



# Isofield Vista Overboots

Sterile Cleanroom Overboots

Last updated 29 May 2024

PRODUCT CODE	<b>REF 80761</b>	
	SIZE UNIVERSAL	

## PRODUCT INFO

Sterile Cleanroom overboots  
Extra long — 50cm knee height  
Two ties for added security  
Anti-slip PU sole  
Aseptically folded

## 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 ISO 9001:2015 quality management system  
Processed in a NEBB certified ISO Class 5 cleanroom

## APPLICATIONS

Pharmaceutical product preparation  
Cleanroom cleaning and preparation  
Aseptic filling and labelling  
Medical device manufacturing  
Blending operations for biotechnologies  
Handling of active materials  
Maintenance of equipment and instruments

## 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

1 pair per inner bag,  
10 pairs per outer bag,  
8 outer bags per carton,  
80 pairs per carton

## MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic Weight	g/m <sup>2</sup>	ISO 9073-1-1989	±2	60
Machine Direction Strength	N/5cm		≥50	69
Machine Direction Elongation	%		≥100	109
Cross Direction Strength	N/5cm		≥25	43
Cross Direction Elongation	%		≥100	111
Hydrostatic Head	mmH <sub>2</sub> O	ISO 811-1981	≥100	213
Air Permeability	l/m <sup>2</sup> /S	GB/T5453	≥	2000
Surface Resistivity	Ω	ISO 9073-1-1989	/	10 <sup>-7</sup>
Slip Resistance	Coefficient of Friction (COF)	ASTM D1894	≥0.5	0.6 (Static) 0.5 (Dynamic)

## HELMKE DRUM TEST RESULT

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	TYPICAL
≥ 0.3µm	781	less than 2000	< 700
≥ 0.5µm	310	less than 1200	< 1000

## ASTM F739-20 TEST METHOD

### CHEMOTHERAPY DRUGS TESTED

MEAN BREAKTHROUGH TIME (MBT), MINUTES BREAKTHROUGH OF THE TEST CHEMICAL IS DEEMED TO HAVE OCCURRED WHEN THE PERMEATION RATE HAS REACHED 0.11 µG/CM<sup>2</sup>/MIN\*

Carmustine	30 mins
Cisplatin	> 480 mins
Cyclophosphamide	> 480 mins
Doxorubicin HCl	> 480 mins
Etoposide	> 480 mins
Fluorouracil	> 480 mins
Methotrexate	> 480 mins
Paclitaxel	> 480 mins
Thiotepa	60 mins

\*Results achieved under controlled laboratory conditions, by accredited ISO 17025 third party testing laboratory

## LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	7.8kg	7.8kg
Carton size	W43 L28 H31cm	W43 L28 H31cm
Nett weight	6.0kg	6.0kg
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)  
CERTIFICATE OF IRRADIATION (COI)

View [sample](#) of COC, COA, COI



FACTORY RELATED CERTIFICATIONS  
To request ISO9001 Certificate,  
please [email us](#)



Country of origin: **Malaysia / China**  
HS Code: 6210109000

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