

## KIMTECH PURE\* G3 NXT\* Nitrile Gloves

**Engineered for Protection. Designed for Comfort.** 





## Vital Process Protection and Comfort of Use

## KIMTECH PURE\* G3 NXT\* Nitrile Gloves

KIMTECH PURE\* G3 NXT\* Nitrile Gloves offer a highly advanced protection of processes, helping you to reduce the risk of contamination.

- Recommended for ISO Class 3 or higher cleanroom environments
- Contain no natural rubber latex reducing the potential for TYPE I glove –associated reactions
- · Textured fingertip
- · Beaded cuff, for added strength and ease in donning
- · Static dissipative in use
- Ambidextrous
- Double-bagged with case liner
- · Certificate of Analysis (by Lot) available online
- Trend Data available online to demonstrate product quality over time

Whether there is the need for rigid contamination control in the class ISO 3-4 critical environment or class ISO 5-8 controlled environment, KIMBERLY-CLARK PROFESSIONAL\* provides a complete line of gloves, masks, apparel and wipers to meet these needs.

All KIMBERLY-CLARK PROFESSIONAL\* Products are manufactured to exacting quality standards. Our rigorous process controls ensure every product performs above and beyond the required class or grade for your cleanrooms and clean manufacturing facilities. We continually review our product lines through certification, validation, independent testing and, most importantly, customer satisfaction to ensure your most valuable assets — your processes, your people and your reputation, are protected.









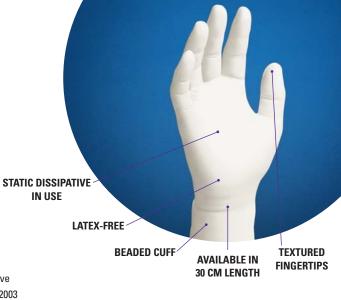
## KIMTECH PURE\* G3 NXT\* Nitrile Gloves Formerly SAFESKIN\* NXT\* Nitrile Gloves

## **Product Specifications**

- Synthetic nitrile<sup>1</sup> polymer (Acrylonitrile Butadiene)
- Contains no natural rubber latex. Silicone-free

## **Quality Standards**

- This is a PPE Category III product classified by EC Council Directive 89/686/EEC. It is tested in accordance with the EN Norms EN 420:2003
- Packaged in a Class 100 Cleanroom
- Meets or exceeds AQL level of 1.5 for pinholes
- Manufactured in accordance with Quality System ISO 9001



<sup>1</sup> Nitrile is a synthetic material exhibiting many of the properties of natural rubber latex while offering other distinct advantages: comfortable fit, resistance to puncturing and abrasion without compromising dexterity or electrostatic dissipative properties.

## **PHYSICAL PROPERTIES (Target values)**

Characteristics		Value				Test Method	
Freedom from holes		1.5AQL <sup>1</sup>					ASTM D 5151 and EN 374-2
<sup>1</sup> AQL as defined per ISO 2859-1 for sampling by attributes						•	
Tensile Properties	Ter	ısile Streı	ngth		Ultimate	Elongation	
- Before Aging	18	MPa, nom	iinal		600% nominal		ASTM D 412 and ASTM D 573
- After Accelerated Aging	20	20 MPa, nominal			600% non	ninal	
Dimensional		Measured Point		mm			
- Nominal Thickness		Middle Finger		0.16			ASTM D 3767 and D 6319
		Palm		0.13			
		Cuff		0.10			
Palm Widths							
- Nominal Width (mm)	X-Small	Small	Medium	Large	Large plus	X-Large	ASTM D 3767 and D 6319
	74	84	96	111	116	123	

## KIMTECH PURE\* G3 NXT\* Nitrile Gloves

Size ar	nd Code	30 cm		
		10x		
XS S M L XL L+	62990 62991 62992 62993 62994 62995	100x = 1000		

## **CLEANLINESS CHARACTERISTICS**

Parameter	Limit		Test Method
Particles			
Per cm² ≥ 0.5 micron		950	IEST-RP-CC005
Extractables	µg/g	μg/cm²	IEST-RP-CC005
Sodium (Na+)	5	0.03	
Ammonium (NH4+)	5	0.03	
Potassium (K+)	5	0.03	
Magnesium (Mg2+)	5	0.03	
Calcium (Ca2+)	50	0.33	
Chloride (CI-)	35	0.23	
Nitrate (NO3-)	20	0.13	
Sulfate (SO42-)	10	0.07	

