

Certificate of Conformity

VWR Catalogue Number	See List
Description	VWR Cleanroom Nitrile Class 10 Gloves, White
Country of Origin	Manufactured in Malaysia
Date of Issue (yyyy-mm-dd)	2023-06-14

Catalogue Number	Glove size
112-6199	VWR Cleanroom Nitrile Class 10 Gloves, XS
112-6200	VWR Cleanroom Nitrile Class 10 Gloves, S
112-6201	VWR Cleanroom Nitrile Class 10 Gloves, M
112-6202	VWR Cleanroom Nitrile Class 10 Gloves, L
112-6203	VWR Cleanroom Nitrile Class 10 Gloves, XL
112-6204	VWR Cleanroom Nitrile Class 10 Gloves, XXL
112-6205	VWR Cleanroom Nitrile Class 10 Gloves, Tacky, XS
112-6206	VWR Cleanroom Nitrile Class 10 Gloves, Tacky, S
112-6207	VWR Cleanroom Nitrile Class 10 Gloves, Tacky, M
112-6208	VWR Cleanroom Nitrile Class 10 Gloves, Tacky, L
112-6209	VWR Cleanroom Nitrile Class 10 Gloves, Tacky, XL
112-6210	VWR Cleanroom Nitrile Class 10 Gloves, Tacky, XXL

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)
Glove Weight (gram/pc)	7.0 ± 0.3	7.5 ± 0.3	8.0 ± 0.3	8.5 ± 0.3	9.0 ± 0.3	9.5 ± 0.3
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

Cleanliness Properties

Parameter		Test Method	Class 10
Barrier Integrity		ASTM D 5151	G1 AQL 1.5
LPC (≥ 0.50 micron)	Counts/cm ²	IEST RP-CC 005.4	Max 750
Chloride, Cl ⁻	ug/cm ²	IEST RP-CC 005.4	0.200
Nitrate, NO ₃ ⁻			0.100
Sulfate, SO ₄ ²⁻			0.050
Sodium, Na ⁺			0.050
Potassium, 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
TNVR in IPA			5.0
Silicone, Amide, DOP			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  K P T	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	Product are gamma irradiated and meets a minimum requirement of 10 ⁻⁶ SAL with a specified dose range of 25 kGy.
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 2023-01-17 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	3 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.
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