Certificate of Conformity

VWR Catalogue Number	112-3101
Description	VWR®, Nitrile Gloves, 240 mm Length, Blue, XL
Lot Number	2022-11 L021618 2211
Date of Manufacture (yyyy-mm-dd)	2022-11
Expiry Date (yyyy-mm-dd)	2025-10
Country of Origin	Manufactured in Malaysia
Date of Issue (yyyy-mm-dd)	2023-05-30

Quality System Compliance

Products are manufactured under the **ISO 9001 and ISO 13485** 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

The products are in compliance with CE directive PPE 2016/425/EU

Ambidextrous / hand-specific	Ambidextrous
Disposable / reusable	Disposable
Powdered / powder-free	Powder-free
Latex	Latex-free
Cuff style	Beaded
Cuff thickness	0.20 mm*
Finger thickness	0.30 mm*
Palm thickness	0.22 mm*
EN norm	EN ISO 374-1 Type B (KTP), EN ISO 374-5 VIRUS

Food contact approved	Yes

Compliance to European Directives and Regulations:

PPE Regulation (EU) 2016/425 relating to Personal protective equipment, CAT III against complex risks
EU Type Examination Certificate N° 2777/11462-01/E08-01, issued by Notified Body 2777, SATRA
Regulation EC 1935/2004 - Regulation on materials and articles intended to come into contact with food

European Standards:

EN 420:2003+A1:2009 - Protective gloves – General Requirements and test methods
EN ISO 374-1:2016 + A1:2018 Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical
EN 374-2:2015 Protective gloves against dangerous chemicals and micro-organisms Part 2: Determination of resistance to penetration
EN 16523-1:2015 Determination of material resistance to permeation by chemicals Part 1: Permeation by liquid chemical under conditions of continuous contact
EN 374-4:2013 Protective gloves against chemicals and micro-organisms Part 4: Determination of resistance to degradation by chemicals
EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks

Material	Nitrile Butadiene Rubber (NBR).
Sterilization	Non-Sterile.
ATP Assay	Not applicable.
DNase & RNase Free	Product is not certified as DNase &RNase free as no test has been done in this regard.
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	Testing is conducted as part of 10993-biocomp testing standards for cytotoxicity and have been shown to be acceptable for the intended use of the device as a disposable protective glove.

Non-Pyrogenic Statement	Not applicable.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenol are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	This product is free of DEHP.
RoHS	Not applicable.
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 analysis is performed.
Storage Conditions	Store in original packaging in a dry and dark place at 10° to 30°C. Ensure that storage area is kept cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolour the glove. Protect gloves against ultraviolet light sources, such as sunlight and oxidizing agents. Storage above 30 °C will lead to accelerated aging and should be avoided.
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.
This document has been produced electronically and is valid without a signature.

Annex

Parameter	Specification	Result	Sampling size
1.Dimension			
Palm width	Min 110	Min. 115 Max: 118	Pass
Length	Median : 240mm	Median : 247 mm	Pass
Cuff Thickness	Min. 0.10 mm	Min. 0.10 mm	Pass
Palm Thickness	Min. 0.11 mm	Min. 0.12 mm	Pass
Finger Thickness	Min. 0.15 mm	Min. 0.17 mm	Pass
2. Functionality and Appearance test			
Barrier	G1 AQL 1.5	Pass	
Visual	G1 AQL 2.5	Pass	

Parameter	Specification	Result	Sampling size
3. Lab testing			
Tensile Strength (Un-aged) (Mpa)	Min : N/A	N/A	N/A
Tensile Strength (Aged) (Mpa)	Min : N/A	N/A	N/A
Elongation at Break (Un-aged) (%)	Min : N/A	N/A	N/A
Elongation at Break (Aged) (%)	Min : N/A	N/A	N/A
Force at Break (After challenge test)(N)	Median : 6 N	10.8	Pass
Powder (mg)	≤ 2 mg	0.46	Pass