



Nitrile Powder Free 9" Medical Gloves Certifications

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.		Thickness (mm) min. Finger 0.09-0.13 Palm 0.09-0.13	Substantially equivalent
Physical Properties	Meets ASTM D 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