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Product Datasheet

MICR FLEX®

SUPRENO® EC High Risk Exam Nitrile Gloves

NBR Durable extra protection for high risk chemicals and drugs Nitrile Industries • Chemical Dental • Healthcare Laboratory Manufacturing **Applications** Analytical testing Assembly and inspection • Emergency services Food processing · Laboratory analysis and testing

• Maintaining equipment & instruments

• Protection from blood and other bodily fluids

• Pharmaceutical manufacturing • Preparing pharmaceutical products

• Paint and spray shops

• Patient examinations

• Printing industry

FEATURES AND BENEFITS:

Reliable Hazard Protection

Extended cuff provides additional protection for the wrist and arm for hazardous environments. Advanced nitrile formulation offers up to 3 times the puncture resistance of latex or vinyl disposable gloves. Combined with the lowest acceptable pinhole rates (AQL 0.65) these gloves help set a new standard in 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 excellent worker protection.

Protection from Type 1 Allergies

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

Approved for use with chemotherapy drugs

WWW.ANSELL.COM









SUPRENO® EC High Risk Exam Nitrile Gloves

TECHNICAL DATA SHEET:

PRODUCT INFORMATION:

	SUPRENO EC		
Material	Nitrile		
Color	Blue		
Glove Design	Ambidextrous, Powder-Free, Chlorinated, Textured Fingers, Extended Cuff		
Cuff Beaded Cuff			
Audit Standards	ISO 13485		
Regulatory Compliance US QSR/FDA 510(K), US NFPA, APPROVED FOR USE WITH CHEMOTHERAPY DRUGS			
* Packaging	50 gloves per dispenser, 10 dispensers per shipper carton, 500 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		
	*YYYL contains 40 gloves/box		

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	10.5 - 11 XXL	11.5 - 12 XXXL		
Length (mm)	295	295	295	295	295	295	295		
Average Palm Width (mm)	80	86	98	108	115	122	128		

Freedom from Holes (Inspection level I)	0.65	ASTM D5151/EN 374-2	
Palm Thickness Single Wall	(mm : 0.14)	ASTM D3767/EN 420	
	BEFORE AGING	AFTER AGING	
Ultimate Tensile Strength	30 Mpa	27 Mpa	ASTM D 412-06a
Elongation at Break (%)	> 500	> 500	ASTM D 412-06a
Force at break (N)	18	18	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	10.5 - 11 XXL	11.5 - 12 XXXL
SUPRENO* EC	REORDER NO.	SEC-375-XS	SEC-375-S	SEC-375-M	SEC-375-L	SEC-375-XL	SEC-375-XXL	SEC-375-XXXL

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

For additional information visit us at www.ansell.com, or call us at

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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 EC (SEC-375)						
	ASTM Standard						
ASTM	Standard Specification for Nitrile Examination Gloves for Medical Application						
D6319							
	ASTM Standard Test Methods						
ASTM	Standard Test Method for Detection of holes in Medical Gloves						
D5151							
ASTM	Standard Test Method for Resistance of Materials Used in						
F1671	Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174						
	Bacteriophage Penetration as a Test System						
ASTM	Standard Test Methods for Vulcanized Rubber and						
D412	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 EC	Lot Number: 101500203750151
Product ID: SEC-375	Manufacture Date: January 2015

Test Results:

Dimensions:

SKU	Palm Width (mm)	Glove Length (mm)
Small	86	290
Medium	97	290
Large	106	296
X-Large	116	294
XX-Large	123	290
XXX-Large	129	291

Thickness Single Wall:

Cuff Thickness	Palm	Finger Tip			
(mm)	Thickness(mm)	Thickness(mm)			
0.10	0.14	0.19			
0.10	0.14	0.19			
0.11	0.15	0.20			
0.11	0.15	0.20			
0.10	0.15	0.19			
0.10	0.14	0.19			
	Cuff Thickness (mm) 0.10 0.10 0.11 0.11 0.11	Cuff Thickness (mm) Palm Thickness(mm) 0.10 0.14 0.10 0.14 0.11 0.15 0.11 0.15 0.10 0.15			

Physical Properties:

	Before Aging	UOM	After Aging	UOM
Tensile	25.56	MPa	28.62	MPa
Elongation min.	631	%	543	%

Other Properties:

5 .		
Powder		UOM
Content:		
Small	0.8	mg/glove
Medium	1.4	mg/glove
Large	1.0	mg/glove
X-Large	0.8	mg/glove
XX-Large	1.2	mg/glove
XXX-Large	1.0	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: 50 gloves per dispenser by weight

Arlene Voskamp	5/4/15
Quality Assurance Department (Print Name)	Date
Arla Voskap	
Quality Assurance Department (Signature)	

