December 4, 2020

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

Dear Mr. Jainapur:

This letter is in response to your[1] request that the U.S. Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of your product[2] for use in decontaminating compatible N95 respirators[3] for single-user reuse[4] by healthcare personnel (HCP)[5] to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators (FFRs) resulting from the Coronavirus Disease 2019 (COVID-19) pandemic.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[6] 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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Ecolab Inc. Also referenced in this letter is Bioquell Inc., a subsidiary of Ecolab Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the Bioquell Technology System.
[3] For purposes of this EUA, "compatible N95 respirators" are limited to 3M's respirator models 1860, 8210, 1804, and 1870+ only. 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.
[4] Single-user reuse means that the same respirator is returned for reuse to the same healthcare personnel following its decontamination.
[5] For purposes of this EUA, HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).
[6] 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).

authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[7]

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 and other information related to decontamination and the use and reuse of FFRs; information related to compatible N95 respirator fit testing; and performance data for decontamination of compatible N95 respirators, such as material compatibility, residual analysis of hydrogen peroxide post-decontamination, sporicidal testing, filtration efficiency, breathability, and worst-case scenario challenges.

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 Bioquell Technology 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 Bioquell Technology 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 Bioquell Technology System may be effective at decontaminating compatible N95 respirators for single-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 Bioquell Technology System for decontaminating compatible N95 respirators for single-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.[8,9]

[7] 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).

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

[9] There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95

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 Bioquell Technology 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 single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Consistent with the Conditions of Authorization (Section IV) specified below, Bioquell Inc. will work with the healthcare facility to ensure that the room is properly configured for the Bioquell Technology System to deliver a controlled and monitored decontamination process. Bioquell Inc. will train designated personnel at the healthcare facility during the setup verification on execution of the decontamination process. Completion of such training and setup is documented with the form "Decontamination of Compatible N95 Respirators: Training and Setup Verification Form" (Setup Verification Form), which the healthcare facility completes and then signs and submits, along with photographic evidence, to solutions@bioquell.com. Bioquell Inc. will review the Setup Verification Form completed by the healthcare facility. If it is found to be acceptable, Bioquell Inc. will sign the Setup Verification Form and share it with Ecolab Inc., Bioquell Inc.'s parent company, for final review and approval. Ecolab Inc. will review the Setup Verification Form that has been completed and signed by the healthcare facility and reviewed and signed by Bioquell Inc. If the Setup Verification Form is acceptable to Ecolab Inc., Ecolab Inc. will sign the Setup Verification Form and provide Bioquell Inc. and the healthcare facility a final signed copy to indicate approval for the healthcare facility to start routine decontamination procedures. If requested by FDA, Ecolab Inc. must also submit to FDA the form "Decontamination of Compatible N95 Respirators: Training and Setup Verification Form," and any supporting documents as a report to the Division of Infection Control and Plastic and Reconstructive Surgery/Office of Health Technology 4: Office of Surgical and Infection Control Devices /Office of Product Evaluation and Quality/Center for Devices and Radiological Health.

Authorized Bioquell Technology System

The Bioquell Technology System is a decontamination system that uses a Bioquell hydrogen peroxide generator (ProTeQ or BQ50) that is placed in a room with dimensions of 28 m^3 for the ProTeQ generator or 30 m^3 for the BQ50 generator. The Bioquell Technology System delivers 35% hydrogen peroxide vapor to the enclosure with an exposure of hydrogen peroxide in the range of 10.3 g/m^3 – 15 g/m^3 per run. The Bioquell Technology System can decontaminate a maximum capacity of 160 compatible N95 respirators per cycle. Each respirator can be decontaminated a maximum of 4 times (4 decontamination cycles). This decontamination system enables the reuse of compatible N95 respirators that would otherwise be disposed of after a

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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.

single use. However, respirators that are visibly soiled must be discarded and must not be reused or decontaminated.

The table below shows the parameters for one cycle for each generator model:

Bioquell Generator	Room Volume	Injection Rate (max)	H_2O_2 Concentration	Dwell Time	Aeration Time	Temperature & Humidity
ProteQ	28 m^3	16 g/min	10.3 – 15 g/m^3	10 minutes	180 minutes or until concentration ≤1.0 ppm	22 – 25°C 36.8 – 56.6%
BQ50	30 m^3	16 g/min	10.3 – 15 g/m^{3re}	10 minutes	180 minutes or until concentration ≤1.0 ppm	21 – 27°C 20 – 36%

HCP and healthcare facilities will collect compatible N95 respirators in accordance with the Instructions for HCP and Instructions for Healthcare Facilities (further outlined below) for decontamination using the Bioquell Technology System. The decontamination process involves conditioning the room to a humidity level as specified in the table above, injecting vaporized hydrogen peroxide (VHP) into a controlled, airtight chamber, and allowing that concentrated VHP to dwell for a period of 10 minutes to ensure penetration into the filtration material of the compatible N95 respirators. The chamber is then aerated to reduce the VHP to a level of 1.0 parts per million (ppm) or lower.[10] The compatible N95 respirators then continue to "off-gas" the remaining hydrogen peroxide held within the respirators.

