SHIELD Scientific
compliance comfort protection

SHIELDskin XTREME™
Sterile Latex 300 DI

Powder Free DI washed Hand-specific Sterile 30 cm 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
5.5	69 5551	EN 374:2003  EN 374:2003  Level 2  CE 0120*
6.0	69 5552	
6.5	69 5553	
7.0	69 5554	EN 420:2003 + A1:2009
7.5	69 5555	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
8.0	69 5556	
8.5	69 5557	
9.0	69 5558	
10	69 5559	

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

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 ≤30µg/g as per Modified Lowry Method.

Design: Natural colour, hand-specific, beaded cuff with textured palm and fingers.

Packaging: Packaging designed to comply with sterile processing environments. Gloves pair packed in a sealed polyethylene pouch. Twenty (20) pouches per sealed (double) poly bag. Ten (10) poly bags per double-walled shipping case. Total of 200 pairs per outer case.

PHYSICAL PROPERTIES

Characteristics	Value	Test Method
Freedom from holes	1.5 AQL[1]	EN 374:2003

[1] AQL as defined per ISO 2859 for sampling by attributes

Tensile Properties	Tensile Strength (min)	Typical	Ultimate Elongation	
- Before Aging	10.0N, min.	>10.0N	700%, min.	EN 455-2:2015, ASTM D573-04(2015) and ASTM D 412-15a
- After Accelerated Aging	7.5N, min.	>7.5NN	500%, min.	

PHYSICAL PROPERTIES (Continued)

Characteristics	Value			Test Method
Dimensional	**Measured Point**	**Mm**	**mil**	
- Nominal Thickness	Middle Finger	0.18	7.1	ASTM D3767-03(2014)
	Palm	0.14	5.5	
	Cuff	0.10	3.9	
- Length	290mm, min.		300mm, typical	EN 420:2003 + A1:2009

Hand Circumference

Nominal circumference	5.5	6	6.5	7	7.5	8	8.5	9	10	EN 420:2003 + A1:2009
(mm)	140	152	165	178	191	203	216	229	254	

CLEANLINESS PROPERTIES

Particles						Test Method
		Specification		Typical value		
Particles	Per $cm^2 \geq 0.5\mu m$	<3.000	particles	2.500	particles	IEST-RP-CC005.4

Extractables						Test Method
Ion		Specification		Typical value		
Ammonium	NH_4	0.100	ug/cm^2	0.070	ug/cm^2	IEST-RP-CC005.4
Bromide	Br	0.100	ug/cm^2	0.070	ug/cm^2	
Calcium	Ca	0.500	ug/cm^2	0.300	ug/cm^2	
Chloride	Cl	0.750	ug/cm^2	0.600	ug/cm^2	
Fluoride	F	0.100	ug/cm^2	0.070	ug/cm^2	
Magnesium	Mg	0.100	ug/cm^2	0.070	ug/cm^2	
Nitrate	NO_3	0.900	ug/cm^2	0.600	ug/cm^2	
Nitrite	NO_2	0.100	ug/cm^2	0.070	ug/cm^2	
Potassium	K	0.200	ug/cm^2	0.100	ug/cm^2	
Phosphate	PO_4	0.100	ug/cm^2	0.070	ug/cm^2	
Sodium	Na	0.100	ug/cm^2	0.070	ug/cm^2	
Sulphate	SO_4	0.100	ug/cm^2	0.070	ug/cm^2	

ADDITIONAL DATA

- **Biocompatibility** demonstrated by Modified Buehler and Primary Skin Irritation Tests.
- **Non-detectable levels of chemical allergens** using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
- **Thiuram and Thiazole free** – 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 level 2 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).
- **Compatible with sterile processing environments** due to paperless packaging and multiple post leaching of gloves.
- **Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6}**, in accordance with guidelines detailed in EN ISO 11137-2:2015 "Sterilization of Healthcare Products – Radiation".
- **Low Endotoxin content at <20 EU/pair (EN 455-3:2015)** demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.
- **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).

QUALITY SYSTEMS

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

"SHIELDskin™, A revolution in Glove Technology"

SHIELD Scientific
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www.shieldscientific.com

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