SHIELD Scientific
compliance comfort protection

SHIELDskin XTREME™ Sterile Latex 330 DI+

Powder Free Extra Length, extra DI washed Hand-specific Sterile 33 cm Natural Rubber Latex Gloves

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

Fully compliant to the latest PPE norms - EN374:2003 "Protective gloves against chemicals and micro-organisms"

PRODUCT INFORMATION

Size	Catalogue Numbers	Applicable Norms with Pictograms			
5.5	69 5761	EN374-1: 2003 	EN374-2: 2003  Level 3		CE 0120*
6.0	69 5762				
6.5	69 5763				
7.0	69 5764	EN420:2003			
7.5	69 5765	Also meets or exceeds EN455-1: 2000, EN455-2: 2009, EN455-3:2006 & EN455-4:2009 relating to Council Directive 93/42/EEC for Medical Devices			
8.0	69 5766				
8.5	69 5767				
9.0	69 5768				
10	69 5769				

* SGS United Kingdom Limited (Notified Body No: 0120), Camberley, Surrey, GU15 3EY, UK

Material: Natural Rubber Latex. Contains 50 micrograms or less of total water extractable protein per gram, using the EN455-3: 2006/ ASTM D5712-05 Modified Lowry Method. Typical measurements for latex protein are ≤30µg/g as per Modified Lowry Method.

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

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	0.65 AQL[1]	EN374-2: 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.	EN455-2: 2009, ASTM D 412-06a and ASTM D 573-04
- After Accelerated Aging	7.5N, min.	>7.5N	500%, min.	

PHYSICAL PROPERTIES (Continued)

Characteristics	Value			Test Method
Dimensional	**Measured Point**	**Mm**	**mil**	
- Nominal Thickness	Middle Finger	0.20	7.9	ASTM D 3767-03
	Palm	0.18	7.1	
	Cuff	0.13	5.1	
- Length	330mm, min.		335mm, typical	EN420:2003

Hand Circumference

Nominal circumference	5.5	6	6.5	7	7.5	8	8.5	9	10
(mm)	140	152	165	178	191	203	216	229	254

EN420:2003

CLEANLINESS PROPERTIES

Extractables				Test Method
		Specification	Typical value	
Particles	≥0.5µm	<1.200 particles	950 particles	IEST-RP-C005.3

Extractables						Test Method
Ion		Specification		Typical value		
Ammonium	NH_4	0.100	ug/cm^2	0.030	ug/cm^2	IEST-RP-CC005.3
Bromide	Br	0.050	ug/cm^2	0.010	ug/cm^2	
Calcium	Ca	0.500	ug/cm^2	0.250	ug/cm^2	
Chloride	Cl	0.750	ug/cm^2	0.600	ug/cm^2	
Fluoride	F	0.050	ug/cm^2	0.010	ug/cm^2	
Magnesium	Mg	0.050	ug/cm^2	0.010	ug/cm^2	
Nitrate	NO_3	0.400	ug/cm^2	0.250	ug/cm^2	
Nitrite	NO_2	0.050	ug/cm^2	0.010	ug/cm^2	
Phosphate	PO_4	0.050	ug/cm2	0.010	ug/cm2	
Potassium	K	0.100	ug/cm^2	0.050	ug/cm^2	
Sodium	Na	0.050	ug/cm^2	0.015	ug/cm^2	
Sulphate	SO_4	0.100	ug/cm^2	0.050	ug/cm^2	

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
- Thiuram and Thiazole free – these chemical accelerators are excluded from the manufacturing process
- Micro-organism and virus resistant – passes highest level of micro-organism resistance per EN374-2: 2003 (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 (ASTM F1671-97b)
- 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 "Medical gloves – Determination of removable surface powder")
- Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6}, in accordance with guidelines detailed in ANSI/AAMI/ EN ISO 11137:2006 "Sterilization of Healthcare Products – Radiation"
- Compatible with sterile processing environments due to paperless packaging and multiple post leaching of gloves
- FTIR: non-detectable levels of silicone, amide and DOP (IEST-RP-C0005.3)
- Low Endotoxin content at <20 EU/pair (EN455-3:2006) demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test

QUALITY SYSTEMS

- Manufactured in accordance with ISO 9001:2000 and ISO 13485:2003

"SHIELDskin™, A revolution in Glove Technology"

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www.shieldscientific.com

Galvanistraat 1 ◦ 6716 AE EDE ◦ The Netherlands - Phone +31 (0)318 754 141 ◦ Fax +31 (0)318 503 742 ◦ Info@shieldscientific.com