

MEDIUM WEIGHT: 55-100/55-102/55-104 55-106/55-108/55-110

HEAVY WEIGHT: 55-101/55-103/55-105 55-107/55-109/55-111

MITTEN: 55-113





3



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**Global Product Datasheet** 

# AlphaTec®

NATURAL RUBBER LATEX MEDIUM WEIGHT ISOLATOR BOX GLOVE



## A COMFORTABLE CHOICE IN PHYSICALLY DEMANDING WORK ENVIRONMENTS

Latex construction provides a good defense against tears, abrasions, cuts and punctures

- Translucent and unlined for effective cleaning
- Effective protection for medium duty physical environments, especially for defense against abrasions and tears
- The medium thickness (20mil/0.51mm) increases dexterity, which improves the ability to manipulate objects
- Available port sizes fit most isolator glove boxes







# AlphaTec®



NATURAL RUBBER LATEX MEDIUM WEIGHT (20 mil/0.51 mm) ISOLATOR BOX GLOVE

#### TECHNICAL DATA SHEET

#### **PRODUCT INFORMATION**

Material	Natural rubber latex
Color	Natural
Glove Design	Ambidextrous hand shape, smooth grip
Glove Description	For protection in medium duty work environments. Highly durable in physical demanding applications. Resistant to most acids, alkalis, alcohols, aldehydes and ketones. The latex formulation makes the gloves an affordable choice.
Audit Standards	Manufacturing facility registered to ISO 9001 and ISO 14001
Operating Temperature	Range of -30°C to 50°C
Applications	Pharmaceutical, chemical, and electronic industries
Quality Control	Compliant with EN388, EN420 and EN374
Packaging	10 pairs in black vacuum-sealed bags per case
Storage	Store in cool dry place, temperature 15°C to 30°C, away from direct sunlight and sources of heat.
Country of Origin	Malaysia

#### PHYSICAL PROPERTIES

PROPERTY	TYPICAL	TESTING METHOD	
Freedom from holes (inspection level I)	AQL <0.65		EN 374-2
Palm thickness single wall	20 mil/0.51 mm		EN 420
	BEFORE AGING	AFTER AGING	
Ultimate tensile strength	14 MPa, min	9.1 MPa, min	BS 903 / ISO 37:2005
Elongation at break	600%, min	480%, min	BS 903 / ISO 37:2005
Modulus @ 500%	5.5 MPa, max	5.5 MPa, max	BS 903 / ISO 37:2005
Force at break	23 N, max	15 N, max	BS 903 / ISO 37:2005

#### ORDERING INFORMATION

Style	Port Size (in/mm)	Length (in/mm)	SIZE	8	9	10
FF 100	6 in/150 mm	128 in/711 mm	ASPN	256258	256259	256260
55-100	6 m/ 150 mm		ORACLE	114937	114938	114939
55-102	7 in/180 mm	28 in/711 mm	ASPN	-	256264	256265
55-102	7 m/ 160 mm		ORACLE	-	114943	114944
55-104	8 in/200 mm	32 in/813 mm	ASPN	-	256268	256269
			ORACLE	-	114947	114948
55-106	9 in/230 mm	131 in/787 mm	ASPN	-	256272	256273
			ORACLE	-	114951	114952
55-108	10 in/250 mm 32 in/813 mm	70 : /017	ASPN	-	256276	256277
55-108		52 11/015 11111	ORACLE	-	114955	114956
55-110	12 in/300 mm	32 in/813 mm	ASPN	-	256279	256280
	12 m/ 500 mm	52 11/015 11111	ORACLE	-	114958	114959

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#### TESTING INFORMATION

EN374
6 K-Sodium hydroxide 40%
EN388
3 Abrasion
0 Cut
1 Tear
0 Puncture
EN 420
5 Dexterity









### NATURAL RUBBER LATEX HEAVY WEIGHT ISOLATOR BOX GLOVE



## A COMFORTABLE CHOICE IN PHYSICALLY DEMANDING WORK ENVIRONMENTS

Latex construction provides a good defense against tears, abrasions, cuts and punctures

- Translucent and unlined for effective cleaning
  - Effective protection for heavy duty physical environments, including great defense against tears and abrasions and good protection against cuts and punctures
- The heavyweight thickness (30 mil/0.76mm) increases durability, augmenting chemical and physical resistance
- Available port sizes fit most isolator glove boxes

Style 55-101 / 103 / 105 107 / 109 / 111





# AlphaTec®



NATURAL RUBBER LATEX HEAVY WEIGHT (30 mil/0.76 mm) ISOLATOR BOX GLOVE

#### TECHNICAL DATA SHEET

#### **PRODUCT INFORMATION**

Material	Natural rubber latex
Color	Natural
Glove Design	Ambidextrous hand shape, smooth grip
Glove Description	For protection in heavy duty work environments. Highly durable in physical demanding applications. Resistant to most acids, alkalis, alcohols, aldehydes and ketones. The latex formulation makes the gloves an affordable choice.
Audit Standards	Manufacturing facility registered to ISO 9001 and ISO 14001
Operating Temperature	Range of -30°C to 50°C
Applications	Pharmaceutical, chemical, and electronic industries
Quality Control	Compliant with EN388, EN420 and EN374
Packaging	10 pairs in black vacuum-sealed bags per case
Storage	Store in cool dry place, temperature 15°C to 30°C, away from direct sunlight and sources of heat.
Country of Origin	Malaysia

#### PHYSICAL PROPERTIES

PROPERTY	TYPICAL	TESTING METHOD	
Freedom from holes (inspection level I)	AQL <0.65		EN 374-2
Palm thickness single wall	30 mil/0.76 mm		EN 420
	BEFORE AGING	AFTER AGING	
Ultimate tensile strength	14 MPa, min	9.1 MPa, min	BS 903 / ISO 37:2005
Elongation at break	600%, min	480%, min	BS 903 / ISO 37:2005
Modulus @ 500%	5.5 MPa, max	5.5 MPa, max	BS 903 / ISO 37:2005
Force at break	23 N, max	15 N, max	BS 903 / ISO 37:2005

