Maco Press Release

February, 17, 2021

Macopharma receives Emergency Use Authorization (EUA) for FFP2 NR D Face Masks in the United States.

On January 22, 2021, Macopharma received notice from the CDRH Non-diagnostic EUA team at the United States Food and Drug Administration (FDA) that the Macopharma F2001N FFP2 NR D face mask for import has been approved as an authorized respirator to June 6, 2020, Emergency Use Authorization (EUA), which was issued under Section 564 of the Federal Food, Drug, and Cosmetic Act. Reference F2001N meets the eligibility criteria set forth under the EUA for non-NIOSH-approved respirators, and as such, Macopharma is officially an authorized importer under this EUA.

The World Health Organization (WHO) recommends "health workers to wear the N95 or FFP2 or FFP3 standard types of mask/respirator in addition to other personal protective equipment for reducing the spread of SARS-CoV-2, the virus that causes COVID-19."(1)

The Macopharma respiratory protection masks are designed to protect against solid and liquid particles and meet the performance(2) requirements for FFP2 NR D of the standard EN149+A1:2009. The Macopharma facemask is designed with a nose clip and two self-adjusting head harnesses for a great fit and seal.

Please refer to the FDA Exhibit 1: Authorized Imported, Non-NIOSH Disposable Filtering Facepiece Respirators (FFR) (Updated January 22, 2021) website below for the Macopharma website address (URL) link to the F2001N reference IFU.

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

Macopharma has built on its expertise in non-woven materials to expand its product range, above all for filtration applications. In March 2020, Macopharma relaunched its protective mask activity to respond to the urgent need resulting from the SARS-CoV-2 (COVID-19) pandemic.

As of December 2020, Macopharma has produced 75M of masks in response to the global pandemic.

Macopharma F2001N respiratory face masks are authorized for use by healthcare personnel in healthcare settings under CDC recommendations and the EUA specific Conditions of Authorization per Section IV of the June 6, 2020, FDA letter.

(1) World Health Organization. (2020). Mask use in the context of COVID-19: interim guidance, 1 December 2020. World Health Organization. https://apps.who.int/iris/handle/10665/337199. License: CC BY-NC-SA 3.0 IGO

(2) Filtration efficiency: 94% of all particles measuring up to 0.6 um

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Macopharma Respiratory Protection Masks FFP2 NR D for single-use meet the requirements of standard EN149+A1:2009.

EU Class: FFP2 NR D

Reference: F2001N

Trademark: MACOPHARMA

Manufacturer: MACOPHARMA - Rue Lorthiois - 59420 MOUVAUX - France

Description: Filtering half mask to protect against particles class FFP2 NR D without exhalation valve, limited to single shift use. Foldable half mask designed with a nose clip and two self-adjusting head harnesses. Filtering media is housed between an internal and external spun-bond material. The mask are packed per case with 50 masks. (10 per carton)

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