

## PERSONAL PROTECTIVE EQUIPMENT (PPE) DECONTAMINATION SERVICES AGREEMENT

WHEREAS, on March 12, 2020, the World Health Organization declared COVID-19 a pandemic. On March 13, 2020, the President of the United States declared a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak;

WHEREAS, the Food and Drug Administration on March 29<sup>th</sup>, 2020 issued an Emergency Use Agreement (“EUA”) authorizing Battelle Memorial Institute to operate the Battelle Critical Care Decontamination System (CCDS)<sup>™</sup> for use in decontaminating compatible N95 or N95-equivalent respirators (“compatible N95 respirators”) for reuse by healthcare personnel (HCP)<sup>1</sup> to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of Filtering Facepiece Respirators (FFR) during the COVID-19 pandemic;

WHEREAS, on April 10<sup>th</sup>, 2020 the Defense Logistics Agency, under authority of 10 U.S.C. 2304(c)(2), FAR Part 6.302-2, issued a contract to Battelle Memorial Institute to operate the CCDS<sup>™</sup>, in accordance with conditions of the EUA, to decontaminate compatible N95 respirators at site locations throughout the United States as directed by the U.S. Government (the “DLA Contract”). Under this program, qualifying customers can submit qualifying PPE to be decontaminated at a Battelle approved facility without cost to the customer;

WHEREAS, Client and Battelle acknowledge and understand that the provision of these services is intended to be within the scope of the Public Readiness and Emergency Preparedness Act (“PREP Act”) and the PREP Act COVID-19 declaration by the U.S. Department of Health and Human Services, effective as of February 4, 2020;

WHEREAS, the EUA directs and requires Battelle to enter into agreements with customers requesting decontamination of compatible N95 respirators prior to providing such services to the facility; and

THEREFORE, now comes Battelle and [REDACTED] (and at Client’s option, its affiliates and/or subsidiaries) (“Client”), referred to herein individually as a “Party” and collectively as the “Parties”, to set forth the terms and conditions under which a customer can elect to participate in this program.

### 1. DURATION OF AGREEMENT

This Agreement shall begin upon execution and last indefinitely until any one of the following occurrences:

- a) The Client notifies Battelle in writing that it no longer wishes to participate in the program;
- b) The DLA Contract under which this program operates expires or is terminated by the US Government;
- c) The US Government directs Battelle to no longer operate at the site location used by Client and an alternate location is not available;
- d) The EUA is revoked by the FDA pursuant to Section 564(b)(2) of the Federal Food, Drug, and Cosmetic Act;
- e) The participating healthcare facility violates the terms and conditions of this agreement, or any applicable US law or regulation governing this program, or whose status changes so that it no longer qualifies as an eligible healthcare facility; or
- f) Funding of the program is exhausted and is not available to continue processing N95 respirators.

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<sup>1</sup> Healthcare personnel (“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).

- g) Battelle may terminate this agreement at its convenience for any reason.
- h) Battelle is unable to continue to process PPE for decontamination due to a force majeure event as described in Section 10 below.

Battelle will notify Client upon occurrence of any of the preceding events as soon as practical. In no event will Battelle be responsible to process PPE submitted by Client after occurrence of any of the preceding events regardless of Client's expectations or reliance on the program. Battelle will not be liable for any costs of substitute decontamination services sought by Client subsequent to the end of this program.

## **2. SERVICES PROVIDED**

Battelle will provide decontamination services to Client for hospital Personal Protective Equipment (PPE), limited to the PPE approved by the FDA as set forth in EUA for decontamination processing. Battelle will receive and store contaminated PPE prior to decontamination. Battelle will decontaminate and repackage PPE. Battelle will deliver a chain of custody form (or equivalent) indicating conditions of the decontamination implementation process in addition to chemical indicators which will be used to qualify each decontamination cycle will be provided for each decontamination cycle performed for all PPE upon retrieval. Battelle will comply with the terms and conditions of the EUA. If Client wishes to have Battelle assist in the transportation of PPE to and from Client, Client can request such assistance. In response, and at Battelle's sole discretion, Battelle may provide a subcontractor to coordinate transportation of PPE to and from the Battelle approved decontamination facility to Client location. These services will be provided to the Client at no cost.

## **3. CLIENT'S RESPONSIBILITIES**

- a. Client will be responsible for preparing PPE for transportation in the manner described in the instructions provided to Client
- b. Client shall make available to HCP who are or may be using the decontaminated respirators the authorized Fact Sheet for Healthcare Personnel that is required to be provided by Battelle.
- c. Client shall monitor HCP who use such respirators for the signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to Battelle, so that Battelle can provide a weekly report to FDA. Reports of adverse health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.
- d. Client shall inspect the decontaminated respirators upon receipt from Battelle. Any discoloration or other signs of degradation with a decontaminated respirator should promptly be reported to Battelle, and the healthcare facility should dispose of such respirator.
- e. The maximum number of times a N95 respirator can undergo the decontamination cycle is twenty (20) and the Client shall not submit N95 respirators that have reached this limit for decontamination.
- f. Client shall provide Battelle with a complete list of all subsidiaries and/or affiliates who utilize Services provided for in this Agreement. Client is responsible for obtaining a three-digit site code for each Client location that will be utilizing the Services provided for in this Agreement.
- g. Client shall make the literature listed in Section 4 below available to all subsidiaries and/or affiliates who utilize the Services provided for in this Agreement.

