

# The Future of Contamination Control is now in your hands.



**KIMTECH PURE\* G3 Sterile  
Cleanroom Gloves.**

Superior Protection for Exceptional Cleanrooms.

# The business case for Superior Protection in Pharmaceutical manufacturing



>€2 Million

## Contamination Happens

Microbial contamination is #1 major GMP deficiency cited by FDA and EMA<sup>1</sup>

>€2 million. Average cost of annual contamination remediation at a production site<sup>2</sup>



>€200 Million

## People are the #1 source

Lower quality gloves have higher particle & endotoxin levels and are more likely to tear and contaminate<sup>3</sup>

>€200 million. Amount spent by one company dealing with microbial contamination<sup>4</sup>



>€1 Billion

## You can't afford the risk

1/3 of production capacity offline because of quality issues<sup>5</sup>

>€1 Billion. One company's loss in Global Sales due to production shutdown<sup>6</sup>

## Together we create Exceptional Cleanrooms

KIMTECH PURE\* G3 Sterile Cleanroom gloves can drive **cGMP COMPLIANCE** by reducing contamination risk and improving worker safety.



### Protection of Processes

- Manufactured in state-of-the-art ISO 5 Cleanrooms.
- Lowest Particle & Endotoxin levels in the industry<sup>7</sup>
- Validated Sterility Assurance Level of 10<sup>-6</sup>
- Non detectable levels of Silicone, Phthalates and DOP



### Protection of People

- Chemical splash protection from Disinfectants & Cytotoxic drugs<sup>8</sup>
- Micro-Organism, Blood-Borne Pathogen and Virus Protection<sup>9</sup>
- Antistatic Tested, EN1149-3 :2008 static decay time <4 seconds<sup>10</sup>
- Biocompatible per ISO10993-1 non-detectable accelerators



### Assured Compliance

- PPE Category III certified EC Directive 89/686/EEC
- ISO9001, ISO13485 and FDA 21 CFR part 820 accreditation
- ISO11137 Sterile Dose Setting ISO11737 Sterility Validation
- Lot-specific Certificates of Analysis and Irradiation

1. [www.fda.org](http://www.fda.org)

2. PDA Midwest Meeting 032510

3. [www.fda.org](http://www.fda.org)

4. <http://www.fiercepharmamanufacturing.com/story/hospira-manufacturing-problems-arise-inopportune-time/2013-02-28>

5. [http://www.nytimes.com/2012/10/18/business/drug-makers-stalled-in-a-cycle-of-quality-lapses-and-shortages.html?pagewanted=all&\\_r=16](http://www.nytimes.com/2012/10/18/business/drug-makers-stalled-in-a-cycle-of-quality-lapses-and-shortages.html?pagewanted=all&_r=16)

6. <http://www.forbes.com/sites/edsilverman/2012/01/10/254/4>

7. Comparison of published specification data from sterile glove manufacturer websites, performed October 2013. <http://www.forbes.com/sites/edsilverman/2012/01/10/254/>

8. EN374-1:2003 Chemical Splash protection, EN374-3:2003 permeation results on [www.kimtech.eu](http://www.kimtech.eu)

9. EN374-2:2003, ISO16604:2004

10. Applicable to G3 Sterile White Nitrile and G3 Sterile STERLING Nitrile glove only.

# Quality by Design

**Quality is built** into Kimberly-Clark's proprietary glove formulations, state-of-the-art manufacturing processes and accredited laboratory testing.