INFORMATION SERVICE

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

## www.kcprofessional.com

Visit our website and discover a brand new concept in cleanroom: the CONTAMINOMICS\* Programme –







## **CERTIFICATE OF ANALYSIS**

Product Description: KIMTECH PURE\*G3 NXT\* Nitrile Gloves, 12" Ambi

(Formerly SAFESKIN\* NXT\*)

Catalog Numbers: 62990, 62991, 62992, 62993, 62995, 62994

Lot #: 880190 Total Cases per Lot: 4044

Batches: SM900101X to SM903101X Date of Manufacture: Jan-09

Physical Test Data							
			Visual	Defects	Elongation (%)	Tensile (MPa)	
_	Watertight	Dimensions	Minor	Major	Pre Aging	Pre Aging	
Sample Size:	7510	808	7510	7510	768	768	
AQL Level:	1.5	2.5	4.0	2.5	2.5	2.5	
Failures Allowed per AQL:	168	35	418	280	33	33	
Failures:	0	0	0	1	0	0	
Inspection Results:	Accept	Accept	Accept	Accept	Accept	Accept	
•		-		Averages:	773	21.4	

Test Methods: Watertight ASTM D 5151, Elongation and Tensile ASTM D 412

## **Particle Test Data**

Particle Size (µm)	Min	Max	Standard Deviation	Average Particles/cm²
0.5 - 1.0	64	614	136	253
1.0 - 2.0	3	90	15	17
2.0 - 5.0	0	153	19	7
5.0 - 10.0	0	9	1	1
10.0 - 20.0	0	1	0	0
>20	0	0	0	0
Total per Sample	86	674	145	277

Test Method: IEST-RP-CC005

	Extractable Ion Test Data							
	Anions Results							
	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulfate	
	F <sup>-</sup>	CI	NO <sub>2</sub>	Br <sup>-</sup>	NO <sub>3</sub>	P0 <sub>4</sub> <sup>-3</sup>	S0 <sub>4</sub> <sup>-2</sup>	
μg/g glove	<0.5	13.1	<2.5	<2.5	3.2	<5	2.0	
μg/cm <sup>2</sup>	< 0.003	0.087	<0.016	<0.016	0.020	<0.031	0.013	
	Cations Results					Trace Element Results		
	Sodium	Ammonium	Potassium	Magnesium	Calcium	Zinc		
	Na⁺	$NH_4^+$	K⁺	Mg <sup>+2</sup>	Ca <sup>+2</sup>	Zn		
μg/g glove	0.5	0.6	0.9	0.3	10.0	1.7		
μg/cm²	0.003	0.004	0.006	0.002	0.066	0.011		

Test Method: IEST-RP-CC005

Review By: Conn. B,
( QA Executive - SSMT )

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## **Declaration of Conformity**

Product:	KIMTECH* Pure G3 NXT* Nitrile	125
Product Codes:	KC Code	Size
	62990	XS
	62991	S
	62992	M
	62993	L
	62995	L+
	62994	XL

Notified Body: TUV Product Service (0123)

Classification: PPE Class III

Applicable Norms: Protective Gloves against Chemicals and Micro-Organisms (EN 374-1)

Protective Gloves against Mechanical Risks (EN 388)

General Requirements for Gloves (EN 420)

EEC Representative: Kimberly-Clark N.V.; Belgicastraat 13; 1930 Zaventem; Belgium

Kimberly-Clark Corporation, Roswell, GA 30076-2199, USA declares that the new Personal Protective Equipment: Protective Gloves against Chemicals and Micro-Organisms, Model KIMTECH\* Pure G3 NXT\* Nitrile (Product Codes as aforementioned) is in conformity with the provisions of Council Directive 89/686/EEC and with the harmonized standard EN 420, EN 388 and EN 374-1/3. The device is identical to the Personal Protective Equipment, which is the subject of EC certificate of conformity N° P2 03 04 45160 004 issued by TUV Product Service GmbH, Munich, Germany. This device is subject to the procedure set out in Article 11 point B of Directive 89/686/EEC under the supervision of the Notified Body TUV Product Service, Munich (0123).

### Intended Use:

The Glove shall protect the wearer against mechanical action whose effects are superficial; cleaning materials of weak action and easily reversible effects; risk encountered in the handling of hot components which do not expose the user to a temperature higher than 50  $^{0}$ C; minor impact and vibrations which do not effect vital areas of the body and whose effect cannot cause irreversible lesions; and is **not intended** for prolonged, direct exposure to harsh chemicals than stated.