#### ORDERING INFORMATION

Style	Port Size (in/mm)	Length (in/mm)	SIZE	8	9	10
FF 101	C in (150 mm	128 in/711 mm	ASPN	256261	256262	256263
55-101	6 in/150 mm		ORACLE	114940	114941	114942
55-103	7 in/180 mm	28 in/711 mm	ASPN	-	256266	256267
55-105	7 11/ 160 11111		ORACLE	-	114945	114946
55-105	8 in/200 mm	32 in/813 mm	ASPN	-	256270	256271
			ORACLE	-	114949	114950
55-107	9 in/230 mm	31i n/787 mm	ASPN	-	256274	256275
			ORACLE	-	114953	114954
55-109	10 in/250 mm 32	22 in/217 mm	ASPN	-	-	256278
55-109			ORACLE	-	-	114957
55-111	12 in/300 mm	32 in/813 mm	ASPN	-	256281	256282
	12 m/ 300 mm	<u>52 III/615</u> IIIIII	ORACLE	-	114960	114961

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#### TESTING INFORMATION

EN374
6 K-Sodium hydroxide 40%
EN388
3 Abrasion
1 Cut
2 Tear
1 Puncture
EN 420
5 Dexterity





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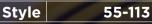


NATURAL RUBBER LATEX MITTEN ISOLATOR BOX GLOVE

## A COMFORTABLE CHOICE IN PHYSICALLY DEMANDING WORK ENVIRONMENTS

Latex construction provides a good defense against tears, abrasions, cuts and punctures

- Translucent and unlined for effective cleaning
- Mitten shape provides effective protection for major risk environments
- Protective defense against abrasions and tears
- The medium thickness (20mil/0.51mm) increases dexterity







# AlphaTec®



NATURAL RUBBER LATEX MITTEN (20 mil/0.51 mm) ISOLATOR BOX GLOVE

#### TECHNICAL DATA SHEET

#### **PRODUCT INFORMATION**

Material	Natural rubber latex
Color	Natural
Glove Design	Ambidextrous hand shape, smooth grip
Glove Description	For protection in medium duty work environments. Highly durable in physical demanding applications. Resistant to most acids, alkalis, alcohols, aldehydes and ketones. The latex formulation makes the gloves an affordable choice.
Audit Standards	Manufacturing facility registered to ISO 9001 and ISO 14001
Operating Temperature	Range of -30°C to 50°C
Applications	Pharmaceutical, chemical, and electronic industries
Quality Control	Compliant with EN388, EN420 and EN374
Packaging	10 pairs in black vacuum-sealed bags per case
Storage	Store in cool dry place, temperature 15°C to 30°C, away from direct sunlight and sources of heat.
Country of Origin	Malaysia

#### PHYSICAL PROPERTIES

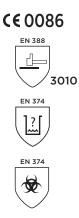
PROPERTY	TYPICAL	TESTING METHOD	
Freedom from holes (inspection level I)	AQL <0.65		EN 374-2
Palm thickness single wall	20 mil/0.51 mm		EN 420
	BEFORE AGING	AFTER AGING	
Ultimate tensile strength	14 MPa, min	9.1 MPa, min	BS 903 / ISO 37:2005
Elongation at break	600%, min	480%, min	BS 903 / ISO 37:2005
Modulus @ 500%	5.5 MPa, max	5.5 MPa, max	BS 903 / ISO 37:2005
Force at break	23 N, max	15 N, max	BS 903 / ISO 37:2005

#### TESTING INFORMATION EN374

EN374
6 K-Sodium hydroxide 40%
EN388
3 Abrasion
0 Cut
1 Tear
0 Puncture
EN 420
5 Dexterity

#### ORDERING INFORMATION

Style	Port Size (in/mm)	Length (in/mm)	SIZE	10
55-113	8 in/200 mm	32 in/813 mm	ASPN	256284
55-115	8 m/200 mm	32 11/013 11111	ORACLE	114963



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# **Alphalec**<sup>®</sup>

#### **Technical Datasheet**

## AlphaTec® 55-100

#### **Special Purpose**

#### **Glove material**

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

- Sensitizers
- Natural rubber proteins Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

Reach Regulation 1907/2006 For more information, please consult the REACH statement on the Ansell website

#### Properties

#### **EN Test Data**

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 0 Tear resistance: Performance level 1 Puncture resistance: Performance level 0

European	conformity

**TECHNICAL** DATASHEET

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

Print date 09-06-2015

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

Coating material	Grip design	Cuff style	Colour	AQL (EN374)	EN Size	Length mm	Thickness mm	Packaging
Natural rubber	Smooth Finish	Rolled beaded	Natural	0.65	8, 9, 10	711 (Port size	0.51	10 pairs in black vacuum-
latex						150mm)		sealed bags per case

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Alphale

### TECHNICAL DATASHEET

#### **Special Purpose**

Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

Natural rubber proteins

- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 1 Tear resistance: Performance level 2 Puncture resistance: Performance level 1

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel

Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

Thickness mm AQL (EN374) EN Size Coating material Grip design Cuff style Colour Length mm Packaging Natural 0.65 8. 9. 10 0.76 Natural rubber Smooth Finish Rolled beaded 700 (Port size 10 pairs in black vacuumlatex 150mm) sealed bags per case

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Print date 09-06-2015

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#### **Special Purpose**

Glove materialNatural rubber latex (Coating material)

### Possible Harmful ingredients

Sensitizers

Natural rubber proteins

- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 0 Tear resistance: Performance level 1 Puncture resistance: Performance level 0

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

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#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

AQL (EN374) EN Size Coating material Grip design Cuff style Colour Length mm Thickness mm Packaging Natural 0.65 9.10 0.51 Natural rubber Smooth Finish Rolled beaded 711 (Port size 10 pairs in black vacuumlatex 180mm) sealed bags per case

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### TECHNICAL DATASHEET



## Special Purpose

#### Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

- Natural rubber proteins
- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 1 Tear resistance: Performance level 2 Puncture resistance: Performance level 1

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Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

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#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

Coating material	Grip design	Cuff style	Colour	AQL (EN374)	EN Size	Length mm	Thickness mm	Packaging
Natural rubber	Smooth Finish	Rolled beaded	Natural	0.65	9, 10	711 (Port size	0.76	10 pairs in black vacuum-
latex						180mm)		sealed bags per case

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### TECHNICAL DATASHEET

Print date 09-06-2015



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#### **Special Purpose**

Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

- Natural rubber proteins
- ParabensZinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 0 Tear resistance: Performance level 1 Puncture resistance: Performance level 0

#### European conformity

TECHNICAL DATASHEET

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

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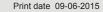
#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

AQL (EN374) EN Size Coating material Grip design Cuff style Colour Length mm Thickness mm Packaging Natural 0.65 9.10 813 (Port Size 0.51 Natural rubber Smooth Finish Rolled beaded 10 pairs in black vacuumlatex 200mm) sealed bags per case

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Alphale

### TECHNICAL DATASHEET

#### **Special Purpose**

Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

Natural rubber proteins

Parabens
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Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 1 Tear resistance: Performance level 2 Puncture resistance: Performance level 1

