



PRO HOSPITAL SUPPLY
+ Medical and Healthcare Equipment +

Air Pro™

REPIRATORY PROTECTION

N95

Authorized for use in healthcare settings by healthcare personnel



Made in Mexico NAFTA/TEMEC Compliant



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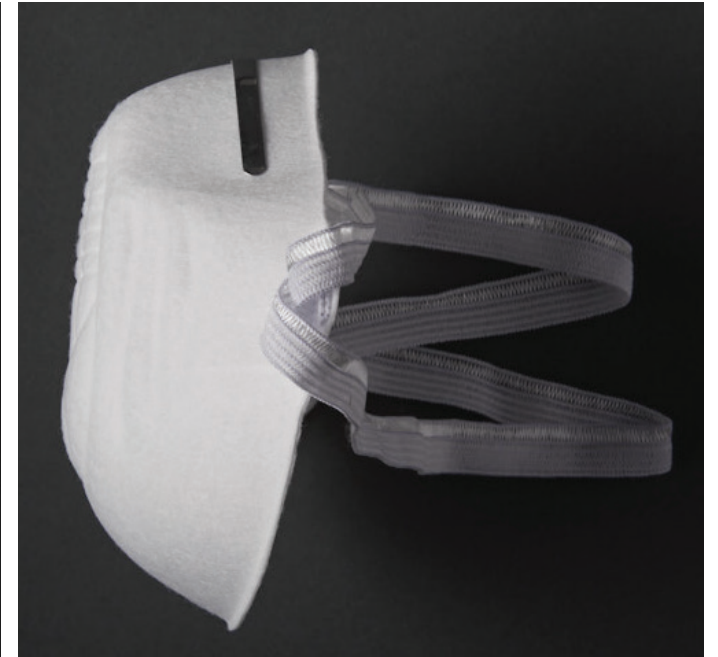


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Our Air Pro N95 M10 (Ap Mascarillas model M10) is officially an authorized non-NIOSH-approved respirator for use in healthcare settings by healthcare personnel, when used under CDC recommendations. In the list of six authorized products, four are 3M factories in Asia. We're the only all-NAFTA certified producer in the list, shipping anywhere in the USA within 3 business days, and producing 2mm respirators per week.

1 million ready for immediate shipment
\$3.65 delivered anywhere in the USA



- NAFTA Hardshell cup N95 respirator with two elastic head bands
- With aluminum nosepiece
- Ergonomic design that comfortably adjusts to face for perfect fit and seal
- N stands for non-powered air purifying particulate respirators in workplaces free of oil aerosols with a minimum efficiency of 95%
- The cup design prevents the respirator from getting wet from breath humidity and thus avoids bad smells.

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We're now an official "Exhibit 1: Authorized Imported, Non-NIOSH Disposable Respirator" approved by the Federal Government.

You can find the link to the official list here:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#imported>

The FDA listed us yesterday (6/22) as one of only 6 non-NIOSH-authorized imported N95 producers, and the only one in North America.



June 19, 2020

Annie Castillo
Ap Mascarillas S.A. de C.V.
Nuevos Horizontes Lte 3017 Int Mza 414 Colonia Lazaro,
Cardenas, MEX 54189
Tlalnepantla, Edo Mex C.P.
EUA201328

Re: Imported FFRs

Dear Ms. Castillo:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirators as authorized respirators to the June 6, 2020 Emergency Use Authorization (EUA)¹, which was issued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). We have reviewed your email and determined that models Z6 and M10 meet the eligibility criteria in the June 6, 2020 EUA for imported, non-NIOSH approved respirators. As such, these respirators are hereby added to Exhibit 1² as authorized respirators.

Having concluded that the eligibility criteria are met, I am adding your respirators to Exhibit 1, as described in the Scope of Authorization (Section II). As such, the respirator is authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Manufacturers

- A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. FDA will make this information available to the public on its EUA website at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>. Manufacturers must notify FDA of any changes to this page.
- B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

¹ The EUA Letter of Authorization is available at, <https://www.fda.gov/media/136403/download>

² Exhibit 1 is available at, <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#exhibit1>.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

AP MASCARILLAS, S.A. DE C.V.
NUEVOS HORIZONTES MANZANA 414 LOTE 3917,
LAZARO CARDENAS TLANEPANTLA DE BAZ, MEXICO
54189 MEXICO

has completed the FDA Establishment Registration (as manufacturer, contract manufacturer) and Device Listing with the US Food & Drug Administration, through

Registration Number: 3016687960
Operator Number: 10071491
Device Listing#: See annex

G & C Brokers, Inc will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. G & C Brokers, Inc makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. G & C Brokers, Inc assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, G & C Brokers, Inc is not affiliated with the U.S. Food and Drug Administration.



Executive Director
Issued: Apr 17 2020
Cert. No.: 2006US114558
Expiration Date: Dec. 31 2020

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About Pro Hospital Supply

Pro Hospital Supply has been in business since 2014 with our main office in South Florida. We have 10 employees in the USA and 4 people on the ground in China that make their rounds on a daily basis to our factory's to ensure our orders are processing on time. We have been actively selling new and used medical equipment and making strategic partnerships with direct manufacturing plants around the globe for a variety of new medical equipment which we sell directly on our website, and to our current list of active clients on a daily basis. We also purchase used medical equipment from hospitals and resell them mainly to Central and South America. Having all these connections in place for many years has really helped us with the current Covid-19 PPE situation since we already had long lasting relationships with manufacturers to secure large quantities of varies Masks, Goggles, Gloves, Gowns, PPE – Other, and Covid-19 Antibody Test kits. We have been servicing first responders and state/ government agencies with PPE and Antibody Test Kits and continue to secure reorders and new orders on a daily basis. Mason Arnao, the CEO of PHS was just recently on the news for donating some of our test kits to first responders in Palm Beach, Martin, and Saint Lucie County. Link to story (http://www.prohospitalsupply.com/Pro-Hospital-Supply-Is-helping-Fight-the-Corona-Virus-War_b_1.html). Currently we have over 100 million US dollars in current active contracts that we are producing product specifically for the Covid-19 pandemic and have satisfied and closed over 60 million (gross) in PPE contracts in the past 2 months. Our internal logistics and external connections make it possible for us to navigate products throughout the globe and through customs at all borders. We are looking forward to working with you and your team I am more than confident we will be able to meet any scale of demand on products you need or help with any logistics. We open up our connections and resources to your team if needed. Please let me know if you would like to get on a call or if you have any additional questions.

Thanks

Peter Bradford
COO / PHS
801-971-2081

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Peter Bradford

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