

NBR
Nitrile

Lab
Environment

MICROFLEX®

SUPRENO® SE

VALIDATION PACK

Ansell



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VALIDATION PACK

Product Datasheet

MICROFLEX®

SUPRENO® SE

Durable, Heavy-Duty Coverage
Nitrile Exam GlovesProvides sturdy coverage
for demanding applications

FEATURES AND BENEFITS:

Exceptional Protection

The Microflex Supreno® SE offers an advanced barrier protection against contaminants due to its lower acceptable pinhole rates. Its 0.65 Acceptance Quality Limit for pinholes help set a new standard for protection.

Increased Productivity

Non-stick properties are built into the glove formulation to create a resistance to tape or adhesives, and to assist workers with improved efficiency and speed.

Secure and Confident Grip

Textured fingers ensure strong, efficient grip and maximum worker protection.

Effortless Donning and Doffing

Polymer coating assures easy donning to help protect workers in fast-paced environments.

Protection from Type 1 Allergies

Constructed without natural rubber latex materials or powder, to help protect from allergies, skin irritation and dryness.

Industries

- Automotive
- Chemical
- Healthcare
- Laboratory
- Law Enforcement
- Manufacturing

Applications

- Crime scene evaluation
- Patient examinations
- Analytical testing
- Assembly and inspection
- Electronics
- Food processing
- Glass manufacturing
- Laboratory analysis and testing
- Light assembly tasks
- Maintaining equipment & instruments
- Paint and spray shops
- Patient examinations
- Pharmaceutical manufacturing
- Preparing pharmaceutical products
- Printing industry
- Protection from blood and other bodily fluids

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TECHNICAL DATA SHEET:
PRODUCT INFORMATION:

SUPRENO® SE	
Material	Nitrile
Color	Blue
Glove Design	Ambidextrous, Powder-Free, Chlorinated, Polymer Coated, Textured Fingers
Cuff	Beaded Cuff
Audit Standards	ISO 13485
Regulatory Compliance	MDD 93/42/EEC, PPED 89/686/EEC CATEGORY III, COMPLEX DESIGN, EN 455 1,2 AND 3, EN374-3, EN374-2 LEVEL 3 AQL .65, ASTM D6319, EN420 (SIZING FOR SPECIAL PURPOSES), REACH COMPLIANT, TGA, US QSR/FDA 510(K)
Packaging	100 gloves per dispenser, 10 dispensers per shipper carton, 1000 gloves per shipper 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

PHYSICAL PROPERTIES:

	TYPICAL VALUES					TESTING METHOD
	5.5 - 6 XS	6.5 - 7 S	7.5 - 8 M	8.5 - 9 L	9.5 - 10 XL	
Length (mm)	245	245	245	245	245	ASTM D3767/EN 420
Average Palm Width (mm)	75	86	98	108	115	
Freedom from Holes (Inspection level I)	0.65 AQL					ASTM D5151/EN 374-2
Palm Thickness Single Wall	(mm : 0.11) / (mil : 4.3)					ASTM D3767/EN 420
	BEFORE AGING		AFTER AGING			
Ultimate Tensile Strength	30 Mpa		30 Mpa		ASTM D 412-06a	
Elongation at Break (%)	> 500		> 400		ASTM D 412-06a	
Force at break (N)	10		11		EN 455-2	

ORDERING INFORMATION:

	SIZE	5.5 - 6 XS	6.5 - 7 S	7.5 - 8 M	8.5 - 9 L	9.5 - 10 XL
SUPRENO® SE	REORDER NO.	SU-690-XS	SU-690-S	SU-690-M	SU-690-L	SU-690-XL

Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of gloves for a specific application

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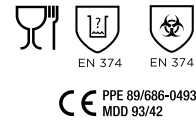
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CE Declaration of Product Conformity

DECLARATION OF STANDARDS CONFORMITY

This document certifies that the product(s) listed below are in full compliance with the following ASTM standards and tested according to the following ASTM standard test methods.