Five (5) Bioquell biological indicators and five (5) Bioquell chemical indicators must be used in each run to confirm that decontamination cycles have been effectively conducted. For the first two weeks, the loads of decontaminated, compatible N95 respirators are released based on the results of the biological indicators to demonstrate process control (i.e., no growth on the biological indicator after one-week incubation). After successful demonstration of the two-week process control using biological indicators, the decontaminated, compatible N95 respirators may be released based on the results of either the biological indicators or per parametric release criteria using the results of the chemical indicators. However, biological indicators must continue to be used in each decontamination cycle and the results of the biological indicators must be recorded and monitored weekly to continue to monitor process control. Critical process parameters (room volume, injection rate, dwell time, and aeration) must always be monitored.

The above described product is authorized to be accompanied with the BQ50 User Manual, the ProTeQ User Manual, and the Decontamination of Compatible N95 Respirators: Training and Setup Verification Form ("Setup Verification Form"), as well as the following product-specific information (that will be made available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices) pertaining to

[10] Please note that the concentration of ≤1.0 ppm is consistent with the OSHA permissible exposure limit (PEL) for H_2O_2.

emergency use, and is required to be made available to HCP and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Emergency Decontamination of Compatible N95 Respirators Using the Bioquell Technology System

- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination Using the Bioquell Technology System

In addition, following decontamination, compatible N95 respirators decontaminated by the Bioquell Technology System must be accompanied by the following labeling, developed by Ecolab Inc., upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: Bioquell Technology System for Decontaminating Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, BQ50 User Manual, ProTeQ User Manual, and Setup Verification Form are collectively referred to as "authorized labeling." The above described product, when accompanied with the authorized 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 Bioquell Technology 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 Bioquell Technology System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic, when used consistently with the Scope of Authorization (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 Bioquell Technology 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 Bioquell Technology 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 Bioquell Technology 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:

Ecolab Inc.

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

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

D. Ecolab Inc. may request changes to this EUA for the Bioquell Technology System, including changes to the Scope of Authorization (Section II in this letter), process, procedures, and/or 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) and require appropriate authorization from FDA prior to implementation.

E. Ecolab Inc. may add compatible N95 respirator models upon request and subject to review and concurrence of DHT4B/OHT4/OPEQ/CDRH prior to implementation. To support such a request, Ecolab Inc. must provide to FDA validation data to support new respirator models.

F. Ecolab Inc. may increase the maximum capacity of 160 compatible N95 respirators per decontamination cycle upon request and subject to review and concurrence of DHT4B/OHT4/OPEQ/CDRH prior to implementation. To support such a request, Ecolab Inc. must provide FDA validation data to support the increased decontamination capacity.

G. Use of the Bioquell Technology 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.

H. Ecolab Inc. will have a process in place and adequate Medical Device Reporting procedures, in accordance with 21 CFR 803, to report to FDA adverse events of which Ecolab Inc. becomes aware related to the Bioquell Technology System and compatible N95 respirators that have undergone decontamination using the Bioquell Technology 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 Bioquell Technology System and users of the decontaminated, compatible N95 respirators. 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. Ecolab Inc. will have a process in place to collect information on the performance of the Bioquell Technology 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. Ecolab Inc. 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. Ecolab Inc. 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. Ecolab Inc. must review the form "Decontamination of Compatible N95 Respirators: Training and Setup Verification Form" (Setup Verification Form) that has been completed and signed by the healthcare facility and reviewed and signed by Bioquell Inc. If the Setup Verification Form is acceptable to Ecolab Inc., Ecolab Inc. will sign the Setup Verification Form and will provide Bioquell Inc. and the healthcare facility with the final signed copy to indicate approval for the healthcare facility to begin routine decontamination operations.

M. If requested by FDA, Ecolab Inc. must submit to FDA the form "Decontamination of Compatible N95 Respirators: Training and Setup Verification Form," and any supporting documents as a report to DHT4B/OHT4/OPEQ/CDRH.

N. Ecolab Inc. 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 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[11] 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[12]
2. Filtration Efficiency (**Required**)
    a. Acceptance Criteria: ≥ 95%
    b. Sampling: Minimum of 10 representative[11] 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[13]
3. Indelible Markings (**Required**)
    a. Acceptance Criteria: Markings must be clearly legible.
    b. Sampling: Minimum of 10 representative[11] compatible N95 respirators from Fit Testing following 4 decontamination cycles.
    c. Test Design: Respirators must be visually inspected prior to Fit Testing. An agreement will be met between 2 people evaluating legibility with a form to complete with "yes" or "no" on legibility.

O. Following completion of Condition N, Ecolab Inc. may increase the maximum number of decontamination cycles per compatible N95 respirator upon request and subject to review and concurrence of DHT4B/OHT4/OPEQ/CDRH prior to implementation. To support such a request, Ecolab Inc. must provide to FDA information regarding, filtration efficiency and

[11] 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.
[12] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA.
[13] https://www.cdc.gov/niosh/npptl/respirators/testing/pdfs/NIOSHApproved_Decon_TestPlan10.pdf.

