



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-21472

Mfr. Reference: DOB013

Centers for Disease Control
and Prevention (CDC)

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
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July 27, 2017

Mr. Brian Kim
Dobu Life Tech Co. Ltd.
3943 Irvine Blvd #113
Irvine, California 92602

Dear Mr. Kim:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted March 6, 2017. This request was for approval of the model 201 air purifying filtering facepiece respirator for protections against particulates at a N95 filter efficiency level. Reference the assembly matrix file AsmblyMtrx201_a_AM1.xls, revision number 1 and dated 1/15/2017.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-7851 has been assigned. This respirator is approved for protection against particulates at a N95 filter efficiency level.

The final respirator label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label.

Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

A handwritten signature in dark ink, appearing to read "David Chirdon". The signature is fluid and cursive, with the first and last names being more prominent.

David Chirdon
Chief, Conformity Verification and
Standards Development Branch

Enclosures

User Instructions:

Doc id: *UIDBFFR02* v:2

Filtering Facepiece Respirator : 201 series

User Instructions for Dobu Mask Model 201 Series
Filtering Facepiece Respirators

Important information is provided in the User Instructions with each of the air filtration respirators 201 series that are NIOSH certified. **Failure to follow User Instructions for the air filtration being used may result in sickness or death.**



Warning

Misuse may result in sickness or death.

For proper use, see supervisor, or *User Instructions*, or call DOBU LIFE TECH in USA 3530 Wilshire Blvd Ste 1414, Los Angeles, 90010. +1 314 743 6243

Important

Before use, the user must read and understand the User Instructions. Keep these User Instructions for reference.

Use For

Respiratory protection from certain airborne contaminants according to NIOSH approvals, OSHA limitations,

User Instructions

- Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and may result in sickness or death..
- Leave contaminated area immediately and contact supervisor if you smell or taste contaminants or if dizziness, irritation, or other distress occurs.
- Store respirator away from contaminated areas when not in use.
- Dispose of used product in accordance with applicable regulations
- Filtering facepieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred. enlarged holes resulting from ripped or torn filter material around staple/sonic welds punctures are considered damage. The User Instructions are also to provide information that the respirator has been tested and small punctures around the staples/sonic welds are normal and do not interfere with the respirator compliance with Part 84 approval requirements.

GENERAL SAFETY INFORMATION

Intended Use

The Dobu Mask 201 series filtering facepiece respirators are NIOSH approved and designed to help provide respiratory protection against certain airborne contaminants when used in accordance with all use instructions and limitations and applicable safety and health regulations.

Before occupational use of this product a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134 such as training, medical evaluation, and fit testing and applicable OSHA substance specific standards. In Canada, CSA standard Z94.4 requirements must be met.

Use Limitations

- This respirator does not supply oxygen. Do not use in atmospheres containing less than 19.5% oxygen
- Do not use in atmospheres immediately dangerous to life or health
- Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown or when concentrations exceed 10 times the permissible exposure limit (PEL) or according to specific OSHA standards or applicable government regulations, whichever is lower
- Do not use when the U.S. Occupational Safety and Health Administration (OSHA) substance specific standards, such as those for, arsenic, cadmium or lead in the construction industry, specify other types of respiratory protection.
- Do not use with facial hair that can potentially prevent a good seal between the face and the face seal of the respirator
- Do not use when you have health problem that can hinder breathing.
- Do not use this product when your skin is known to have an allergic reaction, skin rash, or other irritant reaction to the respirator face piece

Time Use Limitation

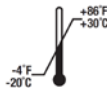
If respirator becomes damaged, soiled or breathing becomes difficult, leave contaminated area immediately and replace the respirator

Storage Conditions and Shelf Life

Before use, store respirators in the original packaging and away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals. When stored in accordance with temperature and humidity conditions specified below, the product may be used until the "use by" date specified on packaging. Always inspect product and conduct a user seal check before use as specified in the User Instructions. If you cannot achieve a proper seal, do not use the respirator.



End of Shelf Life
Use respirators before the "use by" date specified on packaging



Storage Temperature Range
-20°C (-4°F) to +30°C (+86°F).



Storage Maximum Relative Humidity
<80% RH

Fitting Instructions

1. Hold the respirator in your hand, allowing the headbands to hang freely below your hand.
2. Position the respirator under your chin. Pull the bottom strap over your head and position it around the neck below the ears.
3. Position the respirator under your chin. Pull the top strap over your head resting it high at the top of your head.
4. Pull the straps until it fits to the face to make sure that it has nice tight fit. .
5. Perform a user seal check prior to each wearing. To check the respirator-to-face seal, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the straps as described in step 4. If air leaks at the respirator edges, work the straps back along the sides of your head.

If you can not achieve a proper seal, do not enter the contaminated area. See your supervisor.



Removal Instruction

See step 2 of Fitting Instructions and respirator in hand to maintain position on face. Pull bottom strap over head. Still holding respirator in position, pull top strap over head and remove respirator



Filter Configuration

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION

TC-	Protection	Respirator		Cautions and Limitations
		201	201V	
84A-7851	N95	X		ABCJMNOP
84A-7852	N95		X	ABCJMNOP

1. Protection

N95 - Particulate Filter (95% filter efficiency level)
Effective against particulate aerosols free of oil;
time use restrictions may apply

2. Cautions and Limitations

- A - Not for use in atmospheres containing less than 19.5% oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- J - Failure to properly use and maintain this product could result in injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations"
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer"
- O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators."
- P - NIOSH does not evaluate respirators for use as surgical masks