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

Print date 09-06-2015

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

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#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

AQL (EN374) EN Size Coating material Grip design Cuff style Colour Length mm Thickness mm Packaging Natural 0.65 9.10 813 (Port Size 0.76 Natural rubber Smooth Finish Rolled beaded 10 pairs in black vacuumlatex 200mm) sealed bags per case

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### **TECHNICAL** DATASHEET

#### **Special Purpose**

**Glove material** 

Natural rubber latex (Coating material)

#### **Possible Harmful ingredients**

Sensitizers

Natural rubber proteins

- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### **EN Test Data**

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 **Chemical permeation:** For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 0 Tear resistance: Performance level 1 Puncture resistance: Performance level 0

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

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#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

AQL (EN374) EN Size Coating material Grip design Cuff style Colour Length mm Thickness mm Packaging Natural 0.65 9.10 0.51 Natural rubber Smooth Finish Rolled beaded 787 (Port size 10 pairs in black vacuumlatex 230mm) sealed bags per case

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#### Print date 09-06-2015



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### TECHNICAL DATASHEET

#### **Special Purpose**

Print date 09-06-2015

#### Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

- Natural rubber proteins
- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 1 Tear resistance: Performance level 2 Puncture resistance: Performance level 1

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Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel

Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

Coating material	Grip design	Cuff style	Colour	AQL (EN374)	EN Size	Length mm	Thickness mm	Packaging
Natural rubber	Smooth Finish	Rolled beaded	Natural	0.65	9, 10	787 (Port size	0.76	10 pairs in black vacuum-
latex						230mm)		sealed bags per case

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<u>Alphale</u>

### Special Purpose

Glove materialNatural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

Natural rubber proteins

- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 0 Tear resistance: Performance level 1 Puncture resistance: Performance level 0

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Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel

Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

AQL (EN374) EN Size Thickness mm Coating material Grip design Cuff style Colour Length mm Packaging Natural 0.65 9, 10 0.51 Natural rubber Smooth Finish Rolled beaded 813 (Port size 10 pairs in black vacuumlatex 250mm) sealed bags per case

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

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#### Print date 09-06-2015

Alphale

### TECHNICAL DATASHEET

#### **Special Purpose**

Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

Natural rubber proteins

- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 1 Tear resistance: Performance level 2 Puncture resistance: Performance level 1

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

Print date 09-06-2015

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel

Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

Coating material	Grip design	Cuff style	Colour	AQL (EN374)	EN Size	Length mm	Thickness mm	Packaging
Natural rubber	Smooth Finish	Rolled beaded	Natural	0.65	10	813 (Port size	0.76	10 pairs in black vacuum-
latex						250mm)		sealed bags per case

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

Riverside Business Park, Block J Boulevard International 55, 1070 Brussels, Belgium Tel. +32 (0) 2 528 74 00 • Fax +32 (0) 2 528 74 01 • Fax Customer Service +32 (0) 2 528 74 03 http://www.ansell.eu • E-mail info@ansell.eu

**Alphalec**<sup>®</sup>

### TECHNICAL DATASHEET

#### **Special Purpose**

Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

- Natural rubber proteins
- Parabens
   Zing Diathy delthises
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 0 Tear resistance: Performance level 1 Puncture resistance: Performance level 0

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

Print date 09-06-2015

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel

Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

Coating material	Grip design	Cuff style	Colour	AQL (EN374)	EN Size	Length mm	Thickness mm	Packaging
Natural rubber	Smooth Finish	Rolled beaded	Natural	0.65	9, 10	813 (Port size	0.51	10 pairs in black vacuum-
latex						300mm)		sealed bags per case

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

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**Alphalec**<sup>®</sup>

### **TECHNICAL** DATASHEET

#### **Special Purpose**

Glove material

Natural rubber latex (Coating material)

#### **Possible Harmful ingredients**

<u>Sensitizer</u>s

- Natural rubber proteins
- Parabens
- Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### **EN Test Data**

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 1 Tear resistance: Performance level 2 Puncture resistance: Performance level 1

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel

Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

Coating mater	al Grip design	Cuff style	Colour	AQL (EN374)	EN Size	Length mm	Thickness mm	Packaging
Natural rubber	Smooth Finish	Rolled beaded	Natural	0.65	9, 10	813 (Port size	0.76	10 pairs in black vacuum-
latex						300mm)		sealed bags per case

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

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#### Print date 09-06-2015



### TECHNICAL DATASHEET

#### **Special Purpose**

Glove material

Natural rubber latex (Coating material)

#### Possible Harmful ingredients

Sensitizers

Natural rubber proteins

Parabens
 Zing Distant dittainen

Zinc Diethyldithiocarbamate

Only a very small number of users may be sensitised to this ingredient in the glove and hence may develop irritant and/or allergic contact reactions.

#### Reach Regulation 1907/2006

For more information, please consult the REACH statement on the Ansell website

#### Properties

#### EN Test Data

Liquidproofness: Acceptable Quality Level 0.65 or EN performance level 3 Chemical permeation: For more information on chemical permeation, please consult Ansell website Abrasion resistance: Performance level 3 Blade cut resistance: Performance level 0 Tear resistance: Performance level 1 Puncture resistance: Performance level 0

#### European conformity

Gloves conform to the requirements of the European Directive 89/686/EEC and to the European standards EN 420:2003 + A1:2009 and EN 388:2003,EN 374:2003

They are categorised in "Complex Design" (= Protection against mortal risks).

EC-Type Examination Certificate and EC-quality control for the final product by

Centexbel

Technologiepark 7 B-9052 Zwijnaarde

#### Storage

Keep away from sources of ozone or ignition. Keep out of direct sunlight; store in a cool and dry place.

EN Size AQL (EN374) Coating material Grip design Cuff style Colour Length mm Thickness mm Packaging Natural 0.65 10 813 (Port Size 0.75 Natural rubber Smooth Finish Rolled beaded 10 pairs in black vacuumlatex 200mm) sealed bags per case

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

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#### Print date 09-06-2015





#### **CE Declaration of Product Conformity**

## Ansell

Ansell Healthcare Europe N.V.

