

Welcome to today's FDA/CDRH Webinar

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FDA's Enforcement Policy and Umbrella EUA for Gowns and Other Apparel for Use by Healthcare Personnel

Office of Health Technology 4: Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Gowns



Minimal-to-Low Barrier Protection

- ANSI/AAMI PB70 Level 1 protection or equivalent
- ANSI/AAMI PB70 Level 2 protection or equivalent

Moderate-to-High Barrier Protection

- ANSI/AAMI PB70 Level 3 protection or equivalent
- ANSI/AAMI PB70 Level 4 protection or equivalent

Resources

- Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency (<https://www.fda.gov/media/136540/download>)
- FDA Letter for Emergency Use Authorization (EUA) of Gowns and Other Apparel (<https://www.fda.gov/media/138326/download>)
- Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings (<https://www.fda.gov/media/92146/download>)
- Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes (<https://www.fda.gov/media/72369/download>)
- Surgical Mask and Gown Conservation Strategies - Letter to Health Care Providers (<https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers>)

Questions?

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under Heading Specialty Technical Topics; Sub-heading:
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