De-Ionized Water Wash  
ISO 5 Cleanroom



HEPA Filter Drying  
ISO 5 Cleanroom



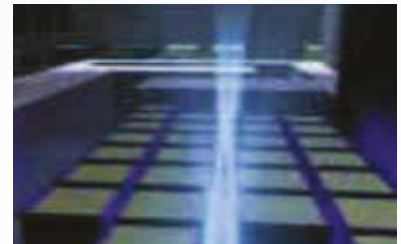
Cleanroom Packing  
ISO 5 Cleanroom



Particle & Extractable Test  
IEST-RP-CC005.3



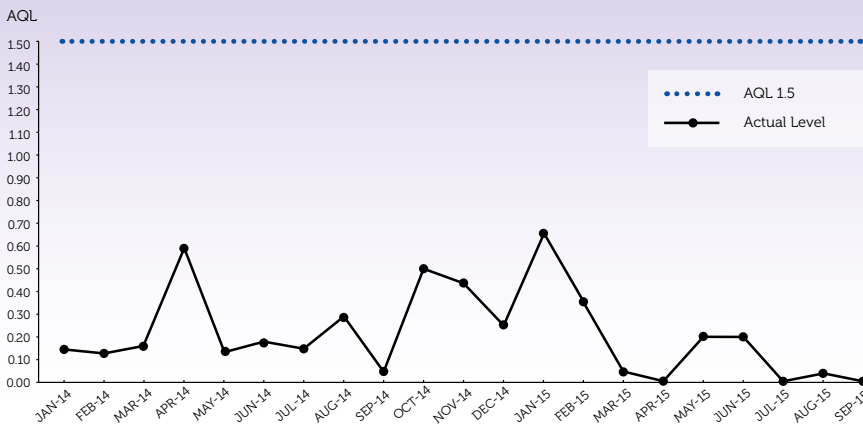
Endotoxin Test  
LAL ASTM D7102-10



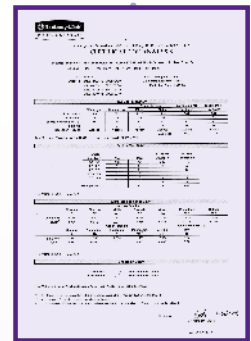
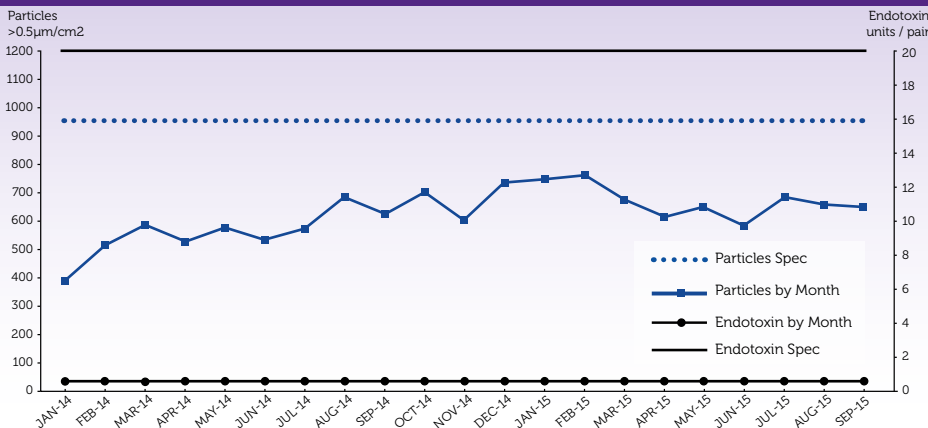
Gamma Irradiation  
EN556-1:2001

**Compliance is delivered** with EC Type Examination, Performance Trend Data, Certificates of Analysis, Certificates of Irradiation and Sterile Dose Validation.

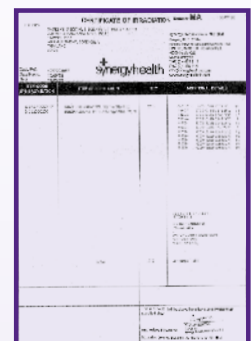
Freedom from Pinholes trend data. KIMTECH PURE\* G3 Sterile Nitrile Gloves, 12" Handspecific Pair.



Particles and Endotoxin trend data. KIMTECH PURE\* G3 Sterile Nitrile Gloves, 12" Handspecific Pairs.



Certificate of Analysis



Certificate of Irradiation

Certificates and trend data available:  
[www.kcproductselector.com/certificates](http://www.kcproductselector.com/certificates)

# KIMTECH PURE\* G3 Sterile Cleanroom Gloves Disinfectant & Chemicals

## Breakthrough times with test method EN374-3:2003

EN374-3:2003 Permeation breakthrough times							
Class	0	1	2	3	4	5	6
Time	<10	10-30	30-60	60-120	120-240	240-480	>480
Usage	Not recommended	Splash protection		Medium protection		High protection	