Riverside Business Park Boulevard International 55 Block J B-1070 Brussels Tel. 32 (0)2-528 74 00 Fax 32 (0)2-528 74 01

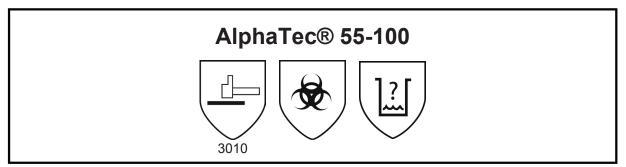
### EC DECLARATION OF PRODUCT CONFORMITY

## **Category III**

The manufacturer, established in the European Economic Community:

#### ANSELL HEALTHCARE EUROPE N.V. RIVERSIDE BUSINESS PARK, BLOCK J BOULEVARD INTERNATIONAL 55 B-1070 BRUSSELS

declares that the PPE described hereafter:



is in conformity with the provisions of the Council Directive 89/686/EEC and with the European harmonised standards EN420:2003+A1:2009, EN388: 2003, EN374: 2003, and is identical to the PPE which is subject to the EC Type Examination certificate number 03213889 issued by the Notified Body:

#### CENTEXBEL (0493) Technologiepark 7 B-9052 Zwijnaarde

is subject to the procedure set out in Article 11 point B of Directive 89/686/EEC under the supervision of the Notified Body

BSI (0086) Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom

Thursday, June 11, 2015 Alison Arnot-Bradshaw Senior Director – EMEA/APAC Regulatory Affairs Ansell





Ansell Healthcare Europe N.V. Riverside Business Park Boulevard International 55

Block J B-1070 Brussels Tel. 32 (0)2-528 74 00 Fax 32 (0)2-528 74 01

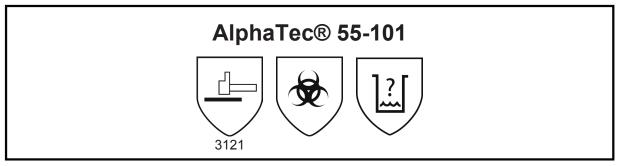
EC DECLARATION OF PRODUCT CONFORMITY

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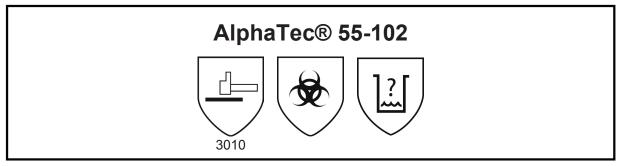
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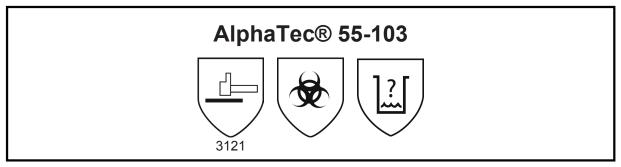
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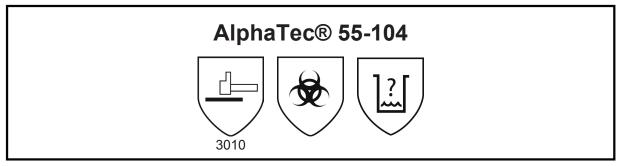
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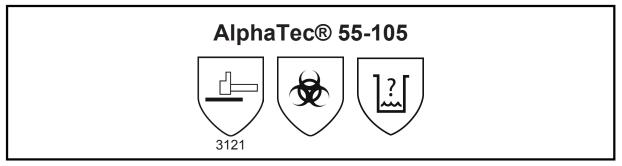
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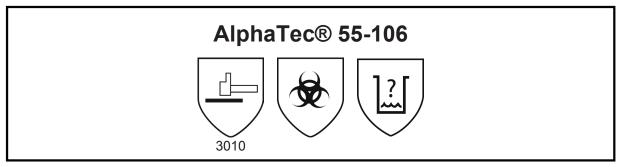
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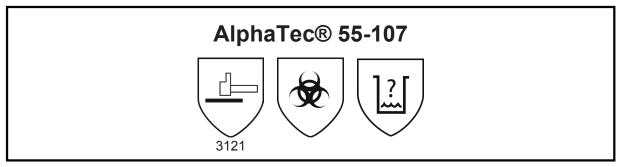
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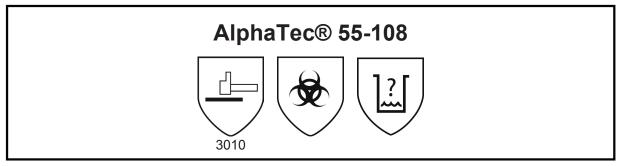
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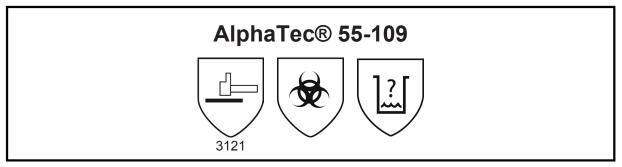
EC DECLARATION OF PRODUCT CONFORMITY

## Category III

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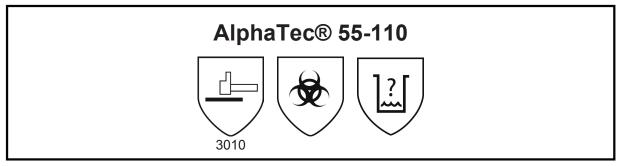
EC DECLARATION OF PRODUCT CONFORMITY

## Category III

The manufacturer, established in the European Economic Community:

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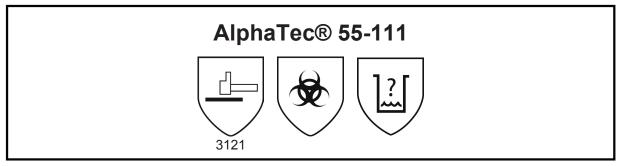
EC DECLARATION OF PRODUCT CONFORMITY

## Category III

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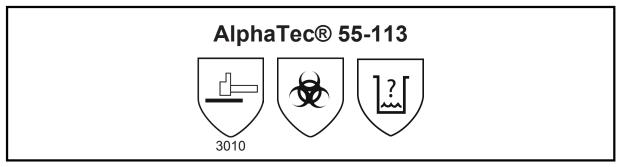
EC DECLARATION OF PRODUCT CONFORMITY

## Category III

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ANSELL HEALTHCARE EUROPE N.V. RIVERSIDE BUSINESS PARK, BLOCK J BOULEVARD INTERNATIONAL 55 B-1070 BRUSSELS

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BSI (0086) Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom

Thursday, June 11, 2015 Alison Arnot-Bradshaw Senior Director – EMEA/APAC Regulatory Affairs Ansell





**CE Certificate** 



In application of the directive 89/686/EEG of 21 December 1989 concerning the harmonisation of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorised by decree AV/OA235/ST dated 94-05-25 of the Ministry of Employment and Labour has issued

to: Ansell Healthcare Europe nv Riverside Business Park - Spey House

Spey House Internationalelaan 55 1070 Brussel Belgium

### **CE TYPE EXAMINATION CERTIFICATE**

#### Nr. 03213889

This CE Type examination certificate is valid until 12/12/2018

for: The gloves AlphaTec 55-100, 55-102, 55-104, 55-106, 55-108, 55-110 and 55-113

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Directive 89/686/EEG.

