

Sterile latex cleanroom gloves, designed for use in Class 10 (ISO 4) environments

- **Enhanced comfort and dexterity:** Designed for Class 10 (ISO 4) cleanroom environments and aseptic applications, AccuTech[®] 91-210 sterile gloves' hand-specific design enhances both comfort and dexterity
- **Assured product protection:** Product protection is also improved thanks to these latex gloves' low levels of extractables and particles
- **Reduced allergy risks:** Their thick latex design features low protein content, reducing related allergy risks
- **Improved usability:** In addition, these sterile disposable gloves' silicone coating facilitates both donning and double gloving



KEY FEATURES & BENEFITS

- **Hand-specific design:** Dexterous, comfortable hand protection
- **Low extractable and particle levels:** Assured product protection
- **Latex formulation with lower protein content:** Fewer allergy risks

Industries

- Biotechnology Manufacturing
- Laboratory Research and Development
- Pharmaceutical Manufacturing
- Controlled and Critical Environments

Recommended For

- Aseptic filling and labelling
- Blending, compounding solids and liquids
- Sample taking and processing
- Transferring liquids and solids



TECHNICAL DATA SHEET

Product Information	
Material	Natural Rubber Latex
Color	Natural
Shape	Hand Specific
Cuff	Beaded
Manufacturing/QMS Audit Standards	ISO 9001:2015
Regulatory/Standard Compliance	CE 0493, EN 420:2003 + A1:2009, EN 556-1:2001, EN ISO 21420:2020, EN ISO 374-5:2016, EN 421:2010, Please consult the IFU, ISO 13485, ISO 14001
Packaging	1 pair per poly wallet, sealed in inner polybag; 10 poly wallet per master polybag; 5 master polybags per intermediate liner; 4 intermediate liners per carton; 200 pairs per carton
Storage	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.
Country of Origin	Malaysia
Available sizes	6.0 (XS), 6.5(S), 7.0 (S), 7.5(M), 8.0(M), 8.5(L), 9.0(L)
Powder Content	Powder-Free
External Glove Surface	Textured Fingers
Internal Glove Surface	Chlorinated
Sterilization Method	GAMMA irradiation (25 kGy)
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
Shelf Life	3 years
Tested for use with Chemotherapy Drugs	No
Protein Level	50 µg/dm ² or less of total extractable protein
Anti-static	Not Tested

Physical Properties		Testing Method
Typical Length (mm/in)	280 / 11	EN 420/ASTM D3767
Freedom from Holes	1.5 AQL	EN 455-1/ASTM D3577
Typical Particle Count $\geq 0.5\mu\text{m}$ (counts / cm^2)	< 600 particles / cm^2	IENT-RP-CC005.4
Target Single Wall Palm Thickness (mm/mil)	0.21 (+/-0.03) / 8.3	EN 420/ASTM D3767
Target Single Wall Finger Thickness (mm/mil)	0.24 (+/-0.04) / 9.4	EN 420/ASTM D3767
Target Single Wall Cuff Thickness (mm/mil)	0.18 (+/-0.02) / 7.1	EN 420/ASTM D3767
Ultimate tensile strength (MPa) Before Aging	20	ASTM D412-06a
Ultimate tensile strength (MPa) During Aging	N/A	ASTM D412-06a
Force at Break (N) Before Aging	N/A	EN 455-2
Force at Break (N) During Aging	N/A	EN 455-2

PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE



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