

Health Care Masks: Types, Definitions, Classifications and Approved Models

To assist our health care supply chain peers, AHRMM has researched and outlined the types of masks and respirators and their efficacies, CDC and FDA approved models, EUA guidance and definitions. Refer to the indicated websites for more information.

FDA and CDC Mask Product Classifications and Approved Models

Product Classification	Approved Models
NIOSH-approved/FDA-Cleared N95; N99; N100; R95, P95; P99; P100	https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html
Appendix A: Authorized Respirators Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China	https://www.fda.gov/media/136663/download
NIOSH-Approved Particulate Filtering Facepiece Respirators Halfmask; Full Facepiece; PAPRs	https://www2a.cdc.gov/drds/cel/cel_results.asp?startrecord=1&Search=cel_form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbauses=&privatelabel
CDC Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies	https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html

Definitions

Face Mask – A mask that covers the user’s nose and mouth and may or may not meet fluid barrier or filtration efficiency levels.

Surgical Mask – A mask that covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests

Filtering Facepiece Respirator – A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.

N95 Respirator – A disposable half-mask filtering facepiece respirator (FFR) that covers the user’s airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH).

NIOSH Approved N95 Respirator – An N95 respirator, approved by NIOSH that meets filtration efficiency level per 42 CFR 84.181.

Surgical N95 Respirator – A disposable FFR used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH).

Click here for more information: [FDA Enforcement Policy for Face Masks and Respirators](#)