ISOFIELD




## Empfohlene Reinraumklassen

**ISO** 5 | 6 | 7 | 8 | 9

**GMP** C | D

# Latex-Handschuhe Isofield LS400

pure[11]-Nr.: 1130468, Marke: ISOFIELD

## Eigenschaften

- AQL (Acceptable Quality Level)-Wert: 1,5
- Chemikalienbeständigkeit - Typ: Typ B
- Handschuhtyp: Dünnfilm
- Im Reinraum hergestellt
- Länge in cm: 40 cm
- Länge in Inches: 16 In
- Lebensmittelkonformität
- Material: Latex
- Materialzusammensetzung: Reinmaterial
- Puderfrei
- Rollrand
- Texturierte Fingerspitzen
- Passform Hand: beidhändig
- Verpackungsform: Beutel
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,2 mm
- Marke: ISOFIELD

we care

**pure[11] GmbH** |
Bavariafilmplatz 7 | D-82031 Grünwald
T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

### Material

- Latex

### Verpackung

- 1000STK

## Produktvarianten

**pure[11]-Nr.: 1130468NCL, Latex-Handschuhe Isofield LS400**

Farbe: Natur; Größe: L / VE: 1000STK

**pure[11]-Nr.: 1130468NCM, Latex-Handschuhe Isofield LS400**

Farbe: Natur; Größe: M / VE: 1000STK

**pure[11]-Nr.: 1130468NCS, Latex-Handschuhe Isofield LS400**

Farbe: Natur; Größe: S / VE: 1000STK

**pure[11]-Nr.: 1130468NCXL, Latex-Handschuhe Isofield LS400**

Farbe: Natur; Größe: XL / VE: 1000STK

**pure[11]-Nr.: 1130468NCXXL, Latex-Handschuhe Isofield LS400**

Farbe: Natur; Größe: XXL / VE: 1000STK

Isofield®
Protecting Life Science



# Isofield LS400

## 400mm (16”) Non-sterile latex Cleanroom gloves

Last updated **25 Mar 2024**

PRODUCT CODE

REF **10140**

| | |
|---|---|
| SMALL | 10140S |
| MEDIUM | 10140M |
| LARGE | 10140L |
| XLARGE | 10140XL |

CE 2797 UK CA 0086 AQL 1.5

## PRODUCT INFO

Non-sterile latex Cleanroom gloves
400mm (16”) elbow length
Ambidextrous
Natural colour
Textured palm & fingers
Beaded cuff
Low endotoxin levels
Protein level less than 50µg/g
Double donnable
IPA resistant ink pouches

## CLEANROOM COMPATIBILITY

ISO Class 4 cleanroom
ISO Class 5 cleanroom

Class 10 cleanroom
Class 100 cleanroom

## QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5 cleanroom

Physical properties comply with European medical glove standard EN 455-2:2015

## APPLICATIONS

Handling of washed components

Preparation of solutions to be sterile-filtered

Loading and transporting vials

## STORAGE & SHELF LIFE

Store in a dry, cool place (<40°C) away from direct sunlight

Do not expose open cartons to prolonged direct fluorescent light

Three (3) years from date of manufacture

## PACKAGING

100 gloves per sealed inner PE bag,

1 inner PE bag per sealed outer PE bag,

10 outer bags per lined carton (1000 pieces)

## PHYSICAL PROPERTIES

| THICKNESS, SINGLE WALL | MM* | MILS | TEST METHOD |
|---|---|---|---|
| Finger tip | 0.20 | 7.87 | EN 455-2:2015 |
| Palm | 0.17 | 6.69 | EN 455-2:2015 |
| Cuff | 0.11 | 4.33 | EN 455-2:2015 |

** +/- 0.02mm*

| LENGTH | MIN | TYPICAL | TEST METHOD |
|---|---|---|---|
| From tip of middle finger to edge of cuff | 390mm | 400mm | EN ISO 21420:2020 |

| STRENGTH PROPERTIES | FORCE AT BREAK | TEST METHOD |
|---|---|---|
| Throughout shelf life | ≥ 6.0 N | EN 455-2:2015 |

| FREEDOM FROM HOLES | PERFORMANCE | TEST METHOD |
|---|---|---|
| Acceptable Quality Level (AQL) | 1.5 - Level 2 of 3 | EN 374-2:2016 |

