December 3, 2020

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

Dear Mr. Estafanous:

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 bioburden reduction of compatible N95 respirators[3] for single-user reuse[4] by healthcare personnel (HCP)[5] to supplement the Centers for Disease Control and Prevention (CDC) reuse recommendations[6] to prevent exposure to pathogenic biological airborne particulates when there

[1] For ease of reference, this letter will use the term "you" and related terms to refer to 3B Medical, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the Lumin LM3000 Bioburden Reduction UV System ("Lumin LM3000").
[3] For purposes of this EUA, "compatible N95 respirators" are limited to the 3M Model 1860 N95 respirators 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 bioburden reduction.
[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] The CDC has issued specific recommendations on the reuse of N95 respirators (collectively, "CDC reuse recommendations"). Refer to the CDC recommendations for Decontamination and Reuse of Filtering Facepiece Respirators, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html, Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings, available at https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html, and Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during Shortages, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html.

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.[7] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[8]

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 bioburden reduction of 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 bioburden reduction validation demonstrating a 3-log mean reduction in non-enveloped virus applied to the surface of compatible N95 respirators, qualitative fit testing and information regarding filtration and breathability of compatible N95 respirators, analysis of ozone process residuals, and scientific literature and other information related to bioburden reduction and the use and reuse of FFRs.

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 Lumin LM3000, 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 Lumin LM3000, 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 Lumin LM3000 may be effective at bioburden reduction of compatible N95 respirators for single-user reuse by HCP to supplement CDC reuse recommendations to

[7] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[8] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

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 Lumin LM3000 for bioburden reduction of compatible N95 respirators for single-user reuse by HCP to supplement CDC reuse recommendations to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during FFR shortages during the COVID-19 pandemic.[9,10]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the Lumin LM3000, for use in bioburden reduction of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of 4 bioburden reduction cycles per respirator or 5 donnings, whichever comes first, for single-user reuse by HCP to supplement CDC reuse recommendations to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

Authorized Lumin LM3000

The Lumin LM3000 utilizes ultraviolet germicidal irradiation (UVGI) cycle to reduce the bioburden on one compatible N95 respirator at a time by exposing the outer surface of the respirator for 5 minutes, followed by the exposing the inside surface of the respirator for 5 minutes. Prior to bioburden reduction, the compatible N95 respirator must be placed in a breathable paper bag and held for a minimum of 5 days, in accordance with the CDC reuse recommendations. If used as directed, the Lumin LM3000 offers a reliable method for achieving a 3-log mean reduction in non-enveloped virus, which provides additional safety when used to supplement the CDC reuse recommendations of a 5-day wait time.

The Lumin LM3000 consists of a plastic housing with a retractable plastic drawer. The inner surfaces of the drawer are lined with mirrors. One compatible N95 respirator is placed in the drawer with the outer surface facing up. When the drawer is pushed into place (closed), the respirator in the drawer is brought under the UV-C lamps. The Lumin LM3000 runs a single cycle of 5 minutes to emit UV-C light at 254 nm under a nominal dose of 1 J/cm^2. The drawer is then opened, the respirator is flipped over, and the drawer is closed again to reposition the

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

[10] There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of N95 respirators, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be reused. The CDC has issued specific recommendations on the reuse of N95 respirators. Providing a method for bioburden reduction of compatible N95 respirators for single-user reuse by HCP to supplement CDC reuse recommendations 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.

respirator under the UV-C lamp to irradiate the inner surface of the respirator for 5 more minutes. ***Two 5 minute cycles of 1 J/cm^2 (i.e., one 5 minute cycle on each side of the compatible N95 respirator) is considered one bioburden reduction cycle.*** A UV dosimetry strip with a sensitivity of 1 J/cm^2 is placed in every 5 minute cycle to confirm the proper dose has been provided.

The Lumin LM3000 is currently only authorized for use with 3M Model 1860 N95 respirators, previously referenced as "compatible N95 respirators." The Lumin LM3000 is not authorized for use with any other respirator model.

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 HCP and healthcare facilities, respectively:

- Instructions for Healthcare Personnel: Preparation and Collection of Compatible N95 Respirators for Bioburden Reduction Using the Lumin LM3000 Bioburden Reduction UV System; and

- Instructions for Healthcare Facilities: Lumin LM3000 Bioburden Reduction UV System User's Manual.

In addition, following bioburden reduction, compatible N95 respirators that have been bioburden reduced by the Lumin LM3000 must be accompanied by the following labeling, developed by 3B Medical, Inc., upon return of the respirators to HCP:

- Fact Sheet for Healthcare Personnel: Lumin LM3000 for Bioburden Reduction of Compatible N95 Respirators.

The Fact Sheet for Healthcare Personnel, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities (collectively referred to as "authorized labeling") must each include the following boxed warning:

WARNING: The Lumin LM3000 does not sterilize or decontaminate. Prior to use of the Lumin LM3000 to reduce bioburden on the compatible N95 respirator, the respirator must be placed in a breathable paper bag and held for a minimum of 5 days, in accordance with the CDC recommendations for reuse of N95 respirators.