Chemicals	Concentration	CAS Number	Application	Breakthrough time (minutes)		
				KIMTECH PURE* G3 Sterile Latex	KIMTECH PURE* G3 Sterile STERLING	KIMTECH PURE* G3 Sterile White Nitrile
Premier Klercide-CR Biocide A	100%	N/A	Biguanide and Quat	>480	>480	>480
Premier Klercide Biocide B	100%	N/A	Chlorine based and Quat	Not tested	>480	>480
Premier Klercide-CR Biocide C	100%	N/A	Peroxide	>480	>480	>480
Premier Klercide Biocide X	100%	N/A	Biguanide and Quat	>480	Not tested	Not tested
Premier WFI Klercide 70/30 IPA	N/A	N/A	Alcohol	Not tested	103	158
Premier-WFI Klercide 70/30 Sterile Denatured Ethanol	N/A	N/A	Alcohol	<5	28	39
Amphospray 41 IP Sterile	100%	N/A	Alcohol, Biguanide and Quat	<5	45	31
Anios H2O2 6% IP Sterile	100%	N/A	Peroxide	>480	>480	>480
Aniospray SF IP Sterile	100%	N/A	Alcohol and Aldehyde	<5	74	57
Anioxy Spray WS IP Sterile	100%	N/A	Alcohol and Peroxide	<5	>480	191
Bacterianos SF IP Sterile	100%	N/A	Aldehyde and Quat	>480	>480	>480
Hexanios G+R IP Sterile	100%	N/A	Biguanide and Quat	>480	>480	>480
Surfanios IP Sterile	100%	N/A	Quat	>480	>480	>480
Environ LpH	0.8%	N/A	Phenolic	46	>480	>480
Environ LpH	100%	N/A	Phenolic	12	65	111
Formaldehyde	37%	50-00-0	Aldehyde Disinfectant, Chemical Synthesis	>480	>480	>480
Hydrogen Peroxide	30%	7722-84-184-1	Peroxide	>480	>480	>480
Peracetic acid	5%	79-21-0	Disinfectant	>480	180	>480
Sodium Hypochlorite (Bleach)	14%	7681-52-9	Chlorine Based Disinfectant	>480	Not tested	Not tested
SporKlenz	100%	N/A	Peracetic Acid and Hydroxide	>480	>480	>480
Acrylamide	40%	79-06-1	Electrophoresis, DNA analysis	Not tested	>480	>480
1-butanol	99%	71-36-3	Chemical Extraction, Liquid Chromotography	Not tested	32	174
Citric acid monohydrate	30%	5949-29-1	Passivate high-purity process piping	Not tested	>480	>480
Cyclohexane	99.7%	110-82-7	Differential scanning calorimetry	Not tested	>480	>480
Dimethyl formamide	99%	68-12-2	Solvent	<5	<5	<5
Dimethyl sulphoxide	99%	67-68-5	PCR, Organic Synthesis, Biological Extraction	Not tested	21	43
Ethidium bromide	1%	1239-45-8	Electrophoresis	>480	>480	>480
Ethanol	70%	64-17-5	Disinfectant, Solvent	Not tested	26	41
Glutaraldehyde	50%	111-30-8	Biochemical synthesis	Not tested	>480	>480
Hydrazine monohydrate	55%	7803-57-8	Organic Synthesis of Pharmaceuticals	Not tested	>480	>480
Hydrochloric acid	30%	7647-01-0	Chemical Synthesis, pH regulation	206	397	>480
Isopropanol	70%	67-63-0	Disinfectant, Solvent in Pharma production	6	145	131
Methanol	99%	67-56-1	Solvent, Electrophoresis	8	<5	<5
Sodium Hydroxide	50%	1310-73-2	Disinfectant, pH regulation	Not tested	>480	>480
Sulphuric Acid	50%	7664-93-9	Dehydrating agent, pH regulation	>480	>480	>480

Data given are based on results of tests performed in accordance with EN374-3:2003, by an independent laboratory. These tests may not adequately replicate any specific condition of use. Kimberly-Clark has no detailed knowledge or control over the conditions of end use, therefore data must be for advisory purposes only, and Kimberly-Clark must decline any liability.





Visit [www.kimtech.eu](http://www.kimtech.eu)

- Full list of EN374-3:2003 chemical permeation test results for all gloves
- Technical data sheets, declarations of conformity and EC type examination certificate
- Regulatory information, importance of certified personal protective equipment vs. medical device gloves
- GreenMeter measuring reduction in waste, space, cost and environmental impact

# Choosing the right glove

KIMTECH PURE\* G3 Sterile Cleanroom Gloves use Quality by Design to drive **cGMP COMPLIANCE**, reduce contamination risk and improve worker safety.  
**– Superior Protection for Exceptional Cleanrooms.**

**CE 0123**    
**STERILE R** **ISO16604:2004**  
**ISO9001 FDA 21 CFR Part 820**



## KIMTECH PURE\* G3 Sterile White Nitrile Gloves

- Highest Personal and Process Protection in the Range
- Max 950 Particles >0.5µm/cm<sup>2</sup>  
Typical Particles level <550
- Max 20 Endotoxin units/pair  
Typical Endotoxin level <5
- EN374-1:2003, ASTM D6978-05  
Chemical & Chemotherapy Protection
- EN374-2 Level 2, ISO16604:2004  
Micro Organism Protection



Want to find out more?  
Simply scan the QR Code  
using your smartphone.



