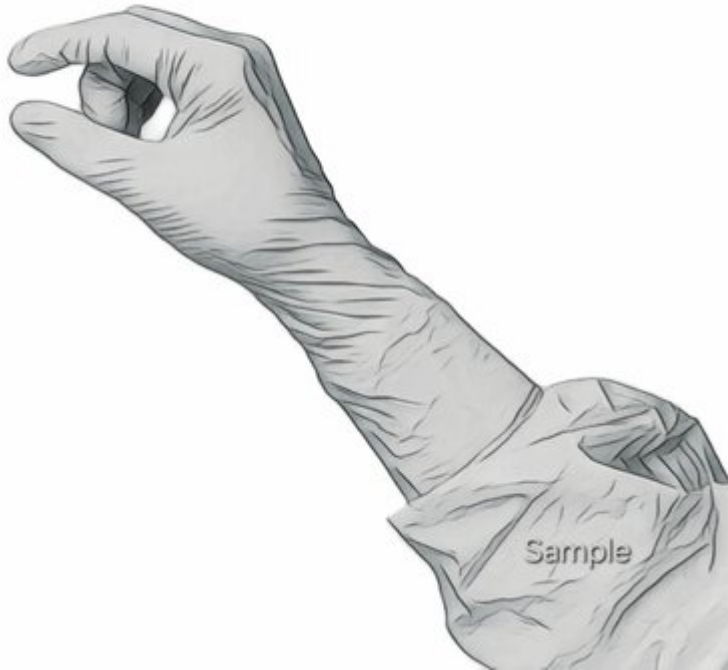


pure¹¹-Nr.: 1130467, Marke:

Eigenschaften



Empfohlene Reinraumklassen

ISO

GMP

Material

-

Verpackung

- Box

Produktvarianten

pure¹¹-Nr.: 1130467,

pure¹¹-Nr.: 1130467WHL, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: L / VE: 1000STK

pure¹¹-Nr.: 1130467WHM, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: M / VE: 1000STK

pure¹¹-Nr.: 1130467WHS, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: S / VE: 1000STK

pure¹¹-Nr.: 1130467WHXL, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: XL / VE: 1000STK

pure¹¹-Nr.: 1130467WHXXL, Nitril-Handschuhe Isofield NS400

Farbe: Weiß; Größe: XXL / VE: 1000STK



Isofield NS400

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

Last updated **18 Mar 2024**

| | | | | |
|---------------------|--------------|----------------|-----------------|--|
| PRODUCT CODE | REF | SMALL | 20340S |              |
| | 20340 | MEDIUM | 20340M | |
| | | LARGE | 20340L | |
| | | XLARGE | 20340XL | |
| | | XXLARGE | 20340XXL | |

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

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.



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