

# Protection of Products and Processes

### **KIMTECH PURE\* Gloves**

Kimberly-Clark\* has long been recognised for the development of technologically advanced products that meet the quality needs of laboratories and cleanrooms worldwide.

Our KIMTECH PURE\* Glove range is built from the former Safeskin products and supports the critical and controlled cleanroom environments.

Whatever the individual needs of your environment...

Our trusted and reliable products for use in cleanroom environments are designed to provide solutions for cleanliness, contamination control and people protection

- Pharmaceutical manufacturing
- Drug manufacturing
- Biotechnology
- Biomedical
- Medical devices
- Semiconductor
- Electronics

When selecting the appropriate cleanroom glove, the following factors may be taken into account.

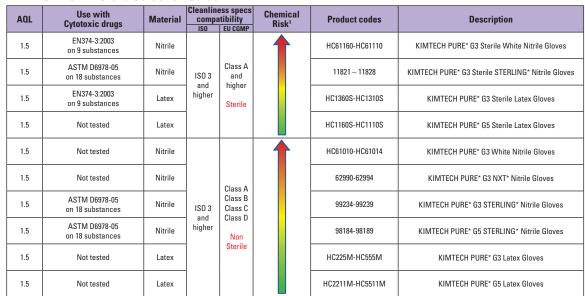
Compliance with standards / norms	Barrier protection (chemical and biohazard)	Bio- compatibility	Traceability	Ergonomics / Allergenicity
Personal Protection  CE Marking  89/686/EEC  EN 420:2003  Process Protection  ISO 14644-1  EC GMP  IEST-RP-CC005  LAL Test (Kinetic Turbimetric Tech)  Low Pre-Sterilization Bioburden Level  Processed to reduce & control  DNAse, RNase, Protease	Chemical Protection EN374:2003 Cytotoxic Drugs Protection EN374-3-2003 ASTM F 739-99 a ASTM 6978-05 Biohazard Protection EN374-2-2003 ISO 16604 Proc. B:2004 AQL and Inspection Level	Non-cytotoxic Non-pyrogenic Low-endotoxic Non-hemolytic	Product Quality Monitoring Plan cGMP Regulation FDA Regulation ISO Regulation ISO 9002 QSR Packaging	Ergonomics Double donning application Tactile sensitivity and grip Comfort and fit Wearer health and safety  Allergenicity Low in chemical residue Low in protein Low in endotoxin







#### **KIMTECH PURE\* Glove Selection Guide**



<sup>&</sup>lt;sup>1</sup> This information is not intended to replace a hazard analysis and risk assessment by a safety professional or professional judgment in the selection of Personal Protective Equipment(PPE). It is the responsibility of the user to assess the type of hazards and risks associated with exposure and then decide on the appropriate PPE for each circumstance.

## Detailed Quality Assurance and trend data is provided for each lot including the following information:

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Certificate of Analysis (available online www.kimtech.com/certificates)				
Product Information Section Product Description Catalogue numbers Lot Number Batches Number Total case per lot Date of Manufacture  Physical Properties Test Data Visual defects Barrier defects Dimensional defects Pre/post aging tensile strength and elongation	Particle Contamination Test Data  Particle size range (μm)  Minimum Quantity  Maximum Quantity  Standard Deviation  Average particles/cm²  Extractable Contamination Test Data (μg/g glove and μg/cm²)  Anion results (Fluoride, Chloride, Nitrite, Bromide, Nitrate, Phosphate, Sulfate)  Cation results (Sodium, Ammonium, Potassium, Magnesium, Calcium)  Trace element results (Zinc)  Endotoxin Test Data  Endotoxin Units/device (pair) - for G3 Sterile gloves only			

### **Certificate of Irradiation**

Sterilisation batch, Item Specifications, Irradiation date, Quantity processed, Minimum and Maximum Dose required, Minimum and Maximum Dose received

### KIMBERLY-CLARK PROFESSIONAL\* specific Quality Assurance requirements are:

- Low Pre-Sterilisation Bioburden Level
- Complies with universally recognised standard: ANSI/AAMI/ISO 11137
- Meets or Exceeds ASTM Standards

INFORMATION SERVICE For technical enquiries please email infofax@kcc.com For sales enquiries please email kimtech.support@kcc.com

### www.contaminomics.com





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