



# SHIELDskin XTREME™

## Bright Latex 300 DI<sup>+</sup>

Powder Free Extra DI washed Ambidextrous Non-Sterile 30 cm Natural Rubber Latex Gloves

PPE Category III (Complex Design) according to Council Directive 89/686/EEC

Fully compliant to the latest PPE norms – EN 374:2003 “Protective gloves against chemicals and micro-organisms”

### PRODUCT INFORMATION

Size	Catalogue Numbers	Applicable Norms with Pictograms			
Extra Small (XS/6)	69 5651	<b>EN 374:2003</b> 	<b>EN 374:2003</b>  <b>Level 2</b>		
Small (S/7)	69 5652				
Medium (M/8)	69 5653				
Large (L/9)	69 5654				
Extra Large (XL/10)	69 5655	<b>EN 420:2003 + A1:2009</b>			
Extra Extra Large (XXL/11)	69 5656	<small>Also meets or exceeds EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 &amp; EN 455-4:2009 relating to Council Directive 93/42/EEC for Medical Devices</small>			

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**Material:** Natural Rubber Latex. Contains 50 micrograms or less of total water extractable protein per gram, using the EN 455-3:2015 / ASTM D5712-15 Modified Lowry Method. Typical measurements for latex protein are  $\leq 30\mu\text{g/g}$  as per Modified Lowry Method.

**Design:** Natural colour, ambidextrous, beaded cuff and fully textured.

**Packaging:** One hundred gloves (100) per inner poly bag. Packaging designed to comply with cleanroom environments processes. Gloves are flat-packed. Ten (10) poly bags per inner bag. Packed in a double-walled shipping case. 1000 gloves per case.

### PHYSICAL PROPERTIES

Characteristics	Value	Test Method
Freedom from holes	1.5 AQL <sup>1</sup>	EN 374: 2003

<sup>1</sup> AQL as defined per ISO 2859 for sampling by attributes

Tensile Properties	Tensile Strength (min) Typical		Ultimate Elongation	
- Before Aging	>9.0N, min.	>9.0N	700%, min.	EN 455-2:2015, ASTM D573-04(2015) and ASTM D 412-15a
- After Accelerated Aging	>6.0N, min.	>9.0N	500%, min.	

## PHYSICAL PROPERTIES (Continued)

Characteristics		Value		Test Method
<b>Dimensional</b>	Measured Point	mm	mil	
- Nominal Thickness	Middle Finger	0.16	6.2	ASTM D3767-03(2014)
	Palm	0.14	5.3	
	Cuff	0.10	3.9	
- Length	300mm, min.	305mm, typical		EN 420:2003 + A1:2009

### Palm Widths

-Nominal Width (mm) (+/- 5 mm)	XS/6	S/7	M/8	L/9	XL/10	EN 455-2:2015
	75	85	95	106	116	

### Hand Circumference

Nominal circumference (mm)	XS/6	S/7	M/8	L/9	XL/10	EN 420:2003 + A1:2009
	152	178	203	229	254	

## CLEANLINESS PROPERTIES

Particles				Test Method
		Specification	Typical value	
Particles	Per cm <sup>2</sup> ≥ 0.5µm	<1.200 particles	900 particles	IEST-RP-CC005.4

Extractables					Test Method	
Ion		Specification		Typical value		
Ammonium	NH <sub>4</sub>	0.100	ug/cm <sup>2</sup>	0.030	ug/cm <sup>2</sup>	IEST-RP-CC005.4
Bromide	Br	0.030	ug/cm <sup>2</sup>	0.015	ug/cm <sup>2</sup>	
Calcium	Ca	0.300	ug/cm <sup>2</sup>	0.190	ug/cm <sup>2</sup>	
Chloride	Cl	0.750	ug/cm <sup>2</sup>	0.600	ug/cm <sup>2</sup>	
Fluoride	F	0.010	ug/cm <sup>2</sup>	0.005	ug/cm <sup>2</sup>	
Magnesium	Mg	0.100	ug/cm <sup>2</sup>	0.050	ug/cm <sup>2</sup>	
Nitrite	NO <sub>2</sub>	0.150	ug/cm <sup>2</sup>	0.015	ug/cm <sup>2</sup>	
Nitrate	NO <sub>3</sub>	0.400	ug/cm <sup>2</sup>	0.250	ug/cm <sup>2</sup>	
Phosphate	PO <sub>4</sub>	0.050	ug/cm <sup>2</sup>	0.030	ug/cm <sup>2</sup>	
Potassium	K	0.100	ug/cm <sup>2</sup>	0.050	ug/cm <sup>2</sup>	
Sodium	Na	0.100	ug/cm <sup>2</sup>	0.050	ug/cm <sup>2</sup>	
Sulphate	SO <sub>4</sub>	0.100	ug/cm <sup>2</sup>	0.050	ug/cm <sup>2</sup>	
Zinc	Zn	0.600	ug/cm <sup>2</sup>	0.300	ug/cm <sup>2</sup>	

## ADDITIONAL DATA

- **Biocompatibility** demonstrated by the Primary Skin Irritation Test CPSC 16-11-1500 and dermal sensitization test ASTM F720-13.
- **Non detectable levels of chemical allergens** using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
- **Free of Thiazoles and Thiurams** - these chemical accelerators are excluded from the manufacturing process.
- **Powder free** to minimize the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006 “Medical gloves - Determination of removable surface powder”).
- **Micro - organism and virus resistant** - passes highest level of micro - organism resistance per EN 374-2:2014 (Performance level 3, AQL <0.65 and inspection level G1 according to 1000ml water test) and passes viral penetration test using Phi-X 174 bacteriophage (ISO 16604:2004 Procedure B & ASTM F1671-97b).
- **FTIR:** non detectable levels of silicone, amide and DOP (IEST-RP-CC005.4).
- **NVR:** maximum 30mg/g (IEST-RP-CC005.4).
- **Extensively tested for chemical permeation** according to EN 16523-1:2015 (please refer to chemical resistance guide on website - [www.shieldscientific.com/public/chemical-resistance-guide](http://www.shieldscientific.com/public/chemical-resistance-guide)).

## QUALITY SYSTEMS

- Manufactured in accordance with ISO 9001:2015 and ISO 13485:2016.

“SHIELDskin™, A revolution in Glove Technology”



[www.shieldscientific.com](http://www.shieldscientific.com)

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V12 SHIELDskin XTREME™ Bright Latex 300 DI+ EN 10062016