

Certificate of Conformity

VWR Catalogue Number	112-6201
Description	VWR Cleanroom Nitrile Class 10 Gloves, M, White
Lot Number	2301N2303
Date of Manufacture (yyyy-mm)	2023-01
Expiry Date (yyyy-mm-dd)	2027-12
Country of Origin	Manufactured in Malaysia
Date of Issue (yyyy-mm-dd)	2023-10-18

Quality System Compliance

Products are manufactured under the **ISO 9001:2015** standard. Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP.

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirements.

Product Specifications

Dimensional Parameters

Parameter	Extra small (XS)	Small (S)	Medium (M)	Large (L)	Extra Large (XL)	Extra Extra Large (XXL)
Palm Width (mm)	75 ± 5	85 ± 5	95 ± 5	105 ± 5	115 ± 5	125 ± 5
Total Length (mm)	300 ± 5					

Dimensional Parameters

Parameter	Extra small (XS)	Small (S)	Medium (M)	Large (L)	Extra Large (XL)	Extra Extra Large (XXL)
Thickness - Cuff (mm)	0.09-0.12					
Thickness - Palm (mm)	0.11-0.15					
Thickness - Finger (mm)	0.13-0.18					

Physical Properties

Parameter	Specification	Test Method
Tensile Strength (MPa)	≥ 18	ASTM D 412
Modulus @300 (MPa)	≤ 9	ASTM D 412
Ultimate Elongation (%)	≥ 500	ASTM D 412

Barrier Property:

Test item	Result	Test Standard
Freedom from Holes (AQL)	1.5	ASTM D5151

Cleanliness Properties:

Test Item	Result	Test Standard
Particles, LPC (max. ≥0.5 µm/cm ²)	750	IEST-RP-CC005.4
Extractable Ions (max. µg/cm ²)		
Chloride, Cl ⁻	0.200	
Nitrate, NO ₃ ⁻	0.100	
Sulfate, SO ₄ ²⁻	0.050	
Sodium, Na ⁺	0.050	
Pottasium, K ⁺	0.030	

Calcium, Ca ²⁺	0.300
Aluminium, Al ³⁺	0.010
Ferric, Fe ³⁺	0.010
Zinc, Zn ²⁺	0.010
Copper, Cu ²⁺	0.0004
Ammonium, NH ₄ ⁺	0.005
Bromide, Br ⁻	0.005
Chromium, Cr ⁶⁺	0.005
Fluoride, F ⁻	0.005
Lead, Pb ²⁺	0.005
Lithium, Li ⁺	0.001
Magnesium, Mg ²⁺	0.005
Nickel, Ni ²⁺	0.005
Nitrite, NO ₂ ⁻	0.005
Phosphate, PO ₄ ³⁻	0.005
Strontium, Sr ²⁺	0.005
Tin, Sn ⁴⁺	0.005
Total Non-Volatile Residue, TNVR (max. µg/cm ²)	
In Solvent IPA	5.0
Fourier Transform Infra-Red, FTIR	
Silicon, Amide & Dioctylphthalate	Absent

PERFORMANCE AND LIMITATIONS OF USE

These products have been tested in accordance with EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016 and have achieved the following performance levels: -

EN ISO 21420:2020	Length & Fit Dexterity pH Value	Pass Pass Pass
EN ISO 374-5:2016  Virus	Water Leak Protection against bacteria and fungi Protection against virus	Pass Pass Pass

EN ISO 374-1:2016+A1:2018 EN ISO 374-1:2016/type B 	40% Sodium hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T) 70% IPA	Level=6 Level=5 Level=6 Level=3
EN ISO 374-4:2019	40% Sodium hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T) 70% IPA	-7.3% 33.8% 17.8% 61.2%

Material	Copolymer of Acrylonitrile / Butadiene / Methylacrylic acid. Complies with FDA 21CFR.
Sterilization	Non-Sterile.
ATP Assay	Not Applicable.
DNase & RNase Free	Not Applicable.
BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE).
Cytotoxicity	Not Applicable.
Non-Pyrogenic Statement	Not Applicable.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Please see RoHS below.
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analyse is performed).

