



Extra DI washed Ambidextrous Non-Sterile 30cm Cleanroom Nitrile 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)	68 8651	<b>EN 374:2003</b> 	<b>EN 374:2003</b>  Level 2	 0120*
Small (S/7)	68 8652			
Medium (M/8)	68 8653			
Large (L/9)	68 8654	<b>EN 420:2003 + A1:2009</b>		
Extra Large (XL/10)	68 8655			
Extra Extra Large (XXL/11)	68 8656	Also meets or exceeds EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 & EN 455-4:2009 relating to Council Directive 93/42/EEC for Medical Devices		

\* SGS UK Ltd (Notified Body No: 0120), Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom

**Material:** Synthetic nitrile polymer (Acrylonitrile Butadiene), based on Torque Nitrile™ technology. Contains no natural rubber latex.

**Design:** White, ambidextrous, beaded cuff, with textured finger tips.

**Packaging:** One hundred gloves (100) per inner poly bag. Packaging designed to comply with cleanroom environments processes. Gloves are flat-packed. Fifteen (15) poly bags per inner bag. Packed in a double-walled shipping case. 1500 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	6.0N, min.	7.0N	500%, min.	EN 455-2:2015, ASTM D573-04(2015) and ASTM D 412-15a
- After Accelerated Aging	6.0N, min.	8.0N	400%, min.	

## PHYSICAL PROPERTIES (Continued)

Characteristics		Value		Test Method
Dimensional	Measured Point	mm	mil	
- Nominal Thickness	Middle Finger	0.12	4.8	ASTM D3767-03(2014)
	Palm	0.10	3.9	
	Cuff	0.07	2.8	
- Length	285mm, min.	300mm, typical		EN 420:2003 + A1:2009

### Palm Width

	XS/6	S/7	M/8	L/9	XL/10	XXL/11	
Nominal Width(mm)	≤80	85	95	105	115	≥120	EN 455-2:2015

### Hand Circumference

	XS/6	S/7	M/8	L/9	XL/10	XXL/11	
Nominal Circumference (mm)	152	178	203	229	254	279	EN 420:2003 + A1:2009

## 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	0.200	ug/cm <sup>2</sup>	0.070	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>	
Nitrate	NO <sub>3</sub>	0.200	ug/cm <sup>2</sup>	0.100	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>	
Nitrite	NO <sub>2</sub>	0.050	ug/cm <sup>2</sup>	0.150	ug/cm <sup>2</sup>	
Phosphate	PO <sub>4</sub>	0.050	ug/cm <sup>2</sup>	0.030	ug/cm <sup>2</sup>	

## ADDITIONAL DATA

- **Biocompatibility** demonstrated by Modified Buehler and Primary Skin Irritation Tests.
- **Non detectable levels of chemical accelerators** using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
- **Free of Thiurams and Thiazoles** - 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 2, AQL <1.5 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).
- **Surface Resistivity:**  $10^8 - 10^{10} \Omega/\text{sq}$ . (ASTM D257-14).
- **NVR:** maximum 30mg/g (IEST-RP-CC005.4).
- **Tested for electrostatic properties** according to EN 1149-1/2/3 & 5.
- **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”



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