



Powder Free Extra Length Ambidextrous 30 cm Sterile Nitrile Gloves with Textured Fingertips

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		
Extra Small (XS/6)	67 6351	EN374-1 :2003 	EN374-2 :2003 Level 3	 0321*
Small (S/7)	67 6352			
Medium (M/8)	67 6353			
Large (L/9)	67 6354	EN420: 2003		
Extra Large (XL/10)	67 6355	Also meets or exceeds EN455-1, 2 & 3:2000 relating to Council Directive 93/42/EEC for Medical Devices		

*SATRA Technology Centre (Notified body No: 0321), SATRA House, Rockingham Road, Kettering, Northamptonshire, NN16 9JH, United Kingdom

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

Design: Orange, ambidextrous, beaded cuff and with textured fingertips.

Packaging: Packaging designed to comply with sterile processing environments. Gloves pair packed in a sealed polyethylene pouch. Twenty (20) pouches per sealed polyethylene bag. Eight (8) polyethylene bags per double-walled shipping case. Total of 160 pairs per outer case.

PHYSICAL PROPERTIES

Characteristics	Value	Test Method
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Freedom from holes	<0.65 AQL ¹	EN374-2: 2003
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¹AQL 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.	

Dimensional	Measured Point	Mm	mil	
- Nominal Thickness	Middle Finger	0.13	5.1	ASTM D 3767-03
	Palm	0.10	3.9	
	Cuff	0.08	3.1	
- Length	300mm, min.		305mm, typical	EN420: 2003

Palm Widths

- Nominal Width (mm)	XS/6	S/7	M/8	L/9	XL/10	EN455-2: 2000
	≤80	85	95	105	≥110	

Hand Circumference

- Nominal circumference (mm)	XS/6	S/7	M/8	L/9	XL/10	EN420: 2003
	152	178	203	229	254	

ADDITIONAL DATA

- Biocompatibility demonstrated by 200 person Modified Draize, 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.
- 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 (ASTM D6124-06 “Standard Test Method for Residual Powder on Medical Gloves”).
- 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).
- Compatible with sterile processing environments due to paperless packaging and multiple post leaching of gloves. Typical particle levels (per cm² and at > 0.5 µg) are <3.000 particles.
- 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”.
- 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”



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