

CRS 100

Sterile Nitrile Cleanroom gloves

- ISO Class 5 & EU GMP Grade A
- Surface: Finger Texture
- Shape: Hand Specific (left and right)
- Sterilisation: Gamma Irradiation
- Powder free
- Anti-static
- Micro Textured
- Trippel Packed
- Accelerator free
- AQL 1.0

Tested according to:

- AQL 1,5
- 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	White	Min. 300 mm	10 pairs per tripple pack 200 pairs per carton

SIZE	6,5	7,0	7,5	8,0	8,5	9,0
ITEM NO.	100137	100138	100139	100140	100141	100142



SPECIFICATIONS



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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	Max. 30 mg/g (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. 0.14
Palm (at center of palm)	Min. 0.12
Cuff (at 25 ± 5mm from cuff edge)	Min. 0.08

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

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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

Odateret: 02.03.2025