- h. Client shall certify that the personnel benefiting from the use of the Services herein are Healthcare Personnel as provided for in the EUA.

#### **4. RECEIPT OF LITERATURE**

Client acknowledges that it has received the following literature from Battelle related to this program.

- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System ("Instructions for Healthcare Personnel");
- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System ("Instructions for Healthcare Facilities"); and
- Labeling and instructions for use developed by Battelle that include the Fact Sheet, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities.

#### **5. WARRANTY AND LIMITATION OF LIABILITY**

**ALL SERVICES ARE PROVIDED TO CLIENT AS-IS. BATTELLE MAKES NO OTHER WARRANTY OR GUARANTEE, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR FOR ANY PARTICULAR RESULT.**

Notwithstanding any other provision of this Agreement to the contrary, in no event shall either Party be liable to the other for any indirect, incidental, special, punitive, or consequential damages, arising from or in connection with this Agreement and regardless of the cause of action or theory of law asserted.

In no event shall Battelle's maximum cumulative liability, regardless of the cause of action or theories of law asserted, exceed the total amount paid by Client to Battelle under this Agreement.

6. If Client is prohibited by law from indemnifying Battelle against third-party claims, then Section 6.A. will apply. If Section 6.A. does not apply, then Section 6.B. shall apply.

##### **A. LIABILITIES**

Each Party agrees to be responsible for any liability, claim, loss, damage or expenses, including without limitation, reasonable attorney fees, arising from its negligent acts or omissions in connection with its performance of this Agreement, or its failure to comply with the terms of this Agreement, as determined by a court of competent jurisdiction.

##### **B. INDEMNIFICATION**

Client agrees to indemnify, defend, and hold Battelle, its affiliates, and their respective directors, officers, employees, consultants, and agents harmless from any and all liabilities, demands, damages, costs and expenses (including reasonable attorneys' fees and court costs) arising from any third-party suits or claims to the extent based upon or resulting from Client's use of Battelle's services provided pursuant to this Agreement. Notwithstanding the foregoing, Battelle shall not be entitled to indemnification protection for claims related to its willful misconduct or gross negligence.

## **7. COMPLIANCE WITH LAWS**

The Parties agree to comply with all laws and regulations applicable to the performance of their respective obligations under this Agreement, including those related to export control, and neither Party shall export nor re-export any tangible goods, service or information related to this Agreement without first obtaining any required export licenses or other governmental approvals, if required by law. Each Party is responsible for its own compliance with this provision.

## **8. NON-ENDORSEMENT AND USE OF NAME**

Client agrees that it will not use or imply Battelle's name or marks, or use Battelle's reports, for advertising, promotional purposes, raising of capital, recommending investments, or in any way that implies endorsement by Battelle without Battelle's prior written approval.

## 9. FORCE MAJEURE

Neither Client nor Battelle shall be liable for any expenses, losses or damages (except payment of monetary obligations) resulting from delay or failure to perform caused by acts beyond the control of the Party delayed or unable to perform including, without limitation, acts or failure to act of government, war, acts of terror, civil unrest, extreme weather conditions, and pandemics (a "Force Majeure Event"). In the event of any delay or failure to perform occasioned by the foregoing, the time for performance will be extended by a period of time equal to the time lost by reason of such delay or failure to perform and any other affected provision(s) of the Agreement including, without limitation, price, shall be equitably adjusted provided that the Party delayed or unable to perform provided the other Party with written notice of the occurrence and impact of the Force Majeure Event.

## 10. MISCELLANEOUS

Each Party is, at all times, acting as an independent contractor under this Agreement and not as an agent, employee, joint venturer or partner of the other.

This Agreement may not be assigned in whole or in part without the prior written consent of both Parties, which shall not be unreasonably withheld or delayed. This Agreement shall be binding upon, inure to the benefit of, and be enforceable by and against the successors and permitted assigns of each Party.

Battelle makes no commitments with regards the time necessary to complete the decontamination process once PPE is received from the Client. Processing time will be dependent on the amount of PPE received from numerous health care providers.

The failure by one Party to require performance of any provision or to exercise any right, remedy or option available under this Agreement shall not affect that Party's right to require performance or to exercise such right, remedy or option at any time thereafter, nor shall a waiver of any breach or default of this Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

If any part of this Agreement shall be held invalid or unenforceable, such invalidity or unenforceability shall not affect any other part of this Agreement.

This Agreement may be modified or amended only by mutual agreement in writing. Battelle may require additional conditions of participation at any time in order for client to continue participation. No course of dealing, usage of trade, waiver, or non-enforcement shall be construed to modify or otherwise alter the terms and conditions of this Agreement.

This Agreement represents the entire agreement of the Parties and supersedes any prior discussions or understandings, whether written or oral, relating to the subject matter hereof and neither Party makes any representations other than as expressly set forth in this Agreement. In the event of any conflict or inconsistency between these terms and conditions and those of any Task Order, these terms and conditions shall control.

This Agreement shall be construed in accordance with the laws and enforced within the jurisdiction of the State of Ohio, without regard to its conflicts of law principles.

Clauses 5, 6, 7, 8, 9, and 10 shall survive termination or expiration of this Agreement.

**IN WITNESS WHEREOF**, the terms and conditions of this agreement are accepted by Client.

*[signature page to follow]*

**CLIENT**

BY: \_\_\_\_\_

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_

**Battelle Memorial Institute**

BY: \_\_\_\_\_

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_