Isofield®
Protecting Life Science

Isofield Volta

300mm (12”) Sterile nitrile Cleanroom gloves

Last updated **01 May 2024**

PRODUCT CODE

REF **20530**

SIZE 6.0	2053060	SIZE 8.0	2053080
SIZE 6.5	2053065	SIZE 8.5	2053085
SIZE 7.0	2053070	SIZE 9.0	2053090
SIZE 7.5	2053075	SIZE 10.0	20530100

CE 2797 UK CA 0086 AQL 0.65 STERILE R

PRODUCT INFO

Sterile nitrile Cleanroom gloves
300mm (12”)
Hand-specific
Neon green colour
Textured fingers
Beaded cuff
Low endotoxin levels
Gamma irradiation, minimum 25kGy
Sterility Assurance Level 10^{-6}
Accelerator free
Tested against a range of chemotherapy drugs

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

Physical properties comply with European medical glove standard EN 455-2:2015

APPLICATIONS

Manufacture of sterile liquid and lyophilized vials

Filtration, filling, stoppering and capping of vials

Aseptic compounding and mixing

Preparation of sterile emulsions

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 PE wallet,

1 PE wallet per sealed PE pouch,

10 pouches per PE bag,

20 sealed PE bags per lined carton (200 pairs)

PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM*	MILS	TEST METHOD
Finger tip	0.16	6.30	EN 455-2:2015
Palm	0.14	5.51	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	290mm	300mm	EN ISO 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)	0.65 - Level 3 of 3	EN 374-2:2016

CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm^2)	< 900	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm^2)	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.110	IEST-RP-CC005.4
Bromide (Br)	ND	IEST-RP-CC005.4
Nitrate (NO_3)	0.318	IEST-RP-CC005.4
Phosphate (PO_4)	ND	IEST-RP-CC005.4
Sulphate (SO_4)	0.021	IEST-RP-CC005.4
Sodium (Na)	0.006	IEST-RP-CC005.4
Ammonium (NH_4)	0.014	IEST-RP-CC005.4
Potassium (K)	0.034	IEST-RP-CC005.4
Calcium (Ca)	0.522	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 (MINS)	TEST METHOD
Carmustine	48 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	108 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
Permeation based on Chemotherapy Drugs	ASTM D6978-05 (2019)	Assesses the resistance of glove materials to permeation by potentially hazardous chemotherapy drugs
Sterility validation test	EN ISO 11137 Part 2:2015	Specifies requirements for the development, validation and routine control of a radiation sterilization process
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	W80 L120cm
Gross weight	4.77 - 6.41kg	4.77 - 6.41kg
Carton size	W28 L32 H30cm	W28 L32 H30cm
Nett weight	2.27 - 3.91kg	2.27 - 3.91kg
Air freight pallet	Max height: 135cm Layers: 4 Cartons: 32	Max height: 135cm Layers: 4 Cartons: 48
Sea freight pallet	Max height: 165cm Layers: 5 Cartons: 40	Max height: 165cm Layers: 5 Cartons: 60

DOCUMENTATION

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

View sample of COC, COA, COI

DECLARATION OF CONFORMITY (DOC)

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FACTORY RELATED CERTIFICATIONS

To request ISO9001 Certificate, please email us

Country of origin: **Malaysia**
HS Code: 4015199000

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