

## Surgical Masks EUA Template for Addition to Appendix A

This template includes the data/information requirements needed by FDA to support addition of a surgical mask to the list of authorized surgical masks in Appendix A under the Surgical Masks EUA (the “Surgical Masks EUA” or “EUA”), as set forth in the EUA. *As explained in the EUA, once completed, please send this interactive review template with the subject line “Surgical Masks Eligible for EUA” to [CDRH-nondiagnosticEUA-templates@fda.hhs.gov](mailto:CDRH-nondiagnosticEUA-templates@fda.hhs.gov).*

### GENERAL INFORMATION ABOUT THIS TEMPLATE

- In order to be added to Appendix A, consistent with the criteria and requirements in Section II of the EUA, text highlighted in yellow [text] must be provided to FDA as applicable to each model number.
- This is a template for addition to Appendix A of the Surgical Mask EUA and is not a guidance document. It contains no new information.
- Any trade secret or confidential commercial information provided within the template and during the interactive review process will remain confidential.
- Please remember that if your product is added to this specific EUA, the authorization would only be for the use specified in the EUA and subject to the conditions in the EUA. This device must not be introduced into interstate commerce for uses outside the authorized use without obtaining marketing clearance, approval, IDE, or another EUA by the FDA.
- The Surgical Mask EUA is only in effect until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) or the EUA is revoked under Section 564(g) of the Act.
- ***The EUA is not a pathway to permanent marketing of your product.*** For information on premarket submissions, refer to FDA’s website on “How to Study and Market Your Device” at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device>. For information on FDA’s enforcement policy for surgical masks, see FDA guidance [Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency \(Revised\)](#). For guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to FDA guidance [Deciding When to Submit a 510\(k\) for a Change to an Existing Device](#).

## Template for Addition to Appendix A of the Surgical Mask EUA

### A. Required Information from Section II of the EUA:

#### 1) Applicant

**Applicant information:**

- Applicant Company Name:
- Applicant Address:
- Applicant Contact Person:
- Applicant Contact Phone#:
- Applicant Contact Email:

**Correspondent information (if different from the Applicant):**

- Correspondent Company Name:
- Correspondent Address:
- Correspondent Contact Person:
- Correspondent Contact Phone#:
- Correspondent Contact Email:

#### 2) Device proprietary or brand name, model number:

Proprietary Name - [product trade name]

Established Name - [generic name]

Model number - [model number]

#### 3) Product Labeling

[Provide a copy of the product labeling, including the instructions for use.]

As stated in the EUA, the product labeling must:

- Describe the product as a disposable, single-use surgical mask. The labeling must include a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);
- State that the product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators;
- State that surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure;
- Not include statements that would misrepresent the product or create an undue risk in light of the public health emergency. For example, the labeling must not include any express or implied claims for: (1) reuse, (2) antimicrobial or

antiviral protection or related uses, (3) infection prevention, infection reduction, or related uses, or (4) viral filtration efficiency.

#### 4) Device Marketing Estimate

[Provide an estimate of the number of surgical masks you are planning to market and distribute during the public health emergency.]

#### 5) Evidence Demonstrating The Surgical Mask Meets The Criteria

[Provide a summary of the evidence demonstrating that the surgical mask meets the criteria required in the EUA, including test reports.]

As set forth in the EUA, a surgical mask is authorized if it has been designed, evaluated, and validated consistent with the following performance criteria and is not excluded from the scope of authorization. The following surgical masks are excluded from the scope and are not authorized under this EUA: (1) surgical masks that are FDA-cleared; (2) surgical masks that are manufactured in China; and (3) surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents.

##### a. Fluid Resistance Requirements

[Provide test reports to demonstrate that the model meets fluid resistance requirements (liquid barrier performance) consistent with ASTM F1862: *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*.]

##### b. Flammability Testing

[Provide test reports to demonstrate that the textiles used in the surgical mask meet flammability performance consistent with the definition of either a Class 1 or Class 2 textile in 16 CFR Part 1610]

##### c. Particle Filtration Testing

[Provide test reports to demonstrate that the model meets particulate filtration efficiency requirements consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks*.]

##### d. Air Flow Resistance (i.e., Breathability) Assessment

[Provide evidence, including test reports, to demonstrate that the model meets air flow resistance (i.e., breathability) requirements with an acceptance criterion of  $<6 \text{ mm H}_2\text{O}/\text{cm}^2$  for differential pressure (delta P) testing consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks* for those masks composed of 4 or more layers.]

**e. Biocompatibility Assessment**

[Provide evidence, including test reports, indicating how the model has materials of manufacture that are either (1) non-cytotoxic, non-irritating and non-sensitizing consistent with the recommendations in FDA’s guidance, “*Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’*” or (2) conform to the following biocompatibility standards:

- ISO 10993-1: *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- ISO 10993-5: *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10: *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.*

**6) Authorized Distributors and/or Authorized Importers**

[Please provide a list of authorized distributors and/or authorized importers, including contact information (name, address, contact person, phone number, and email).]

**B. FDA Summary of Documentation and Review [for FDA Internal Use Only]**

FDA reviewers will include a brief summary of the documentation provided and their conclusion of whether the product meets the criteria identified in Section II.

FDA reviewers should clearly distinguish their comments and edits in the document from the information provided by the sponsor.

**C. Review Log [for FDA Internal Use Only]**

Use the table below to document interactions between FDA or the sponsor.

Date	Type of Interaction (phone/ email/ formal submission-DCC)	Brief Description (e.g., questions asked/ feedback from FDA received / any word documents included)
[X]	[X]	[X]

**D. Next Steps**

Once FDA review is completed, if the eligible product has been confirmed to meet the criteria of the EUA, then you will receive an email notification with that information and your product will be added to Appendix A of the Surgical Mask EUA. If the product is

not eligible for addition to or fails to meet the criteria of the EUA, then you will receive an email notification with that information. Please note that, as set forth in FDA's guidance [Emergency Use Authorization of Medical Products and Related Authorities](#), FDA intends to prioritize its review of EUA requests during a declared emergency based on various factors, including the extent to which the product would serve a significant unmet medical need.

**E. Finalizing Review [for FDA Internal Use Only]**

Once FDA review is completed, FDA reviewers should finalize the documentation, sign and date this template, and document concurrence from the OHT management.