Product(s)	
Supreno (SU-690)	
ASTM Standard	
ASTM D6319	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM Standard Test Methods	
ASTM D5151	Standard Test Method for Detection of holes in Medical Gloves
ASTM F1671	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
ASTM D412	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

Document issued by Microflex on: September 17, 2015



Donald J Cronk
Regulatory Affairs Manager
Microflex Corporation
Don.cronk@ansell.com
800-876-6866 x1730

Certificate of Analysis

Certificate of Analysis

Product Name: Supreno SE	Lot Number: 1700206900157
Product ID: SU-690	Manufacture Date: January 2015

Test Results:

Dimensions:

SKU	Palm Width (mm)	Glove Length (mm)
X-Small	82	246
Small	88	245
Medium	98	244
Large	107	245
X-Large	115	243

Thickness Single Wall:

SKU	Cuff Thickness (mm)	Palm Thickness(mm)	Finger Tip Thickness(mm)
X-Small	0.09	0.11	0.17
Small	0.09	0.11	0.16
Medium	0.09	0.11	0.17
Large	0.09	0.11	0.18
X-Large	0.09	0.11	0.17

Physical Properties:

	Before Aging	UOM	After Aging	UOM
Tensile	25.95	MPa	30.25	MPa
Elongation min.	579	%	501	%

Other Properties:

Powder Content:		UOM
X-Small	0.20	mg/glove
Small	0.14	mg/glove
Medium	0.22	mg/glove
Large	0.14	mg/glove
X-Large	0.22	mg/glove

Criteria:

	AQL Level	Results
Visual Defects – Major	2.5	PASS
Visual Defects – Minor	4.0	PASS
Freedom From Holes	0.65	PASS



Test Methods utilized in the preparation of Certificate of Analysis:

- Protein Level: NA
- Powder Content: ASTM D 6124
- Freedom from Holes: ASTM D 5151
- Material Standard: ASTM D 6319
- Packaging: 100 gloves per dispenser by weight

Arlene Voskamp

 Quality Assurance Department (Print Name)

6/30/2015

 Date

Arlene Voskamp

 Quality Assurance Department (Signature)

ESD Statement

Ansell

-

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111 Wood Avenue South, Suite 210
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www.ansell.com

DECLARATION OF CONFORMITY

This letter certifies that the Supreno SE (SU-690) and Supreno EC (SEC-375) can be considered an electrostatic dissipative material per the requirements of EN 1149-5 (electrostatic performance requirements for protective clothing). The EN 1149-5 standard requires a glove to comply with half decay time AND/OR surface resistivity values.

Supreno SE and Supreno EC PF Nitrile Exam gloves have been tested for antistatic properties in accordance to the EN 1149 standard test methods for electrostatic properties. Under this standard,

1. Our SU-690 gloves achieved a half decay time of 1.63 seconds whilst the EN 1149-5 requires < 4 seconds. The surface resistivity is $2.56 \times 10^{12} \Omega$ whilst the EN 1149-5 requires < $5 \cdot 10^{10} \Omega$.
2. Our SEC-375 gloves achieved a half decay time of 1.35 seconds whilst the EN 1149-5 requires < 4 seconds. The surface resistivity is $1.24 \times 10^{11} \Omega$ whilst the EN 1149-5 requires < $5 \cdot 10^{10} \Omega$.

As such, we can confirm that Supreno SE and Supreno EC are anti-static as per EN 420:2003 and EN 1149:2005.

Sincerely,

Donald J Cronk
Regulatory Affairs Manager
Microflex Corporation
Don.cronk@ansell.com
800-876-6866 x1730

BSE-TSE Declaration

TSE / BSE Statement for Supreno SE, SU-690

Hereby, I confirm that the Supreno SE, SU-690 gloves do not contain any Transmissible Spongiform Encephalopathy (=TSE) sources.

Hence, we can also confirm that using this glove would not cause any diseases such as BSE (Bovine Spongiform Encephalopathy).

Regards,



Donald J. Cronk
Regulatory Affairs Manager
Single Use GBU
Email: don.cronk@ansell.com



Statement of Freedom of Latex

July 27, 2015

To Our Valued Customer,

We hereby declare that the Nitrile products listed below from Microflex are made of synthetic latex and is not made from Natural Rubber Latex, NRL.

Product Name	Product Code
Sensation	N73
Supreno SE	SU-690
Supreno EC	SEC-375
XCEED	XC-310

I hope this information is helpful to you. If I can be of any further assistance, please do not hesitate to contact me at (800) 876-6866, ext. 1730.

