

ecoSHIELD™

Eco Latex PF 250





- ⇒ Powder-free ambidextrous extra length (250-260 mm / 9.8"-10.2") non-sterile natural rubber latex protective gloves.
- ⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.
- ⇒ Medical Device Class 1 (MDR) according to the Regulation (EU) 2017/745.
- ⇒ Fully compliant to the latest EU PPE norms relating to protective gloves against chemicals, micro-organisms and viruses.

| DESCRIPTION | |
|-------------|--|
| Formulation | Natural rubber latex (<i>Hevea brasiliensis</i>). |
| Design | Natural colour, ambidextrous, beaded cuff, smooth finish. |
| Packaging | 100 gloves per dispenser - 10 dispensers per carton = 1000 gloves. |

| SIZES | 6/XS | 7/S | 8/M | 9/L | 10/XL |
|-------|---------|---------|---------|---------|---------|
| Codes | 62 3131 | 62 3132 | 62 3133 | 62 3134 | 62 3135 |

| STANDARDS | |
|----------------------|---|
| CE/UKCA registration | PPE Category III (Complex Design) - Regulation (EU) 2016/425. CE Notified Body No 2797: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, Unit 4.2, 1066 EP Amsterdam, The Netherlands. UKCA Notified Body No 0086: BSI Assurance UK Ltd, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom. MDR Class 1 - Regulation (EU) 2017/745. |
| EU PPE norms | ISO 21420:2020+A1:2022, EN 421:2010, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B. |
| EU MDR norms | EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. |
| USA standards | ASTM D3767-03 (2020), ASTM D573-04 (2019), ASTM D412-16, ASTM D5712-15. |
| Other standards | ISO 21171:2006, ISO 10993-10:2021. |

| QUALITY | |
|-------------------|--|
| Quality assurance | Production management in accordance with ISO 9001:2015 and ISO 13485:2016. Environmental management systems in accordance with ISO 14001:2015. |
| Technology | uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection. |
| Ecological | Ink on the packaging reduced by 60%. Packaging made from recycled cardboard. Supply chain optimised to reduce CO ₂ emissions by more than 15% in the delivery of product. |

| DOCUMENTATION | |
|---------------------------------|---|
| Declaration of conformity | These documents can be freely downloaded from the product page on our website: www.shieldscientific.com . For easy access, scan the QR code. |
| EU type examination certificate | |
| User's instructions | |



PHYSICAL PROPERTIES



| NOMINAL THICKNESS | mm ¹ | mil | Norm |
|-------------------|-----------------|-----|----------------------|
| ⇒ Finger | 0.19 | 7.5 | ASTM D3767-03 (2020) |
| ⇒ Palm | 0.16 | 6.3 | |
| ⇒ Cuff | 0.10 | 3.9 | |

¹ Thickness (+/- 0.03 mm)

| LENGTH | Minimum | Typical | Norm |
|--|-----------------|----------------|------------------------|
| ⇒ From middle finger tip to edge of cuff | ≥ 250 mm / 9.8" | 255 mm / 10.0" | ISO 21420:2020+A1:2022 |

| STRENGTH PROPERTIES | Force at break (spec.) | | Ultimate elongation (spec.) | Force at break (typical) | Norm |
|---------------------|------------------------|--------|-----------------------------|--------------------------|--|
| ⇒ Before aging | ≥ 9.0N | 18 MPa | ≥ 700% | 10.0N | EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16 |
| ⇒ After aging | ≥ 6.0N | 14 MPa | ≥ 500% | 8.0N | |

| FREEDOM FROM HOLES | Performance | Norm |
|----------------------------------|----------------------------------|---------------------------------|
| ⇒ Acceptable Quality Level (AQL) | < 0.65 ² G1 - Level 3 | ISO 374-2:2019 EN 455-1:2020 |

² AQL as defined per ISO 2859-1:1999 for sampling by attributes.

PROTECTION PROPERTIES

| RISKS | Description | Norm |
|-----------------|--|---|
| Micro-organisms | 1000 ml water test. Performance level 3, AQL < 0.65 (inspection level G1). | ISO 374-2:2019 |
| Viruses | Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B. | ISO 374-5:2016 |
| Chemicals | <u>Performance</u> : Type B (KPT). <u>Permeation</u> : Extensively tested. Online chemical resistance guide on www.shieldscientific.com . <u>Degradation</u> : Tested for determination of resistance to degradation by chemicals. | ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 ISO 374-4:2019 |
| Radioactivity | Protection from radioactive contamination. | EN 421:2010 |

| ALLERGIES | |
|-------------------|---|
| Bio-compatibility | Demonstrated by skin irritation and sensitisation tests in accordance with ISO 10993-10:2021. |
| Accelerators | Free of Thiazoles and Thiurams. These chemical accelerators are excluded from the manufacturing process. |
| Residual powder | Powder-free to minimise the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006). |
| Latex protein | ≤ 50 µg/g as per Modified Lowry Method (EN 455-3:2015/ASTM D5712-15). |