



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



10 MAR 2021

**FDA ADVISORY**  
No. 2020-1181-A

**TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT: Updated 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 8 March 2021:

	<b>PRODUCT NAME</b>	<b>COMPANY NAME</b>
1	FACE MASK PM2.5 DISPOSABLE MASK	FUNTASTIC INTERNATIONAL
2	DISPOSABLE FACE MASK	HEXAGON MEDICAL SUPPLIES
3	MCBRIDE DEVICE NAME: KN95 PROTECTIVE MASK	AMB HK ENTERPRISES INC.
4	INDOPLAS FACE MASK	INDOPLAS PHILIPPINES INC.
5	KN95 DISPOSABLE FACE MASK	FUNTASTIC INTERNATIONAL, INC.
6	SAFEPLUS KN95 PROTECTIVE MASK	AMB HK ENTERPRISES INC.
7	INDOPLAS FACE MASKS	INDOPLAS PHILIPPINES INC.
8	SURE-GUARD® DEVICE NAME: KN95 PROTECTIVE MASK	AMB HK ENTERPRISES INC.
9	SURE-GUARD FACE MASK	AMB HK ENTERPRISES INC.
10	MEDICLEAN DEVICE NAME: FACE MASK	AMB HK ENTERPRISES INC.
11	MCBRIDE FACE MASK	AMB HK ENTERPRISES INC.
12	SURGITECH DISPOSABLE SURGICAL GOWN	MEDASIA MEDICAL PRODUCTS CORPORATION
13	SAFEPLUS FACE MASK	AMB HK ENTERPRISES INC.
14	RESPROTEC DISPOSABLE SURGICAL MASK	PHARMATECHNICA LABORATORY INC.
15	SURE-GUARD CARBON FACE MASK	AMB HK ENTERPRISES INC.
16	RESPOKARE ANTI-VIRAL FACE MASK (CHILD)	IDS MEDICAL SYSTEMS PHILIPPINES, INC.
17	BLUE CROSS DISPOSABLE SURGICAL MASK	PHARMATECHNICA LABORATORY INC.
18	SAFEPLUS FACE MASK FOR KIDS	AMB HK ENTERPRISES INC.



19	INDOPLAS KN95 FACE MASK	INDOPLAS PHILIPPINES INC.
20	ENDURE KN95 MASK	ENDURE MEDICAL, INC.
21	MCBRIDE FACE MASK	AMB HK ENTERPRISES INC.
22	EMS N88 SURGICAL FACE MASK	EMS COMPONENTS ASSEMBLY, INC.
23	MEDTECS FACE MASK	MEDTEX CORPORATION
24	ELITE TOKYO JAPAN FACE MASK FOR KIDS	INDOPLAS PHILIPPINES INC.
25	MCBRIDE FACE MASK FOR KIDS	AMB HK ENTERPRISES INC.
26	YOU JI BEAR DISPOSABLE MEDICAL MASK (NON-STERILE)	PHILIPPINE BLUE CROSS BIOTECH CORPORATION
27	ELITE TOKYO JAPAN FACE MASK	INDOPLAS PHILIPPINES INC.
28	SURGICAL MASK (STERILE)	FIREFLY ELECTRIC AND LIGHTING CORPORATION
29	3M AURA™ HEALTH CARE PARTICULATE RESPIRATOR AND SURGICAL MASK	3M PHILIPPINES, INC.
30	3M VFLEX™ HEALTH CARE PARTICULATE RESPIRATOR AND SURGICAL MASK	3M PHILIPPINES, INC.
31	3M HEALTH CARE PARTICULATE RESPIRATOR AND SURGICAL MASK	3M PHILIPPINES, INC.
32	BENEHAL N95 PARTICULATE RESPIRATOR	AMB HK ENTERPRISES INC.
33	RESPOKARE N95 RESPIRATOR PLUS ANTI-VIRAL FACE MASK	IDS MEDICAL SYSTEMS PHILIPPINES, INC.
34	RESPOKARE ANTI-VIRAL FACE MASK (ADULT)	IDS MEDICAL SYSTEMS PHILIPPINES, INC.
35	EMS KN95 RESPIRATORY PROTECTIVE MASK (5 LAYERS)	EMS COMPONENTS ASSEMBLY, INC.
36	EMS KN95 RESPIRATORY PROTECTIVE MASK (6 LAYERS)	EMS COMPONENTS ASSEMBLY, INC.
37	RISTEA FACE MASK	SURGICOM TRADING CORPORATION
38	BENEHAL N95 PARTICULATE RESPIRATOR (CARBON)	AMB HK ENTERPRISES INC.
39	PROHEALTHCARE DISPOSABLE SURGICAL FACE MASK	VMED MEDICAL CO.
40	"MEDTECS" STANDARD TIE-BACK FACE MASK	MEDTEX CORPORATION
41	"MEDTECS" STANDARD EAR-LOOP FACE MASK	MEDTEX CORPORATION
42	DISPOSABLE FACE MASK	QUANTA PAPER CORPORATION
43	"MEDTECS" N88 PROTECTIVE FACE MASK	MEDTEX CORPORATION
44	PARTNERS SURGICAL FACE MASK	CHAMPION BIOTECH AND PHARMA CORP
45	DISPOSABLE MEDICAL MASK (NON-STERILE)	FIREFLY ELECTRIC AND LIGHTING CORPORATION
46	MEDICAL SURGICAL MASK	LUOXIN PHARMACEUTICALS (PH) CORP
47	DISPOSABLE MEDICAL MASK (NON-STERILE)	LUOXIN PHARMACEUTICALS (PH) CORP