Ansell



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ESD Statement

Ansell

Corporate Offices 111 Wood Avenue South, Suite 210 Iselin, NJ 08830 United States T + 1 732 345 5400 F + 1 732 219 5114

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 <u>half decay time</u> of 1.63 seconds whilst the EN 1149-5 requires < 4 seconds. The <u>surface resistivity</u> is $2.56 \times 10^{12} \Omega$ whilst the EN 1149-5 requires $< 5.10^{10} \Omega$.
- 2. Our SEC-375 gloves achieved a <u>half decay time</u> of 1.35 seconds whilst the EN 1149-5 requires < 4 seconds. The <u>surface resistivity</u> is 1.24 x $10^{11} \Omega$ whilst the EN 1149-5 requires < 5. $10^{10} \Omega$.

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 EC, SEC-375

Hereby, I confirm that the Supreno EC, SEC-375 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





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Allergen Statement

Allergen Statement for Supreno EC, SEC-375

This is to confirm that the Supreno EC, SEC-375 glove does not have the following materials:

1. Allergenic protein of natural rubber latex

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® EC

	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 p	rotection	Medium p	protection	High pr	otection	

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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Cytotoxic Contact Test Results

ANSELL GLOVES	Microflex® Supreno® EC	TouchNTuff* 92-605		
POLYMER	Non-Sterile Nitrile	Non-Sterile Nitrile		
Chemotherapy Drug Tested	Minimum Breakthrough Time (Minutes) us	sing ASTM F739 and EN374 Test Methods		
Amethopterine Hydrate	15	2		
Bleomycin Sulfate	No data	No breakthrough up to 240 minutes		
Carboplatin (Paraplatin)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Carmustine	15	No data		
Cisplatin	No data	No data		
Cyclophosphamide	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Cytarabine	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Dacarbazine	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Daunorubicin HCI (Cerubidine)	No data	No data		
Doxorubicin Hydrochloride	No data	No data		
Etoposide (Toposar)	No data	No data		
Fluorouracil	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Idarubicin HCI	No data	No data		
Ifosfamide	No data	No data		
Melphalan (Alkeran)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Methotrexate	15	No breakthrough up to 240 minutes		
Mitomycin	No data	No data		
Mitoxantrone	No breakthrough up to 240 minutes	No data		
Paclitaxel (Taxol)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Thiotepa	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes		
Vincristine Sulfate	No breakthrough up to 240 minutes	No data		

PERMEATION BREAKTHROUGH TIMES ACCORDING TO EN374 (minutes)							
0	1	2	3	4	5	6	
< 10	10 - 30 30 - 60		60 - 120	120 - 240	240 - 480	> 480	
Not Recommended	Splash Pi	rotection	Medium F	Protection	High Pro	otection	





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
SEC-375	XS 5-6	SEC-375-XS	10 dispenser boxes per case	48	10.6	290 x 268 x 261	769799032554	769799032509
SEC-375	S 6.5-7	SEC-375-S	10 dispenser boxes per case	48	11.1	291 x 268 x 261	769799032561	769799032516
SEC-375	M 7.5-8	SEC-375-M	10 dispenser boxes per case	48	11.7	292 x 268 x 261	769799032578	769799032523
SEC-375	L 8.5-9	SEC-375-L	10 dispenser boxes per case	48	12.2	293 x 268 x 261	769799032585	769799032530
SEC-375	XL 9.5-10	SEC-375-XL	10 dispenser boxes per case	48	12.8	294 x 268 x 261	769799032592	769799032547
SEC-375	XXL 10.5-11	SEC-375-XXL	10 dispenser boxes per case	48	13.2	295 x 268 x 261	769799032509	769799032554
SEC-375	XXXL 11.5-12	SEC-375-XXXL	10 dispenser boxes per case	48	11.5	290 x 268 x 261	769799325014	769799325113





Packaging Explanation



290 mm x 268 mm x 261 mm



DOWDER-FREE Suprence EXAMINATION GLOVES Lot# Case # Case No. Manufacturing Date M





Quality Management ISO 13485:2003

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.: Certificate Registration No.: Expiry Date: 31191311 004 74 500 4553 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)



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

12055Sage 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.: Certificate Registration No.:

Expiry Date:

31191311 004 74 500 4553 August 24, 2017



Certification Officer: Prian 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) 426-0988 Fax(203)426-400



MICR#FLEX*

SUPRENO® EC

Instructions for Use

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

CE&DI



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INSTRUCTIONS FOR USE CATEGORY III / COMPLEX DESIGN

ANSELL 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

This Instruction for Use note is to be used in combination with the specimic information that is the insuried on or insure 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

Please ensure the gloves are used only for the designated purposes.

