



# Isofield Exa+ 250

## Validated sterile pouch-style earloop Cleanroom facemask with clip

Last updated **10 Feb 2025**

<b>PRODUCT CODE</b>	<b>REF 60411</b>		<b>STERILE R</b>
	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 ( $\Delta P$ ), mm H <sub>2</sub> O/cm <sup>2</sup>	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,  
please [email us](#)



Country of origin: **China**  
HS Code: 6307909

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