

# Certificate of Conformity

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>VWR Catalogue Number</b>       | See List                                         |
| <b>Description</b>                | VWR® NITRILE LIGHT, Nitrile Gloves, 240 mm, Blue |
| <b>Country of Origin</b>          | Manufactured in Malaysia                         |
| <b>Date of Issue (yyyy-mm-dd)</b> | 2024-11-06                                       |

| Catalogue Number | Glove Size |
|------------------|------------|
| 112-2765         | XS         |
| 112-2754         | S          |
| 112-2755         | M          |
| 112-2756         | L          |
| 112-2757         | XL         |

## 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 as last amended.

|                                                    |                                                          |
|----------------------------------------------------|----------------------------------------------------------|
| <b>Shape</b>                                       | Ambidextrous                                             |
| <b>Color</b>                                       | Blue                                                     |
| <b>Inner</b>                                       | Online Chlorinated                                       |
| <b>Outer</b>                                       | No treatment                                             |
| <b>Thickness (double measured, minimum values)</b> | Finger min. 0.20 mm<br>Palm min. 0.16 mm<br>min. 0.12 mm |

|                                         |                                  |
|-----------------------------------------|----------------------------------|
| AQL (acc EN 420)                        | Level 2 – AQL 1.5                |
| Residual powder (according to EN 455-3) | ≤ 2 mg/glove                     |
| Cuff/ Surface                           | Rolled cuff/Fingertip textured   |
| Length (according to EN 455-2)          | Median 240 mm                    |
| Force at break (according to EN 455-2)  | Median 6.0 N (during shelf life) |

#### Compliance to European Directives and Regulations:

|                                                                                                        |
|--------------------------------------------------------------------------------------------------------|
| PPE Regulation (EU) 2016/425, as last amended<br>Regulation (EU) 2017/745 as last amended              |
| EU Type Examination Certificate (Module B) 2777/11461-04/E04-01, issued by Notified Body 2777, SATRA   |
| Council Directive 1993/42/EC amended by 2007/47/EC, relating to Medical Devices, Class 1               |
| Regulation EC 1935/2004 - Regulation on materials and articles intended to come into contact with food |

#### European Standards:

|                              |                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Harmonized Standards:</b> | EN ISO 21420:2020<br>EN ISO 374-1:2016+A1:2018<br>EN ISO 374-2:2019 EN ISO 374-4:2019<br>EN ISO 374-5:2016<br>EN 16523-1:2015+A1:2018<br>EN 421:2010<br>EN 455-1:2020<br>EN 455-2:2015 EN 455-3:2015<br>EN 455-4:2009<br>EN 62366-1:2015 + AC:2016 + A1:2020<br>EN ISO 10993-1:2020<br>EN ISO 14971:2019 + A11:2021 EN ISO 15223-1:2021<br>EN ISO 20417:2021<br>EN ISO 13485:2016+AC:2018+A11:2021 |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### Caution

|                                                                               |                                                 |
|-------------------------------------------------------------------------------|-------------------------------------------------|
| <b>This product contains accelerators which may cause allergic reactions!</b> |                                                 |
| Potentially allergenic ingredients                                            | Dithiocarbamate type Zinc-mercapto-benzothiazol |

|                                |                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Material</b>                | Nitrile Butadiene Rubber (NBR).                                                                                                                                                                                                                                                                                                                             |
| <b>Sterilization</b>           | Non-Sterile.                                                                                                                                                                                                                                                                                                                                                |
| <b>ATP Assay</b>               | Not applicable.                                                                                                                                                                                                                                                                                                                                             |
| <b>DNase &amp; RNase Free</b>  | Product is not certified as DNase & RNase free as no test has been done in this regard.                                                                                                                                                                                                                                                                     |
| <b>BSE/TSE</b>                 | 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). |
| <b>Cytotoxicity</b>            | 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.                                                                                                                                                                  |
| <b>Non-Pyrogenic Statement</b> | Not applicable.                                                                                                                                                                                                                                                                                                                                             |
| <b>Latex Statement</b>         | This product is not made from natural rubber latex.                                                                                                                                                                                                                                                                                                         |
| <b>BPA Statement</b>           | Bisphenols are not used in the manufacture of the raw material and are not expected to be present.                                                                                                                                                                                                                                                          |
| <b>DEHP Statement</b>          | This product is free of DEHP.                                                                                                                                                                                                                                                                                                                               |
| <b>RoHS</b>                    | Not applicable.                                                                                                                                                                                                                                                                                                                                             |
| <b>REACH Statement</b>         | No substances as listed on >Substance of Very High Concern< candidate list are used in manufacturing of the raw materials used to produce this product. No routinely analysis is performed.                                                                                                                                                                 |
| <b>Storage Conditions</b>      | Store in original packaging in a dry and dark place at 10° to 30°C. Protect from ozone.                                                                                                                                                                                                                                                                     |
| <b>Shelf Life</b>              | 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.

## Version History

| Sl.no | Version number | Description                          | Month & Year |
|-------|----------------|--------------------------------------|--------------|
| 1     | 1.0            | Created General CoC using new layout | 11-2024      |
|       |                |                                      |              |