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 N.

Bioquell Inc.

P. Bioquell Inc. must work with the healthcare facility to ensure that the room that each healthcare facility elects to use for the Bioquell Technology System is properly configured to deliver a controlled and monitored decontamination process.

Q. Bioquell Inc. must train personnel at the healthcare facility who will execute the setup verification and decontamination process according to the authorized labeling. Bioquell Inc. will collect and maintain training records on the initial setup verification for designated healthcare facility personnel. Bioquell Inc. must provide Ecolab Inc. access to these records and Ecolab Inc. must make these records available to FDA upon request.

R. Bioquell Inc. must review the completed and signed Setup Verification Form that is received from the healthcare facility. If it is found to be acceptable, Bioquell Inc. will sign the Setup Verification Form and share it with Ecolab Inc. for final review and approval.

Healthcare Facilities

S. Prior to initiating decontamination processes, healthcare facilities must designate personnel at the healthcare facility to be trained by Bioquell Inc. staff during the setup verification process and must work with Bioquell Inc. to ensure that the room is properly configured for the Bioquell Technology System. Completion of such training and setup is documented with the Setup Verification Form, which the healthcare facility must complete and then sign and submit, along with photographic evidence, to solutions@bioquell.com.

T. Healthcare facilities must receive approval from Ecolab Inc. to begin routine decontamination operations. Approval is obtained after review and concurrence of the Setup Verification Form, first by Bioquell Inc. and subsequently by Ecolab Inc. Ecolab Inc. will indicate final approval for each healthcare facility to use the Bioquell Technology System by providing Bioquell Inc. and the healthcare facility with a signed copy of the Setup Verification Form.

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 Ecolab Inc.

V. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the Bioquell Technology System and the decontaminated, compatible N95 respirators in accordance with 21 CFR Part 803. This includes, but is not limited to, monitoring healthcare facility personnel using the Bioquell Technology System and HCP using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. 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 Ecolab Inc., and the healthcare facility must discard the respirator.

X. Healthcare facilities 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. Healthcare facilities must ensure that the decontaminated, compatible N95 respirator is returned to its previous user.

Y. Healthcare facilities shall maintain documentation for use of the Bioquell Technology System consistent with current healthcare facility protocols. Healthcare facilities shall maintain documentation of exposure conditions, including time, temperature, and pressure, as well as confirmation that the specified critical process parameters (room volume, injection rate, dwell time, and aeration) were met to achieve decontamination of compatible N95 respirators for each cycle. Healthcare facilities shall maintain this documentation associated with this EUA until otherwise notified by FDA. Such documentation will be made available to FDA upon request.

Z. Healthcare facilities shall maintain responsibility for ongoing operational execution of the decontamination process using the Bioquell Technology System, including management of HCP using the Bioquell Technology System and training.

AA. After receiving approval from Ecolab Inc. to operate the Bioquell Technology System at the healthcare facility, the healthcare facility is authorized to use the Bioquell Technology System to decontaminate up to 160 compatible N95 respirators per load, consistent with the information submitted and approved in the Setup Verification Form. Healthcare facilities must include five (5) Bioquell biological indicators (one biological indicator per 15 m^3) and five (5) Bioquell chemical indicators in every decontamination cycle. One Bioquell biological indicator must be placed on each wall and one Bioquell biological indicator must be placed in the center of the room. Healthcare facilities must record each biological indicator location on a floor plan of the target enclosure and keep this record with documentation for use of the Bioquell Technology System consistent with current healthcare facility protocols.

BB. Prior to release of decontaminated, compatible N95 respirators, healthcare facilities must confirm that decontamination cycles have been effectively conducted using biological indicators and chemical indicators as follows:

1. Demonstrate process control for the first two-week period by using biological indicators to support release of the decontaminated, compatible N95 respirators.
2. If no positive growth is observed for the biological indicators used through the two-week period, the healthcare facility may use parametric release criteria using chemical indicators to release loads of decontaminated, compatible N95 respirators.

While the respirator load release criteria may change after the initial two-week period (which relies on data from the biological indicators), healthcare facilities must always use five (5) Bioquell biological indicators and five (5) Bioquell chemical indicators per decontamination load to confirm that decontamination cycles have been effectively conducted and to continue to monitor process control. Critical process parameters (room volume, injection rate, dwell time, and aeration) must always be monitored even when using Bioquell biological indicators and Bioquell chemical indicators.

CC. In the event of positive growth in a biological indicator or other data demonstrating incomplete decontamination, the healthcare facility must initiate a root cause analysis followed by a correction and removal of the affected respirators. The healthcare facility will report these activities to Ecolab Inc. and to FDA in accordance with 21 CFR Part 803. After such correction and removal, the healthcare facility must reinstate the respirator load release criteria per Condition BB.

Conditions Related to Printed Materials, Advertising and Promotion

DD. 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.

EE. 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 single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

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

- the Bioquell Technology 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 single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;

- the emergency use of the Bioquell Technology 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 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