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 Lumin LM3000, 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 Lumin LM3000 may be effective at bioburden reduction of compatible N95 respirators for single-user reuse by HCP to supplement CDC reuse recommendations 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 Lumin LM3000 (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 Lumin LM3000 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 Lumin LM3000 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:

3B Medical, Inc.

A. 3B Medical, 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. 3B Medical, Inc. must provide to all healthcare facility customers the authorized labeling and Chain of Custody Log Form before the bioburden reduction process begins.

C. 3B Medical, Inc. must notify all healthcare facility customers about the conditions of this authorization applicable to healthcare facilities before the bioburden reduction process begins.

D. 3B Medical, Inc. may request changes to this EUA for the Lumin LM3000, 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. 3B Medical, 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, 3B Medical, Inc. must provide to FDA validation data to support new respirator models.

F. Use of the Lumin LM3000 on other types of personal protective equipment is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.

G. 3B Medical, Inc. 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 3B Medical, Inc. becomes aware related to the Lumin LM3000 and compatible N95 respirators that have undergone bioburden reduction using the Lumin LM3000 ("the bioburden reduced, compatible N95 respirators"). This includes, but is not limited to, reports from healthcare facilities concerning infection or potential infection of the personnel involved in the use of the Lumin LM3000 and users of the bioburden reduced, compatible N95 respirators.

H. 3B Medical, Inc. will have a process in place to collect information on the performance of the Lumin LM3000, including information regarding degradation of bioburden reduced, compatible N95 respirators, and evaluate this information to determine if adverse event reporting in accordance with 21 CFR Part 803 is warranted.

I. 3B Medical, 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.

J. 3B Medical, 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.

K. 3B Medical, Inc. must collect and submit to FDA human factors data for FDA review and confirmation of the continued appropriate use of the product, in accordance with the study plan agreed upon with the DHT4B/OHT4/OPEQ/CDRH, to confirm that users are able to

correctly select and use the Lumin LM3000 for bioburden reduction of compatible N95 respirators in accordance with its intended use, based on reading the authorized labeling. In accordance with the study plan agreed upon with the DHT4B/OHT4/OPEQ/CDRH, the study design must include the following:

- Phase 1: Self-selection Study
  The self-selection study must enroll, at minimum, 25 individuals of various educational levels and professions across a wide range of demographics. In accordance with the self-selection study protocol agreed upon with FDA, each participant must read the authorized labeling and any additional descriptive printed matter, advertising, and promotional materials that would be made available prior to purchase of the Lumin LM3000, correctly answer questions regarding the Lumin LM3000's intended use, and make correct decisions about whether or not the Lumin LM3000 is appropriate for them to use. Study success will be defined as correct self-selection by 100% of the study participants.

- Phase II: Reading Comprehension Study
  The reading comprehension study must be comprised of, at minimum, 30 bioburden reduction personnel serving in various types of healthcare settings for which the Lumin LM3000 is intended. The study must be completed by a different group of individuals than the Self-selection Study (Phase I). In accordance with the reading comprehension study protocol agreed upon with FDA, each participant must be provided the Instructions for Healthcare Facilities and be provided a test to assess whether the user is able to understand critical tasks and warnings required for correct use of the Lumin LM3000. Study participants must obtain at least 80% correct responses to pass the test, and study success will be defined as a 100% pass rate among study participants.

- Phase III: Observed Use Study
  The observed use study must be completed by bioburden reduction personnel serving in various types of healthcare settings for which the Lumin LM3000 is intended. The study must be completed by a different group of individuals than the Self-selection Study (Phase I), but may be the same group of individuals as the Reading Comprehension Study (Phase II). A test observer must observe each participant and take notes on any errors made as the participant carries out bioburden reduction of the compatible N95 respirator using the Lumin LM3000 in accordance with the Instructions for Healthcare Facilities. Study success will be defined as 100% of the study participants being able to appropriately use the Lumin LM3000 for bioburden reduction of compatible N95 respirators based on reading the Instructions for Healthcare Facilities. 3B Medical, Inc. must provide within 7 days of this authorization, their detailed protocol for the observed use study. Following FDA concurrence of the observed use study protocol, the study must be initiated within 7 days. 3B Medical, Inc. may seek adjustment of these timeframes where agreed upon by DHT4B/OHT4/OPEQ/CDRH.

Following completion of the study, 3B Medical, Inc. must provide a test report with study results to FDA for review, which includes the following:

- Summary of data that demonstrates the authorized labeling and any additional descriptive printed matter, advertising, and promotional materials support the appropriate selection and use of the Lumin LM3000 by the intended users in the intended use environment;
- Discussion of how the intended use environments affected use of the Lumin LM3000, and a discussion of human factors processes and any residual use-related risks;
- A description of any training provided to users, along with the training material; and
- Raw data, with participant names omitted, and analyses of the results.