## CLEANLINESS PROPERTIES

| PARTICLES | TYPICAL PARTICLE COUNT | TEST METHOD |
|---|---|---|
| ≥ 0.5µm (counts/cm$^2$) | < 1200 | IEST-RP-CC005.4 |

| EXTRACTABLES (ION) | TYPICAL VALUE (µg/cm$^2$) | TEST METHOD |
|---|---|---|
| Fluoride (F) | 0.005 | IEST-RP-CC005.4 |
| Chloride (Cl) | 0.750 | IEST-RP-CC005.4 |
| Nitrite ($NO_2$) | 0.042 | IEST-RP-CC005.4 |
| Bromide (Br) | 0.043 | IEST-RP-CC005.4 |
| Nitrate ($NO_3$) | 0.410 | IEST-RP-CC005.4 |
| Phosphate ($PO_4$) | 0.044 | IEST-RP-CC005.4 |
| Sulphate ($SO_4$) | 0.120 | IEST-RP-CC005.4 |
| Lithium (Li) | 0.006 | IEST-RP-CC005.4 |
| Sodium (Na) | 0.040 | IEST-RP-CC005.4 |
| Ammonium ($NH_4$) | 0.110 | IEST-RP-CC005.4 |
| Potassium (K) | 0.050 | IEST-RP-CC005.4 |
| Calcium (Ca) | 0.510 | IEST-RP-CC005.4 |
| Magnesium (Mg) | 0.010 | IEST-RP-CC005.4 |
| Zinc (Zn) | 0.536 | IEST-RP-CC005.4 |

** ND = Not Detected*

# TECHNICAL PROPERTIES

| NORM | TEST REFERENCE | EXPLANATION |
|---|---|---|
| Chemical innocuousness | EN ISO 21420:2020 | Ensures the gloves do not adversely affect the health of the user. The materials present in the gloves must not release substances that are toxic |
| Sizing & dexterity | EN ISO 21420:2020 and<br>EN ISO 374-2:2019 | Determines sizing compliance and glove dexterity |
| Air leak & water leak | EN ISO 374-2:2019 | Assesses the resistance of the glove to penetration |
| Chemical degradation | EN ISO 374-4:2019 | Determines the resistance to degradation by dangerous chemicals |
| Chemical permeation | EN 16523-1:2015+A1:2018 | Determines the resistance of protective glove materials to permeation by potentially hazardous non-gaseous chemicals |
| Viral penetration | EN 16604:2004 | Assesses the resistance of glove materials to penetration by blood-borne pathogens |
| Endotoxin test | EN 455-3, USP | Specifies requirements for the evaluation of biological safety for gloves |
| EU type certificate | EN ISO 374-1:2016+A1:2018 Type B<br>EN ISO 374-5:2016<br>EN ISO 374-4:2019 | The applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product |
| UKCA type certificate | EN ISO 374-1:2016+A1:2018 Type B<br>EN ISO 374-5:2016<br>EN ISO 374-4:2019 | The applicable essential health and safety requirements of PPE Regulation (2016/425) as brought into UK law and amended as a Category III product |



## LOADING

| | EURO-PALLET | STANDARD PALLET |
|---|---|---|
| Pallet size | W80 L120cm | W100 L120cm |
| Gross weight | 14.1 - 16.4kg | 14.1 - 16.4kg |
| Carton size | W28 L43 H31cm | W28 L43 H31cm |
| Nett weight | 12.1 - 14.4kg | 12.1 - 14.4kg |
| Air freight pallet | Max height: 139cm<br>Layers: 4<br>Cartons: 24 | Max height: 139cm<br>Layers: 4<br>Cartons: 32 |
| Sea freight pallet | Max height: 170cm<br>Layers: 5<br>Cartons: 30 | Max height: 170cm<br>Layers: 5<br>Cartons: 40 |

## DOCUMENTATION

**CERTIFICATE OF CONFORMANCE (COC)**
**CERTIFICATE OF ANALYSIS (COA)**
View sample of COC, COA

**DECLARATION OF CONFORMITY (DOC)**
Download

**FACTORY RELATED CERTIFICATIONS**
To request ISO9001 Certificate, please email us




Country of origin: **Malaysia**
HS Code: 4015199000

*This data sheet and any other claims made by or on behalf of Isofield shall not be taken as a warranty of merchantability or as a statement that any Isofield products are suitable for a specific purpose. Isofield shall not be held responsible for the end user's choice of product for a particular application.*

**EUROPE**

**ISOFIELD (IRELAND) LTD**
70 Northumberland Road, Ballsbridge Dublin 4,
Ireland T +44 (0) 1638 6762 39

**ASIA**

**ISOFIELD SDN BHD**
6 Jalan Gudang 16/9, Seksyen 16, 40200, Shah Alam,
Selangor, Malaysia, T +603 5512 1709

**CONTACT**

www.isofield.com
info@isofield.com