Sincerely,


 Donald J. Cronk
 Manager, Regulatory Affairs
 Microflex Corp
dcronk@barriersafe.com

Allergen Statement

Allergen Statement for Supreno SE, SU-690

This is to confirm that Supreno SE, SU-690 glove does not use the following materials:

1. Allergenic protein of natural rubber latex

This is to confirm that Supreno SE, SU-690 gloves does use the following materials:

1. Zinc Diethyldithiocarbamate
2. Zinc Diebutyldithiocarbamate

We further confirm the products do not contain the following items:

1. Animal derivative material
2. Cornstarch
3. Lactose
4. Nickel

The below materials are not used intentionally in our formulations but they have not been tested specifically for the content:

1. Gluten
2. Nuts
3. Egg/Protein
4. Soy
5. Fish
6. Metabisulphite
7. Melamine

Regards,



Donald J. Cronk
Regulatory Affairs Manager
Single Use GBU
Email: don.cronk@ansell.com

Permeation Breakthrough Time

Permeation breakthrough times according to EN374-3:2003 (minutes)

Glove :

Microflex® SUPRENO® SE

	Chemical Agent	Breakthrough Time	Protection Index	CAS Number	Notified Body	EN Standard
	Heptane	23	1	142-82-5	TÜV Rheinland	374-3:2003
	Sodium Hydroxide, 40%	> 480	6	1310-73-2	TÜV Rheinland	374-3:2003
	Sulphuric acid, 96%	10	1	7664-93-9	TÜV Rheinland	374-3:2003
	Toluene	0	0	108-88-3	TÜV Rheinland	374-3:2003

Permeation breakthrough times according to EN374-3:2003 (minutes)

0	1	2	3	4	5	6
< 10	10-30	30-60	60-120	120-240	240-480	> 480
Not recommended	Splash protection		Medium protection		High protection	
Data given in the table above are based on results of laboratory tests performed on the palm area of the glove or are based on extrapolations from the results of laboratory tests. These tests were run using standard test methods that may not adequately replicate any specific conditions of end use. Because Ansell has no detailed knowledge or control over the conditions of end use, any of these data must be advisory only, and Ansell must decline any liability.						

Ansell Healthcare Europe N.V. (European Head Office)

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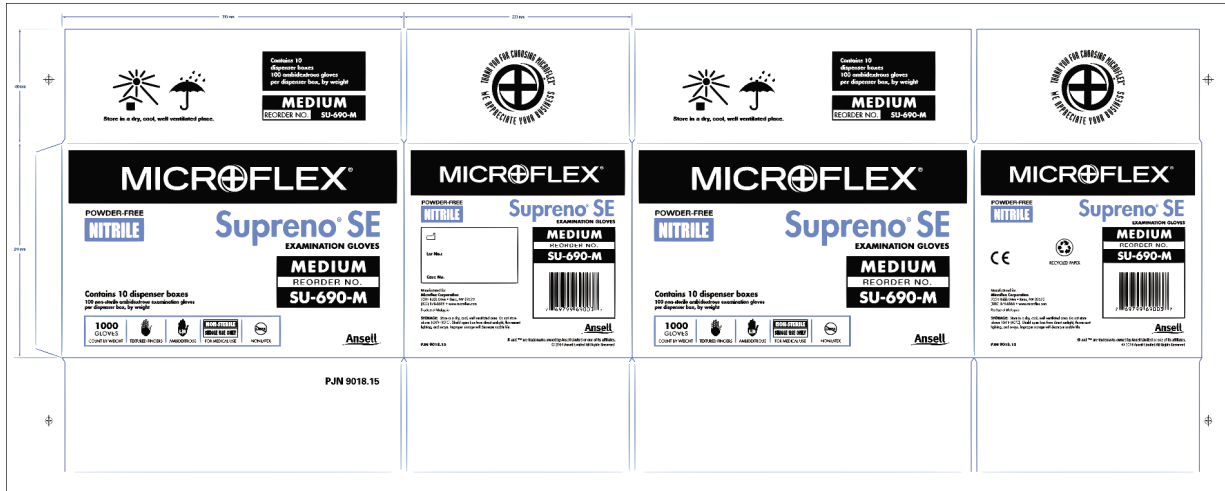
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Packaging Data

