



Powder Free Extra Length DI washed Hand-specific Sterile 33cm Nitrile 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 8761	EN374-1: 2003	EN374-2: 2003	
6.0	69 8762			
6.5	69 8763			
7.0	69 8764	EN420: 2003		
7.5	69 8765	Also meets or exceeds EN455-1, 2 & 3:2000 relating to Council Directive 93/42/EEC for Medical Devices		
8.0	69 8766			
8.5	69 8767			
9.0	69 8768			
10	69 8769			

- TÜV Produkt Service, (Notified Body No:0123), Ridlestrasse 3, D-80339 München, Germany

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

Design: White, 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	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	6.0N, min.	7.0N	500%, min.	EN455-2: 2000, ASTM D573-4 and ASTM D 412-06a
- 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	0.15	5.9	ASTM D 3767-03
	Palm	0.12	4.7	
	Cuff	0.10	4.0	
- Length	330mm, min.	335mm, typical		EN420:2003

Hand Circumference

Nominal circumference	5.5	6	6.5	7	7.5	8	8.5	9	10	EN420:2003
(mm)	140	152	165	178	191	203	216	229	254	

CLEANLINESS PROPERTIES

Particles			Test Method
	Specification	Typical value	
Particles $\geq 0.5\mu\text{m}$	<1.200 particles	950 particles	IEST-RP-C005.3

Extractables				Test Method	
Ion		Specification		Typical value	
Ammonium	Nh	0.100	$\mu\text{g}/\text{cm}^2$	0.070	$\mu\text{g}/\text{cm}^2$
Bromide	Br	0.200	$\mu\text{g}/\text{cm}^2$	0.140	$\mu\text{g}/\text{cm}^2$
Calcium	Ca	0.350	$\mu\text{g}/\text{cm}^2$	0.250	$\mu\text{g}/\text{cm}^2$
Chloride	Cl	0.350	$\mu\text{g}/\text{cm}^2$	0.250	$\mu\text{g}/\text{cm}^2$
Copper	Cu	0.050	$\mu\text{g}/\text{cm}^2$	0.030	$\mu\text{g}/\text{cm}^2$
Fluoride	F	0.200	$\mu\text{g}/\text{cm}^2$	0.140	$\mu\text{g}/\text{cm}^2$
Iron	Fe	0.050	$\mu\text{g}/\text{cm}^2$	0.030	$\mu\text{g}/\text{cm}^2$
Magnesium	Mg	0.350	$\mu\text{g}/\text{cm}^2$	0.250	$\mu\text{g}/\text{cm}^2$
Nitrate	No	0.030	$\mu\text{g}/\text{cm}^2$	0.020	$\mu\text{g}/\text{cm}^2$
Potassium	K	0.100	$\mu\text{g}/\text{cm}^2$	0.070	$\mu\text{g}/\text{cm}^2$
Sodium	Na	0.100	$\mu\text{g}/\text{cm}^2$	0.070	$\mu\text{g}/\text{cm}^2$
Sulfate	So	0.100	$\mu\text{g}/\text{cm}^2$	0.070	$\mu\text{g}/\text{cm}^2$
Zinc	Zn	0.350	$\mu\text{g}/\text{cm}^2$	0.250	$\mu\text{g}/\text{cm}^2$

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
- 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 (ASTM D6124-06)
- 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)
- 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
- NVR: maximum 30mg/g (IEST-RP-C0005.3)
- FTIR: non detectable levels of silicone, amide and DOP (IEST-RP-C0005.3)
- Low Endotoxin content at <20 EU/pair (EN455-3:2000) 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”



www.shieldscientific.com