

BADGER SHIELD

Disclaimer and Limits of Authorization and Use



On April 9, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) in response to concerns relating to insufficient supply and availability of face shields for use by health care personnel (HCP) as personal protective equipment (PPE) in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection during the Coronavirus Disease 2019 (COVID-19) pandemic.

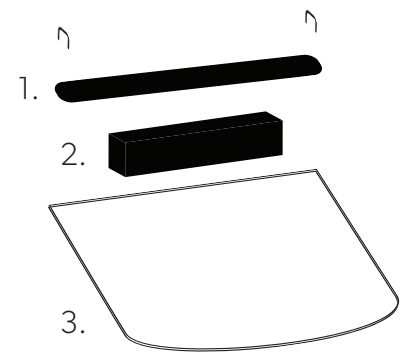
On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.

Badger Shield face shields are produced, marketed and sold under the protection of the above mentioned EUA.

For the most current CDC recommendations on the use of face shields during COVID-19, please visit CDC's webpage: [Strategies to Optimize the Supply of PPE and Equipment](#).

Please read and understand the following statement of disclaimer regarding Badger Shields:

- A. Badger Shield has not been reviewed, cleared or approved by the FDA.
- B. Per the EUA, Badger Shield is to be used by healthcare providers (HCP) as personal protective equipment (PPE).
- C. Badger Shield is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.
- D. The following materials are used in its manufacture and may come in contact with the body, none of which include any drugs or biologics, please contact us for additional information (numbers correspond with graphic on the right):
 - 1. Elastic band (not made with latex)
 - 2. Black Foam with adhesive backing
 - 3. Clear PET lens
- E. Badger Shield is not integrated with any other article of PPE such as a face mask, but rather is for use as a standalone face shield.
- F. Badger Shield is intended for single use.
- G. Badger Shield should not be used in the presence of high intensity heat source or flammable gas
- H. Use of Badger Shield alone will not prevent infection from microbes or viruses, and is not effective protection against radiation.



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comments or
questions should
be directed to:**

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