



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



19 JUN 2020

FDA ADVISORY
No. **2020-1181**

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: List of FDA Notified Medical Face Masks

In the interest of protecting public health and safety, the Food and Drug Administration (FDA) hereby provides the list of registered face masks for medical use as of 16 June 2020:

	PRODUCT NAME	COMPANY NAME
1	Blue Cross Disposable Surgical Mask	Pharmatechnica Laboratory Inc.
2	Disposable Face Mask	Hexagon Medical Supplies
3	Face Mask PM2.5 Disposable Mask	Funtastic International, Inc.
4	Indoplas Face Masks	Indoplas Philippines, Inc.
5	Indoplas KN95 Face Mask	Indoplas Philippines Inc.
6	Indoplas Face Mask	Indoplas Philippines Inc.
7	KN95 Disposable Face Mask	Funtastic International, Inc.
8	McBride Device Name: KN95 Protective Mask	AMB HK Enterprises Inc.
9	McBride Face Mask	AMB HK Enterprises Inc.
10	Mediclean Device Name: Face Mask	AMB HK Enterprises Inc.
11	Resprotec Disposable Surgical Mask	Pharmatechnica Laboratory, Inc.
12	Safeplus Face Mask	AMB HK Enterprises Inc.
13	Safeplus Face Mask For Kids	AMB HK Enterprises Inc.
14	Safeplus KN95 Protective Mask	AMB HK Enterprises Inc.
15	Sure-Guard Carbon Face Mask	AMB HK Enterprises Inc.
16	Sure-Guard Face Mask	AMB HK Enterprises Inc.
17	Sure-Guard® Device Name: KN95 Protective Mask	AMB HK Enterprises Inc.

The above list shall be regularly updated. For reference, please click the link: <https://docs.google.com/spreadsheets/d/1OAE1MAByyve9wcqKiw1VifGtMUCoaHe7ntgSwV9JMvw/edit#gid=0>

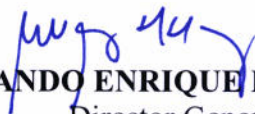
Retailers, hospitals and other healthcare facilities are hereby advised to procure only FDA notified medical face masks from FDA licensed manufacturers and distributors.

The public is enjoined to be vigilant in the purchase and use of face masks in light of the proliferation of these products in the market to curb the spread of COVID-19. The public is likewise advised to purchase health products only from legitimate and reputable retailers or establishments.

In addition, the FDA informs all concerned of the list of respirators (N95, KN95 or similar face masks) that failed the performance requirement of greater than or equal to 95 percent (%) filtration efficiency assessed by the United States (US) Centers for Disease Control and Prevention (CDC) - The National Institute for Occupational Safety and Health (NIOSH). These products were recalled and are currently not authorized by the US-FDA. The public is advised not to use these respirators especially healthcare workers who provide care to COVID-19 patients in settings and areas where aerosol generating procedures are undertaken. The list can be accessed at <https://www.fda.gov/media/137928/download>.

For more information and inquiries, kindly contact the FDA – Center for Device Regulation, Radiation Health, and Research through e-mail at cdrhr@fda.gov.ph or call (02) 857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20200611141923