

pure[11]-Nr.: 1130467, 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.: 1130467,

pure[11]-Nr.: 1130467WHL, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: L / VE: 1000STK

pure[11]-Nr.: 1130467WHM, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: M / VE: 1000STK

pure[11]-Nr.: 1130467WHS, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: S / VE: 1000STK

pure[11]-Nr.: 1130467WHXL, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: XL / VE: 1000STK

pure[11]-Nr.: 1130467WHXXL, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: XXL / VE: 1000STK

Isofield®
Protecting Life Science



Isofield NS400

400mm (16”) Non-sterile nitrile Cleanroom gloves

Last updated **18 Mar 2024**

PRODUCT CODE

REF 20340

SMALL	20340S
MEDIUM	20340M
LARGE	20340L
XLARGE	20340XL
XXLARGE	20340XXL

CE 2797 AQL 1.5

PRODUCT INFO

Non-sterile nitrile Cleanroom gloves
400mm (16”) elbow length
Ambidextrous
White colour
Textured palm & fingers
Beaded cuff
Low endotoxin levels
Tested against a range of chemotherapy drugs
Complies with EU food-grade regulation (EU) No 10/2011
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 components before and after washing

Transportation and loading of vials

Preparation of ointments and creams before filling

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	0.17	6.69	EN 455-2:2015
Palm	0.11	4.33	EN 455-2:2015
Cuff	0.09	3.54	EN 455-2:2015

** +/- 0.02mm*

LENGTH	MIN	TYPICAL	TEST METHOD
From tip of middle finger to edge of cuff	390mm	400mm	EN 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)	< 1800	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm^2)	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.031	IEST-RP-CC005.4
Bromide (Br)	ND	IEST-RP-CC005.4
Nitrate (NO_3)	0.500	IEST-RP-CC005.4
Phosphate (PO_4)	0.062	IEST-RP-CC005.4
Sulphate (SO_4)	0.012	IEST-RP-CC005.4
Sodium (Na)	0.050	IEST-RP-CC005.4
Ammonium (NH_4)	0.020	IEST-RP-CC005.4
Potassium (K)	0.064	IEST-RP-CC005.4
Calcium (Ca)	0.432	IEST-RP-CC005.4
Magnesium (Mg)	ND	IEST-RP-CC005.4
Zinc (Zn)	ND	IEST-RP-CC005.4

** ND = Not Detected*

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME	TEST METHOD
Carmustine	66 min	ASTM D6978-05
Cisplatin	> 240 min	ASTM D6978-05
Cyclophosphamide	> 240 min	ASTM D6978-05
Doxorubicin HCl	> 240 min	ASTM D6978-05
Etoposide	> 240 min	ASTM D6978-05
Fluorouracil	> 240 min	ASTM D6978-05
Methotrexate	> 240 min	ASTM D6978-05
Paclitaxel	> 240 min	ASTM D6978-05
Thiotepa	117 min	ASTM D6978-05

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
Permeation based on Chemotherapy Drugs	ASTM D6978-05 (2019)	Assesses the resistance of glove materials to permeation by potentially hazardous chemotherapy drugs
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	11.3 - 14.9kg	11.3 - 14.9kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	9.3 - 12.9kg	9.3 - 12.9kg
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