For the argumentation, the following standards are used:

EN 420:2003+A1:2009: Protective gloves - general requirements

EN 388:2003: Gloves for protection against mechanical risks (see annex)

EN 374-1:2003 (low): Protective gloves against chemicals and micro-organisms

This is PPE of category III, subject to regular checks in accordance with article 11 of the European PPE directive. In agreement with the manufacturer's choice audits shall be carried out to assess the quality control system (art.11B). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31.12. 2015 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical file that is registered with number 6229

Issued by Centexbel, Notified Body 0493 <sup>(*)</sup> , in Ghent, on	
	12 December 2013
Inge De Witte Certification Manager	Jan Laperre directeur-generaal



attached: Annex 2 pages CENTEXBEL, TEXTILE COMPETENCE CENTRE Recognized by decree AV/OA235/ST of 94-05-25 of the Ministry of Labor and Employment Technologiepark 7 • BE 9052 Gent • Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be • www.centexbel.be var • BE 0459.218.289 • IBAN • BE 44 2100 4729 6545 • BIC • GEBABEBB









Annex to certificate 03213889

The gloves AlphaTec 55-100, 55-102, 55-104, 55-106, 55-108, 55-110 and 55-113 fulfil the requirements of EN 388:2003

to use the following pictogram:





CENTEXBEL, TEXTILE COMPETENCE CENTRE

Technologiepark 7 • BE 9052 Gent • Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be • www.centexbel.be • Www.centexbel.be • Ware BE 0459.218.289 • IBAN • BE 44 2100 4729 6545 • BIC • GEBABEBB



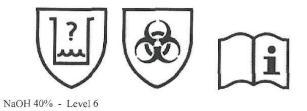




Annex to certificate 03213889

The gloves AlphaTec 55-100, 55-102, 55-104, 55-106, 55-108, 55-110 and 55-113 fulfils the requirements of EN 374-1:2003 (low):

to use the following pictogram





Technologiepark 7 • BE 9052 Gent • Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be • www.centexbel.be VAT • BE 0459.218.289 • IBAN • BE 44 2100 4729 6545 • BIC • GEBABEBB







In application of the directive 89/686/EEG of 21 December 1989 concerning the harmonisation of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorised by decree AV/OA235/ST dated 94-05-25 of the Ministry of Employment and Labour has issued

#### to: Ansell Healthcare Europe nv Riverside Business Park - Spey House

Spey House Internationalelaan 55

1070 Brussel

Belgium

#### **CE TYPE EXAMINATION CERTIFICATE**

#### Nr. 03213890

This CE Type examination certificate is valid until 12/12/2018

for: The gloves AlphaTec 55-101, 55-103, 55-105, 55-107, 55-109 and 55-111

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Directive 89/686/EEG.

For the argumentation, the following standards are used:

EN 420:2003+A1:2009: Protective gloves - general requirements

Gloves for protection against mechanical risks (see annex) EN 388:2003:

EN 374-1:2003 (low): Protective gloves against chemicals and micro-organisms

This is PPE of category III, subject to regular checks in accordance with article 11 of the European PPE directive. In agreement with the manufacturer's choice audits shall be carried out to assess the quality control system (art.11B). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31.12. 2015 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical file that is registered with number 6230

Issued by Centexbel, Notified Body 0493(\*), in Ghent, on

Inge De Witte

Certification Manager



attached: Annex 2 pages

("Recognized by decree AV/OA235/ST of 94-05-25 of the Ministry of Labor and Employment









Annex to certificate 03213890

The gloves AlphaTec 55-101, 55-103, 55-105, 55-107, 55-109 and 55-111 fulfils the requirements of EN 374-1:2003 (low):

to use the following pictogram



NaOH 40% - Level 6









Annex to certificate 03213890

The gloves AlphaTec 55-101, 55-103, 55-105, 55-107, 55-109 and 55-111 fulfil the requirements of EN 388:2003

to use the following pictogram:









#### **Certificate of Conformance**

Ansell Industrial & Specialty Gloves Malaysia Sdn Bhd (Company No. 038030-K) (Formerly known as Marigold Industrial (Malaysia) Sdn. Bhd.) P.O. Box 7, 1A & 1B, Lorong Perusahaan 1 Kulim Industrial Estate, 09000 Kulim Kedah Darul Aman, Malaysia.

T. +604-4945123 F. +604-4891980



### **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 100
Description :	Isolator Gloves 6R2028A
Material Identification:	Natural Rubber Latex
Batch Number:	15041602C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213889</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date : 16 July 2015





T. +604-4945123 F. +604-4891980



## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 101
Description :	Isolator Gloves 6R3028A
Material Identification:	Natural Rubber Latex
Batch Number:	
	15040102C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213890</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date: 16 July 2015





T. +604-4945123 F. +604-4891980



## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 102
Description :	Isolator Gloves 7R2028A
Material Identification:	Natural Rubber Latex
Batch Number:	15031902C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213889</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date : 16 July 2015





T. +604-4945123 F. +604-4891980



## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 103
Description :	Isolator Gloves 7R3028A
Material Identification:	Natural Rubber Latex
Batch Number:	15040102C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213890</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date: 16 July 2015





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## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 104
Description :	Isolator Gloves 8R2032A
Material Identification:	Natural Rubber Latex
Batch Number:	15040102C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213889</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date : 16 July 2015





T. +604-4945123 F. +604-4891980



## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 – 105
Description :	Isolator Gloves 8R3028A
Material Identification:	Natural Rubber Latex
Batch Number:	15030701C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213890</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date: 16 July 2015





T. +604-4945123 F. +604-4891980



## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 106
Description :	Isolator Gloves 9R2031A
Material Identification:	Natural Rubber Latex
Batch Number:	14101502C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213889</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date : 16 July 2015





T. +604-4945123 F. +604-4891980



## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 – 107
Description :	Isolator Gloves 9R3031A
Material Identification:	Natural Rubber Latex
Batch Number:	15040201C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213890</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date: 16 July 2015





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## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 108
Description :	Isolator Gloves 10R2032A
Material Identification:	Natural Rubber Latex
Batch Number:	14120101C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213889</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date : 16 July 2015





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## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 – 109
Description :	Isolator Gloves 10R3032A
Material Identification:	Natural Rubber Latex
Batch Number:	14082601C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213890</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date: 16 July 2015





