



Nitrile Powder Free 9" Medical Gloves FDA Certification



Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 043

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 Ra-

tionale 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FDA recognition of ASTM D6319-10 (Reapproved 2015) [Rec# 6-244] will be superseded by recognition of ASTM D6319-19 [Rec# 6-446].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
§880.6250 ²²	Polymer Patient Examination Glove	Class 1	LZA23