Style	Size	External ID	Quantity Per Case	Cases Per Pallet	Case Weight Kg	Case Dimensions (in mm - L x D x H)	Inner Carton Bar Code	Outer Case Bar Code
SU-690	XS 5-6	SU-690-XS	10 dispenser boxes per case	60	15.0	390 x 260 x 244	769799690068	769799690013
SU-690	S 6.5-7	SU-690-S	10 dispenser boxes per case	60	16.1	390 x 260 x 244	769799690075	769799690020
SU-690	M 7.5-8	SU-690-M	10 dispenser boxes per case	60	16.7	390 x 260 x 244	769799690082	769799690037
SU-690	L 8.5-9	SU-690-L	10 dispenser boxes per case	60	17.8	390 x 260 x 244	769799690099	769799690044
SU-690	XL 9.5-10	SU-690-XL	10 dispenser boxes per case	60	18.9	390 x 260 x 244	769799690006	769799690051

Packaging Explanation



POWDER-FREE
NITRILE

Supreno® SE
EXAMINATION GLOVES

Manufacturing Date
Lot#
Case#

Lot No.
Case No.

MEDIUM
REORDER NO.
SU-690-M



Barcode

Manufactured for
Microflex Corporation
2581 Route 100 • Bldg. 100 • NY 10925
(800) 676-8852 • www.microflex.com
Product of Malaysia

STORAGE: Store in dry, cool, well-ventilated area. Do not store above 104°F (40°C). Should open box from closed position. Recurrent lighting and/or excessive temperature storage will decrease useful life.

Ansell

PJN 9018.15

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Certificate



TUV Rheinland of North America, Inc., a CMDCAS
recognized registrar, certifies that

Microflex Corporation
2301 Robb Drive
Reno NV 89523
USA

has established and maintained a
Quality Management System
according to
ISO 13485:2003

Audit Report No.: 31191311 004
Certificate Registration No.: 74 500 4553
Expiry Date: August 24, 2017

for the Design and Development,
Manufacture and Distribution of

Powder Free and Powdered Natural Rubber Latex and
Synthetic Rubber Latex Examination Gloves

(see attachment for additional sites under certification)



A handwritten signature in blue ink, appearing to read "B. Ludovico".

Certification Officer: B. Ludovico

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: August 25, 2014



Doc. 1/1, Rev. 0

Attachment
**Quality Management System
according to ISO 13485:2003**

for

**Microflex Corporation
2301 Robb Drive
Reno, NV 89523
USA**

The scope of the registration also includes the following sites:

Microflex Corporation

150 Field Drive, Suite 210, Lake Forest, IL 60045 USA

Scope: Aspects related to administration.**Microflex Corporation**

6940 San Tomas, Elkridge, MD 21075 USA

Scope: Aspects related to distribution.**Microflex Corporation**

12055 Sage Point Court, Suite 107, Reno, NV 89506 USA

Scope: Aspects related to distribution.**Microflex Corporation**

1186 Arbor Drive, Romeoville, IL 60446 USA

Scope: Aspects related to distribution.

Audit Report No.:	31191311 004
Certificate Registration No.:	74 500 4553
Expiry Date:	August 24, 2017




Certification Officer: Brian Ludovico
TUV Rheinland of North America, Inc.
Newtown, Connecticut
Effective Date: August 25, 2014

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel(203) 426-0888 Fax(203)426-4009

Instructions for Use

	EN	ES	IT	NL	DA	NO	AR
	FR	DE	PT	EL	FI	SV	RU
CS	HU	LV	PL	BG	SL	KO	TH
ET	LT	MT	RO	SK	TR	MS	ZH

CE&DI



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INSTRUCTIONS FOR USE
 CATEGORY III / COMPLEX DESIGN

EN

ANSSELL DISPOSABLE AND CRITICAL
 ENVIRONMENT GLOVES

A. Use

This Instruction for Use note is to be used in combination with the specific information that is mentioned on or inside each packaging enclosure.
 These gloves are designed as single use gloves and should be disposed of after use. The gloves are liquid proof, and can therefore be used for splash protection against certain chemicals.
 They are in conformity with, and are marked per the requirements of the European Directive 89/686/EEC and its amendments. They also comply with the applicable European Standards.
 Gloves which are accompanied with the pictogram which designates contact with foodstuffs, are also in conformity with the European Regulations 1935/2004 and 2023/2006 as well as with all applicable National Regulations for Food-contact materials.
 Please ensure the gloves are used only for the designated purposes.

