

CERTIFICATE OF CONFORMITY & CERTIFICATE OF ANALYSIS

Brand	Nitrilite®
Size(s)	S (6.5 - 7),M (7.5 - 8),L (8.5 - 9)
Material	Nitrile
Style	93-311
Short Description	Clean Nitrile Glove
Lot Number	2104EV
Batch Number	21043113EV
Manufacturing Date	2021-04
Expiration Date	2026-03

DECLARATION OF CONFORMITY

Ansell certifies that the above product is manufactured in accordance with Ansell product specifications and is in conformity with the following standards or normative documents:

Standard/Normative Document	Result
FDA 21 CFR 177-2600	Conforms
Reach Regulation	Conforms
PPER (EU) 2016/425	Conforms
Free from BSE/TSE (EMEA/410/01)	Conforms

DECLARATION OF ANALYSIS

Property	Test Method	Specification	Result
Freedom from Holes - Final Release	EN455-1/ASTM D3577	G1, AQL 2.5	Conforms
Glove Length (mm)	ASTM D3767/EN420	min. 300	Conforms
Palm Thickness (mm)	ASTM D3767/EN420	min. 0.09	Conforms
Tensile Strength (MPa)	ASTM D412	Min. 18	Conforms
Ultimate Elongation (%)	ASTM D412	min. 500	Conforms
Liquid Particle Count 0.5-20 µ (particles/cm²)	IEST-RP-CC005.4	<2400	Conforms
Non Volatile Residue NVR (µg/cm²)	IEST-RP-CC005.4	<5.0	Conforms
Silicone, Amide, DOP - FTIR	IEST-RP-CC005.4	Not detectable	Conforms
Aluminium Al3+ (µg/cm²)	IEST-RP-CC005.4	<0.050	Conforms
Calcium Ca2+ (µg/cm²)	IEST-RP-CC005.4	<0.500	Conforms
Chloride Cl- (µg/cm²)	IEST-RP-CC005.4	<0.600	Conforms
Copper Cu2+ (µg/cm²)	IEST-RP-CC005.4	<0.050	Conforms
Iron Fe3+ (µg/cm²)	IEST-RP-CC005.4	<0.050	Conforms
Lithium Li+ (µg/cm²)	IEST-RP-CC005.4	<0.0004	Conforms
Magnesium Mg2+ (µg/cm²)	IEST-RP-CC005.4	<0.050	Conforms
Nitrate NO3- (µg/cm²)	IEST-RP-CC005.4	<0.500	Conforms

Property	Test Method	Specification	Result
Potassium K+ (µg/cm ²)	IENT-RP-CC005.4	<0.050	Conforms
Sodium Na+ (µg/cm ²)	IENT-RP-CC005.4	<0.500	Conforms
Sulphate SO ₄ 2- (µg/cm ²)	IENT-RP-CC005.4	<0.200	Conforms
Zinc Zn ²⁺ (µg/cm ²)	IENT-RP-CC005.4	<0.300	Conforms

Electronically Signed by:

Ann Van den Borre

Global Quality Sr Manager – Life Sciences Solutions Ansell

Date: 18 May 2021

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