Certificate of Conformity

VWR Catalogue Number	112-2750
Description	Latex gloves, Powder free, 240 mm Length, Natural, Small
Lot Number	2022-06 L016985 2206
Date of Manufacture (yyyy-mm-dd)	2022-06
Expiry Date (yyyy-mm-dd)	2025-05
Country of Origin	Manufactured in Malaysia
Date of Issue (yyyy-mm-dd)	2023-05-12

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
Finish	Textured fingers
Cuff style	Beaded
Cuff thickness	0.12 mm*
Finger thickness	0.20 mm*
Palm thickness	0.16 mm*
EN norm	EN ISO 374-1 Type C, EN ISO 374-5 VIRUS, EN 455 1-4
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 VN620 143495, Additum 26, issued by Notified Body 0534, ÖTI
MD Regulation (EU) 2017/745, relating to Medical Devices, Class 1
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
EN 455-1:2000 Medical gloves for single use Part 1: Requirements and testing for freedom from holes
EN 455-2:2015 Medical gloves for single use Part 2: Requirements and testing for physical properties
EN 455-3:2015 Medical gloves for single use Part 3: Requirements and testing for biological evaluation
EN455-4: 2009 – Medical Gloves for single use Part 4: Requirements and testing for shelf life determination

Material	Latex. Conforms to Standards: EN ISO 374-1 Type C, EN ISO 374-5 VIRUS, EN 455 1-4; ASTM D3578 (except stress at 500% elongation), ASTM F1671; MDR Class I; PPE Cat. III Food contact approved.
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 inteded use of the device as a medical examination glove.
Non-Pyrogenic Statement	Not applicable.
Latex Statement	This product is 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 2022-06-10 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.

Annex

PARAMETER	SPECIFICATION	RESULT	
1. DIMENSION*			
Palm Width	85 ± 5	Min: 85 Max: 87	Pass
Length (mm)	Median: 240	246	Pass
Cuff Thickness (mm)	Min: 0.06	0.06	Pass
Palm Thickness (mm)	Min: 0.08	0.08	Pass
Finger Thickness (mm)	Min: 0.10	0.10	Pass
2. FUNCTIONALITY & APPERANCE TEST*			
Barrier	G1 AQL 1.5	Pass	
Visual	G1 AQL 2.5	Pass	
3. LAB TESTING			
Tensile Strength (Un-aged) (MPa)	Min: 18	28.5	Pass
Tensile Strength (Aged) (MPa)	Min: 14	27.3	Pass
Elongation at Break (Un-aged) (%)	Min: 650	740	Pass
Elongation at Break (Aged) (%)	Min: 500	680	Pass
Force at Break (After Challenge Test) (N)	Median: 6	7.4	Pass
Powder	≤ 2 mg	0.58 mg	Pass