicator or equivalently validated chemical indicator, and 3) residual hydrogen peroxide below the permissible exposure limit of 1 ppm on the compatible N95 respirators.

R. Duke must use biological indicators and chemical indicators to confirm that decontamination cycles have been effectively conducted. Duke is authorized to release decontaminated, compatible N95 respirators by parametric release based on chemical indicators.

S. Duke 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 representive[14] 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[15]
2. Filtration Efficiency (**Required**)
   a. Acceptance Criteria: ≥ 95%
   b. Sampling: Minimum of 10 representative[14] 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[16]
3. Indelible Markings (**Required**)
   a. Acceptance Criteria: Markings must be clearly legible.
   b. Sampling: Minimum of 10 representative[14] 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, Duke may request and be allowed to increase the maximum number of decontamination cycles per compatible N95 respirator under condition B. To support such a request, Duke must provide to FDA information regarding, filtration efficiency and respirator fit testing based on RWE, including, but not limited to, evidence collected in the study design and methods adopted in accordance with Condition S.

U. Duke must ensure that HCP receive the same model of decontaminated, compatible N95 respirator for which they have been fit tested. If such respirator model is unavailable, then Duke must provide HCP with fit testing[17] prior to using an alternative model of decontaminated, compatible N95 respirator.

Conditions Related to Advertising and Promotion

[14] 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 samples 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.
[15] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA
[16] https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf
[17] 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.

V. 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.

W. 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.

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

- the Duke 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;

- the emergency use of the Duke 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