

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization to Decontaminate Millions of N95 Respirators

For Immediate Release:

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The U.S. Food and Drug Administration issued (<https://www.fda.gov/media/136884/download>) an emergency use authorization (EUA) that has the potential to decontaminate approximately 4 million N95 or N95-equivalent respirators per day in the U.S. for reuse by health care workers in hospital settings.

“Our nation’s health care workers are among the many heroes of this pandemic and we need to do everything we can to increase the availability of the critical medical devices they need, like N95 respirators,” said FDA Commissioner Stephen M. Hahn, M.D. “FDA staff continue to work around the clock, across government and with the private sector to find solutions. This authorization will help provide access to millions of respirators so our health care workers on the front lines can be better protected and provide the best care to patients with COVID-19.”

The FDA granted the EUA to Advanced Sterilization Products (ASP) for the STERRAD Sterilization Cycles (STERRAD 100S Cycle, STERRAD NX Standard Cycle, or STERRAD 100NX Express Cycle), which uses vaporized hydrogen peroxide gas plasma sterilization. There are approximately 9,930 STERRAD Sterilization systems in approximately 6,300 hospitals across the U.S. STERRAD 100S Cycle, STERRAD NX Standard Cycle and STERRAD 100NX Express Cycle vary in reprocessing times from 55 minutes, to 28 minutes, and 24 minutes. Each can reprocess approximately 480 respirators per day.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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- [Emergency Use Authorization: Coronavirus \(/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations\)](#)

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