48	BYD SINGE-USE MEDICAL MASK	BYD PHILIPPINES CORP.
49	RUNDATOPLIN MEDICAL SURGICAL MASK (NON-STERILE)	AMBICA INTERNATIONAL CORPORATION
50	DISPOSABLE FACE MASK MEDICAL GRADE 3-PLY FACE MASK	ORTHONE, INC.
51	BYD N95 PARTICULATE RESPIRATOR	BYD PHILIPPINES CORP.
52	SURGICAL FACE MASK	PHIL PHARMAWEALTH, INC.
53	DISPOSABLE FACE MASK	JKA SAFETY FIRST TRADING CORP.
54	DISPOSABLE MEDICAL MASK (STERILE)	LUOXIN PHARMACEUTICALS (PH) CORP
55	N95 PARTICULATE RESPIRATOR	SUNWEST CONSTRUCTION AND DEVELOPMENT CORPORATION
56	BYD KN95 PARTICULATE RESPIRATOR	BYD PHILIPPINES CORP.
57	MEDIPLAST N95 PARTICULATE RESPIRATOR	AMB HK ENTERPRISES INC.
58	TUDOR SURGICAL FACE MASK (DISPOSABLE)	CHAMPION BIOTECH AND PHARMA CORP
59	3M NEXCARE EARLOOP MASK	3M PHILIPPINES, INC.
60	N95 PARTICULATE RESPIRATOR	SUNWEST CONSTRUCTION AND DEVELOPMENT CORPORATION
61	WINNER SURGICAL FACE MASK EARLOOP, 3-PLY, BLUE	PINNACLE SUPPLIES & SERVICES UNLIMITED INC.
62	DISPOSABLE FACE MASK	NIPPON BIOPHARMACEUTICAL INDUSTRIES INC.
63	DISPOSABLE MEDICAL NON-WOVEN FACEMASK	ALVEZ COMMERCIAL, INC.
64	DISPOSABLE MEDICAL PROTECTIVE FACE MASK	NAGALAND DEVELOPMENT CORPORATION
65	WINNER MEDICAL FACE MASK TIE-ON, 3-PLY, BLUE	PINNACLE SUPPLIES & SERVICES UNLIMITED INC.
66	ENDURE SURGICAL FACE MASK	ENDURE MEDICAL, INC.
67	LIFE TEK W.E. CARE FACE MASK SURGICAL DISPOSABLE 3-PLY WITH EARLOOPS	LIFE TEK TRADING
68	ALWAYS KF94 PROTECTIVE FACE MASK	MEDIC-PRO CORP.
69	WINNER N95 FACE MASK HEAD-LOOP TYPE, EXTERNAL NOSEPIECE	PINNACLE SUPPLIES & SERVICES UNLIMITED INC.
70	N95 PARTICULATE RESPIRATOR	SUNWEST CONSTRUCTION AND DEVELOPMENT CORPORATION
71	N95 PARTICULATE RESPIRATOR	SUNWEST CONSTRUCTION AND DEVELOPMENT CORPORATION
72	RYCORTECH PRIME 3 PLY MEDICAL GRADE FACEMASK	RYCORTECH CORPORATION
73	GERMINATOR X MEDICAL LEVEL FACE MASK	SJ CONSO INC.
74	SURGITech DISPOSABLE FACEMASK	MEDASIA MEDICAL PRODUCTS CORPORATION
75	MEDIPLAST KN95 PROTECTIVE MASK	AMB HK ENTERPRISES INC.