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## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 110
Description :	Isolator Gloves 12R2032A
Material Identification:	Natural Rubber Latex
Batch Number:	14030012C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213889</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date : 16 July 2015





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## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 – 111
Description :	Isolator Gloves 12R3032A
Material Identification:	Natural Rubber Latex
Batch Number:	14111302C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213890</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date: 16 July 2015





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## **Certificate Of Conformity**

We declare that the following Product,

Style Number:	55 - 113
Description :	Isolator Gloves 8R2032M
Material Identification:	Natural Rubber Latex
Batch Number:	15061802C1
Shelf Life:	35 months

is in conformity with the following standards or other normative documents: FDA positive list CFR Vol. 21. Directive 89/686/EEC EC Type Test Certificate <u>03213889</u> EN420:2003+A1:2009: Protective Gloves –General Requirements EN388:2003: Gloves for Protection against Mechanical Risk EN374-1:2003 (low): Protective Glove against Chemicals and Micro-organism

Layz

LK Khoo Quality Assurance Manager Date: 16 July 2015





#### **BSE/TSE Declaration**

#### 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

#### TSE / BSE Statement for Alpha Tec Isolator Gloves

All Ansell isolator glove products do not contain any raw materials produced from, or substances derived of animal origin. Furthermore, these products are not derived from specific-risk materials as defined in European Commission Decision 97/534/EC.

The manufacturing process does not use any ingredient of animal origin nor do our products come in contact with animal products during storage and transportation.

I hereby confirm that the product(s) listed below do not contain any Transmissible Spongiform Encephalopathy (=TSE) sources and using this glove would not cause any diseases such as BSE (Bovine Spongiform Encephalopathy).

Product Name	Item Number		
Alpha Tec Isolator Glove EPDM	85-500, 501, 502, 503, 504 & 505		
Alpha Tec Isolator Glove EPDM Plus	85-600, 601 & 602		
Alpha Tec Isolator Glove CSM	85-300, 301, 302, 303, 304, 305		
Alpha Tec Isolator Glove Latex	55-100, 101, 102, 103, 104, 105,		
	106, 107, 108, 109, 110, 111,		
	112,113		
Alpha Tec Isolator Glove Neoprene	55-300, 301, 302, 303, 304, 305,		
	306, 307, 308, 309		

Regards,

0/hl

Donald J Cronk Manager of Regulatory Affairs and Technical Services

don.cronk@ansell.com





#### **FDA Positive 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

#### Re: FDA Positive Statement

This letter certifies that the product(s) listed below are in full compliance with FDA Food Contact Regulations (FDA Positive List) 21 CFR 177 INDIRECT FOOD ADDITIVES: POLYMERS & Part 110.10 CURRENT GMP IN MANUFACTURING, PACKING OR HOLDING HUMAN FOOD.

Product Name	Item Number		
Alpha Tec Isolator Glove EPDM	85-500, 501, 502, 503, 504 & 505		
Alpha Tec Isolator Glove EPDM Plus	85-600, 601 & 602		
Alpha Tec Isolator Glove Latex	55-100, 101, 102, 103, 104, 105,		
	106, 107, 108, 109, 110, 111,		
	113		
Alpha Tec Isolator Glove Neoprene	55-300, 301, 302, 303, 304, 305,		
	306, 307, 308, 309		

Regards,

s /hk

Don Cronk Regulatory Affairs Manager Email:don.cronk@ansell.com



## 

#### Allergen 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

#### Allergen Statement

55-100	55-104	55-108	55-113
55-101	55-105	55-109	
55-102	55-106	55-110	
55-103	55-107	55-111	

This is to confirm that the styles listed above do contain the following materials:

- 1. Allergenic protein of natural rubber latex
- 2. Zinc Diethyldithiocarbamate
- 3. Parabens

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: <u>don.cronk@ansell.com</u>



# AlphaTec®

### Permeation Breakthrough Time

Chemical	Neoprene Medium Weight (0.51 mm)	Neoprene Heavy Weight (0.76 mm)	Latex Light Weight (0.51 mm)	Latex Heavy Weight (0.76 mm)
SOLVENTS	P		n	•
Acetic Acid	6	6	4	3
Acetone (2-Propanone)	1	2	0	1
Acetonitrile	3	4	0	0
C12/C13 alkanes	6	6	2	3
Chloroform	1	1	0	0
Dichloromethane (Methylene chloride)	0	0	0	0
Diethylamine	0	1	0	0
Diethylether (Ether)	1	1	0	0
Ethylacetate	1	1	0	1
Formic Acid	6	6	4	5
Heptane	4	6	0	0
Hexane	2	3	0	0
Methyl Ethyl Ketone (2-Butanone, MEK)	1	1	0	1
PAH's (Polycyclic aromatic hydrocarbons)	1	1	0	0
Sodium Hydroxide, NaOH 40%	6	6	6	6
Sulfuric acid 96%	4	4	3	3
Tetrahydrofurane (THF)	1	5	3	4
Toluene	1	1	0	0
DISINFECTANTS				
1-propanol (Propylalcohol)	6	6	2	3
Deconclean	6	6	6	6
DeconSpore 200 Plus	6	6	6	6
Ethanol (Ethylalcohol)	6	6	1	3
Hydrogen Peroxide 30%	6	6	4	6
Isopropylalcohol IPA (2-propanol)	6	6	3	4
LpH se	6	6	6	6
Methanol	6	6	2	3
SporeKlenz	6	6	6	6
Vesphene IIse	6	6	6	6

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 P	Protection Medium Prote		Protection	High Pro	otection



