

# Isofield CRN+

## Sterile 400mm (16") Cleanroom Nitrile Gloves



### PRODUCT INFO

GMP Grade A compatible  
ISO Class 4 & 5 compatible  
Sterile  
Nitrile  
White colour  
Elbow length 400mm (16")  
Ambidextrous  
Textured palm and fingers  
Beaded cuff

### 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 EN455-2:2015

### STERILIZATION

Gamma irradiation, Minimum 25 kGy

### SHELF LIFE

Three (3) years from date of manufacture

### STORAGE

Store in a dry, cool place (<40°C) away from direct sunlight. Do not expose open cartons to prolonged direct fluorescent light

### PACKING

One pair per inner PE wallet,  
One PE wallet per sealed PE pouch,  
10 pouches per PE bag,  
20 sealed PE bags per lined carton (200 pairs)

PRODUCT CODE		
<b>REF 20240</b>		
SMALL	6.0-6.5	20240S
MEDIUM	7.0-7.5	20240M
LARGE	8.0- 8.5	20240L
XLARGE	9.0	20240XL



### PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM*	MILS	TEST METHOD
Finger tip	0.17	6.69	EN455-2:2015
Palm	0.11	4.33	
Cuff	0.09	3.54	

\* +/- 0.02mm

LENGTH	MIN	TYPICAL	TEST METHOD
From tip of middle finger to edge of cuff	390mm	400mm	EN ISO 21420 :2020

STRENGTH PROPERTIES	FORCE AT BREAK	TEST METHOD
Throughout shelf life	≥ 6.0 N	EN455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	0.65 - Level 3 of 3	EN374-2:2016

### CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm <sup>2</sup> )	1800	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm <sup>2</sup> )	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.031	
Bromide (Br)	ND	
Nitrate (NO <sub>3</sub> )	0.500	
Phosphate (PO <sub>4</sub> )	0.062	
Sulphate (SO <sub>4</sub> )	0.012	
Sodium (Na)	0.050	
Ammonium (NH <sub>4</sub> )	0.020	
Potassium (K)	0.064	
Calcium (Ca)	0.432	
Magnesium (Mg)	ND	
Zinc (Zn)	ND	

\* ND = Not Detected