

ISOFIELD



Empfohlene Reinraumklassen

ISO 4|5|6|7|8|9

GMP A/B|C|D



Mundschutz Isofield Exa+ 250

pure¹¹-Nr.: 1131310, Marke: ISOFIELD

Eigenschaften

- Steril
- Marke: ISOFIELD
- Art des Mundschutzes: Reinraum-Mundschutz
- Gebrauch: Einweg
- Fixierung: mit Kopfband
- Material: Polyester
- Anzahl Lagen: 3
- Passform: breit
- Farbe: Weiß
- Verpackungsform: einzeln verpackt
- Anzahl in kleinster Unterverpackung: 1
- Breite in cm: 25 cm
- Latexfrei
- Materialzusammensetzung: Reinmaterial
- Nasenbügel
- Verwendbar mit Halteclip

Material

- Polyester

Verpackung

- 500STK

Produktvarianten

pure¹¹-Nr.: 1131310, Mundschutz Isofield Exa+ 250

Steril; Fixierung: Mit Clip; Breite: 25 cm / VE: 500STK



Isofield Exa+ 250

Validated sterile pouch-style earloop
Cleanroom facemask with clip

Last updated **10 Feb 2025**

PRODUCT CODE

REF 60411
SIZE UNIVERSAL



PRODUCT INFO

Validated sterile earloop Cleanroom facemask with clip
Ultra-wide 250mm length with malleable nose strip
Large pouch style breathing chamber
Extended lower breathing chamber provides excellent coverage at neck
Highly efficient bacterial and particle filtration
Gamma irradiation, minimum 25 kGy
Sterility Assurance Level 10^{-6}
Particle Shedding (Helmke Drum) Category I
Printed with IPA resistant ink to maintain traceability

CLEANROOM COMPATIBILITY

GMP Grade A cleanroom
GMP Grade B cleanroom
ISO Class 4 cleanroom
ISO Class 5 cleanroom
Class 10 cleanroom
Class 100 cleanroom

QUALITY ASSURANCE

Manufactured in a facility operating under an ISO 9001:2015 quality management system
Processed in a NEBB certified ISO Class 5 cleanroom

APPLICATIONS

Removal and cooling of items from heat sterilizers
Handling sterile starting materials and components
Replenishment of sterile product, containers and closures

STORAGE & SHELF LIFE

Store in a dry, cool place ($<40^{\circ}\text{C}$) away from direct sunlight
Do not expose open cartons to prolonged direct fluorescent light
Five (5) years from date of manufacture

PACKAGING

1 piece per sealed inner PE bag,
50 inner bags per sealed outer PE bag,
10 outer bags per lined carton
(500 pieces)

PHYSICAL PROPERTIES

LENGTH	WIDTH	COLOUR	STYLE
250mm (± 5mm)	95mm (± 5mm)	White	Earloop with clip

MATERIALS

Outer layer	Non-woven spunbond polyester
Filtration Layer	Non-woven meltblown polyester
Inner facing layer	Non-woven spunbond polyester
Earloops	Non-latex knitted earloops with green polypropylene clip fastener

FILTRATION PROPERTIES

Particle Filtration Efficiency (PFE) @ 0.1 Micron	94.9%
Bacterial Filtration Efficiency (BFE) @ 0.3 Micron	97.1%
Differential Pressure (ΔP), mm H ₂ O/cm ²	6.0



TECHNICAL PROPERTIES

NORM	TEST REFERENCE	EXPLANATION
Sterility Validation Test	EN ISO 11137 Part 2:2015	Specifies requirements for the development, validation and routine control of a radiation sterilization process
Particle Generation Test by Helmke Drum	IEST-RP-CC003.4	Specifies methods for particle shed analysis in Helmke Drum applications

HELMKE DRUM TEST RESULT

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	CLASS
≥ 0.3µm	85	less than 2000	1
≥ 0.5µm	26	less than 1200	1

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	5.20kg	5.20kg
Carton size	W29.5 L47 H21cm	W29.5 L47 H21cm
Nett weight	3.40kg	3.40kg
Air freight pallet	Max height: 141cm Layers: 6 Cartons: 36	Max height: 141cm Layers: 6 Cartons: 42
Sea freight pallet	Max height: 162cm Layers: 7 Cartons: 42	Max height: 162cm Layers: 7 Cartons: 49

DOCUMENTATION



CERTIFICATE OF CONFORMANCE (COC)
CERTIFICATE OF ANALYSIS (COA)
CERTIFICATE OF IRRADIATION (COI)

Please [email us](#)



FACTORY RELATED CERTIFICATIONS
To request ISO9001 Certificate,
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Country of origin: **China**
HS Code: 6307909

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