REACH Statement	No substances as listed on >Substance of Very High Concern< candidate list published 2023-06-14 are used in manufacturing of the raw materials used to produce this product. No routinely analyse is performed.
Storage Conditions	Store in Cool, dry place. Keep away from naked flame, direct sunlight or ozone sources. Recommended storage temperature: 10° C - 40° C.
Shelf Life	5 years.

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.
This document has been produced electronically and is valid without a signature.

Annexure

1. Water Extractable Ions Test

Anions	F ⁻	Br ⁻	Cl ⁻	NO ₂ ⁻	NO ₃ ⁻	SO ₄ ²⁻	PO ₄ ³⁻
Specification	<0.005	<0.005	<0.20	<0.005	<0.10	<0.05	<0.005
Result (ug/cm ²)	ND	ND	0.130	ND	0.066	0.012	ND

PASS	FAIL
√	

Test Method

☒ IEST-RP-CC005.4

☐ Others

Cations	Na ⁺	K ⁺	Ca ²⁺	Mg ²⁺	Li ⁺	NH ₄ ⁺	Sr ²⁺
Specification	<0.05	<0.03	<0.30	<0.005	<0.001	<0.005	<0.005
Result (ug/cm ²)	0.029	0.015	0.185	ND	ND	ND	ND

PASS	FAIL
√	

Heavy Metal	Al ³⁺	Fe ³⁺	Cr ⁶⁺	Zn ²⁺	Sn ⁴⁺	Ni ²⁺	Pb ²⁺
Specification	<0.01	<0.01	<0.005	0.01	<0.005	<0.005	<0.005
Result (ug/cm ²)	0.004	0.001	ND	0.005	ND	ND	ND

PASS	FAIL
√	

Heavy Metal	Cu ²⁺						
Specification	<0.0004						
Result (ug/cm ²)	ND						

PASS	FAIL
√	

2. Liquid Particle Count Test

LPC	Specification	1	2	3	Ave
Counts / cm ² (≥ 0.5 micron)	<750	600.11	595.85	571.58	589.18

PASS	FAIL
√	

Test Method

☒ IEST-RP-CC005.4

☐ Others

3. Total Non Volatile Residue Test

TNVR	Specification	Result
Solvent IPA (μg/cm ²)	<5.0	4.0

PASS	FAIL
√	

Test Method

☒ IEST-RP-CC005.4

☐ Others

☐ Not Tested

4. Fourier Transform Infra-Red Test

FTIR	Specification	Result
Silicone, Amide, DOP	Not Detected	Not Detected

PASS	FAIL
√	

Test Method

☒ IEST-RP-CC005.4

☐ Others

☐ Not Tested

5. Electrical Properties Test

ESD	Specification	Result
Surface Resistance(ohms)	5x 10 ¹¹ @ 50% RH	8.5 x 10 ¹⁰ 9.3 x 10 ¹⁰ 9.9 x 10 ¹⁰
Static Decay(Sec.)	< 2 @ 50% RH	0.7 0.8 0.8
Tribo Electric Charge	NA	NA NA NA

PASS	FAIL
√	
√	
√	

Test Method

☒ ESD/EOS S11.11
FTMS 101-C, 4046
& ASTM 257

☐ Others

☐ Not Tested

Note: NA-Not Applicable, ND- Not Detected

6. Watertight test: Inspection level = G1; AQL 1.5

7. Visual inspection: Inspection level = G1; AQL 1.5 (critical defects)

AQL 2.5 (major defects)

AQL 4.0 (minor defects)

8. Dimensional: Inspection level = S2; AQL 4.0

9. Physical Property: Inspection level = S2; AQL 4.0

10. Glove count: Inspection level = 5 bags; Tolerance 100 +/- 2 pieces