

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

Eigenschaften

Empfohlene Reinraumklassen

ISO

GMP

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

-

Verpackung

- Box

Produktvarianten

pure[11]-Nr.: 1130468,

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 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

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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