Summary Report

Performance Characteristics	Test Method	Acceptance Criteria or Results
Fluid Resistance Performance (mmHg)	N/A	80mmHg (Design Estimate Only)
Bacterial Filtration Efficiency (%)	GB/T 19083-2010	99.1%
Particulate Filtration Efficiency (%)	GB/T 19083-2010	96.5%
Microbial Cleanliness for Face Masks (CFU/g)	GB/T 19083-2010	< 20CFU/g
Differential Pressure (Delta-P) (mm H_2O/cm^2)	N/A	< 4.0 (Design Estimate Only)
Flammability class Class 1	GB/T 19083-2010	Class 1

Noted results were assessed via third-party testing by the Guangdong Provincial Medical Device Quality Supervision and Inspection Institute, in order to demonstrate adherence to face mask requirements per the China-Guangzhou-Guangdong Food and Drug Administration. The report filing docket number is: MZ200010052. Please be advised that the U.S. FDA does not officially recognize testing methods, results, or standards originating from China. Standards and guidelines from Australia, Brazil, Europe, Japan, Korea, and Mexico for non-NIOSH approved respirators are recognized. As such, the abovementioned summary report data table shall not be interpreted as evidence for the submission of this face mask as an FDA-approved or -cleared medical device providing adequate liquid barrier protection. Per the FDA's guidance on "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff" (March 2020), the device being offered is indicated as a face mask intended for a medical purpose that is NOT intended to provide liquid barrier protection.

While the FDA does not intend to object to the distribution and use of medical purpose face masks with unknown or inadequate liquid barrier protection, please take under advisement that the device is not intended for:

- Use in any surgical setting or where significant exposure to liquid, bodily, or other hazardous fluids, may be expected;
- Use in a clinical setting where the infection risk level through inhalation/aerosolization of infectious pathogenic particulates is high;
- And use in the presence of a high intensity heat source or flammable gas.

Cautionary Note to Healthcare Professionals on Front Lines During the Coronavirus Disease (COVID-19) Public Health Emergency Regarding Bacterial Filtration Efficiency (BFE): This tests assesses the ability of a medical purpose face mask to provide a barrier to large particles expelled by the wearer. It is not a substitute for a regulatory respirator filtration efficiency test and it does not evaluate the medical purpose face mask's ability to provide any protection to the wearer. The test method used to evaluate BFE is GB/T 19083-2010 and is not currently recognized by the FDA or CDC.

Description of the device and indications for use: 3-ply single-use non-woven fine fiber meltblown fabric masks for humanitarian crisis clinical setting use with concealed flexible nose piece and anti-tamper ear loops. In light of the COVID-19 outbreak, this device is being offered "as-is" so that it may offer some benefit to health care providers for the duration of the public health emergency.

Device and Predicate Device Descriptions

Description	**Device**	**Predicate (with 510(k) number, if available)**
Materials	Outer layer: 20g/m² PP blue spunbond Filter layer: 20g/m² Meltblown, 99.1% BFE Inner layer ES Thermobonded soft Nosepiece: plastic and wire Earloop: Stretch thermobonded PET, latex-free	Outer layer: 20g/m² PP blue spunbond Filter layer: 20g/m² Meltblown, 99.1% BFE Inner layer ES Thermobonded soft Nosepiece: plastic and wire Earloop: 3mm round elastic earloop, latex-free (K910182)
Specification and dimensions	18cm x 9.5cm	18cm x 9.5cm (K910182)
Mask style	Flat pleated	Flat pleated (K910182)
Design features	Stretch thermobonded PET	Elastic ear loops (latex-free)

	demarcated pop-out anti-tamper ear loops, latex-free	
NIOSH certification number (when available)	N/A (Reason: The medical purpose face mask is not a respirator or NIOSH-qualifying device.)	N/A (Reason: The medical purpose face mask is not a respirator or NIOSH-qualifying device.)
USPTO (U.S. Patent and Trademark Office) application number	29729526	N/A

Resources

https://emergency.cdc.gov/coca/ppt/2020/3-25-20-COCA-Call-PDF-updated.pdf
https://www.fda.gov/media/136449/download
https://www.fda.gov/files/medical%20devices/published/Guidance-for-Industry-and-FDA-Staff--Surgical-Masks---Premarket-Notification-[510(k)]-Submissions--Guidance-for-Industry-and-FDA-(PDF-Version).pdf