## AlphaTec®

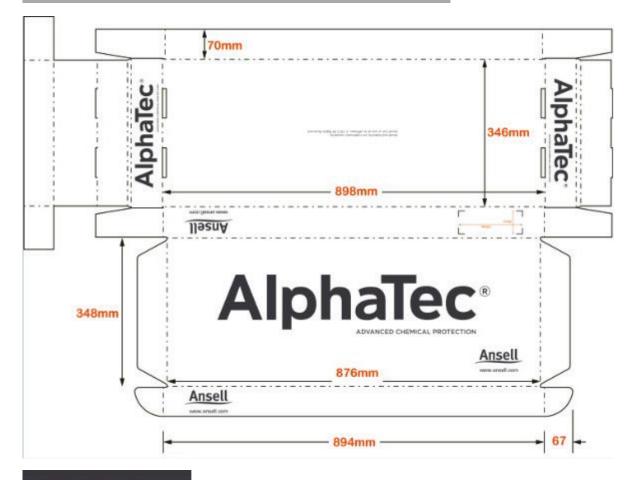
### Packaging Data

Style	Size	External ID	иом	Quantity per case	Case Wt. Kg	Case Dimensions (in mm – L x D x H)	Inner Bar Code	Outer Case Bar Code
55-100	8	55100080	1 pair packed in black polybag	10 pairs	4.200	L:880 X W: 346 X H: 70MM	(01) 0076490045036	(01)20076490045030
55-100	9	55100090	1 pair packed in black polybag	10 pairs	3.570	L:880 X W: 346 X H: 70MM	(01) 0076490045043	(01)20076490045047
55-100	10	55100100	1 pair packed in black polybag	10 pairs	4.700	L:880 X W: 346 X H: 70MM	(01) 0076490045050	(01)20076490045054
55-101	8	55101080	1 pair packed in black polybag	10 pairs	3.870	L:880 X W: 346 X H: 70MM	(01) 0076490045067	(01)20076490045061
55-101	9	55101090	1 pair packed in black polybag	10 pairs	4.170	L:880 X W: 346 X H: 70MM	(01) 0076490045074	(01)20076490045078
55-101	10	55101100	1 pair packed in black polybag	10 pairs	5.050	L:880 X W: 346 X H: 70MM	(01) 0076490045081	(01)20076490045085
55-102	9	55102090	1 pair packed in black polybag	10 pairs	4.700	L:880 X W: 346 X H: 70MM	(01) 0076490045098	(01)20076490045092
55-102	10	55102100	1 pair packed in black polybag	10 pairs	3.870	L:880 X W: 346 X H: 70MM	(01) 0076490045104	(01)20076490045108
55-103	9	55103090	1 pair packed in black polybag	10 pairs	4.470	L:880 X W: 346 X H: 70MM	(01) 0076490045111	(01)20076490045115
55-103	10	55103100	1 pair packed in black polybag	10 pairs	5.650	L:880 X W: 346 X H: 70MM	(01) 0076490045128	(01)20076490045122
55-104	9	55104090	1 pair packed in black polybag	10 pairs	5.700	L:880 X W: 346 X H: 70MM	(01)0076490045135	(01)20076490045139
55-104	10	55104100	1 pair packed in black polybag	10 pairs	5.950	L:880 X W: 346 X H: 70MM	(01)0076490045142	(01)20076490045146
55-105	9	55105090	1 pair packed in black polybag	10 pairs	6.850	L:880 X W: 346 X H: 70MM	(01)0076490045159	(01)20076490045153
55-105	10	55105100	1 pair packed in black polybag	10 pairs	5.870	L:880 X W: 346 X H: 70MM	(01)0076490045166	(01)20076490045160
55-106	9	55106090	1 pair packed in black polybag	10 pairs	5.070	L:880 X W: 346 X H: 70MM	(01)0076490045173	(01)20076490045177
55-106	10	55106100	1 pair packed in black polybag	10 pairs	5.170	L:880 X W: 346 X H: 70MM	(01)0076490045180	(01)20076490045184
55-107	9	55107090	1 pair packed in black polybag	10 pairs	5.870	L:880 X W: 346 X H: 70MM	(01)0076490045197	(01)20076490045191
55-107	10	55107100	1 pair packed in black polybag	10 pairs	6.370	L:880 X W: 346 X H: 70MM	(01)0076490045203	(01)20076490045207
55-108	9	55108090	1 pair packed in black polybag	10 pairs	6.470	L: 880 X W: 480 X H: 70MM	(01) 0076490045210	(01)20076490045214
55-108	10	55108100	1 pair packed in black polybag	10 pairs	6.470	L: 880 X W: 480 X H: 70MM	(01) 0076490045227	(01)20076490045221
55-109	10	55109100	1 pair packed in black polybag	10 pairs	7.700	L: 880 X W: 480 X H: 70MM	(01) 0076490045234	(01)20076490045238
55-110	9	55110090	1 pair packed in black polybag	10 pairs	8.300	L: 880 X W: 480 X H: 70MM	(01)0076490045241	(01)20076490045245
55-110	10	55110100	1 pair packed in black polybag	10 pairs	7.260	L: 880 X W: 480 X H: 70MM	(01)0076490045258	(01)20076490045252
55-111	9	55111090	1 pair packed in black polybag	10 pairs	9.360	L: 880 X W: 480 X H: 70MM	(01)0076490045265	(01)20076490045269
55-111	10	55111100	1 pair packed in black polybag	10 pairs	9.360	L: 880 X W: 480 X H: 70MM	(01)0076490045272	(01)20076490045276
55-113	10	55113100	1 pair packed in black polybag	10 pairs	4.470	L:880 X W: 346 X H: 70MM	(01) 0076490045296	(01)20076490045290





#### Packaging and Label Explanation



Ansell	L L
Alph	• ® ▶ N

Ansell	123456 P/N 114948 LOT 1310C1
ALPHATEC® 55-104 8R2032A SIZE 10	2018-10
PRODUCT OF MALAYS	ASPN:256269 SZ:10

10	Size
LOT 1310C1	Lot #
······································	Manufacturing Date
<b>≧</b> 2018-10 ────	Expiry Date
	Bar Code



**Shelflife Statement** 

**AlphaTec**<sup>®</sup>

#### **Shelflife Statement**

Current accelerated aging studies suggest that there is a minimum three-year shelf life for the products listed below. However, the shelf life of the product can be affected by storage conditions. Store in a dry, cool, well-ventilated area. When possible shield open box from direct sunlight, florescent lighting and x-rays. Improper storage will decrease usable life.

If you notice any signs of aging or improper storage such as discoloration, tearing, holes or degradation we would advise that you discard and replace the gloves.

Product Name	Item Number		
AlphaTec Isolator Glove EPDM	85-500, 501, 502, 503, 504 & 505		
AlphaTec Isolator Glove EPDM Plus	85-600, 601 & 602		
AlphaTec Isolator Glove CSM	85-300, 301, 302, 303, 304 & 305		
AlphaTec Isolator Glove Latex	55-100, 101, 102, 103, 104, 105,		
	106, 107, 108, 109, 110, 111,		
	113		
AlphaTec Isolator Glove Neoprene	55-300, 301, 302, 303, 304, 305,		
	306, 307, 308, 309		

Best regards,

- Ill

Donald J. Cronk Manager Regulatory Affairs and Technical Services





#### **Quality Management ISO 9001 2008**



EM CERTIFICA

SG.

