







Powder-free Ambidextrous Non-Sterile 24 cm Nitrile Exam Gloves with Textured Fingertips.

Registered as a Class 1 Medical Device according to Council Directive 93/42/EEC and as PPE Category III (Complex Design) according to Council Directive 89/686/EEC. Fully compliant to the latest PPE and MDD norms.

## PRODUCT INFORMATION

Size	Catalogue Numbers	Applicable Norms with Pictograms			
Extra Small (XS/6)	65 8121	<b>EN 455-1:2000</b> "Medical Gloves for single use – Part 1: Requirements & testing for freedom of holes"	<b>EN 455-2:2015</b> "Medical Gloves for single use – Part 2: Requirements & testing for physical properties"	<b>EN 455-3:2015</b> "Medical Gloves for single use – Part 3: Requirements & testing for Biological Evaluation"	<b>EN 455-4:2009</b> "Medical Gloves for single use – Part 4: Requirements & testing for shelf life determination"
Small (S/7)	65 8122				
Medium (M/8)	65 8123				
Large (L/9)	65 8124	<b>ISO 374-1:2016</b> Type C  KT	<b>ISO 374-5:2016</b> Level 3  VIRUS	 <b>EN 420:2003+A1:2009</b>	
Extra Large (XL/10)	65 8125				

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**Material:** Nitrile synthetic rubber (acrylonitrile butadiene). Contains no natural rubber latex.

**Design:** White colour, ambidextrous, beaded cuff and textured fingertips.

**Packaging:** Two hundred (200) gloves per dispenser. Gloves are flat-packed. Ten (10) dispensers per case. Packed in a high density single-walled shipping case. 2000 gloves per case.

## PHYSICAL PROPERTIES

Characteristics	Value	Test Method
Freedom from holes	<0.65 AQL <sup>1</sup>	EN 374-2:2014 and EN 455-1:2000

<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	700%, min.	EN 455-2:2015, ASTM D6319-10(2015) ASTM D573-04(2015) and ASTM D412-16
- After Accelerated Aging	6.0N, min.	8.0N	500%, min.	

Dimensional	Measured Point	Mm	mil	
- Nominal Thickness	Middle Finger	0.10	3.9	ASTM D3767-03(2014) and ASTM D 6319-10(2015)
	Palm	0.08	3.1	
	Cuff	0.07	2.8	
- Length	240mm, min.			EN 420:2003+A1:2009 / EN 455-2:2015

#### Palm Widths

- Nominal Width (mm)	XS /6	S/7	M/8	L/9	XL/10	
	≤80	85	95	105	≥110	EN 455-2:2015

## ADDITIONAL DATA

- **Biocompatibility** demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
- **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”).
- **Free of Thiazoles**- this chemical accelerator is excluded from the manufacturing process.
- **Micro - organism and virus resistant** - passes highest level of micro - organism resistance per EN 374-2:2014 (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 (ISO 16604: 2004 Procedure B).

## QUALITY SYSTEMS

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

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