

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 <ul style="list-style-type: none"> • CE Marking • 89/686/EEC • EN 420:2003 Process Protection <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • EN374:2003 Cytotoxic Drugs Protection <ul style="list-style-type: none"> • EN374-3-2003 • ASTM F 739-99 a • ASTM 6978-05 Biohazard Protection <ul style="list-style-type: none"> • EN374-2-2003 • ISO 16604 Proc. B:2004 • AQL and Inspection Level 	Non-cytotoxic Non-pyrogenic Low-endotoxigenic Non-hemolytic	Product Quality Monitoring Plan cGMP Regulation FDA Regulation ISO Regulation ISO 9002 QSR Packaging	Ergonomics <ul style="list-style-type: none"> • Double donning application • Tactile sensitivity and grip • Comfort and fit • Wearer health and safety Allergenicity <ul style="list-style-type: none"> • Low in chemical residue • Low in protein • Low in endotoxin



KIMTECH PURE* Glove Selection Guide

AQL	Use with Cytotoxic drugs	Material	Cleanliness specs compatibility		Chemical Risk ¹	Product codes	Description
			ISO	EU CGMP			
1.5	EN374-3:2003 on 9 substances	Nitrile	ISO 3 and higher	Class A and higher Sterile		HC61160-HC61110	KIMTECH PURE* G3 Sterile White Nitrile Gloves
1.5	ASTM D6978-05 on 18 substances	Nitrile				11821 – 11828	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves
1.5	EN374-3:2003 on 9 substances	Latex				HC1360S-HC1310S	KIMTECH PURE* G3 Sterile Latex Gloves
1.5	Not tested	Latex				HC1160S-HC1110S	KIMTECH PURE* G5 Sterile Latex Gloves
1.5	Not tested	Nitrile	ISO 3 and higher	Class A Class B Class C Class D Non Sterile		HC61010-HC61014	KIMTECH PURE* G3 White Nitrile Gloves
1.5	Not tested	Nitrile				62990-62994	KIMTECH PURE* G3 NXT* Nitrile Gloves
1.5	ASTM D6978-05 on 18 substances	Nitrile				99234-99239	KIMTECH PURE* G3 STERLING* Nitrile Gloves
1.5	ASTM D6978-05 on 18 substances	Nitrile				98184-98189	KIMTECH PURE* G5 STERLING* Nitrile Gloves
1.5	Not tested	Latex				HC225M-HC555M	KIMTECH PURE* G3 Latex Gloves
1.5	Not tested	Latex				HC2211M-HC5511M	KIMTECH PURE* G5 Latex Gloves
1.5	Not tested	Latex					



CE 0123

¹ 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:

Certificate of Analysis <small>(available online www.kimtech.com/certificates)</small>	
<p>Product Information Section</p> <ul style="list-style-type: none"> Product Description Catalogue numbers Lot Number Batches Number Total case per lot Date of Manufacture <p>Physical Properties Test Data</p> <ul style="list-style-type: none"> Visual defects Barrier defects Dimensional defects Pre/post aging tensile strength and elongation 	<p>Particle Contamination Test Data</p> <ul style="list-style-type: none"> Particle size range (µm) Minimum Quantity Maximum Quantity Standard Deviation Average particles/cm² <p>Extractable Contamination Test Data (µg/g glove and µg/cm²)</p> <ul style="list-style-type: none"> Anion results (Fluoride, Chloride, Nitrite, Bromide, Nitrate, Phosphate, Sulfate) Cation results (Sodium, Ammonium, Potassium, Magnesium, Calcium) Trace element results (Zinc) <p>Endotoxin Test Data</p> <ul style="list-style-type: none"> 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
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