## KIMTECH PURE\*G3 Sterile STERLING\* Nitrile Gloves

- Innovation combines protection, comfort and tactile sensitivity
- Max 1200 Particles >0.5µm/cm<sup>2</sup>  
Typical Particles level <750
- Max 20 Endotoxin units/pair  
Typical Endotoxin level <5
- EN374-1:2003, ASTM D6978-05  
Chemical & Chemotherapy Protection
- EN374-2 Level 2, ISO16604:2004  
Micro Organism Protection



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## KIMTECH PURE\* G3 Sterile Latex Gloves

- High quality Latex gloves with good comfort and dexterity
- Max 1500 Particles >0.5µm/cm<sup>2</sup>  
Typical Particles level <800
- Max 20 Endotoxin units/pair  
Typical Endotoxin level <5
- EN374-1:2003  
Chemical Splash Protection
- EN374-2 Level 2, ISO16604:2004  
Micro Organism Protection



Want to find out more?  
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EC Directive 89/686/EEC PPE Category III Complex Design	Description	Product Codes	Cleanliness specs compatibility		Chemical & Process Protection	Max Particles >0.5µm / cm <sup>2</sup>	Max Endotoxins Units / pair	Material	Pairs per Case
			ISO	EU CGMP					
  LEVEL 2	KIMTECH PURE* G3 Sterile White Nitrile Gloves	HC61160-HC61110				<950	<20	Nitrile	200
	KIMTECH PURE* G3 Sterile STERLING* Nitrile Gloves	11821 – 11828	G3 for ISO 3	Grade A Grade B		<1200	<20	Nitrile	300
  LEVEL 2	KIMTECH PURE* G3 Sterile Latex Gloves	HC1360S-HC1310S	G5 for ISO 5	Sterile		<1500	<20	Latex	200
	KIMTECH PURE* G5 Sterile Latex Gloves	HC1160S-HC1110S				<3000	No Spec	Latex	200
<b>Applications for G3 Sterile Gloves:</b>	<b>EU GMP ISO 5 Grade A</b>	<b>Aseptic Processing and Biosafety Hoods</b>	<b>Parenteral Drug Manufacturing</b>	<b>Biotechnology</b>	<b>Pharmaceutical Compounding</b>	<b>Ophthalmic product manufacturing</b>			

EN374-1:2003 Protective gloves against chemicals and micro-organisms. Terminology and performance requirements.  
 EN374-2:2003 Protective gloves against chemicals and micro-organisms. Determination of resistance to penetration.  
 EN374-3:2003 Protective gloves against chemicals and micro-organisms. Determination of resistance to permeation by chemicals.  
 ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.  
 ISO16604:2004 Determination of resistance of protective clothing materials to penetration by blood-borne pathogens. Test method using Phi-X174 Bacteriophage.

# Introducing RIGHTCYCLE\* by KIMBERLY-CLARK PROFESSIONAL\*

Your company needs an effective solution to mitigate waste and help you reach your Corporate Social Responsibility (CSR) and Sustainability goals. But what's the best solution for your business? Introducing RIGHTCYCLE\* by KIMBERLY-CLARK PROFESSIONAL\*.

We have resolved the recycling process – beyond downcycling, upcycling and other ideas – with the right way to recycle. RIGHTCYCLE\* makes it easy to recycle previously hard-to-recycle products like cleanroom garments and gloves. Now the garments and gloves from KIMBERLY-CLARK PROFESSIONAL\* used in your facility can be turned into a variety of useful, eco-friendly products. RIGHTCYCLE\* is good for your business and good for the environment.



## The RIGHTCYCLE\* process from distributor to park bench



For more information, contact  
**KIMBERLY-CLARK PROFESSIONAL\***  
at [kimtech.support@kcc.com](mailto:kimtech.support@kcc.com)



For more information visit us at [www.kimtech.eu](http://www.kimtech.eu) or email [kimtech.support@kcc.com](mailto:kimtech.support@kcc.com)



Exceptional  
Workplaces\*