

Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 056

Date of Entry 03/01/2021

FR Recognition Number 6-460

Standard

ASTM F3502-21
Standard Specification for Barrier Face Coverings

Scope/Abstract

1.1 This specification is primarily intended to help ensure barrier face coverings meeting the stated requirements provide (1) a means of source control for individual wearers by reducing the number of expelled droplets* and aerosols from the wearer's nose and mouth into the air, and (2) to potentially offer a degree of particulate filtration to reduce the amount of inhaled particulate matter by the wearer.

1.2 This specification establishes minimum design, performance (testing), labeling, user instruction, reporting and classification, and conformity assessment requirements for barrier face coverings.

1.2.1 Design criteria include setting minimum areas of face coverage over the wearer's nose and mouth, prohibiting open vents or valves, requiring a means for retaining the barrier face covering on the wearer's head, and providing a representation of product sizing. Manufacturers are further required to perform a design analysis for assessing leakage of exhaled air from the barrier face covering. Manufacturers are permitted to conduct quantitative testing as specified in this standard to supplement the design analysis.

1.2.2 Performance and testing criteria define minimum barrier face covering filtration efficiency and airflow resistance performance properties. Sub-micron particulate filtration efficiency represents the ability to capture and reduce respirable droplets* and aerosols that potentially contain viruses and bacteria. Airflow resistance represents the wearer's ease of breathing or breathability while wearing the barrier face covering. The impact of repeated cleaning or laundering on continued performance is applied for measuring performance properties for those barrier face coverings that are intended to be reusable. Manufacturers are permitted to also provide test results for bacterial filtration efficiency (BFE) as supplemental information to the mandatory performance measurement of sub-micron particulate filtration efficiency.

* See Extent of Recognition section below for further information.

Extent of Recognition

Partial recognition. The following part(s) of the standard is (are) not recognized:

The use of the word "droplets" in Subsections 1.1, 1.2.2, and 3.1.12.

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

This standard is recognized in part because:

The use of the word "droplets" in Subsections 1.1, 1.2.2, and 3.1.12 is not consistent with the rest of this standard itself in that there are no corresponding Sections in the standard defining an appropriate test method by which the reduction in the number of expelled droplets from the wearer is quantitatively measured or the liquid barrier performance is evaluated. Droplets are considered liquid in nature and may not be adequately contained without some degree of liquid barrier evaluation and requirement.

Public Law, CFR Citation(s) and Procode(s)*

Regulation Number	Device Name	Device Class	Product Code
Unclassified	Face Mask Per Enforcement Policy For Face Masks And Respirators During The Covid-19 Public Health Emergency	Class N	QKR

Relevant FDA Guidance and/or Supportive Publications*

42 CFR Part 84 Approval of Respiratory Protective Devices

FDA Technical Contacts

Proprietary Name: Brilliance Air
Classification Name: FACE MASK PER ENFORCEMENT POLICY FOR FACE MASKS AND RESPIRATORS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY
Product Code: [QKR](#)
Device Class: Not Classified
Registered Establishment Name: [BRILLIANCE AIR, LLC](#)
Registered Establishment Number: 3018013770
Owner/Operator: [Brilliance Air, LLC](#)
Owner/Operator Number: 10080553
Establishment Operations: Manufacturer

Establishment:
BRILLIANCE AIR, LLC
364 W. Tullock St.
Suite 200
Rialto , CA 92376
Registration Number: 3018013770
FEI Number*: 3018013770
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
[Brilliance Air, LLC](#)
364 W. Tullock St.
Suite 200
Rialto, CA US 92376
Owner/Operator Number: [10080553](#)

Official Correspondent:
David Lennarz
Registrar Corp
144 Research Drive
Hampton, VA 23666
Phone: 1-757-2240177

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Device	Face Mask Per Enforcement Policy For Face Masks And Respirators During The Covid-19 Public Health Emergency
Definition	Face mask is intended to be worn by general public or healthcare personnel and excludes N95 respirators. The mask covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. The device is subject to the Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency provided that the device does not create undue risk by following the recommendations for this device type outlined in the guidance.
Physical State	Solid materials.
Technical Method	Physical barrier to materials.
Target Area	Nose and mouth
Review Panel	General Hospital
Product Code	QKR
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Not Classified Reason	Enforcement Discretion
Submission Type	Enforcement Discretion
Device Class	Not Classified
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	Yes
	Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), <i>as long as the device is <u>not</u> labeled or otherwise represented as sterile.</i>
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Recognized Consensus Standard	<ul style="list-style-type: none"> • 6-460 ASTM F3502-21 Standard Specification for Barrier Face Coverings
Third Party Review	Not Third Party Eligible