These gloves are not intended for applications involving direct exposure to harsh chemicals, where heavy-duty industrial gloves are required. Variability in material thickness and glove integrity, chemical concentration, temperature and length of exposure to chemicals will affect specific performance.

This declaration is valid for the above product in its original, unmodified, unopened and undamaged packaging of the smallest unit.

Kimberly-Clark Corporation

Dr. Holger Most

Regulatory Affairs Europe

Kimberly Clark Corporation; 1400 Holcomb Bridge Road, Roswell,GA 30076-2199, U.S.A. Phone: +31 76 5716 497 Fax: +31 84 2220 589

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## **NXT\* Nitrile Gloves** 12" Ambidextrous

- White Nitrile Gloves 12"/30,5 cm Length 30,5 cm • Ambidextres • Pour usage industriel (R) Gants en nitrile blancs • Longueur 12"/ Ambidextrous • For Industrial Use Only uniquement
- **® Weiße Nitril-Handschuhe 12"/30,5 cm** -änge • Beidhändig tragbar • Nur für den industriellen Gebrauch
- дължина Стават и на двете ръце Само за ® Бели нитрилни ръкавици • 12"/30,5 см промишлена употреба
- ® Bílé nitrilové rukavice Délka 12"/30,5 cm Guantes de nitrilo blanco • 12"/30,5 cm de largo • Ambidiestros • Sólo para uso industrial
  - Na obě ruce Pouze pro průmyslové použití (1) Hvide nitrilhandsker 12"/30,5 cm lange
    - Til begge hænder Kun til industribrug
- Mőlemakäelised Ainult tööstuslikuks kasutuseks E Valged nitriilkindad • Pikkus 12"/30,5 cm •
  - (E) Άσπρα γάντια νιτριλίου Μήκος 12"/30,5 cm Αμφιδέξια • Για βιομηχανική χρήση μόνο
    - 30,5 cm Ambidestri Esclusivamente per uso □ Guanti in nitrile bianchi • Lunghezza 12"/ industriale
- W Balti nitrila cimdi 12"/30,5 cm qari Vienādi Daltos nitrilo pirštinės • 12"/30,5 cm ilgio • ērti abām rokām · Tikai industriālai lietošanai
- Eehér nitrilkesztyű 12"/30,5 mm hosszú Abirankės • Tik pramoniniam naudojimui

Kétkezes • Csak ipari használatra

- ang Aan beide handen te dragen Uitsluitend **W** Witte nitrile handschoenen • 12″/30,5 cm voor industrieel gebruik
- M Hvite nitrilhansker 12"/30,5 cm lange Tipasset hver hånd • Kun for industribruk
- ® Białe rękawice nitrylowe Długość 12"/30,5 cm • Obureczne • Tylko do użytku przemysłowego comprimento · Ambidextras · Somente para uso industrial
- ® Mănuşi albe de nitril 12"/30,5 cm lungime Ambidextre • Numai pentru uz industrial
  - в Белые нитриловые перчатки Длина 12"/30,5 см • На любую руку • Только для промышленного применения
- SE Biele nitrilové rukavice Dĺžka 12"/30,5 cm Na obi dve ruky • Len na priemyselné použitie
- S Bele nitrilne rokavice 12"/30,5 cm dolge Za na obe roki • Samo za industrijsko uporabo
- cm • Sopivat molempiin käsiin • Vain teolliseen käyttöön
- Sv. Vita handskar av nitril 12"/30,5 cm långa Ej handspecifika • Endast för industriellt bruk
  - ⑤ ニトリル手袋(白)・長さ 30,5 cm uzunluăunda • İki Ele de Uvumlu • Sadece Beyaz Nitril Eldivenler • 12"/30,5 cm
     endüstriyel kullanım icindir
    - 両手用・産業用途専用





一回限りの使用

Uso único

## Single Use Only

- Usage unique seulement Nur zur einmaligen Verwendung Üsese una sola vez **EB883**
- Conserver au sec Keep Dry
  - Mantener secos **Trocken halten**
- Manter seco 乾燥した所に保 管して下さい



## (B) Attention: See Insert (m Attention: Voir encart (m Attention: Voir encart (m Attention: Siehe Packungsbeilage (m Attenção: Consultar a liferatura inclusa (ル インサートをご覧下さい

- Protect from Heat and Radioactive Sources
   Protéger des sources de chaleur et radioactives
   Vor Hize und radioaktiven Strahlen schützen
   Proteger del calor y de las fuentes de radiactividad
   Proteger contra o calor e fontes de radioactividade
   熱や放射性源のものから保護して下さい
- Tested for Watertightness and Low Chemical Protection