The agreed upon study plan, including, but not limited to, the study protocol, test content, sample size, success criteria, and test report content may be revised subject to concurrence of DHT4B/OHT4/OPEQ/CDRH.

3B Medical, Inc. must complete the study (i.e., Phases I, II, and III) within 120 days of the issuance of this letter of authorization, and the test report must be submitted to DHT4B/OHT4/OPEQ/CDRH for review within 15 days of the study completion. 3B Medical, Inc. may seek adjustment of these timeframes where agreed upon by DHT4B/OHT4/OPEQ/CDRH. Upon completion of FDA's review, 3B Medical, Inc. must publish the study results on its website.

L. 3B Medical, Inc. must maintain validation test reports for cleaning and disinfection of the Lumin LM3000 devices on file.

M. Use of the Lumin LM3000 outside of a healthcare setting is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.

N. Use of the Lumin LM3000 for any use other than bioburden reduction of compatible N95 respirators for single-user reuse by HCP to supplement CDC reuse recommendations is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.

O. 3B Medical, Inc. must monitor CDC's reuse recommendations and make any necessary changes to the authorized labeling to align with CDC's reuse recommendations, should CDC's reuse recommendations change. In accordance with Condition D, any changes to the authorized labeling must be reviewed and agreed to by DHT4B/OHT4/OPEQ/CDRH.

Healthcare Facilities

P. Healthcare facilities shall notify 3B Medical, Inc. when they intend to use the Lumin LM3000 for the emergency use, consistent with Section II of this letter.

Q. Healthcare facilities shall make available to HCP who are or may be using the bioburden reduced, compatible N95 respirators the authorized Fact Sheet for HCP and Instructions for

HCP that is required to be provided by 3B Medical, Inc.

R. Healthcare facilities will have a process in place to report adverse events of which they become aware related to the Lumin LM3000 and the bioburden reduced, compatible N95 respirators in accordance with 21 CFR Part 803. This includes, but is not limited to, monitoring personnel using the Lumin LM3000 and HCP using the bioburden reduced, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections.

S. Healthcare facilities shall ensure that a standard process for chain of custody is in place to ensure that contaminated, compatible N95 respirators are separated from bioburden reduced, compatible N95 respirators at all times and that the bioburden reduced, compatible N95 respirator is returned to its previous user (i.e., single-user reuse). Healthcare facilities using the bioburden reduced, compatible N95 respirators shall review the Chain of Custody Log Form, which indicates successful bioburden reduction of the compatible N95 respirators, and the authorized labeling.

T. Healthcare facilities using the bioburden reduced, compatible N95 respirators must inspect the bioburden reduced, compatible N95 respirators. Any discoloration or other signs of degradation with a bioburden reduced, compatible N95 respirator shall promptly be reported to 3B Medical, Inc., and the healthcare facility shall discard the respirator.

U. Healthcare facilities must track the number of times a compatible N95 respirator is bioburden reduced, up to a maximum of 4 bioburden reduction cycles, or 5 donnings, whichever comes first, per compatible N95 respirator. Any bioburden reduced, compatible N95 respirator that has exceeded 4 bioburden reduction cycles, or 5 donnings, whichever comes first, shall be discarded.

V. Healthcare facilities are only authorized to bioburden reduce one compatible N95 respirator per bioburden reduction cycle. Healthcare facilities must use UV dosimeter strips with a sensitivity of 1 J/cm^2 in every 5 minute bioburden reduction cycle to confirm that bioburden reduction cycles have been effectively conducted. Healthcare facilities are authorized to release bioburden reduced, compatible N95 respirators by parametric release based on the results of the UV dosimeter strips.

W. Healthcare facilities must only use the Lumin LM3000 for bioburden reduction of compatible N95 respirators for single-user reuse by HCP as a supplement to CDC reuse recommendations. This includes, but is not limited to, placing the compatible N95 respirator in a breathable paper bag and holding for a minimum of 5 days prior to bioburden reduction. The Lumin LM3000 is not authorized for any other use.

X. Healthcare facilities shall maintain documentation for use of the Lumin LM3000 consistent with current healthcare facility protocols.

Y. The Lumin LM3000 shall only be operated by healthcare facilities.

Conditions Related to Printed Materials, Advertising and Promotion

Z. 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.

AA. 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 bioburden reduction of compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates.

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

- the Lumin LM3000 has neither been cleared or approved by FDA, but has been authorized for emergency use by FDA under an EUA for the bioburden reduction of compatible N95 respirators for single-user reuse by HCP to supplement CDC reuse recommendations to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;

- the emergency use of the Lumin LM3000 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.

CC. All descriptive printed matter, advertising, and promotional materials relating to use of your product must include the following boxed warning:

WARNING: The Lumin LM3000 does not sterilize or decontaminate. Prior to use of the Lumin LM3000 to reduce bioburden on the compatible N95 respirator, the respirator must be placed in a breathable paper bag and held for a minimum of 5 days, in accordance with the CDC recommendations for reuse of N95 respirators.

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