Explanation of pictograms:







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. EV-Type examination certificate from Centexeble Belgium (ID. 0439), Echonologiepatr, 79–9052 Zwijnardne, For more detailed information on the glove's performance and to obtain a copy of the Conformity Declaration, please consult Ansali.

B. Precautions for use

1. 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.

2. 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 rathed 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.
- 4. Contaminatest gives should not be used in applications requiring thermal protection.
 5. The glows should not be used in applications requiring thermal protection.
 6. Disposable glove ly versions with a glove length below 250 mm are "Eff to Special Purpose gloves" because they are to be used to protect the hand ONLY from chemical splashos when handling chemicals. Do not use the gloves when
- are to de used to protect the hand UNLY from chemical splasnes when handling nemicals. Do not use the gloves when protection in the culf area is neededed.

 7. Gloves shall not be used for protection against ionising radiation nor for use in containment enclosures.

 8. 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.

 9. If gloves are marked, the printed surfaces shall not come in contact with food.

9. If gloves are market, the printed surfaces shall not come in contact with root.
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 09/2009

Ansell





Product Portfolio

Available in North America

Overview of Single-Use Product Portfolio

Brand	Style	Length	Palm Thickness	Key Features & Benefits
Diana	Style	(in)	(mils)	Rey reacures a benefits
Natural Rubbe	er Latex	•	•	
TouchNTuff®	69-318	9.5	5.0	 Ideal for intricate handling of objects The lightest, powder free natural rubber latex style
Microflex®	E-Grip [®] Max	9.6	5.1	Double chlorinated for easy donning
Microflex®	Diamond Grip™	9.6	6.3	Unique, rugged latex design prevents snags, rips, and tears Stong and durable in mechanical and oily environments
Microflex®	Evolution One®	9.6	5.5	Superior wet and dry grip due to polymer-coating Maximum comfort allows for extended wear
Microflex®	Comfort Grip®	9.6	5.1	Multi-purpose latex glove
Microflex®	SafeGrip [®]	11.6	11.0	 Ideal for heavy duty applications Double chlorinated for easy donning
Microflex®	Ultra One®	11.8	9.8	 Long cuff to protect the forearm Thick latex gloves for extra protection
Microflex®	MegaPro®	11.6	9.8	Blue color, fully textured for secure grip Thick latex gloves for extra protection
Nitrile				
Microflex®	XCEED®	9.5	2.8	 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	 Specialized formulation reduces chances of contact dermatitis Very low sulfur and aluminum content
Microflex®	Ultraform®	9.1	2.4	 Unique, soft formulation for exceptional tactility Ansell ERGOFORM™ technology proven to reduce hand fatigue
Microflex®	Soft White Nitrile	9.4	2.6	Thin, soft nitrile allowing for good tactility
Microflex®	Cobalt®	9.5	3.9	Fully textured for enhanced grip Multi-purpose glove
Microflex®	N85	9.5	3.1	Basic, multi-purpose glove
TouchNTuff®	93-250	9.5	4.7	 Soft nitrile reduces hand and arm fatigue Less force needed to grip wet and dry objects Silicone free





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Available in North America

Nitrile (continu	ned)			
TouchNTuff®	92-600	9.5	4.7	 Enhanced chemical splash protection Proprietary, soft, thin nitrile formulation Silicone free
Microflex®	Supreno® EC	11.6	5.5	 Approved for use with chemotherapy drugs Exceptional barrier integrity with 0.65 AQL
Microflex®	Supreno® SE	9.6	4.3	 Exceptional barrier integrity with 0.65 AQL Ideal for longer wear times
Microflex®	MidKnight [®]	9.6	4.7	 Distinct black color masks stains Fully textured for consistent grip performance No foaming in wet environments
Microflex®	Blaze [®]	10.6	5.1	High visibility Works exceptionally well in oily environments
TouchNTuff®	92-675	9.5	4.3	 Exceptional chemical splash properties Ideal for broad applications
TouchNTuff®	92-500	9.5	4.7	 Powdered for easy donning and moisture absorption Proprietary, soft, thin nitrile formulation Enhanced chemical splash protection
TouchNTuff®	92-605	11.8	4.7	 Enhanced chemical splash protection Very comfortable soft nitrile Silicone free
TouchNTuff®	92-575	9.5	4.3	 Thin, durable glove Textured fingers for good grip Powdered for easy donning and moisture absorption
Neoprene				
Microflex®	Neogard®	9.6	3.9	 Ansell ERGOFORM™ technology proven to reduce hand fatigue Exceptional wet grip
NeoTouch [®]	25-101	9.5	5.1	 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	 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	 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	 Approved for use with chemotherapy drugs (ASTM D 6978) Excellent splash resistance to most acids and alcohols Good wet and dry grip