Explanation of pictograms:

	A: Abrasion resistance B: Cut resistance C: Tear resistance D: Puncture resistance		A = methanol B = acetone C = acetonitrile D = dichloromethane E = carbon disulfide F = toluene G = diethylamine H = tetrahydrofuran I = ethyl acetate J = n-heptane K = sodium hydroxide, 40% L = sulphuric acid, 96%
	A B C D EN 388: 2003 Protection from mechanical risks		A B C D E F G H I J K L EN 374: 2003 Chemical breakthrough time > 30 minutes against :
	EN 374: 2003 Protection against micro-organisms (AQL ≤ 1.5)		EN 374: 2003 Liquidproof gloves. Chemical resistance data available upon request.
	EN 421 Protection against radio-active contamination		Suitable for contact with foodstuffs

Warning! The information given in the pictograms or data provided on chemical resistant breakthrough times is based on lab tests and is therefore advisory only since it does not necessarily reflect the actual duration in the workplace. EC-Type examination certificate from Centexbel Belgium (I.D. 0493), Technologiepark 7, B-9052 Zwijnaarde. For more detailed information on the glove's performance and to obtain a copy of the Conformity Declaration, please consult Ansell.

B. Precautions for use

- Before usage, inspect the gloves for any defects or imperfections. If the gloves are ripped or punctured during use, dispose of them immediately. If in doubt, do not use the gloves, get a new pair.
- If the gloves are used against chemicals, it is essential to keep all chemicals from the skin, even if they are thought to be harmless. Therefore use gloves which are rated with a protection index of 6 or with an excellent degradation resistance rating. In all other cases, the gloves should be used for splash protection or short contact only. Ensure that chemicals cannot enter via the cuff. For more details regarding chemical suitability, please contact the Ansell Technical department.
- Avoid wearing gloves which are dirty on the inside – they may irritate the skin causing dermatitis or worse.
- Contaminated gloves should be cleaned or washed before removal.
- The gloves should not be used in applications requiring thermal protection.
- Disposable glove type versions with a glove length below 260 mm are 'Fit for Special Purpose gloves' because they are to be used to protect the hand ONLY from chemical splashes when handling chemicals. Do not use the gloves when protection in the cuff area is needed.
- Gloves shall not be used for protection against ionising radiation nor for use in containment enclosures.
- Not all gloves that are suitable for contact with foodstuffs can be used against all foodstuffs. Some gloves may show excessive migration towards certain types of foodstuffs. To know which restrictions apply and for which specific foodstuffs the gloves can be used, please obtain advise from the Ansell technical department or consult the Ansell Food Conformity declaration.
- If gloves are marked, the printed surfaces shall not come in contact with food.

C. Ingredients / Hazardous ingredients

Some gloves might contain ingredients which are known to be a possible cause of allergies in sensitised persons, who may develop irritant and/or allergic contact reactions. If allergic reactions should occur, obtain medical advice immediately.
 For more information, please contact Ansell's Technical department.

D. Care instructions

Storage: Keep away from direct sunlight; store in a cool dry place.
 Keep away from ozone sources or naked flame.

Cleaning: The gloves are not designed to be laundered.

E. Disposal

Used gloves may be contaminated with infectious or other hazardous materials.
 Dispose of according to Local Authority Regulations.
 Landfill or incinerate under controlled conditions.

