

The CDC Recommends Using Cloth Face Coverings in Public Settings.

CDC continues to study the spread and effects of the novel coronavirus across the United States. We now know from [recent studies](#) that a significant portion of individuals with coronavirus lack symptoms (“asymptomatic”) and that even those who eventually develop symptoms (“pre-symptomatic”) can transmit the virus to others before showing symptoms. This means that the virus can spread between people interacting in close proximity—for example, speaking, coughing, or sneezing—even if those people are not exhibiting symptoms.



In light of this new evidence, CDC recommends wearing cloth face coverings in public settings where other social distancing measures are difficult to maintain (e.g., grocery stores and pharmacies) especially in areas of significant community-based transmission.

[Click here to read the full document](#)



How to Protect Yourself & Others

Cover your mouth and nose with a cloth face cover when around others



- You could spread COVID-19 to others even if you do not feel sick.
- Everyone should wear a cloth face cover when they have to go out in public, for example to the grocery store or to pick up other necessities.
- Cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.
- The cloth face cover is meant to protect other people in case you are infected.
- Continue to keep about 6 feet between yourself and others. The cloth face cover is not a substitute for social distancing.



Do NOT use a facemask meant for a healthcare worker.

[Click here for more information](#)



The FDA and Face Masks

FDA approved masks are single-use masks intended for medical and surgical applications. They contain a liquid repellency feature to protect both the wearer and patients from fluids as well as bacteria filtration properties.



Face masks marketed to the general public for general, non-medical purposes do **NOT** require FDA device marketing authorization.

[Click here to read the full document](#)



Face Masks, Face Shields, and N95 Respirators Not Intended for a Medical Purpose

Face masks, face shields, and N95 respirators are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act. Under section 201(h) of the FD&C Act, these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

Other face masks, face shields, and filtering facepiece respirators are marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is not required, and all the other requirements of the FD&C Act do not apply to manufacturers, importers, and distributors of these products.

Face masks, face shields, and respirators are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Face masks, face shields, and respirators are not devices when they are intended for a non-medical purpose, such as for use in construction. When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider whether:

1. They are labeled or otherwise intended for use by a health care professional;
2. They are labeled or otherwise for use in a health care facility or environment; and
3. They include any drugs, biologics, or anti-microbial/anti-viral agents.



Where the GALE GUARD™ Reusable Face Mask Fits In

The GALE GUARD™ Reusable Face Mask is an optimal cloth mask solution for the General Public's use. With the launch of our mask we are encouraging the public to wear the GALE GUARD™ Face Mask in order to save the much needed N95 and NIOSH certified masks for medical professionals and frontline workers. The **#saveamask** campaign is in direct support of this effort.

The GALE GUARD™ Reusable Face Mask with Antimicrobial Treated Fabric is a cloth mask that is intended for use by the general public. The GALE GUARD™ Reusable Face Mask is NOT a medical device, and is NOT intended for use by medical/health professionals in medical or surgical settings.

The Disclaimer is included in all marketing collateral and on the packaging itself.

Disclaimer: The GALE GUARD™ Reusable Face Mask with Antimicrobial Treated Fabric is not intended to be a medical device and not to be used BY HEALTH CARE PROFESSIONALS, in medical or surgical settings where significant exposure to liquid, bodily, or other hazardous fluids may be expected, in clinical or healthcare settings where the infection risk level is high, or in the presence of a high intensity heat source or flammable gas.

There are many cloth face mask options on the market, including homemade masks, which are all acceptable and certainly better than not using anything. However, the GALE GUARD™ Reusable Face Mask offers a valuable alternative in the following ways:



Washable and Reusable 30+ times without impacting performance



Nose clip and contour of mask creates a comfortable but secure fit, and will not cause glasses to fog



Neck strap and ear loops eliminate the need to touch the mask when removing



Neck strap can hang around the person's neck when not in use (no need to put it down on a surface)

Learn more at galeguard.com