

Sterile Nitrile Cleanroom gloves Ambidextrous

- ISO Class 5 & EU GMP Grade A
- Surface: Finger Texture
- Shape: Ambidextrous
- Sterilisation: Gamma Irradiation
- Powder free
- Anti-static
- Trippel Packed
- Accelerator free
- AQL 1

Tested according to:

- EN374-2 (2014)
- EN420 6.2 (2003) + AI (2009)
- EN420 6.1 (2003) + AI (2009)
- ISO 3071 (2020)
- EN 16523-1 2015 + AI (2018)
- ISO 374-4 (2019)
- EN ISO 374-1: 2016 TYPE B
- EN ISO 374-5: 2015

Sterilization Method: Gamma irradiation

Minimum Dose: 25kGy

Sterility Assurance Level: 10⁻⁶

Shelf Life & Storage:

Five (5) years from date of manufacture

Store in a dry, cool place



MATERIAL	COLOUR	LENGTH	PACKING
Nitrile	Green	Min. 300 mm	10 pairs per tripple pack 200 pairs per carton

SIZE	XS	S	M	L	XL	XXL
ITEM NO.	200200	200200	200200	200200	200200	200200



SPECIFICATIONS



CRS 200

Sterile Nitrile Cleanroom gloves

Material	100 % Nitrile
Liquid particle test Particle size of 0,5 micron only	Max 1200 counts / cm ² (Tested in accordance to IEST- RP- CC- 005.2: Orbital shaking method)
Cobber corrosion test	No visible discoloration
FTIR	No silicone, amide and DOP detected (Tested in accordance to IES- RP- CC- 005,2)
Non-volatile residue (NVR) in Water	< 3.0ug/cm ² (Tested in accordance to IES- RP- CC- 005,2)
Surface Resistivity (SR)	10 ⁹ 10 ¹¹ Ω/sq (antistatic) (Tested in accordance to ASTM D257-93)
Design and Feature	Ambidextrous, straight fingers, fingertips textured and beaded

TRACE ELEMENTS	Less than (µg/cm ²)
F	<0.01
CL	<0.30
NO ₂	<0.01
Br	<0.01
NO ₃ ⁻	<0.20
PO ₄ ⁻	<0.10
SO ₄ ⁻	<0.05
NA ⁺	<0.05
K ⁺	<0.05
Ca ²⁺	<0.05
Mg ²⁺	<0.05

(Tested in accordance to IEST- RP- CC- 005.2)

LOCATION OF THICKNESS MEASUREMENTS	Single wall (mm)
Finger (at 13 ± 3mm from fingertip)	Min. 0.17
Palm (at center of palm)	Min. 0.13
Cuff (at 25 ± 5mm from cuff edge)	Min. 0.10

PHYSICAL PROPERTIES	BEFORE AGING	AFTER AGING
Force at break	≥ 6N	≥ 6N

Quality Assurance

Meet or exceed ASTM D 6319 on water leak & dimension .
Meet or exceed EN 455 - 1 & 2.

Manufactured under GMP, ISO 9001, ISO 13485 quality system

Recommended usage

Cleanroom ISO 5

Pharmaceutical, Hospital, Biotech, and other areas where clean sterile gloves with good ESD properties are required,



CHEMOTHERAPY TEST

CRS 200



Chemotherapy Drugs	Minimum Breakthrough Time	Average Steady State Perm.Rate
Capecitabine, 26mg/ml (26.000ppm)	>240 min	N/A
Carboplatin 10 mg/ml (10.000ppm)	>240 min	N/A
Carmustine 3.3 mg/ml (3,3000ppm)	128.7 (138.8, 185.6, 128,7)	0.10 0.06, 0.17, 0.06
Cisplatin 1 mg/ml (1,000 ppm)	>240 min	N/A
Cyclophosphamide 20 mg/ml (20,000 ppm)	>240 min	N/A
Docetaxel 20 mg/ml (20,000 ppm)	>240 min	N/A
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	>240 min	N/A
Epirubicin HCl, 2 mg/ml (2,000 ppm)	>240 min	N/A
Etoposide, 20 mg/ml (20,000 ppm)	>240 min	N/A
Fluorouracil, 50 mg/ml (50,000 ppm)	>240 min	N/A
Gemcitabine HCl, 38 mg/ml (38,000 ppm)	>240 min	N/A
Irinotecan HCl, 20 mg/ml (20,000 ppm)	>240 min	N/A
Methotrexate, 25 mg/ml (25,000 ppm)	>240 min	N/A
Mitoxantrone HCl, 2 mg/ml (2,000 ppm)	>240 min	N/A
Oxaliplatin , 5 mg/ml (5,000 ppm)	>240 min	N/A
Paclitaxel, 6 mg/ml (6,000 ppm)	>240 min	N/A
Rituximab, 10 mg/ml (10,000 ppm)	>240 min	N/A
Thiotepa, 10 mg/ml (10,000 ppm)	58.3 (58.3, 58.3, 59.4)	0,02 (0.03, 0.02, 0.02)
Vinorelbine, 10 mg/ml (10,000 ppm)	240 min	N/A

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