Ansell

Product Portfolio

Available in North America

Overview of Single-Use Product Portfolio

Brand	Style	Length (in)	Palm Thickness (mils)	Key Features & Benefits
Natural Rubber Latex				
TouchNTuff®	69-318	9.5	5.0	<ul style="list-style-type: none"> • Ideal for intricate handling of objects • The lightest, powder free natural rubber latex style
Microflex®	E-Grip® Max	9.6	5.1	<ul style="list-style-type: none"> • Double chlorinated for easy donning
Microflex®	Diamond Grip™	9.6	6.3	<ul style="list-style-type: none"> • Unique, rugged latex design prevents snags, rips, and tears • Strong and durable in mechanical and oily environments
Microflex®	Evolution One®	9.6	5.5	<ul style="list-style-type: none"> • Superior wet and dry grip due to polymer-coating • Maximum comfort allows for extended wear
Microflex®	Comfort Grip®	9.6	5.1	<ul style="list-style-type: none"> • Multi-purpose latex glove
Microflex®	SafeGrip®	11.6	11.0	<ul style="list-style-type: none"> • Ideal for heavy duty applications • Double chlorinated for easy donning
Microflex®	Ultra One®	11.8	9.8	<ul style="list-style-type: none"> • Long cuff to protect the forearm • Thick latex gloves for extra protection
Microflex®	MegaPro®	11.6	9.8	<ul style="list-style-type: none"> • Blue color, fully textured for secure grip • Thick latex gloves for extra protection
Nitrile				
Microflex®	XCEED®	9.5	2.8	<ul style="list-style-type: none"> • Strongest thin mil nitrile defends against rip tear • Ansell Ergoform Technology proven to reduce hand fatigue • Exceptional barrier integrity with 0.65 AQL
Microflex®	Sensation®	9.4	2.4	<ul style="list-style-type: none"> • Specialized formulation reduces chances of contact dermatitis • Very low sulfur and aluminum content
Microflex®	Ultraform®	9.1	2.4	<ul style="list-style-type: none"> • Unique, soft formulation for exceptional tactility • Ansell ERGOFORM™ technology proven to reduce hand fatigue
Microflex®	Soft White Nitrile	9.4	2.6	<ul style="list-style-type: none"> • Thin, soft nitrile allowing for good tactility
Microflex®	Cobalt®	9.5	3.9	<ul style="list-style-type: none"> • Fully textured for enhanced grip • Multi-purpose glove
Microflex®	N85	9.5	3.1	<ul style="list-style-type: none"> • Basic, multi-purpose glove
TouchNTuff®	93-250	9.5	4.7	<ul style="list-style-type: none"> • Soft nitrile reduces hand and arm fatigue • Less force needed to grip wet and dry objects • Silicone free

Warning: Natural Rubber Latex may cause allergic reactions in sensitive individuals.

Nitrile (continued)

TouchNTuff®	92-600	9.5	4.7	<ul style="list-style-type: none"> Enhanced chemical splash protection Proprietary, soft, thin nitrile formulation Silicone free
Microflex®	Supreno® EC	11.6	5.5	<ul style="list-style-type: none"> Approved for use with chemotherapy drugs Exceptional barrier integrity with 0.65 AQL
Microflex®	Supreno® SE	9.6	4.3	<ul style="list-style-type: none"> Exceptional barrier integrity with 0.65 AQL Ideal for longer wear times
Microflex®	MidKnight®	9.6	4.7	<ul style="list-style-type: none"> Distinct black color masks stains Fully textured for consistent grip performance No foaming in wet environments
Microflex®	Blaze®	10.6	5.1	<ul style="list-style-type: none"> High visibility Works exceptionally well in oily environments
TouchNTuff®	92-675	9.5	4.3	<ul style="list-style-type: none"> Exceptional chemical splash properties Ideal for broad applications
TouchNTuff®	92-500	9.5	4.7	<ul style="list-style-type: none"> Powdered for easy donning and moisture absorption Proprietary, soft, thin nitrile formulation Enhanced chemical splash protection
TouchNTuff®	92-605	11.8	4.7	<ul style="list-style-type: none"> Enhanced chemical splash protection Very comfortable soft nitrile Silicone free
TouchNTuff®	92-575	9.5	4.3	<ul style="list-style-type: none"> Thin, durable glove Textured fingers for good grip Powdered for easy donning and moisture absorption

Neoprene

Microflex®	Neogard®	9.6	3.9	<ul style="list-style-type: none"> Ansell ERGOFORM™ technology proven to reduce hand fatigue Exceptional wet grip
NeoTouch®	25-101	9.5	5.1	<ul style="list-style-type: none"> Polyurethane inner-coating for easy donning Excellent splash resistance to most acids and alcohols Good wet and dry grip
NeoTouch®	25-201	11.4	5.1	<ul style="list-style-type: none"> Polyurethane inner-coating for easy donning Excellent splash resistance to most acids and alcohols Good wet and dry grip
Microflex®	NeoPro®	9.6	5.1	<ul style="list-style-type: none"> Approved for use with chemotherapy drugs (ASTM D 6978) Excellent splash resistance to most acids and alcohols Good wet and dry grip
Microflex®	NeoPro® EC	11.4	6.3	<ul style="list-style-type: none"> Approved for use with chemotherapy drugs (ASTM D 6978) Excellent splash resistance to most acids and alcohols Good wet and dry grip