

HANES Brands Inc

HanesBrands Proprietary Surgical Face Mask Receives Authorization by U.S. Food and Drug Administration

November 5, 2020

WINSTON-SALEM, N.C.--(BUSINESS WIRE)--Nov. 5, 2020-- HanesBrands (NYSE:HBI) today announced that a proprietary surgical face mask developed in conjunction with North Carolina State University, the University of North Carolina at Chapel Hill and UNC Health has been authorized by the U.S. Food and Drug Administration for use by health care professionals as personal protective equipment.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20201105005771/en/>



Mike Abbott, director of research and development for HanesBrands, credits the collaboration between the company and its university partners for the quick development of a much-needed mask for health care professionals. (Photo: Business Wire)

Authorization for surgical masks in response to concerns relating to the insufficient supply and availability of disposable single-use surgical masks that provide a physical barrier to fluids and respiratory droplets.

The use of unique spun-bond fabric developed by the Nonwovens Institute, the world's first accredited academic program for the field of engineered fabrics, eliminates the need for a third filtration layer for cost efficiency and filtering effectiveness. The spun-bond fabric is composed of two different polymer materials to make a single fiber that has significant strength and bulk that is as effective in filtration as current materials on the market.

"The Nonwovens Institute is proud to be a part of this collaboration to ensure that high-quality and affordable protective gear remains available to frontline health care workers during the pandemic," said Dr. Behnam Pourdeyhimi, executive director of the Nonwovens Institute at NC State.

The Hanes mask was added to the FDA Emergency Use Authorization on Oct. 5, 2020, after meeting FDA requirements for fluid resistance (ASTM F1862), flammability performance, particulate filtration (ASTM F2100), and breathability (ASTM F2100).

UNC Health's testing, supported by the UNC School of Medicine Center for Environmental Medicine, Asthma, and Lung Biology and the U.S. Environmental Protection Agency Human Studies Facility in Chapel Hill, demonstrated the masks exceeded expected performance levels and has used the masks in targeted clinical settings.

"We provided the Hanes mask to clinical areas concerned with protection during specific clinical encounters where N95 respirators are not recommended but the risk of COVID-19 exposure is perceived to be high," said UNC Health's Dr. Emily Sickbert-Bennett, director of infection prevention at UNC Medical Center in Chapel Hill. "The Hanes mask made these providers feel safe and well protected. I expect we will broaden use of the Hanes mask given the degree of protection it provides."

The company is selling the surgical masks to health care organizations for use by professionals in health care settings. Separately, the company is selling all-cotton and polyester blend face masks for consumers under its *Hanes* and *Champion* brands that are available online, in leading retail stores and in company outlet stores.

The two-ply, single-use surgical mask features a unique fabric developed by NC State's Nonwovens Institute combined with a fit design created in collaboration with UNC-Chapel Hill and NC State biomedical engineers and UNC Health infection prevention experts.

The Hanes mask uses a duckbill shape for better breathability, a wire nosepiece and foam insert to enhance a contoured fit, and placement of stretchable straps for a secure fit. UNC Health tested the masks to assure they meet FDA particulate filtration standards and OSHA respiratory protection program requirements.

"We are delighted to have this mask added to the FDA's Emergency Use Authorization for surgical masks during the COVID-19 pandemic," said Mike Abbott, HanesBrands' director of research and development. "It is a testament to the ingenuity and collaboration of our university partners and our R&D team to quickly develop a much-needed mask that is high quality, affordable and comfortable for health care professionals."

The FDA issued its Emergency Use

The U.S. Centers for Disease Control and Prevention recommends the wearing of cloth face coverings to help prevent the spread of COVID-19, especially when social distancing cannot be practiced. Emerging evidence indicates face coverings act as barriers to the dispersion of respiratory droplets when worn over the mouth and nose.

In accordance with the FDA surgical mask Emergency Use Authorization, HanesBrands' disposable, single-use surgical masks:

- Have not been FDA cleared or approved.
- Have been authorized by FDA under an EUA for use in health care settings by health care personnel to provide a physical barrier to fluids and particulate materials to prevent health care personnel exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.
- Are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. Section 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

In accordance with the FDA face coverings Emergency Use Authorization, HanesBrands' government cloth face coverings and consumer face masks:

- Have not been FDA cleared or approved.
- Have been authorized by the FDA under an EUA for use by health care professionals as personal protective equipment to help prevent the spread of infection or illness in health care settings and by the general public to help slow the spread of the virus during the COVID-19 pandemic.
- Are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. Section 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

HanesBrands

HanesBrands, based in Winston-Salem, N.C., is a socially responsible leading marketer of everyday basic innerwear and activewear apparel in the Americas, Europe, Australia and Asia-Pacific. The company sells its products under some of the world's strongest apparel brands, including *Hanes*, *Champion*, *Bonds*, *DIM*, *Maidenform*, *Bali*, *Playtex*, *Lovable*, *Bras N Things*, *Nur Die/Nur Der*, *Alternative*, *L'eggs*, *JMS/Just My Size*, *Wonderbra*, *Berlei*, and *Gear for Sports*. The company sells T-shirts, bras, panties, shapewear, underwear, socks, hosiery, and activewear produced in the company's low-cost global supply chain. A Fortune 500 company and member of the S&P 500 stock index (NYSE: HBI), Hanes has approximately 63,000 employees in more than 40 countries. For more information, visit the company's corporate website at www.Hanes.com/corporate and newsroom at <https://newsroom.hanesbrands.com/>. Connect with the company via social media: Twitter ([@hanesbrands](https://twitter.com/hanesbrands)), Facebook (www.facebook.com/hanesbrandsinc), Instagram ([@hanesbrands](https://www.instagram.com/hanesbrands)), and LinkedIn ([@Hanesbrandsinc](https://www.linkedin.com/company/hanesbrandsinc)).

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