N374-1

- Genrüft auf Wasserfestigkeit und geringen Schutz gegen Chemikalien Testés pour étanchéité à l'eau et faible protection chimique
- químicas leves ® Comprovadas contra a estanqueidade ja água e protecção contra produtos químicos fracos ® 水密性および低度対化学薬品性を検査済 Sometidos a pruebas de impermeabilidad y protección contra sustancias
- EN Tested for Microorganism Hazards

N374-2

- Testés pour les risques causés par les microorganismes
- Sometidos a pruebas contra riesgos presentados por microorganismos Geprüft für Gefahren durch Mikroorganismen 888
  - Comprovadas contra perigos apresentados por microrganismos 彼生物危険性のテスト済み
    - EVEL 2

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0123 **EN420** 

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## Made in Thailand

**AOL 1,5 G1** 

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**101** 

製造番号

Expiration Date Date 使用期限



RFF



## **Test Method for Analyzing Liquid Particle Counts**

This test method is used to analyze the mobile particle contaminants from cleanroom gloves.

## 1. Scope

- 1.1. The test method covers the average particulate contamination found on gloves designated for cleanroom applicability.
- 1.2. The average contaminant concentration will be reported in particles per cm<sup>2</sup> in two ways:
  - 1.2.1. By size grouping, 0.5 to 1.0 microns, 1.0 to 2.0 microns, 2.0 to 5.0 microns, 5.0 to 10.0 microns, 10.0 to 20.0 microns, greater than 20.0 microns, and a total particle count greater than 0.5 microns.
  - 1.2.2. Statistical analysis of each grouping consisting of Minimum Value, Maximum Value, Standard Deviation, and Average Value, for each group of individual gloves.
- 1.3. The safe and proper use of gloves is beyond the scope of this test method.
- 1.4. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

### 2. Referenced Documents

- 2.1. IEST-RP-CC005.3 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
- 2.2. Work Instruction

## 3. Apparatus

- 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
- 3.2. Particle Measuring Systems CLS-900 Liquid Particle Counting System
- 3.3. 2000 mL glass beaker or 1000mL glass conical flask
- 3.4. Stainless Steel Forceps, 10" length
- 3.5. 250 ml Volumetric Flask
- 3.6. 500 ml Volumetric Flask
- 3.7. High Purity Deionized Water System, capable of producing 18.2 MOhm quality water
- 3.8. Point of Use Filter, 0.2 micron size
- 3.9. Orbital Shaker, 3/4" orbit, capable of 200 rpm
- 3.10. Circular Die, 1.5 inch diameter, calibrated

## 4. Procedure

- 4.1. Test Preparation
  - 4.1.1. Prior to extraction, all Erlenmeyer flasks will be cleaned no less than five times with high purity deionized water filtered to 0.2 microns at point of use.
  - 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity deionized water prior to use.

## 4.2. Extraction

- 4.2.1. Randomly pull a glove from the package.
- 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
- 4.2.3. Empty into the inside of the glove 500 ml high purity filtered deionized water.
- 4.2.4. Allow the glove to settle into the Erlenmeyer flask.
- 4.2.5. Place an additional 250 ml high purity filtered deionized water over the glove within the Erlenmeyer flask.
- 4.2.6. Allow the Erlenmeyer flask with glove to agitate on the shaker for 10 minutes ± 10 seconds at a rate of 150 rpm ± 10 rpm.
- 4.2.7. Using clean tongs, immediately remove the glove from the container. Drain any trapped liquid into the beaker by manipulating the fingers on the glove, with the tongs
- 4.2.8. Dispose of the glove.
- 4.2.9. Repeat the extraction two additional times to complete the set.
- 4.2.10. Prepare a process blank, using all the steps in section 4.2, without placing the glove in the Erlenmeyer flask.

## 4.3. Measurement

- 4.3.1. Follow the Work Instruction for the Liquid Particle Counter for analyzing the solutions.
- 4.4. Glove Surface Area
- 4.4.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.
- 4.4.2. Record as A.
- 4.4.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cutout sections.
- 4.4.4. Weight the six cut-out sections. Record this as B.
- 4.4.5. Calculate the surface area of the glove using the following equation :

## 5. Calculations

5.1. Calculate counts/cm<sup>2</sup> by channel size using the following equation:

(Sample (counts/mL)-Blank (Counts/mL) x Extraction volume (mL) x DF Surface area (in cm<sup>2</sup>)

5.2. Total Counts/cm $^2$ : =  $\sum$  AllChannelSizes

## 6. Reporting

- 6.1. The final report should include the Lot Number, Batch number, Product Description, Part Number, and any other pertinent information about the sample, as well as the final calculated counts/cm² by channel size and a total counts/cm² greater than 0.5 microns.
- 6.2. Statistics will be calculated and reported on sample sizes greater than three.