Certificate SG02/20011

The management system of

### Ansell Industrial & Specialty Gloves Malaysia Sdn. Bhd.

1A & 1B, Lorong Perusahaan 1 Kulim Industrial Estate 09000 Kulim, Kedah MALAYSIA

has been assessed and certified as meeting the requirements of

## ISO 9001:2008

For the following activities

Design and Manufacture of Industrial and Consumer Gloves which meet the relevant Personal Protective Equipment (PPE) Standards

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 11 October 2014 until 10 October 2017 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 19 August 2017 Issue 8. Certified since 23 September 2002

Authorised by



SGS United Kingdom Ltd Systems & Services Certification Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

> SGS 9001-8 01 0614 Page 1 of 1



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SG



Ansell

## **AlphaTec**<sup>®</sup>

#### Instructions for Use

	EN	ES	іт	NL	DA	NO	AR
	FR	DE	РТ	EL	FL	sv	RU
CS	HU	LV	PL	BG	SL	ко	тн
ET	LT	МТ	RO	SK	TR	MS	ZH

#### Europe i

Ansell Healthcare Europe NV Blvd International, 55 1070 Brussels, Belgium 🕿 +32 2 528 74 00 📇 +32 2 528 74 01 www.anselleurope.com

#### United States

Ansell Healthcare 200 Schulz Drive, Red Bank NJ 07701 ☎ +1 800 800 0444 = +1 800 800 0445 www.ansellpro.com

#### Japan

Ansell Japan Ltd. Tokyo, Japan **a** +81 3 5805 3781

Malaysia

Ansell Services (Asia) Sdn Bhd **a** +60 3 5541 9797 Canada

105 Lauder Street, Cowansville J2K 2K8 **a** +1 800 363 8340

#### Australia

Ansell Limited Level 3, 678 Victoria Street, Richmond, Vic, 3121 ☎ +61 1800 337 041 = +61 1800 803 578 www.ansellasiapacific.com

#### INSTRUCTIONS FOR USE CATEGORY III / COMPLEX DESIGN ANSELL CHEMICAL **RESISTANT GLOVES**

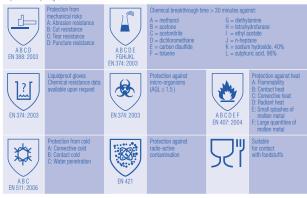
#### A. Use

CR

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 to protect the hands mainly against chemical risks

These gives are designed to protect the native straining against chemical rokes. They are in contomity 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 purpo Explanation of pictograms:



Warning! The information given in the pictograms or data provided on chemical resistant breakthrough times is based on lab For many in the interformating prior in this provide grant and a period of the interformation of the prior and the prior and

B. Precautions for use

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. It is essential to keep all chemicals from contact with 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. For more details regarding chemical suitability, please contact the Ansell Technical department.
3. Avid wearing gloves which are dirty on the inside – they may irritate the skin, causing dermattis or worse.
4. Contaminated gloves should be cleaned or washed before removal.
5. Ensure the chemicals cannot enter via the curit.
6. The ploves should not be used for protection against serrated blades or when there is a risk of entanglement with moving machine parts.

machine parts.

machine parts. 7. The gloves should not come in contact with a naked flame. 8. 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 enclosure c) under shall not be used to photocom against initiality and an another to de in containing references; decl ration

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

11. It gives are marked, the printed surfaces shall not come in contact with food.
 C. Ingredients / Kaazdous 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 direct sunlight; store in a cool dry place.

Keep away from ozone sources or naked flame

Cleaning: Chemical Resistant 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.





09/2009



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# AlphaTec®

### **Product Portfolio**

Material	Style #	Port Size (inches)/(mm)	Thickness (mil)	Length (inches)/(mm)	Hand Sizes
EPDM +	85-600	8″ (200mm)	20 /0.51	31.5/800	9.5, 11
	85-601	10" (250 mm)	20 /0.51	31.5/800	9.5, 11
	85-602	12" (300mm)	20 /0.51	31.5/800	9.5, 11
EPDM	85-500	8″ (200 mm)	16/0.4	31.5/800	9.5, 11
	85-501	8″ (200 mm)	24/0.6	31.5/800	9.5, 11
	85-502	10" (250 mm)	16/0.4	31.5/800	9.5, 11
	85-503	10" (250 mm)	24/0.6	31.5/800	9.5, 11
	85-504	12" (300mm)	16/0.4	31.5/800	9.5, 11
	85-505	12" (300mm)	24/0.6	31.5/800	9.5, 11
CSM	85-300	8″ (200 mm)	16/0.4	31.5/800	9.5, 11
	85-301	8″ (200 mm)	24/0.6	31.5/800	9.5, 11
	85-302	10" (250 mm)	16/0.4	31.5/800	9.5, 11
	85-303	10" (250 mm)	24/0.6	31.5/800	9.5, 11
	85-304	12" (300mm)	16/0.4	31.5/800	9.5, 11
	85-305	12" (300mm)	24/0.6	31.5/800	9.5, 11
NRL	55-100	6" (150mm)	20/0.51	28/711	8,9,10
	55-101	6" (150mm)	30/0.76	28/711	8,9,10
	55-102	7" (180 mm)	20/0.51	28/711	9, 10
	55-103	7" (180 mm)	30/0.76	28/711	9, 10
	55-104	8″ (200 mm)	20/0.51	32/813	9, 10
	55-105	8″ (200 mm)	30/0.76	32/813	9, 10
	55-106	9″ (230 mm)	20/0.51	31/787	9, 10
	55-107	9″ (230 mm)	30/0.76	31/787	9, 10
	55-108	10" (250mm)	20/0.51	32/813	9, 10
	55-109	10" (250mm)	30/0.76	32/813	10
	55-110	12" (300mm)	20/0.51	32/813	9, 10
	55-111	12" (300mm)	30/0.76	32/813	9, 10
	55-113	8″ (200mm)	20/0.51	32/813	10
Neoprene	55-300	6″ (150 mm)	20/0.51	28/711	8,9,10
	55-301	7″ (180 mm)	20/0.51	28/711	9,10
	55-302	8″ (200 mm)	20/0.51	32/813	9,10
	55-303	8″ (200 mm)	30/0.76	32/813	9,10
	55-304	9″ (230 mm)	20/0.51	32/813	9,10
	55-305	10" (250 mm)	20/0.51	32/813	9,10
	55-306	10" (250 mm)	30/0.76	32/813	9,10
	55-307	12" (300 mm)	20/0.51	32/813	9,10
	55-308	12" (300 mm)	30/0.76	32/813	9,10
	55-309	Oval	13/0.33	28/711	8.5

