

## **FDA Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency**

The US Food and Drug Administration (FDA) announced a new enforcement policy for face masks and respirators used during the COVID-19 public health emergency. FDA is lifting requirements for certain masks and respirators to increase their availability.

FDA says it is lifting major regulatory requirements for face masks intended for a medical purpose, but not intended to provide liquid barrier protection. FDA is doing this to increase availability of the face masks. This includes 510(k) submission, quality system regulation (QSR), registration and listing, and unique device identifier (UDI) requirements, so long as the devices do not create an undue risk for users.

FDA recognizes that, when alternatives, such as FDA-cleared masks or respirators, are unavailable, individuals, including healthcare professionals, might improvise PPE. FDA does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared masks or respirators, are available.

FDA says it will allow the distribution and use of surgical masks, which are Class II devices, without 510(k) clearance, given that the masks meet certain standards for fluid resistance and flammability and include accurate labeling.

The agency also says it is interested in allowing companies to disinfect and reprocess otherwise disposable N95 respirators to stretch the supply of the devices under an emergency use authorization (EUA).

This guidance represents the current thinking of FDA on this topic. Manufacturers can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff as listed on the title page.

For more information visit <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health> and download the policy.