## **Test Method for Analyzing Extractables**

This test method is used to analyze the soluble ionic extractable contaminants from cleanroom gloves.

1. Scope

- 1.1. The test method covers the average ionic contamination found on gloves designated for cleanroom applicability.
- 1.2. The average contaminant concentration will be reported in one of two ways:
  - 1.2.1. Micrograms of ionic contaminant per gram of glove weight (ug/g), also described as ppm.
  - 1.2.2. Micrograms of ionic contaminant per square centimeter of glove area (ug/cm²)
- 1.3. This test method does not cover contaminants that are insoluble in water, or organic macromolecules.
- 1.4. The safe and proper use of gloves is beyond the scope of this test method.
- 1.5. This test method does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this Test Method to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

## 2. Referenced Documents

- 1. IEST-RP-CC005.2 Recommended Practice for Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments.
- 2.2. Work Instruction WI 10-05-26, Work Instruction for Performing Ion Chromatography Analysis of Gloves

3. Apparatus

- 3.1. Analytical Balance, capable of readability and repeatability to 0.1 mg
- 3.2. Ion Chromatograph
- 3.3. Extraction Containers, 1 liter capacity, HDPE with screw type lids
- 3.4. Stainless Steel Forceps, 10" length
- 3.5. 500 ml Volumetric Flask
- 3.6. High Purity Deionized Water System, capable of producing 18.0 MOhm quality water
- 3.7. Point of Use Filter, 0.1 micron size
- 3.8. Circular Die, 1.5 inch diameter, calibrated

## 4. Procedure

- 4.1. Test Preparation
  - 4.1.1. Prior to extraction, all extraction containers will be cleaned using high purity deionized water high purity deionized water filtered to 0.2 microns at point of use.
  - 4.1.2. All related equipment (forceps, volumetric flasks, etc.) must be rinsed with high purity de-ionized water prior to use.

## 4.2. Extraction

- 4.2.1. Randomly pull a glove from the package.
- 4.2.2. Place glove finger-first into the one liter Erlenmeyer flask and hold open by cuff using the rinsed forceps.
- 4.3. Empty into the inside of the glove approximately 250 ml high purity filtered deionized water.
- 4.4. Allow the glove to settle into the extraction container.
- 4.5. Pour remaining 250 ml high purity filtered deionized water over the glove within the extraction container.
- 4.6. Place the lid upon the container and seal tightly.
- 4.7. Gently swirl the container to ensure that all surfaces of the glove are wetted.
- 4.8. Allow the glove to extract in the deionized water for at least 10 minutes, but no longer than 11 minutes.
- 4.9. Remove the glove by the fingers, allowing most of the water trapped in the fingers to drain back in to the extraction container.
- 4.10. Dispose of the glove.
- 4.11. Repeat extraction two additional times to complete the set.
- 4.12. Prepare a sample blank, using all the steps in section 2, without placing the glove in the extraction container.

## 4.13. Measurement

- 4.13.1. Follow the guidelines for the Ion Chromatograph for analyzing aqueous solutions.
- 4,14. Glove weight and surface area
  - 4.14.1. Pull three gloves from the production package and weigh to the nearest 0.1 mg.
  - 4.14.2. Record as A.
  - 4.14.3. Cut the 3 gloves with square die (5X5 cm.) by wheel cutter at palm. This will give you six cut-out sections.
  - 4.14.4. Weight the six cut-out sections. Record this as B.
  - 4.14.5. Calculate the surface area of the glove using the following equation :

## 5. Calculations

5.1. Once the data output from the Chromatograph has been reviewed for errors, calculate the following:

5.1.1. ug/g (ppm) contamination: 
$$= \frac{(AnalyteConc.)*(500ml)}{GloveWeight}$$

5.1.2. ug/cm<sup>2</sup> contamination: = 
$$\frac{(AnalyteConc.)^*(500ml)}{SurfaceArea}$$

## 6. Reporting

6.1. The final report should include the Lot number, Batch number, Product description, Part number, and any other pertinent information about the sample, as well as the final calculated contaminant concentration in ug/g and ug/cm<sup>2</sup>.