

hele

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## **Technical Data Sheet**

## **Disposable Nitrile Gloves NITRILE 35**

• Art. 10010919 • Art. 10010916 • Art. 10010904

## **Features**

- Excellent softness and wearing fitting
- Finger textured for a reliable, consistent grip
- Beaded cuff ensures easy donning and prevents roll down
- Compliant with food handling requirements
- Non-sterile, Latex-free, powder-free and odor-free



Art. 10010919

White Art. 10010916

Black Art. 10010904

PRODUCT DESCRIPTION					
Type of the glove	Single-use disposable gloves	Colour	Blue (Art. 10010919) , White (Art. 10010916), Black (Art. 10010904)		
Material	Nitrile	Powder Content	Powder-Free		
Not Made from Natural Rubber Latex	Yes	Sterile	No		
Shape	Ambidextrous	External surface	Fingertip textured		
Cuff	Beaded	Internal surface	Chlorinated		

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Sizes	Weight	Longth (mm)	Dimensions (mm)		Force at break		
Sizes	vveignt	Length (mm)	Difficusions (IIIII)	Finger	Palm	Cuff	rorce at break
XS	$2.9 \pm 0.3 g$		≤ 80	0.10±0.03 mm	0.08±0.03 mm	0.07±0.03 mm	≥ 6N before and after aging
S	$3.2 \pm 0.3g$		$80 \pm 10$				
M	$3.5 \pm 0.3 g$	≥ 240	95±10				
L	$3.8 \pm 0.3 g$		110±10				
XL	$4.1 \pm 0.3 \mathrm{g}$		≥ 110				
XXL	$4.4 \pm 0.3 \mathrm{g}$		≥ 120				

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XXL	4.4±0.3g	≥ 120					
MANUFACTURING AND SAFETY STANDARDS							
AQL	1.5						
Quality Standards	Medical Grade, Food Grade, I	ndustrial Grade					
Powder content	< 2 mg/glove (according to E	N 455-3)					
Classification	Medical Device – Class I Regulation (EU) 2017/745		Personal Protective Equipment – Category III, Type B Regulation (EU) 2016/425				
Protection against KPT	ENISO 374-1:2016+A1:2018/ 40% Sodium Hydroxide (K) 30% Hydrogen peroxide (P) 37% Formaldehyde (T)	Type B	> 30min				
Compliances	EN455-1:2020 EN455-2:2015 EN455-3:2015 EN455-4:2009		EN ISO 374-1:2016+A1:2 EN ISO 374-5:2016 EN ISO 21420:2020	2018			
Viral test	Test in accordance with ASTM F1671 & ISO 16604						
Chemotherapy drugs permeation	Test in accordance with ASTM D6978						
Chemical substances permeation	Test in accordance with EN 16523-1						
Food Contact	Declaration of conformity for food contact in accordance with Regulation (EC) No 1935/2004 and with European Resolution Res AP (2004) 4, and Overall Migration Test in accordance with Commission Regulation (EU) No 10/2011						
Shelf life	5 years from the date of manufacturing						
PACKAGING AND STORAGE							

Packaging	100 pcs/dispenserbox (230 x 125 x 60 mm), 10 boxes/carton (31.5 x 25.8 x 24.5 cm)			
Storage Instructions	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone, heat or fire.			
Storage instructions	Recommeded to store in the temperature of 5-38°C and relative humidity <75%.			