
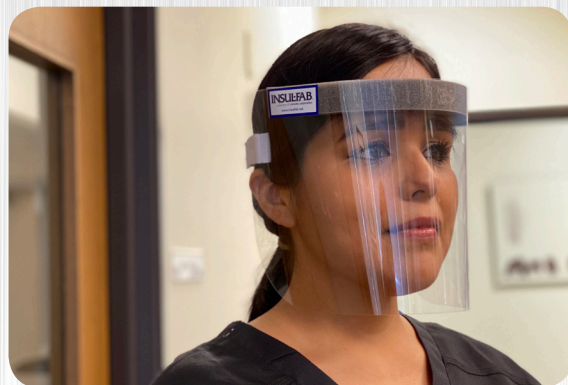


Insul-Fab Adjustable Face Shield

Properties	Notes
Product Benefits	<ul style="list-style-type: none"> - Lightweight Face Shield protects nose, mouth, eyes and ears - Barrier shield prevents transmission of fluids and droplets while allowing clear visibility - Soft foam spacer with Non-woven fabric provides comfortable wearability - Adjustable Hook/Loop fastening strap, allows for a universal fit - Product lays flat providing easy shipping, storage, carrying, and dispensing - Latex free, wipes clean
Product Composition	<ul style="list-style-type: none"> - Shield: Clear, 10 mil film - Spacer: Soft, 2# pcf polyester foam with skin-friendly absorbent non-woven mesh - Adhesive: 3M Acrylic - Adjustable Strap: Hook and Loop
Search "Insulfab Face Shield" on YouTube for assembly instructions and additional information	 <p>INSULFAB FACESHIELD FULL COVERAGE OF EYES, EARS, NOSE, MOUTH</p>



InsulFab Face Shield is compliant to ANSI/ISEA Z87D3 America National Standard Occupational and Educational Personal Eye and Face Protection Devices. A copy of the relevant ANSI/ISEA Z87.1-2015 Standard is on file at InsulFab and can be provided upon request. InsulFab Face Shield is considered a Class I medical device that is exempt from FDA Pre-Market Notification (Form 510[K]), but subject to Quality System Regulation. It is recommended that InsulFab Face Shield be used in combination with, and not as a substitute or replacement for eye protection devices, such as goggles or glasses with solid side shields and a medical/surgical mask (N95 FFR), whenever potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. Guidance and strategies for optimizing the supply of face masks is available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html>. InsulFab Face Shield is considered a single-use, single-user device and should be worn tight and properly situated to cover as much of the eye, nose, and mouth area as possible.

Face Shield Standards, Specifications, and Guidance

There is currently no universal standard for face/eye protection from biological hazards. The major current standards and regulatory bodies are summarized here:

Standards	Notes
American National Standard for Occupational and Educational Eye and Face Protection ANSI/ISEA Z87.1.	InsulFab Face Shield meets ANSI/ISEA Z87D3. Face shield product performance specifications can be found in the recently-revised voluntary ANSI/ISEA Z87.1 – 2015 Standard, but they do not cover bloodborne pathogens (such as viruses), X-rays, high-energy particulate radiation, microwaves, radio-frequency radiation, lasers. Rather, they identify face shields, from an industrial standpoint, as being designed to protect from impact, optical radiation, droplet, and splash (e.g., chemical), dust and fine dust particles. This standard is on file at InsulFab and can be provided upon request.
Occupational Safety and Health Administration (“OSHA”) Bloodborne Pathogens Standard.	OSHA’s Bloodborne Pathogens standard (1910:1030 subpart (d)(3)(i)) states: “Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.” However, no other specific guidance is provided with respect to stand alone face shields. InsulFab does subscribe to an independent and voluntary OSHCON annual audit and review, but auditors do not review products, rather its operations and processes.
Food and Drug Administration (“FDA”).	The Food and Drug Administration does not set standards for medical devices such as face shields, rather it classifies product based upon their need for preliminary review and the for their manufacturers to submit to audit and inspection. Face shields are considered Class I medical devices that are exempt from Food and Drug Administration (FDA) Pre-Market Notification (Form 510[K]), but are subject to the FDA’s Quality System Regulation (21 Code of Federal Regulations 820) that includes periodic inspection and enforcement actions (warning letters, injunctions, seizure, civil monetary penalties). <ul style="list-style-type: none"> a. InsulFab’s Quality System. InsulFab’s quality system is registered to the AS9100:2016 and ISO9001:2015 standard and is registered and audited by ABS Quality Evaluations, its own internal audit and review as well as by customers. Its Certificate of Registration is available for review upon request.
Center for Disease Control (“CDC”).	The CDC does not set any standards or specifications for face shields. It does offer guidance on the use (and re-use) of eye protection and PPE on its website.
National Institute for Occupational Safety and Health (“NIOSH”).	NIOSH is part of the CDC within the United States Department of Health and Human Services. It is the United States federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. While they have guidelines for respirators and the well-known N95 face mask, there is presently no guidance on face shields. InsulFab recommends that its InsulFab Face Shield be used in conjunction with other PPE, including NIOSH-approved, N95 respirator masks whenever practical.

As a result, InsulFab offers the following disclaimer and guidelines with respect to its InsulFab Face Shield Product:

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See Face Shields for infection control: A review, Raymond J. Roberge, J Occup Environ Hyg. 2016; 13(4): 235-242, found at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5015006/>; <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html>