



Empfohlene Reinraumklassen

ISO 5|6|7|8|9

GMP C|D

Latex-Handschuhe Isofield LS400

pure¹¹-Nr.: 1130468, Marke: ISOFIELD

Eigenschaften

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

Material

- Latex

Verpackung

- 1000STK

Produktvarianten

pure¹¹-Nr.: 1130468NCS, Latex-Handschuhe Isofield LS400

Farbe: Natur; Größe: S / VE: 1000STK

pure¹¹-Nr.: 1130468NCL, Latex-Handschuhe Isofield LS400

Farbe: Natur; Größe: L / VE: 1000STK

pure¹¹-Nr.: 1130468NCM, Latex-Handschuhe Isofield LS400

Farbe: Natur; Größe: M / VE: 1000STK

pure¹¹-Nr.: 1130468NCXL, Latex-Handschuhe Isofield LS400

Farbe: Natur; Größe: XL / VE: 1000STK

pure¹¹-Nr.: 1130468NCXXL, Latex-Handschuhe Isofield LS400

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



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



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	IENT-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm ²)	TEST METHOD
Fluoride (F)	0.005	IENT-RP-CC005.4
Chloride (Cl)	0.750	IENT-RP-CC005.4
Nitrite (NO ₂)	0.042	IENT-RP-CC005.4
Bromide (Br)	0.043	IENT-RP-CC005.4
Nitrate (NO ₃)	0.410	IENT-RP-CC005.4
Phosphate (PO ₄)	0.044	IENT-RP-CC005.4
Sulphate (SO ₄)	0.120	IENT-RP-CC005.4
Lithium (Li)	0.006	IENT-RP-CC005.4
Sodium (Na)	0.040	IENT-RP-CC005.4
Ammonium (NH ₄)	0.110	IENT-RP-CC005.4
Potassium (K)	0.050	IENT-RP-CC005.4
Calcium (Ca)	0.510	IENT-RP-CC005.4
Magnesium (Mg)	0.010	IENT-RP-CC005.4
Zinc (Zn)	0.536	IENT-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 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 EN ISO 374-5:2016 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 EN ISO 374-5:2016 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 Layers: 4 Cartons: 24	Max height: 139cm Layers: 4 Cartons: 32
Sea freight pallet	Max height: 170cm Layers: 5 Cartons: 30	Max height: 170cm Layers: 5 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