

MakerMask: Cover

This mask cover was made by:

Name: _____

Contact Info: _____




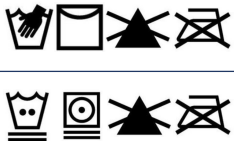

Date Made: _____



Product Description:

The MakerMask: Cover is designed as an N95 accessory to be worn on top of a NIOSH-approved N95. Used in this way: 1) it may help reduce surface contamination and soiling of the underlying N95 in cases of extended N95 use or reuse and 2) it may be used as source control for N95s containing one or more exhalation valves. Follow the manufacturer's guidance for the care and use of the underlying N95. Discard as soon as safely possible if contamination is suspected.

For more information visit:
MakerMask.org

Body Contacting Materials:		Other Materials:	
<input type="checkbox"/> Nonwoven Polypropylene (NWPP)	<input type="checkbox"/> Other (specify): _____		
<input type="checkbox"/> Cotton			
<input type="checkbox"/> Other (specify): _____			
Body contacting materials include all materials used for the main portion of the <u>cover</u> and the head ties. Other materials include those used for the nose piece reinforcement. This Table MUST be filled in!			
Inspect Mask Before Each Use:			
	<ul style="list-style-type: none">➤ Inspect cover for defects.➤ Ensure that mask and cover combination is breathable without restriction.➤ Discard if defects are detected or if concerns arise.		
Recommended Disinfection Instructions: Before first use (select one). After each use (select one):			
	<ul style="list-style-type: none">➤ Boil: Submerge mask in boiling water for 10 minutes. Hang dry.➤ Autoclave: Follow facility infection control policies and autoclave (moist heat) at 15 psi, 121°C for 15 minutes.		
Recommended Cleaning Instructions: Discard heavily soiled <u>covers</u> . Wash lightly soiled <u>covers</u> as needed (select one):			
	<ul style="list-style-type: none">➤ For best results (longer mask life): Hand wash warm. Rinse thoroughly. Hang to dry. Do Not Bleach. Do Not Iron.➤ For simplicity: Machine wash warm (50°C). No fabric softener. Tumble dry low. Do Not Bleach. Do Not Iron.		
Warnings:			
	Use at your own risk. This product is not intended for use as a stand-alone mask. Not for use with N99s. NOT intended for use as a fluid barrier or for filtration. This product has not been FDA cleared or approved. This product is NOT a surgical mask. This product is NOT Personal Protective Equipment (PPE) and should not be used to meet a professional healthcare facility's obligations to protect workers against infectious disease hazards.		

REQUIRED LABEL INFORMATION (10 May 2020): This product has not been FDA cleared or approved. When used as a face covering to cover the mouth and nose, this product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic. This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner. For mor information see: <https://www.fda.gov/media/137121/download>