76	CHOPARD DISPOSABLE MEDICAL MASK	NIPPON BIOPHARMACEUTICAL INDUSTRIES INC.
77	RESPOKARE ANTI-VIRAL FACE MASK (ADULT)	IDS MEDICAL SYSTEMS PHILIPPINES, INC.
78	COVERU DISPOSABLE CHILDREN'S MASK	MEDTEX CORPORATION
79	MEDICAL FACE MASK	PHARMALLY PHARMACEUTICAL CORPORATION
80	GERMINATOR X MEDICAL LEVEL FACE MASK	SJ CONSO INC.
81	RYCORTECH 4 PLY MEDICAL GRADE FACE MASK	RYCORTECH CORPORATION
82	PANAMED® KN95-H PROTECTIVE MASK	PANAMED PHILIPPINES, INC.
83	NANO RESPIRATOR (KN95)	L&T INTERNATIONAL GROUP PHILS., INC.
84	BTL RESPIRATOR C-FIT HEALTHCARE RESPIRATOR	BTL MEDICAL TECHNOLOGIES, INC.
85	MEDIPLAST FACE MASK FOR KIDS	AMB HK ENTERPRISES INC.
86	SUPREME SURGICAL FACE MASK (TYPE IIR)	CHAMPION BIOTECH AND PHARMA CORP.
87	QUALISAFE KN95 PROTECTIVE MASK	IPOLYMER SOLUTIONS CORPORATION
88	TRUCARE SURGICAL FACE MASK (TYPE IIR)	CHAMPION BIOTECH AND PHARMA CORP
89	SURGITech DISPOSABLE FACEMASK	MEDASIA MEDICAL PRODUCTS CORPORATION
90	PANAMED® KN95-W PROTECTIVE MASK	PANAMED PHILIPPINES, INC.
91	WHITE SWAN_ SURGICAL MASK	ATGLOBAL ELECTRONICS MFG.
92	PARTNERS DISPOSABLE MEDICAL FACE MASK ( TYPE I)	CHAMPION BIOTECH AND PHARMA CORP.
93	KAROFI ® DISPOSABLE FACE MASK	ZAFIRE DISTRIBUTORS INC.

The above list shall be regularly updated. For reference, please click the link: <https://docs.google.com/spreadsheets/d/1OAE1MAByyve9wcqKiwIVifGtMUCoaHe7ntgSwV9JMvw/edit#gid=0>

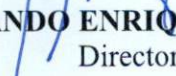
Retailers, hospitals and other healthcare facilities are hereby advised to procure only FDA notified medical face masks from FDA licensed manufacturers and distributors.

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.

Furthermore, FDA strongly reminds all concerned that the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any unnotified medical face mask are prohibited pursuant to the provisions of Republic Act 9711, otherwise known as the "Food and Drug Administration Act of 2009".

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](mailto:cdrhr@fda.gov.ph) or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
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