

Nitrile Powder Free 9" Medical Gloves



High quality powder free patient examination gloves. Beaded cuff for added strength and easier donning with excellent tactile sensitivity.

Sold by the case: 100 / box — 1000 / case

Features

- Disposable nitrile gloves
- Standard blue color
- Powder free
- Beaded cuff for extra strength
- Sizes available: XS-XL
- 9" in length
- 4 mil thickness

Send orders to
contact@rtlasersafety.com
or call 770-332-0092

Certifications

- FDA certified regulation number: 880.6250 — Product code: LZA
- 510K number: K131823
- CE Certified; ISO Certified
- Meets ASTM D6319-19, FEMA, and Strategic National Stockpile (SNS) standards

Dimensions -- Width	Meets ASTM D6319-10 Small 70-90 mm Medium 85-105mm Large 100-120mm Xlarge 110-130 mm	ASTM D6319	Small 82-86 mm Medium 94-98mm Large 107-113mm X large 115-121 mm	Substantially equivalent
Dimensions --Thickness	Meets ASTM D6319-10 Finger 0.05mm min. Palm 0.05mm min.	ASTM D6319	Thickness (mm) min. Finger 0.09-0.13 Palm 0.09-0.13	Substantially equivalent
Physical Properties	Meets ASTM D6319-10 Before aging/after aging Elongation ≥500% Tensile Strength: 14MPa	ASTM D6319	Before aging/after aging Elongation :540-600% Tensile Strength:19-23 MPa	Substantially equivalent
Freedom from Pinholes	Meets • 21 CFR 800.20 • ASTM D6319-10 • ASTM D 5151-06 (Reapproved 2011)	21 CFR 800.20 ASTM D5250 ASTM D 5151	Meets ASTM D5151-06 (Reapproved 2011) Holes at Inspection Level I AQL2.5	Substantially equivalent
Residual Powder	Meets ASTM D 6124-06 (Reapproved 2011) below 2mg of residual powder	ASTM D 6124	Meets ASTM D 6124-06 (Reapproved 2011) Results generated values below 2mg of residual powder	Substantially equivalent
Materials used to fabricate the devices	Nitrile	If the glove is made of a polymer or other type of material, identify the material.	Nitrile	Substantially equivalent
Dusting or Donning Powder:	PU	If a donning lubricant is used, state the composition and include biocompatibility data for the lubricant in an identified attachment; also state the name, manufacturer, and address below	PU-120C	Substantially equivalent
Dusting or Donning Powder: name	PU	Lubricant Generic Name/ Lubricant Brand Name	Surface Coating Agent	Substantially equivalent
Compare performance data supporting substantial equivalence	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	At this time FDA recognizes the following standards: Patient Examination Gloves(PVC)ASTM D5151(Detection of Holes in Medical Gloves)ASTM D6124(Residual Powder on Medical Gloves)ASTM	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)	Substantially equivalent



Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number043

Date of Entry 06/27/2016

FR Recognition Number 6-244

Standard

ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application

Scope/Abstract

1.1 This specification covers certain requirements for nitrile rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures.

1.2 This specification covers nitrile rubber examination gloves that fit either hand, paired gloves, and gloves by . It also provides for packaged sterile or nonsterile or bulk nonsterile nitrile rubber examination gloves.

1.3 This specification is similar to that of Specification D3578 for rubber examination gloves.

Extent of Recognition

Complete standard 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.

Transition Period

FDA recognition of ASTM D6319-10 (Reapproved 2015) [Rec# 6-244] will be superseded by recognition of ASTM D6319-19 [Rec# 6-446]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec# 6-244] until July 11, 2021. After this transition period, declarations of conformity to [Rec# 6-244] will not be accepted.

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

Regulation Number	Device Name	Device Class	Product Code
880.625022	Polymer Patient Examination Glove	Class 1	LZA23